VCU Research and Innovation

HRP-301 | 03/01/2024

WORKSHEET: Review Materials

The purpose of this worksheet is to provide support for IRB staff who prepare review materials for convened IRB meetings or prepare materials for Non-Committee Review. This worksheet lists the information that each IRB member/Designated Reviewer, scientific/scholarly reviewer, or consultant needs to review and the worksheets or checklist to be used. For individuals who have electronic (computer) access to or provided all information, this document describes the subset of materials the IRB member is expected to access and review. For individuals who are provided a subset of the information, this document describes the subset of materials the IRB staff are to provide to each individual.[1]

1. GENERAL INFORMATION FOR ALL IRB MEMBERS FOR CONVENED MEETINGS

List of protocols approved using the expedited procedure. (For Veterans Administration (VA) Research, include the review category.)
For Veterans Administration (VA) research, list of protocols approved after verification of Modifications Required to Secure Approval.
For Veterans Administration (VA) research, determinations for internal unanticipated serious adverse events reported to the IRB regardless of outcome.
Information for Other Business items
Educational Materials

2. FOR EACH PROTOCOL UNDERGOING INITIAL REVIEW

Documents for All IRB Members and Alternate IRB Members

Include when the protocol involves these items:

- ☐ HRP-315 - WORKSHEET - Advertisements
- ☐ HRP-316 - WORKSHEET - Payments
- ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
- ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
- ☐ HRP-401 - CHECKLIST - Pre-review
- ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
- ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
- ☐ HRP-412 - CHECKLIST - Pregnant Women
- ☐ HRP-413 - CHECKLIST - Non-Viable Neonates
- ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability
- ☐ HRP-415 - CHECKLIST - Prisoners

[1] This document satisfies AAHRPP elements I.1.F, I.5.D, I-9, II.1.B, II.2.D, II.2.G, II.2.E-II.2.E.2, II.2.F-II.2.F.3

☐ HRP-416 - CHECKLIST - Children

☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults

☐ HRP-418 - CHECKLIST - Non-Significant Risk Device

☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

Additional Items for the Scientific/Scholarly Reviewer

Include:

☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review

Include when they exist:

☐ Scientific evaluation

Items for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

3. FOR EACH PROTOCOL UNDERGOING CONTINUING REVIEW

Documents for All IRB Members and Alternate IRB Members

Include when the protocol involves these items:

☐ HRP-315 - WORKSHEET - Advertisements

☐ HRP-316 - WORKSHEET - Payments

☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation

☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria

☐ HRP-333 - WORKSHEET - Certificate of Confidentiality

☐ HRP-401 - CHECKLIST - Pre-Review

☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process

☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent

☐ HRP-412 - CHECKLIST - Pregnant Women

☐ HRP-413 - CHECKLIST - Non-Viable Neonates

☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability

☐ HRP-415 - CHECKLIST - Prisoners

☐ HRP-416 - CHECKLIST - Children

☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults

☐ HRP-418 - CHECKLIST - Non-Significant Risk Device

☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

4. FOR EACH PROTOCOL UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members and Alternate IRB Members

Include:

HRP-314a - WORKSHEET - Criteria for Approval_Reviewer Summary

Add when modification involves these items:

- ☐ HRP-315 - WORKSHEET - Advertisements
- ☐ HRP-316 - WORKSHEET - Payments
- ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
- ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
- ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
- ☐ HRP-401 - CHECKLIST - Pre-Review
- ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
- ☐ HRP-412 - CHECKLIST - Pregnant Women
- ☐ HRP-413 - CHECKLIST - Non-Viable Neonates
- ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability
- ☐ HRP-415 - CHECKLIST - Prisoners
- ☐ HRP-416 - CHECKLIST - Children
- ☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults
- ☐ HRP-418 - CHECKLIST - Non-Significant Risk Device
- ☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

Additional Documents for the Scientific/Scholarly Reviewer

Include:

☐ HRP-320 - WORKSHEET - Scientific or Scholarly Review (if the amendments are substantive)

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

5. FOR EACH PROBLEM (UNANTICIPATED PROBLEM INVOLVING RISKS TO SUBJECTS OR OTHERS, OR SERIOUS OR CONTINUING NON-COMPLIANCE)

Documents for All IRB Members, Alternate IRB Members, Primary Reviewer, Prisoner Representative, and Scientific/Scholarly Reviewer

Include:

- ☐ HRP-321 - WORKSHEET - Review of Information Items
- ☐ HRP-314a - WORKSHEET - Criteria for Approval_Reviewer Summary

Add when the problem involves a protocol and the new information affects these items:

- ☐ HRP-315 - WORKSHEET - Advertisements
- ☐ HRP-316 - WORKSHEET - Payments
- ☐ HRP-317 - WORKSHEET - Short Form of Consent Documentation
- ☐ HRP-318 - WORKSHEET - Additional Federal Agency Criteria
- ☐ HRP-333 - WORKSHEET - Certificate of Confidentiality
- ☐ HRP-401 - CHECKLIST - Pre-Review
- ☐ HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process
- ☐ HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent
- ☐ HRP-412 - CHECKLIST - Pregnant Women
- ☐ HRP-413 - CHECKLIST - Non-Viable Neonates
- ☐ HRP-414 - CHECKLIST - Neonates of Uncertain Viability)
- ☐ HRP-415 - CHECKLIST - Prisoners
- ☐ HRP-416 - CHECKLIST - Children
- ☐ HRP-417 - CHECKLIST - Cognitively Impaired Adults
- ☐ HRP-418 - CHECKLIST - Non-Significant Risk Device
- ☐ HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

6. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING INITIAL REVIEW

Documents for All IRB Members and Alternate IRB Members

Include:

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

7. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING CONTINUING REVIEW

Documents for All IRB Members and Alternate IRB Members

Include:

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

8. FOR USE OF A HUMANITARIAN USE DEVICE (HUD) UNDERGOING REVIEW OF MODIFICATIONS

Documents for All IRB Members and Alternate IRB Members

Include when modified:

☐ HRP-323 - WORKSHEET - Criteria for Approval HUD

Documents for Consultants and individuals without reviewer access to the submission

Include:

☐ Cover letter to consultants

Include as appropriate materials provided to any other reviewer.

VCU Research and Innovation

HRP-302 | 10/23/2024

WORKSHEET: Approval Intervals

The purpose of this worksheet is to provide support for IRB staff members who send communications after an IRB review where the letter needs to include approval and Expiration Dates. This worksheet describes how to make these calculations.[1]

INITIAL REVIEW APPROVAL INTERVALS

Type of Review	Date Approved	2018 Common Rule Approval Date	Expiration Date[2]	Expedited Anniversary Date
Convened IRB granted approval	Date of convened IRB meeting	2018 Common Rule – same as date approved *N/A Pre-2018	Date of the convened meeting plus the approval interval minus one day[3]	N/A
Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date of convened IRB meeting	2018 Common Rule – same as date approved *N/A Pre-2018	Date of the convened meeting plus the approval interval minus one day	N/A
Designated Reviewer granted approval	Date the Designated Reviewer granted approval	2018 Common Rule – same as date approved *N/A Pre-2018	APPROVAL DATE plus the approval interval minus one day. *Set 3-year approval interval for 2018 Common Rule expedited and	N/A *For 2018 Common Rule expedited studies with status updates only – same as expiration date

[1] This document satisfies AAHRPP elements II.2.E-II.2.E.2

[2] Approval interval may not exceed one calendar year.

[3] For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007.

			exempt research with no CR requirement.	

CONTINUING REVIEW APPROVAL INTERVALS (when last day of approval interval is 30 days or less away from day of review)[4]

Type of Review	Date Approved	2018 Common Rule Approval Date	Expiration Date	Expedited Anniversary Date
Convened IRB granted approval	Previous END APPROVAL DATE plus one day	2018 Common Rule – date of initial approval from main study workspace *N/A Pre-2018	Previous END APPROVAL DATE plus current approval interval[5]	N/A
Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Previous END APPROVAL DATE plus one day	2018 Common Rule – date of initial approval from main study workspace *N/A Pre-2018	Previous END APPROVAL DATE plus current approval interval	N/A
Designated Reviewer granted approval	Previous END APPROVAL DATE plus one day	2018 Common Rule – date of initial approval from main study workspace *N/A Pre-2018	Previous END APPROVAL DATE plus current approval interval *N/A for exempt research	N/A *For 2018 Common Rule expedited studies with status updates only – same as expiration date, if applicable

[4] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html

[5] For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007.

CONTINUING REVIEW APPROVAL INTERVALS (when last day of approval interval is greater than 30 days from day of review)[6]

Type of Review	Date Approved	2018 Common Rule Approval Date	Expiration Date	Expedited Anniversary Date
Convened IRB granted approval	Date of convened IRB meeting	2018 Common Rule – date of initial approval from main study workspace *N/A Pre-2018	Date of the convened meeting plus the approval interval minus one day[7]	N/A
Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date of convened IRB meeting	2018 Common Rule – date of initial approval from main study workspace *N/A Pre-2018	Date of the convened meeting plus the approval interval minus one day	N/A
Designated Reviewer granted approval	Date the Designated Reviewer granted approval	2018 Common Rule – date of initial approval from main study workspace *N/A Pre-2018	APPROVAL DATE plus the approval interval minus one day *N/A for exempt research	N/A *For 2018 Common Rule expedited studies with status updates only – same as expiration date, if applicable

[6] https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-continuing-review-2010/index.html

[7] For example, if the convened IRB approved research on April 15, 2007 for one year, the end date of the approval interval is April 15, 2007 + one year – one day = April 14, 2008. If the convened IRB approved research on April 15, 2007 for six months, the end date of the approval interval is April 15, 2007 + six months – one day = November 14, 2007.

MODIFICATIONS

Type of Review	Date Approved	2018 Common Rule Approval Date	Expiration Date	Expedited Anniversary Date
Convened IRB granted approval	Date of convened IRB meeting	2018 Common Rule – same as previously set date from main study workspace *N/A Pre-2018	Previous END APPROVAL DATE[8]	N/A
Convened IRB required modifications to secure approval; subsequently verified by Non-Committee Review	Date of convened IRB meeting	2018 Common Rule – same as previously set date from main study workspace *N/A Pre-2018	Previous END APPROVAL DATE	N/A
Designated Reviewer granted approval	Date the Designated Reviewer granted approval	2018 Common Rule – same as previously set date from main study workspace *N/A Pre-2018	Expedited studies: 2018 Common Rule + status updates - APPROVAL DATE plus the approval interval Expedited studies: CR required / Pre-2018 Common Rule - Previous END APPROVAL DATE Exempt studies: Previous END APPROVAL DATE	N/A *For 2018 Common Rule expedited studies with status updates only – same as expiration date

[8] For example, if the last date of the approval interval was April 14, 2008, and the convened IRB approved a modification on November 16, 2007, the end date of the approval interval remains April 14, 2008.

VCU Research and Innovation

HRP-303 | 10/23/2024

WORKSHEET: Communication of Review Results

System-Generated Letter Templates:

The purpose of this worksheet is to provide support for staff who send communications after an IRB review.[1]

IF THE CONVENED IRB, DESIGNATED REVIEWER, or other designee:	COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST
Approved protocol	HRP-510 - LETTER - Approval HRP-510 - LETTER - Approval - CR NOT Req
Approved a participating site	HRP-870 - LETTER - Site Approval
Acknowledged a protocol closure	HRP-511 - LETTER - Closure
Required modifications to protocol to secure approval	HRP-512 - LETTER - Mods Req to Secure Approval
Required site modifications to secure approval	HRP-872 - LETTER - Site Modifications Required to Secure Approval
Determined a protocol to be exempt from regulation	HRP-514 - LETTER - Exemption
Determined that the activity is not Human Research	HRP-513 - LETTER - NHR Determination
Determined that the activity is Human Research in which the organization is not engaged	HRP-527 - LETTER - Not Engaged
Suspension or Termination of IRB Approval	HRP-515 - LETTER - Suspension or Termination
Agreed to provide IRB review for an external site engaged in a multi-site or collaborative study	HRP- 851 - LETTER - Invitation Decision
Agreed to cede IRB review to an external IRB	HRP-857 - LETTER - Acknowledge External IRB
Declined a request to serve as a sIRB	HRP-850- LETTER - Decline to Serve
Declined a request to cede review to an external IRB	HRP-856 - LETTER - Decline Reliance on an External IRB
Acknowledged study modifications approved by an external IRB	HRP-859 - LETTER - Acknowledge External IRB Update

[1] This document satisfies AAHRPP elements I.1.A, I.5.D, I-9, II.2.A, II.2.G, II.2.H, II.2.E-II.2.E.2, III.2.D

THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB	
IRB Determination	COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST
Deferred protocol	HRP-516 - LETTER - Deferral
Deferred site	HRP-876 - LETTER - Site Deferral
Disapproved protocol	HRP-517 - LETTER - Disapproval
Disapproved site	HRP-877 - LETTER - Site Disapproval
Reviewed an information item	HRP-519 - LETTER - Information Item
Reviewed site information item	HRP-879 - LETTER - Review of Site Information Item
When a suspension is lifted	HRP-515a - LETTER - Lifting of Suspension

The purpose of this worksheet is to provide support for staff who send communications after an IRB review or at the discretion of the IRB.

THE FOLLOWING DETERMINATIONS CAN ONLY BE MADE BY A CONVENED IRB	
IRB Determination	**COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST**
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	HRP-521 - LETTER - SR NSR Device
Approved a waiver of the consent process for planned emergency research	HRP-525 - LETTER - OHRP Notif Emerg Waiver

THE FOLLOWING NOTIFICATIONS ARE SENT AT THE IRB'S DISCRETION	
IRB Notification	**COMPLETE THE FOLLOWING TEMPLATE LETTER AND SEND TO ALL INDIVIDUALS LISTED IN CC LIST**
Tabled the protocol	HRP-518 - LETTER - Tabled *(Place on the agenda for the next IRB meeting)*
Reviewed an Unanticipated Problem Involving Risks to Subjects or Others, Serious or Continuing Non-Compliance, or a	HRP-520a - LETTER - External Report OHRP and Other Agencies and OHRP Incident Report Form[2]

[2] See: https://www.hhs.gov/sites/default/files/irpt-pra-incident-report-form.pdf

Suspension or Termination that requires reporting to a federal agency and OHRP	
Determined that a study submitted under the abbreviated requirements involved a significant risk device (FDA)	HRP-521 - LETTER - SR NSR Device
Approved research conducted or funded by DHHS involving prisoners as subjects	HRP-522 - LETTER - Cert Prisoner Research Subpart C Certification Form[iii]
Approved not otherwise approvable research involving children, pregnant women, or neonates	HRP-523 - LETTER - Not Otherwise Appro Research
Approved a waiver of the consent process for planned emergency research	HRP-525 - LETTER - OHRP Notif Emerg Waiver
Certification of approval of prisoner research for DOD research	HRP-522 - LETTER - Cert Prisoner Research
Review of otherwise not approvable research to OHRP/FDA	HRP-523 - LETTER - Not Otherwise Appro Research
Continuation of subjects in expired research	HRP-532 - LETTER - Conti Subj Expired Research
Investigator Quality Improvement assessment	HRP-534 - LETTER - Investigator QI Assessment
IRB Member Appointment	HRP-560 - LETTER - IRB Member Appointment
IRB Member Thank You	HRP-561 - LETTER - IRB Member Thank You
IRB Member Appreciation	HRP-562 - LETTER - IRB Member Appreciation
Pre-Review of Emergency Use (Criteria Met)	HRP-570 - LETTER - Pre-Rev EU - Crit Met
Pre-Review of Emergency Use (Criteria Not Met)	HRP-571 - LETTER - Pre-Rev EU - Crit Not Met
Review of Emergency Use (Criteria Met)	HRP-572 - LETTER - Review of EU - Crit Met
Review of Emergency Use (Criteria Not Met)	HRP-573 - LETTER - Review of EU - Crit Not Met
Failure to Submit Emergency Use Report	HRP-551 - LETTER - Failure to Submit EU Report
Failure to Submit Emergency Use Protocol	HRP-553 - LETTER - Failure to Submit EU Protocol

VCU Research and Innovation

HRP-304 | 03/01/2024

WORKSHEET: IRB Composition

The purpose of this worksheet is to provide support for IRB staff reviewing whether the IRB is appropriately composed. Note: All IRB members are voting members. There are no "non-voting IRB members."

1. Objective Composition (Check if "**Yes**". All must be checked)

☐ The IRB has at least five members, not counting alternate IRB members.

☐ The IRB does not consist entirely of men or entirely of women. *[FDA, DOJ, or when applying the Pre-2018 Common Rule regulations only.]*

☐ The IRB does not consist entirely of members of one profession. *[FDA, DOJ, or when applying the Pre-2018 Common Rule regulations only.]*

☐ The IRB has at least one member who has primary concerns are in scientific areas.

☐ The IRB has at least one member who has primary concerns are in non-scientific areas.

☐ The IRB has at least one member who is unaffiliated with the institution and whose Immediate Family is unaffiliated with the institution.

2. Subjective Composition (Check if "**Yes**". All must be checked)

☐ The qualifications of alternate members are comparable to the primary member to be replaced.

☐ The members have varying backgrounds to promote complete and adequate review of research activities commonly reviewed.

☐ The IRB is sufficiently qualified through its experience, expertise, diversity in terms of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes to promote respect for its advice and counsel in safeguarding the rights and welfare of Human Subjects.

☐ The IRB includes persons knowledgeable of institutional commitments and regulations, applicable law, and standards of professional conduct and practice and has the ability to ascertain the acceptability of proposed research in terms of these areas.

☐ The IRB has the ability to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.

☐ The IRB possesses the professional competence necessary to review research activities.

☐ If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, Prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IRB includes of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.

☐ The IRB has at least one member who represents the perspective of research subjects.

☐ The IRB has no members responsible for business development.

☐ The IRB has no members that own equity in the organization.

3. Additional Requirements (Check if "**Yes**". All must be checked)

☐ The IRB has an IRB chair.

☐ There are sufficient alternate IRB members.

4. Composition of an IRB that Reviews Research Involving Prisoners (Check if "**Yes**". If the IRB reviews research involving Prisoners, all must be checked)

☐ A majority of the Board (exclusive of Prisoner members) has no association with the prison(s) involved, apart from their membership on the Board.

☐ At least one voting member of the Board is a Prisoner, or a Prisoner representative with appropriate background and experience to serve in that capacity, including a working knowledge of the population to be recruited, a reasonable familiarity with the operations of the prison or confinement facility, and any other legally imposed restrictive conditions involved in the research. (The Prisoner representative may be an alternate member who becomes a voting member when needed.)

5. Scope and Composition (Check if "**Yes**". All must be checked)

☐ This IRB conducts: (Select one)

☐ All reviews without limitation.

☐ Limited to the following types of reviews:

☐ The type of research reviewed matches the description in the roster.

☐ The composition of the IRB is appropriate to the types of research reviewed.

List limitation on types of reviews:

Click or tap here to enter text.

6. Composition of an IRB that Reviews Veterans Administration (VA) Research (Check if "Yes". If the IRB reviews VA research, all must be checked)

☐ The IRB has no voting member who is a VA facility research office staff member including, but not limited to, the Associated Chief of Staff (ACOS) for R&D, the Administrative Officer (AO) for R&D, and IRB administrative staff. *They may serve as ex officio, non-voting members or attendees; however, they and the*

IRB must be sensitive to any potential, actual, apparent, or perceived conflicts of interest and appropriately manage such conflicts.

☐ The IRB has no member who is a Research Compliance Officer (RCO). RCOs may attend IRB meetings when requested by the IRB or as specified by the IRB's standard operating procedures (SOPs) as consultants.

☐ The Privacy Officer (PO) and the Information System Security Officer (ISSO) serve in an advisory capacity as either non-voting members or as consultants.

☐ The IRB has no member who is a Facility Director, his/her administrative staff, COS, other facility senior administrators such as Associate or Assistant Directors or Chief Nurse, and NPC Administrative.

☐ Alternate members must have qualifications similar to the member they replace.

☐ Every effort has been made to include a Veteran or Veteran representative as part of the fulfillment of the requirement of relevant diversity of experience and expertise. *VA representation on external IRBs, such as academic IRBs, is optional and at the discretion of the IO and the external IRB.*

☐ The IRB has at least one voting member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. Retired VA employees who are receiving VA retirement benefits are considered to be affiliated when they are members of a VA IRB. Veterans whose only relationship with VA is receiving care at a VA facility or receiving benefits from the Veterans Benefits Administration are considered unaffiliated.

VCU Research and Innovation

HRP-305 | 03/01/2024

WORKSHEET: Quorum and Expertise

The purpose of this worksheet is to provide support for staff who monitor attendance at convened IRB meetings. This worksheet evaluates whether the members present at the meeting comprise a quorum. IRB staff are to consult this worksheet in preparation of meetings and when monitoring attendance at convened meetings. The worksheet does not need to be completed or retained[1].

1. QUORUM REQUIREMENTS (Check if "**Yes**" or "**NA**". All must be checked)

☐ Greater than half of the IRB members *(will be/are)* present.

☐ At least one member whose primary concerns are in scientific areas *(will be/is)* present.

☐ At least one member whose primary concerns are in non-scientific areas *(will be/is)* present.

☐ At least one unaffiliated member *(should be/is)* present. [2]

☐ At least one member who represents the general perspective of subjects *(will be/is)* present.

☐ If both an alternate IRB member and the regular IRB member for whom the alternate IRB member *(will be/is)* substituting (*will be/are*) present, only one *(will be/is)* voting and only one *(will be/is)* counting towards quorum. **("NA" if both an alternate IRB member and the regular IRB member for whom the alternate IRB member *(will be/is)* substituting (*will NOT be/are NOT*) present) NA: ☐**

☐ In order for a DOE IRB to vote on a new or amended protocol that requires full board review, there must be a minimum of five members present, including a scientist, a nonscientist, and an unaffiliated member. For classified research, the unaffiliated member must be a nongovernmental member with the appropriate security clearance. This individual cannot be a current Federal employee or a DOE site contractor. **("NA" if DOE regulations do not apply) NA: ☐**

2. EXPERTISE REQUIREMENTS (Check if "**Yes**" or "**NA**". All must be checked)

☐ At least one member or consultant with scientific or scholarly expertise in the area of research *(will be/is/was)* involved in the review.

☐ At least one member or consultant with knowledge of the local context *(will be/is)* involved in the review.

---

[1] This document satisfies AAHRPP elements I-3, I.4.C, I-9, II.1.B, II.1.E, II.2.D, II.2.E-II.2.E.2, II.4.A

[2] Per AAHRPP accreditation standards, an unaffiliated member will be present at the majority of IRB meetings (e.g., attending >80% of meetings per year).

☐ At least one member or consultant able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.

☐ When the research involves Prisoners as subjects: An IRB member who is a Prisoner or a Prisoner representative with appropriate background and experience to serve in that capacity *(will be/is)* involved in the review as a voting member. The Prisoner representative may attend the meeting by phone, video- conference, or Webinar, as long as the representative is able to participate in the meeting as if they were present in person. **("NA" if no Prisoners.) NA: ☐**

☐ When the research involves a drug or device: An IRB member who is a licensed physician *(will be/is)* involved in the review[3]. **("NA" if no drugs or devices.) NA: ☐**

☐ When the research involves populations vulnerable to coercion or undue influence: An IRB member or consultant who is knowledgeable about or experienced in working with such subjects *(will be/is)* involved in the review.[4] **("NA" if no populations vulnerable to coercion or undue influence.) NA: ☐**

☐ When the research involves other specific expertise: An IRB member or consultant who has that expertise (professional competence) *(will be/is)* involved in the review. **("NA" if no specific expertise needed.) NA: ☐**

☐ When the research is Veterans Administration (VA) research: An IRB member who is a Veterans Administration (VA) representative *(will be/is)* present. **("NA" if not Veterans Administration (VA) research.) NA: ☐**

☐ For international research the IRB has knowledge of local laws and the cultural context of the country where research is going to be conducted Including: (Can be through consultation with a local IRB, government agency, or other qualified consultant.) **("NA" if not international research.) NA: ☐**

- Appropriate expertise and knowledge of the country(ies) either through IRB members or consultants.
- Knowledge of cultural context.
- Application of the same processes for initial review, continuing review, and review of modifications to previously approved research; post-approval monitoring; handling of complaints, non-compliance, and unanticipated problems involving risk to subjects or others; and consent process and document and other language issues as applied to domestic research.
- Coordination and communication with local IRBs or ECs when appropriate.

---

[3] 46 FR 8958 at 8966, January 27, 1981, Comment 55, FDA wrote that it "...would expect that an IRB that reviews investigational new drug studies will include at least one physician." In comment 58, it notes "...an IRB must retain the necessary expertise to effectively review any protocol submitted to it, and therefore, it may need a number of scientists (whether medical doctors, dentists, technical staff, or others) on the IRB."

[4] 45 CFR §46.107(a): "If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects."

□ For community-based participatory research the IRB has done one of the following: **("NA" if not community-based participatory research.**) **NA:** □

- Educated IRB members on community-based participatory research.
- Included IRB members with expertise in community-based participatory research.
- Obtained consultation with expertise in community-based participatory research.

VCU Research and Innovation

HRP-306 | 10/23/2024

WORKSHEET: Drugs and Biologics

The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving drugs. It does not need to be completed or retained [1].

1. DRUG APPLICABILITY

Does the activity involve any of the following? **(Check all that apply) If "No" to both, FDA regulations do not apply.**

☐ In the United States: The use of a drug [2] or a biological product (biologic) [3] in one or more persons other than use of an approved drug in the course of medical practice [4].

☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[5].

2. IND REQUIREMENTS[6] (Check if "**Yes**". One must be "**Yes**." If all are "**No**" IND information is not complete.)

☐ The drug has a valid IND. (Complete Sections 3 and 4)

☐ The drug is exempt from the IND requirements (Complete Section 5)

☐The research is conducted outside of the United States and is conducted under ICH-GCP.

3. IND VALIDATION[7] (Check if "**Yes**". At least one must be "**Yes**." If all are "**No**" IND cannot be validated.)

☐ Sponsor protocol imprinted with the IND number.

---

[1] This document satisfies AAHRPP elements I.7.A, I.7.B

[2] The term ''drug'' means:
- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[3] The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[4] "Other than the use of an approved drug in the course of medical practice" refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

[5] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[6] If there are questions about which category is appropriate, have the investigator apply for an IND following 21 CFR §312.23.

[7] VCU applies this process in lieu of the 30 day rule.

☐ Written communication from the sponsor documenting the IND number.

☐ Written communication from the FDA documenting the IND number. (Required if the investigator holds the IND.)

4. DRUG OR BIOLOGIC CONTROL (Check if "**Yes**". Must be "**Yes**. If "**No**" information regarding drug control is incomplete.)

☐ The plan for storage, control, and dispensing of the drug or biologic is adequate to ensure that only authorized investigators will use the drug and that they will use the drug only in subjects who have provided consent.[8]

5. IND EXEMPTIONS (Check if "**Yes**". All criteria for one category must be "**Yes**" to be met. If none are met, the drug is not exempt from an IND.)

☐ **Category #1 - Lawfully Marketed Drugs (21 CFR 312.2(b)(1)) or Biologics**

- ☐ The drug or biologic is lawfully marketed in the United States.
- ☐ The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug.
- ☐ The research is not intended to support a significant change in the advertising for the product.
- ☐ The research does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product.
- ☐ The research is conducted in compliance with the marketing limitations described in 21 CFR §312.7.

☐ **Category #2 - Serological Tests (21 CFR 312.2(b)(2))**

- ☐ A clinical investigation for an in vitro diagnostic [9] biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin.
- ☐ The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure.
- ☐ The diagnostic test is shipped in compliance with 21 CFR §312.160.

---

[8] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects. The investigator must maintain records that document adequately that the subjects are provided the doses specified by the protocol and reconcile all investigational products received from the Sponsor.

[9] An in vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. IVD products are devices as defined in section 201(h) of the Act and may also be biological products subject to section 351 of the Public Health Service Act.

☐ **Category #3 - Placebos (21 CFR 312.2(b)(5))**

☐ A clinical investigation involving use of a placebo when the investigation does not otherwise require submission of an IND.

☐ **Category #4 - Bioavailability/Bioequivalence Studies (21 CFR 320.31(b) and (d))**

☐ The active moiety in the drug product is identical to that in an FDA approved drug.

☐ The drug product is not radioactively labeled.

☐ The drug product is not cytotoxic.

☐ The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product.

☐ The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31(d)(1).

☐ **Category #5 - Radioactive Drugs for Research Use (21 CFR 361.1)**

☐ The drug has been approved by Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria in 21 CFR 361.1(b)

☐ **Category #6 - Cold Isotopes for Research Use (FDA enforcement discretion [10])**

☐ The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry.

☐ The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.

☐ The dose to be administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies.

☐ The quality of the cold isotope meets relevant quality standard.

6. IND OVERSIGHT FOR INVESTIGATORS WHO HOLD THE IND (Check if "**Yes**". One of the following must be "**Yes**" if the investigator holds the IND.)

☐ The FDA requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.

☐ An audit has documented that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).

[10] (FDA Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs)) Determining Whether Human Research Studies Can Be Conducted Without an IND, September 2013: https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf.

VCU Research and Innovation

HRP-307 | 02/01/2024

WORKSHEET: Devices

The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving devices. This worksheet is to be used. It does not need to be completed or retained.[i]

1. DEVICE[ii] APPLICABILITY (Check if "**Yes**". If either is "**Yes**" use the rest of the worksheet. Otherwise FDA device regulations do not apply.)

☐ Does the activity involve the following? **(Check all that apply)**

☐ In the United States: The use of a device[iii] in one or more persons that evaluates the safety or effectiveness of that device. (If the device is/includes a software function, complete Section 2)

☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA[iv].

☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA[v].

☐ Does this involve a humanitarian use device?

2. SOFTWARE AS A MEDICAL DEVICE[vi] (Check if **"Yes"**. If **"Yes"** then the software function is excluded from the definition of device in section 201(h) of the FD&C Act and the FDA device regulations do not apply.)

☐ Is the device, or does the device include, a software function that does any of the following? **(Check all that apply)**

☐ Administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow.

☐ Maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

☐ Serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as:

i. such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;

ii. such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and

iii. such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

☐ Transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

3. IDE/HDE REQUIREMENTS[vii] (Check if **"Yes"**. One must be **"Yes"** If all are **"No"** IDE/HDE information is not complete.)

☐ The device has an IDE or HDE. (Complete Sections 4 and 5. Complete Section 8, if applicable.)

☐ The device qualifies for an abbreviated IDE. (Complete Section 5 and 6)

☐ The device is exempt from the IDE requirements. (Complete Section 7)

4. IDE/HDE VALIDATION (Check if **"Yes"**. At least one must be **"Yes"** If all are **"No"**, IDE/HDE cannot be validated.)

☐ Sponsor protocol imprinted with the IDE/HDE number.

☐ Written communication from the sponsor documenting the IDE/HDE number.

☐ Written communication from the FDA documenting the IDE/HDE number. *(Required if the investigator holds the IDE/HDE.)*

5. DEVICE CONTROL (Check if **"Yes"**. Must be **"Yes"** If **"No"**, information regarding device control is incomplete.)

☐ The plan for storage, control, and dispensing of the device is adequate to ensure that only authorized investigators will use the device and that they will use the device only in subjects who have provided consent.[viii]

6. ABBREVIATED IDE (Check if **"Yes"**. All must be **"Yes"**)

☐ The device is not banned by the FDA.

☐ The investigator will label the device in accordance with FDA regulations. (21 CFR §812.5)

☐ The IRB will approve the research under 21 CFR §50 and §56 and determine that the study is not a significant risk[ix] device study using HRP-418 - CHECKLIST - Non-Significant Risk Device.

☐ The investigator will comply with FDA requirements for monitoring investigations. (21 CFR §812.46)

☐ The investigator will comply with FDA requirements for records and reports. (21 CFR §812.140, 21 CFR §812.150)

☐ The investigator will not market or promote the device. (21 CFR §812.7)

7. IDE EXEMPTIONS (Check if **"Yes"**. All criteria under one category must be **"Yes"** for a category to be met. If none of the categories is met, the device is not exempt from an IDE.)

Cat. #1

☐ The device was not regulated as a drug before enactment of the Medical Device Amendments. (Transitional device.)

☐ The device is FDA-approved/cleared.[x]

☐ The device is being used or investigated in accordance with the indications in the FDA approved/cleared labeling.

Cat. #2

☐ The device is a diagnostic device.

☐ The sponsor will comply with applicable requirements in 21 CFR 809.10(c).

☐ The testing is noninvasive.[xi]

☐ The testing does not require an invasive sampling procedure that presents significant risk.

☐ The testing does not by design or intention introduce energy into a subject

☐ The testing is not used as a diagnostic procedure without confirmation by another, medically established product or procedure

Cat. #3

☐ The device is undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution, and the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.

Cat. #4

☐ The device is a custom device as defined in 21 CFR 812.3(b) and is NOT being used to determine safety or effectiveness for commercial distribution.

8. IDE OVERSIGHT FOR INVESTIGATORS WHO HOLD THE IDE (Check if **"Yes"**. One of the following must be **"Yes"** if the investigator holds the IDE)

☐ The FDA regulatory requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization.

☐ An audit documents that the investigator is compliant with FDA sponsor requirements (including GMP when applicable).

[i] This document satisfies AAHRPP elements I.7.A, I.7.B

[ii] This includes software functions the FDA considers to be medical devices. Examples of software functions the FDA considers to be a medical device (along with examples of devices that the FDA does NOT consider a medical device) can be found in FDA's Policy for Device Software Functions and Mobile Medical Applications. Note that for certain cases where the FDA is exercising enforcement discretion, such software functions are still subject to the Investigational Device Exemption (IDE) requirements in 21 CFR 812, unless exempt as per 21 CFR 812.2(c).

[iii] The term ''device'' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Due to changes to Section 3060 of the 21st Century Cures act, the term "device" does not include **software function** that is intended for:

a. administrative support of a health care facility, including the processing and maintenance of financial records, claims or billing information, appointment schedules, business analytics, information about patient populations, admissions, practice and inventory management, analysis of historical claims data to predict future utilization or cost-effectiveness, determination of health benefit eligibility, population health management, and laboratory workflow;
b. maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition;
c. serve as electronic patient records, including patient-provided information, to the extent that such records are intended to transfer, store, convert formats, or display the equivalent of a paper medical chart, so long as—
    i. such records were created, stored, transferred, or reviewed by health care professionals, or by individuals working under supervision of such professionals;
    ii. such records are part of health information technology that is certified under section 3001(c)(5) of the Public Health Service Act; and
    iii. such function is not intended to interpret or analyze patient records, including medical image data, for the purpose of the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition; or
d. transferring, storing, converting formats, or displaying clinical laboratory test or other device data and results, findings by a health care professional with respect to such data and results, general information about such findings, and general background information about such laboratory test or other device, unless such function is intended to interpret or analyze clinical laboratory test or other device data, results, and findings.

To review the FDA's guidance regarding the changes to the existing medical definition due to the 21st Century Cures Act, please visit this website: https://www.fda.gov/media/109622/download.
To review software functions that are the focus of the FDA's regulatory oversight, please review the following guidance: https://www.fda.gov/media/80958/download.

[iv] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[v] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[vi] Due to changes to Section 3060 of the 21st Century Cures act, the term "device" does not include **software function** that is intended for the functions listed in this section.
To review the FDA's guidance regarding the changes to the existing medical definition due to the 21st Century Cures Act, please visit this website: https://www.fda.gov/media/109622/download.
To review software functions that are the focus of the FDA's regulatory oversight, please review the following guidance: https://www.fda.gov/media/80958/download.

[vii] If there are questions about which category is appropriate, have the investigator apply for an IDE following 21 CFR §812.20.

[viii] The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the unique code numbers assigned to the investigational products and trial subjects.

[ix] The risk determination is based on the proposed use of a device in an investigation, and not on the device alone. (See http://www.fda.gov/downloads/regulatoryinformation/guidances/ucm126418.pdf).

[x] In commercial distribution immediately before May 28, 1976, or FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 28, 1976, and that is used or investigated in accordance with the indications in the labeling FDA reviewed under subpart E of part 807 in determining substantial equivalence.

[xi] Blood sampling that involves venipuncture is considered non-invasive for purposes of this exemption. The use of surplus samples of body fluids or tissues that are left over from samples taken for non-investigational purposes is also considered non-invasive. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071230.pdf.

VCU Research and Innovation

HRP-308 | 10/23/2024

WORKSHEET: Pre-Review

The purpose of this worksheet is to provide support for IRB staff conducting screening submission materials.[1]

1. All Reviews

☐ Determine the Human Research laws that apply to the Human Research and indicate in the "Regulatory Oversight" section of the Pre-Review Activity.

☐ Determine whether the Human Research has received all required ancillary reviews (per HRP-309 - WORKSHEET - Ancillary Review Matrix) and approval by the appropriate committees and officials.

☐ If the Human Research could be subject to EU GDPR, send to HRPP Director or Designee for consideration of review by privacy office and legal counsel.

☐ If there is a HIPAA authorization, review using HRP-330 – WORKSHEET – HIPAA Authorization.

☐ If a HIPAA waiver of authorization is required, grant using HRP-441 – CHECKLIST – HIPAA Waiver of Authorization.

Note any missing materials necessary for review in the "Notes" section of HRP-401 - Checklist - Pre-Review:

☐ Completed Huron IRB application

☐ Investigator Protocol

☐ Consent document(s) or script(s)

☐ Data collection instruments

☐ Written material to be seen or heard by subjects

☐ Determine whether any new information has been provided (For example, a new risk.) If so, follow HRP-024 - SOP - New Information)

2. INITIAL REVIEW and MODIFICATION (when the modification affects one of the following)

☐ If the submission includes a request to serve as the single IRB of record (sIRB) for a Cooperative Study or Multi-Site Study, determine if an authorization agreement is needed using HRP-801 - SOP - Establishing Authorization Agreements.

☐ For initial reviews, determine whether the principal investigator has any lapsed studies. If so, list in the "Notes" section of HRP-401 - Checklist - Pre-Review.

[1] This document satisfies AAHRPP elements I-9, II.2.C

☐ If the research involves new personnel, confirm all training requirements are satisfied.

☐ If the research involves FDA oversight, confirm the principal investigator is not listed on the FDA debarment list.

☐If the research involves clinical activities, confirm privileges of staff conducting clinical activities.

☐ If the research involves the use of a drug use the HRP-306 - WORKSHEET - Drugs.

☐ If the research involves the use of a device use the HRP-307 - WORKSHEET - Devices.

☐ Note any special determinations that need to be made by the convened IRB or Designated Reviewer in the "Special Determinations" section of the Pre-Review Activity.

☐ If the device meets the abbreviated IDE requirements, note "Non- significant risk device determination" in the "Special Determinations" section of the Pre-Review Activity.

☐ If the research is NIH-funded (regardless of whether the investigator has indicated the use of a Certificate of Confidentiality), note the presence of a Certificate of Confidentiality in the Protocol Tracking section of the Pre-Review Checklist.

Note any missing materials necessary for review in the "Notes" section of HRP-401 - Checklist - Pre-Review:

☐ Qualifications of the key personnel

☐ Complete sponsor protocol (including DHHS protocol)

☐ DHHS- approved sample consent document

☐ Investigator brochure for investigational drug

☐ Package insert for marketed drugs

☐ Executed Reliance Agreement(s)

☐ Product information for medical devices

☐ For Department of Education (ED) research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA

☐ For the Department of Defense research involving DOD-affiliated personnel, ensure approval to conduct the research is submitted from the DOD-affiliated personnel's command or DOD HRPP

☐ For research sharing a Limited Data Set (LDS) from VCUHS to VCU, a Data Use Agreement for LDS form signed by investigator

Note missing/inappropriately answered Investigator Protocol sections in the "Notes" section of HRP-401 - Checklist - Pre-Review:

☐ IRB Review History

☐ Objectives

☐ Background

☐ Setting

☐ Resources Available

☐ Prior Approvals

☐ Study Design

☐ Recruitment Methods

☐ Inclusion/Exclusion Criteria

☐ Compensation for Injury

☐ Local Number of Subjects

☐ Total Number of Subjects

☐ Study Timelines

☐ Study Endpoints

☐ Procedures Involved

☐ Data and Specimen Banking

☐ Data Management

☐ Confidentiality

☐ Provisions to Monitor Data

☐ Withdrawal of Subjects

☐ Risks to Subjects

☐ Potential Benefits to Subjects

☐ Provisions to Protect Privacy

☐ Economic Burden to Subjects

☐ Consent Process

☐ Consent Documentation (e.g., scripts, forms)

☐ Vulnerable Populations

☐ Drugs or Devices

☐ Multi-Site Research

☐ Community Based Participatory Research

☐ Sharing of Results

"Notes" section of HRP-401 - Checklist - Pre-Review:

☐ Research is subject to regulations not overseen or conducted by the organization

☐ Positive financial declaration without a Conflict of Interest report

☐ Protocol information relates to an item in the list of institutional financial interests

☐ An IND is required and there is no IND

☐ An IND is required and there is insufficient documentation

☐ An IDE/HDE is required and there is no IDE/HDE

☐ An IDE/HDE is required and there is insufficient documentation

☐ There are inadequate provisions to control the drug(s) (e.g., the Investigator Brochure, package inserts, description of on-site drug control)

☐ There are inadequate provision to control the device(s) (e.g., device manual, description of on-site device handling)

☐ There are inadequate provisions for an investigator held IND

☐ There are inadequate provisions for an investigator held IDE

☐ External site(s) getting federal funds from the organization does not have a federalwide assurance (FWA)

☐ The research involves adults unable to consent and statements by the investigator and legal counsel regarding which individuals are Legally Authorized Representatives (LAR) do not match.

☐ The research involves children and statements by the investigator and legal counsel regarding who can provide permission for the child if an individual is not a parent do not match

3. INITIAL REVIEW and MODIFICATIONS FOR pSITES RELYING ON THIS IRB (when the modification affects one of the following)

☐ pSite Consent Process

☐ Protocol procedures are consistent with pSite age of majority state law as indicated in Institutional Profile.

□ Protocol procedures are consistent with any pSite policies on assent as indicated in Institutional Profile.

□ pSite Consent Documents

□ Submission includes tracked version of the lead study approved version of consent document(s) (to ensure previously reviewed information and any modifications requested are present).

□ pSite consent documents include pSite name and PI contact information.

□ pSite consent documents contain any pSite required language (e.g., injury language, genetic testing/future use of genetic material, pregnancy reporting, barcode, logo) as indicated in Institutional Profile.

□ HIPAA Authorization

□ HIPAA authorization format is consistent with pSite requirement (e.g., separate or combined with consent)

□ If HIPAA authorization language is included in the consent form, includes any pSite required language as indicated in HRP-815 - FORM - Institutional Profile (e.g., state law on expiration period).

□ Privacy Board

□ Determine if the IRB is serving as the Privacy Board (documented in HRP-830 - WORKSHEET - Communication and Responsibilities in the Institutional Profile), for the study for purposes of review and approval of waivers of HIPAA authorization.

□ HIPAA is not applicable to this study.

□ Recruitment and subject-facing materials

□ Materials are consistent with the materials approved for the lead site.

□ Materials are consistent with local pSite name/logo information.

□ Protocol and/or Site Supplement and/or Basic Site Information Form

□ Drug and Device Storage plan is present (if different from protocol) and consistent with pSite policy where indicated in Institutional Profile.

□ If the drug/device storage plan is different from the parent protocol, use HRP-306 - WORKSHEET - Drugs and Biologics.

□ Study procedures consider relevant tribal, state, or non-US laws, regulations, or policies (i.e., special populations, genetic testing, future use of genetic material) where indicated in Institutional Profile.

□ Completed Local Funding Sources Page (if relevant)

□ pSite Without an IRB/HRPP

□ Qualifications and training of pSite key personnel have been provided (may request proof of human subjects and GCP training, confirmation of any special degrees or certifications needed for study procedures).

□ If a possible conflict exists for pSite personnel is indicated in the submission materials, the COI office has been notified.

4. CONTINUING REVIEW

□ If Continuing review is not required, ask the investigator to discard the submission.

□ Note missing Continuing review form in the “Notes” section of the HRP-401 - Checklist - Pre-Review.

5. MODIFICATION

□ Note missing modification form in the “Missing Materials” section of the Pre-Review.

6. STUDY CLOSURE

□ Confirm that the research meets the criteria for closure and note in the Study Closure Section the Pre-Review.

VCU Research and Innovation

HRP-309 | 03/27/2024

WORKSHEET: Ancillary Review Matrix

Ancillary reviews are reviews by other compliance groups or individuals that inform the IRB's review of a new study or a modification to an existing study.

The impact of an ancillary review group's approval on the IRB's review process varies.

- Typically, final IRB approval is held until the ancillary group concludes their review.
- In some instances, the IRB will not initiate its review without documentation of approval by critical review entities.
- The IRB will not hold for the completion of ancillary reviews for studies that meet exempt criteria.
- Documentation of approval by an ancillary review group is provided to the researcher. The researcher is responsible for uploading that documentation in the "Documents" section of the RAMS IRB application to which it relates.
- In rare instances, either the ancillary review group or an IRB member may request deviations from the typical review path. An IRB member may recommend holding a submission until an ancillary approval is granted from a key committee **OR** an ancillary review group may recommend IRB review move forward while a required approval is still pending.

The tables below highlight the ancillary review groups available and illustrates the typical impact an ancillary review has on IRB review. Please contact the IRB or relevant ancillary review contacts (listed below) with any questions about the ancillary review process or specific requirements.[1]

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Human Research Protection Program	Human Subjects Training	all human subjects research submissions	Initial Review Modifications CR	hrpp@vcu.edu	https://research.vcu.edu/training/citi-training/	Prior
Human Research Protection Program	Good Clinical Practice Training	study meets NIH definition of clinical trial	Initial Review Modifications CR	indide@vcu.edu	Good Clinical Practice (GCP) training - Virginia	Prior

[1] If the requirement for an ancillary review differs for studies relying on an external IRB, the differences will be indicated in this table.

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
					Commonwealth University (vcu.edu)	
Internal DUAs: Human Research Protection Program	Data Use Agreement (DUA) for Limited Data Set (LDS) from VCU Health System	Sharing a LDS from VCUHS to an internal entity	Initial Review Modifications	HRPP@vcu.edu	Complete HIPAA Data Use Agreement for Limited Data Set form and upload in RAMS-IRB application.	Prior/Parallel
Office of Research Integrity and Ethics	Conflict of interest (COI)	For expedited or full board studies, 'COI Investigators' (designated by the PI as having responsibility and independence in the design, conduct, and reporting of research), must complete a Financial Interest Report (FIR) in the Activities and Interests Reporting System (RAMS-AIRS)	Initial Review	AIRS@vcu.edu	The Activity and Interest Reporting System (AIRS) is an electronic Research Administration Management System (RAMS) for the reporting of interests pertaining to research.	Prior
Cost Coverage Analysis	Coverage Analysis	All clinical research studies	Initial Review	Contact your school or center research administration office	Contact your school or center research administration office	Prior
Institutional Biosafety Committee (IBC)	Oversight of rDNA research or biologically hazardous materials	Research involves use of monoclonal antibodies not FDA approved, recombinant/synthetic DNA (rDNA), or administration of pathogens to human subjects	Initial Review	ibc@vcu.edu	Institutional Biosafety Committee - Safety and Risk Management - Virginia Commonwealth University (vcu.edu)	If changes are requested to protocol or consent by IBC, a modification must be submitted to the IRB.
Institutional Review Entity (IRE)	Oversight of DURC agents and/or toxins	Research involves one of the 15 agents/toxins designated as Dual Use Research of Concern (DURC) agents/toxins by United States Government Policy for Institutional Oversight of	Initial Review CR	jjryan@vcu.edu	Regulatory committees - Virginia Commonwealth University (vcu.edu)	Prior/Parallel

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
		Life Sciences Dual Use Research of Concern				
Massey Cancer Center	Protocol Review and Monitoring Committee (PRMC)	Oncology related research	Initial Review	masseyprms@vcu.edu	Clinical Research Committees | VCU Massey Cancer Center	Prior
VCUHS	Protocol Review Committee (PROC)	Use of VCUHS facilities or patients' medical records	Initial Review	mary.harmon@vcuhealth.org	ONETRAC (vcu.edu)	Prior
Scientific Review Committee	Scientific Review	Greater than minimal risk studies where scientific review not provided by the study sponsor	Initial Review	japhifer@vcu.edu	https://cctr.vcu.edu/support/consultation/scientific-review-committee/	Prior
Research Data Privacy Program	GDPR	collecting data about a natural person in the European Economic Area (the E.U., Iceland, Liechtenstein and Norway)	Initial Review	rescomply@vcu.edu	Research data privacy - Virginia Commonwealth University (vcu.edu)	Prior/Parallel
Information Security	Security review of technology	Use of any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data	Initial Review Modifications	infosec@vcu.edu	Information Security | Technology Services | VCU	Parallel
Investigational Drug Pharmacy	Proper storage, handling and disposal of investigational agents	Drug and device studies	Initial Review Modifications	Mary Pak (804) 828-7901 mary.pak@vcuhealth.org	Investigational Drug Services - Virginia Commonwealth University	Prior
Division of Sponsored Programs	Compensation for Injury consent language for industry sponsored studies	Changes to template language in ICF	Initial Review Modifications	ospred@vcu.edu	Proposals and awards - Virginia Commonwealth University (vcu.edu)	Prior/Parallel

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
VCU Health Department of Patient Centered Services		Administration of satisfaction surveys to VCUHS patients	Initial Review Modifications	Nathan.cunningham@vcuhealth.org		Prior/parallel
Clinicaltrials.gov support office at Wright Center	clinicaltrials.gov registration	Meets NIH definition of clinical trial or other registration criteria.	Initial Review	cctrctgov@vcu.edu	ClinicalTrials.gov - Virginia Commonwealth University	Does not affect IRB review. However, when registration is required, consent language must be included.
Division of Sponsored Programs	Material Transfer Agreement	Whenever there is a material transfer that is not covered by any other agreement (e.g., purchase order/procurement, grant award, or sponsored clinical trial)	Initial Review Modifications	mtadua@vcu.edu (804) 828-6772	Pre-proposal - Virginia Commonwealth University (vcu.edu)	does not affect IRB review
Division of Sponsored Programs	Data Use Agreement	Any time non-public data is exchanged between entities (except sharing of Limited Data Set from VCU Health System which is reviewed by VCU IRB)	Initial Review Modifications	ua@vcu.edu	Pre-proposal - Virginia Commonwealth University (vcu.edu)	If protocol does not account for sharing, a modification must be submitted to the IRB
Division of Sponsored Programs	Funding Agreements	Funding provided by or collaboration with external sponsor (including Cooperative Research and Development Agreement, Expanded Access, Clinical Trial Agreement)	Initial Review Modifications	See DSP Decision Tree	Proposals and awards - Virginia Commonwealth University (vcu.edu)	Prior/Parallel
Information Security Office	Data Management System (Data Management Plan)	Use of Category 1 Data as defined by **VCU Data Classification Tool**	Initial Review	infosec@vcu.edu	DMPs are made using the Data Management System (DMS) https://ts.vcu.edu/about-us/information-security/data-management-system/	Prior/Parallel
Information Security Office	assessment of third-party software/platforms	use of third party software/platforms	Initial Review Modifications	infosec@vcu.edu	Information Security | Technology Services | VCU	Prior/Parallel

Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
Human Research Protection Program	Post Approval Monitoring and Quality Improvement Program (PAMQuIP)	for-cause and routine visits of human subjects research	Initial Review CR	pamquip@vcu.edu	Other submissions and monitoring - Virginia Commonwealth University (vcu.edu)	After
Radiation Safety Committee (RSC)	Radiation	study involves radiation exposure and/or scans involving radiation (e.g., PET, MRA, CT, DXA, nuclear medicine)	Initial Review Modifications	kurgatts@vcu.edu	Radiation Safety - Safety and Risk Management - Virginia Commonwealth University (vcu.edu)	If changes are requested to protocol or consent by Radiation Safety, a modification must be submitted to the IRB.
Emergency Department Letter	feasibility	enrolling patients within the VCU Department of Emergency Medicine (EM) or seeking to utilize EM resources	Initial Review	lisa.merck@vcuhealth.org	Research - Department of Emergency Medicine - VCU School of Medicine	Prior
VCU Records and Registration	FERPA	access to student records	Initial Review	infosec@vcu.edu or rar@vcu.edu	Disclosure of student contact information - Records and Registration - Virginia Commonwealth University (vcu.edu)	Prior/Parallel
Regulatory Affairs	Investigator held IND/IDE	All protocols conducted at VCU under a VCU Faculty Held IND/IDE	Initial Review	indide@vcu.edu	Regulatory affairs - Virginia Commonwealth University (vcu.edu)	Prior
VCUHS Department of Pathology	feasibility	study involves: - Storage of Microbiology isolates - New instrumentation provided by clinical trial/study sponsor, or - Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing) - specimen retrieval from Pathology lab	Initial Review		https://pathology.vcu.edu/research/	Prior

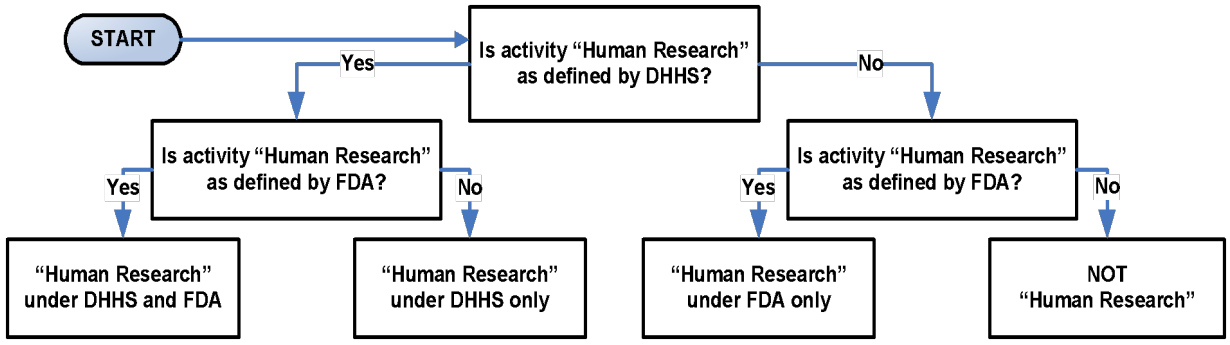
Organization	Review Type	Ancillary Review Triggered by	Affected IRB Submission Types	Relevant Contact	How to Obtain Review	Impact on IRB Review (prior to, after, or parallel with)
VCUHS Privacy Office VCU Informatics	VCUHS Policy COMP-14	access to medical records for research purposes, including screening and eligibility purposes and secondary use	Initial Review Modifications	https://informatics.vcu.edu/	Consult with Informatics to ensure proposed access to medical records is an approved method.	After
VCU Dental School Privacy Office	VCU SOD	When SOD IT will be asked to provide secondary dental records data	Initial Review Modifications	https://support.dentistry.vcu.edu/ Research: Patient Data Request Contact: Mike Talley talleymw@vcu.edu	Does not affect IRB review. SOD approval depends on IRB approval.	After
VA Department of Behavioral Health Regional Local Human Rights Committee (LHRC)	Human research	IRB approval for research on subjects receiving state-funded services from providers of mental health, mental retardation, or substance abuse services in Virginia	Initial Review	Region 1: Cassie Purtlebaugh cassie.purtlebaugh@dbhds.virginia.gov Region 2: Ann Pascoe ann.pascoe@dbhds.virginia.gov Region 3: Mandy Crowder mandy.crowder@dbhds.virginia.gov Region 4: Andrea Milhouse andrea.milhouse@dbhds.virginia.gov Region 5: Reginald Daye reginald.daye@dbhds.virginia.gov Facilities: Brandon Charles brandon.charles@dbhds.virginia	Contact the OHR Regional Manager (listed under relevant contacts) for specific region in which the research is conducted to obtain submission information	Obtained after IRB review and approval, before initiating the research

VCU Research and Innovation

HRP-310 | 03/01/2024

WORKSHEET: Human Research Determination

The purpose of this worksheet is to provide support for individuals in determining whether an activity is Human Research or how it is regulated [1].



1. Research as Defined by DHHS Regulations[2] (Check if "Yes")

☐ Is the activity an investigation? (Investigation: a searching inquiry for facts; detailed or careful examination.)

☐ Is the investigation systematic? (Systematic: having or involving a system, method, or plan.)

☐ Is the systematic investigation designed to develop or contribute to knowledge? (Designed: observable behaviors used to develop or contribute to knowledge. Develop: to form the basis for a future contribution. Contribute: to result in. Knowledge: truths, facts, information.)

☐ Is the knowledge the systematic investigation is designed to develop or contribute generalizable? (Generalizable: universally or widely applicable.)

2. Human Subject Under DHHS Regulations (Check if "Yes")

☐ Is the investigator conducting the Research gathering information or biospecimens *about living* individuals?

3. Human Subject Under DHHS Regulations (Check if "Yes")

[1] This document satisfies AAHRPP elements I.1.A, III.1.A

[2] The following activities conducted or supported by the Department of Defense (DOD) are NOT research involving human subjects: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease in Service members and other mission essential personnel under force health protection programs of the Department of Defense, including health surveillance pursuant to section 1074f of Reference (g) and the use of medical products consistent with DoD Instruction 6200.02. Authorized health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of patient treatment. Activities performed for the sole purpose of medical quality assurance consistent with 10 USC 1102 and DoDD 6025.13. Activities performed solely for an OT&E project where the activities and project meet the definition of OT&E as defined in 10 USC 139(a)(2)(A). Activities performed solely for assessing compliance of individuals and organizations with requirements applicable to military, civilian, or contractor personnel or to organizational units, including such activities as occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. Survey, interview, or surveillance activities and related analyses performed solely for authorized foreign intelligence collection purposes, as authorized by DoDD 5240.01.

☐ Will the investigator use, study, or analyze information or biospecimens obtained through either of the following mechanisms? Specify which mechanism(s) apply, if yes:

- ☐ Physical procedures or manipulations of those individuals or their environment for Research purposes ("Intervention").
- ☐ Communication or interpersonal contact with the individuals. ("Interaction").

4. Human Subject Under DHHS Regulations (Check if "**Yes**")

☐ Will the investigator gather data that is either? Specify which category(s) apply if yes:

- ☐ The data are about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place (i.e. "Private information").
- ☐ Individuals have provided the data for specific purposes in which the individuals can reasonably expect that it will NOT be made public, such as a medical record (i.e. "Private information").
- ☐ Can the individuals' identities be readily ascertained or associated with the information by the investigator (i.e. "Identifiable Private Information")?
- ☐ Can the individuals' identities be readily ascertained or associated with the biospecimens (i.e., "Identifiable Biospecimen")?

If all items are checked under 1, 2, and 3 or 1, 2, and 4, the activity is Human Research under DHHS regulations.

5. Human Research Under DHHS Regulations (Check if "**Yes**")

☐ Has a department or agency head, covered by the Common Rule, retained final judgment (consistent with the ethical principles of the Belmont Report) that the activity is Human Research under DHHS regulations?

If checked, the activity is Human Research under DHHS regulations.

6. Human Research Under FDA Regulations (Check if "Yes")

☐ Does the activity involve any of the following? (Check all that apply)

- ☐ In the United States: The use of a drug [3] in one or more persons other than use of an approved drug in the course of medical practice [4].

[3] The term ''drug'' means:
(A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
(C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and
(D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

[4] "Other than the use of an approved drug in the course of medical practice" refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of the practitioner.

☐ In the United States: The use of a device [5] in one or more persons that evaluates the safety or effectiveness of that device.

☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA [6].

☐ Data regarding the use of a device on human specimens (identified or unidentified) submitted to or held for inspection by FDA [7].

If "Yes", the activity is Human Research under FDA regulations.

7. Human Research under Organizational Policy

If the activity is Human Research under DHHS regulations or under FDA regulations, it is Human Research under organizational policy.

8. Engagement (Complete if the activity is Human Research. (Check if "Yes")

☐ The organization is engaged in Human Research. Use HRP-311 - WORKSHEET - Engagement Determination.

9. Comments

Comments:Click or tap here to enter text.

[5] The term ''device'' means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

[6] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

[7] This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this requirement.

VCU Research and Innovation

HRP-311 | 03/01/2024

WORKSHEET: Engagement

The purpose of this worksheet is to provide support for Designated Reviewers making engagement determinations when there is uncertainty regarding whether the organization is Engaged in Human Research. For the purpose of this worksheet, "Engagement" means that the organization's human research protection program is responsible for the Human Research. For the purposes of being subject to DHHS or other federal agency that has adopted "The Common Rule" engagement applies only to non-exempt Human Research. This worksheet does not need to be completed or retained.[1]

1. FDA Exception for "Engagement" (Check if "**Yes**")

☐ **ONLY** FDA regulations apply to this Human Research as indicated in the "Regulatory Oversight" section on HRP-401 - CHECKLIST - Pre-Review/Submit Pre-Review activity (DHHS regulations or any other Federal agency that has adopted the Common Rule are NOT checked in in the "Regulatory Oversight" section on HRP-401 - CHECKLIST - Pre-Review /Submit Pre-Review activity).

If ONLY FDA regulations apply, **STOP**. The FDA does not have a comparable process that aligns with OHRP's engagement guidance since FDA regulations govern sponsors (and parties they contract with), clinical investigators, and IRBs (and do not address institutions/organizations). If an organization is conducting certain activities of FDA (only) regulated Human Research, determining whether an institution/organization requires IRB oversight depends on many details such as:

- What type of activities are being conducted.
- What the protocol requires.
- Who is conducting the activities.
- Where the activities are being conducted.
- For what purpose the activities are being conducted.

FDA recommends referring to FDA Information Sheet "Use of Investigational Products When Subjects Enter a Second Institution, *Guidance for Institutional Review Boards and Clinical Investigators* (January 1998)" for guidance and to contact the sponsor and/or applicable FDA review division for assistance.[2]

The organization is Engaged in the research if the first item in section 2 is true regardless of whether the organization's involvement is limited to one or more of the items in section 3.

[1] This document satisfies AAHRPP element I.1.A

[2] Huron email correspondence with FDA GCP Program dated October 13, 2020.

The organization is Engaged in the research if any item other than the first item in section 2 is true except when the organization's involvement is limited to one or more of the items in section 3.

2. Conditions Under Which an Organization is Engaged

☐ The organization receives an award through a grant, contract, or cooperative agreement directly from a federal agency for non-exempt Human Research, even where all activities involving Human Subjects are carried out by employees or agents[3] of another organization.

☐ The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by performing invasive or noninvasive procedures.

☐ The organization's employees or agents intervene for Research purposes with any Human Subject of the Research by manipulating the environment.

☐ The organization's employees or agents interact for Research purposes with any Human Subject of the Research.

☐ The organization's employees or agents obtain the informed consent of Human Subjects for the Research.

☐ The organization's employees or agents obtain for Research purposes identifiable private information or identifiable biological specimens from any source for the Research. It is important to note that, in general, the organization's employees or agents obtain identifiable private information or identifiable specimens for Human Research are considered Engaged in the Research, even if the organization's employees or agents do not directly interact or intervene with Human Subjects.

3. Conditions Under Which an Organization is Not Engaged Even Though a Condition in Section 2 is Met

☐ The organization's employees or agents perform commercial or other services for investigators provided that **ALL** of the following conditions also are met:

- ☐ The services performed do not merit professional recognition or publication privileges.
- ☐ The services performed are typically performed by those organizations for non-Research purposes.
- ☐ The organization's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

☐ The organization is not selected as a Research site but its employees or agents provide clinical trial-related medical services that are dictated by the protocol that would typically be performed as part of routine clinical

[3] An organization's employees or agents refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. "Employees and agents" can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation. Contact legal counsel for additional information regarding whether an individual is an agent of the organization.

monitoring or follow-up of Human Subjects enrolled at a study site by clinical trial investigators provided that **ALL** of the following conditions also are met:

- ☐ The organization's employees or agents do not administer the study interventions being tested or evaluated under the protocol.
- ☐ The clinical trial-related medical services are typically provided by the organization for clinical purposes.
- ☐ The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
- ☐ When appropriate, investigators from an organization Engaged in the Research retain responsibility for ALL of the following:
    - ☐ Overseeing protocol-related activities.
    - ☐ Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at an Engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol.

☐ The organization was not initially selected as a Research site but the organization's employees or agents administer the study interventions being tested or evaluated under the protocol limited to a one-time or short-term basis where an investigator from an organization Engaged in the Research determines that it would be in the Human Subject's best interest to receive the study interventions being tested or evaluated under the protocol and **ALL** of the following are true:

- ☐ The organization's employees or agents do not enroll Human Subjects or obtain the informed consent of any Human Subject for participation in the Research.
- ☐ Investigators from the organization Engaged in the Research retain responsibility for **ALL** of the following:
    - ☐ Overseeing protocol-related activities.
    - ☐ Ensuring the study interventions are administered in accordance with the IRB-approved protocol.
    - ☐ Ensuring appropriate arrangements are made for reporting protocol-related data to investigators at the Engaged organization, including the reporting of safety monitoring data and adverse events as required under the IRB-approved protocol. and
- ☐ An IRB designated on the Engaged organization's federalwide assurance (FWA) is informed that study interventions being tested or evaluated under the protocol have been administered at an organization not selected as a Research site.

☐ The organization's employees or agents do **ANY** of the following:

- ☐ Inform prospective Human Subjects about the availability of the Research.
- ☐ Provide prospective Human Subjects with information about the Research but do not obtain Human Subjects' consent for the Research or act as representatives of the investigators.
- ☐ Provide prospective Human Subjects with information about contacting investigators for information or enrollment.
- ☐ Seek or obtain the prospective Human Subjects' permission for investigators to contact them.

☐ The organization is permitting use of its facilities for intervention or interaction with Human Subjects by investigators from another organization.

☐ The organization's employees or agents release to investigators at another organization identifiable private information or identifiable biological specimens pertaining to the Human Subjects of the Research.

☐ The organization's employees or agents:

- ☐ Obtain coded private information or human biological specimens from another organization involved in the Research that retains a link to individually identifying information; and
- ☐ Are unable to readily ascertain the identity of the Human Subjects to whom the coded information or specimens pertain.

☐ The organization's employees or agents access or utilize individually identifiable private information only while visiting an organization that is Engaged in the Research, provided their Research activities are overseen by the IRB of the organization that is Engaged in the Research.

☐ The organization's employees or agents access or review identifiable private information for purposes of study auditing.

☐ The organization's employees or agents receive identifiable private information for purposes of satisfying U.S. Food and Drug Administration reporting requirements.

☐ The organization's employees or agents author a paper, journal article, or presentation describing a Human Research study.

VCU Research and Innovation

HRP-312 | 02/01/2024

WORKSHEET: Exemption

The purpose of this worksheet is to provide support for Designated Reviewers granting exemption determinations. It does not need to be completed or retained.[1]

1. GENERAL EXCLUSIONS FROM EXEMPTIONS (Check if **"Yes"**. If any are checked, the research is not exempt.)

☐ The research involves Prisoners, conducted or funded by DHHS, **Dept. of Defense (DOD)**[2], or **Veterans Administration (VA)**, and is NOT aimed at involving a broader subject population that only incidentally includes prisoners.

☐ The research involves interactions with Prisoners.[3]

☐ **The research is classified and conducted or funded by the Department of Energy (DOE) (may be reviewed by convened IRB only).**[4]

2. Criteria for approval of exempt research (Check if "Yes")

☐ The research involves no more than Minimal Risk to subjects. **(Must be checked.)**

☐ Selection of subjects is equitable. (That is, the research is appropriate for the population being studied.) **(Must be checked).**

☐ There is recording of identifiable information: (If checked, the following must also be checked.)

- ☐ There are adequate provisions to maintain the confidentiality of the data

☐ There are interactions with subjects: **(If checked, all of the following must also be checked.)**

- ☐ There will be a consent process
- ☐ The consent process will disclose that the activities involve research.
- ☐ The consent process will disclose the procedures to be performed.

[1] This document satisfies AAHRPP elements I-9, II.2.A, II.2.B, II.2.C, II.3.F, II.4.A, II.5.A

[2] Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted, but must first be approved by an IRB and meet the requirements of Subpart C and DoDI 3216.02.

[3] AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative.

[4] DOE O 443.1C

☐ The consent process will disclose that participation is voluntary.

☐ The consent process will disclose the name and contact information for the investigator.

☐ There are adequate provisions to maintain the privacy interests of subjects.

☐ Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data.

☐ Contact information for the VA researcher

2018 Requirements

NOTE: For Exempt determinations on or after January 21, 2019, complete section 3. If this study is subject to Pre-2018 Common Rule requirements or is DOJ-regulated, move to sections 4 and 5 below.

3. The research falls into one or more of the following categories (One or more categories must be checked)

☐ 1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR

☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

☐ (iii) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND an IRB conducts limited IRB review. **(See HRP-319 – WORKSHEET – Limited IRB Review)**

☐ VCU applies the restriction when conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), or Veterans Administration (VA), or the Environmental Protection Agency (EPA), and limits procedures involving children to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests when at least one of the following criteria is met:

☐ (i) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly through identifiers linked to the subjects; OR

☐ (ii) Any disclosure of Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational achievement, or reputation.

☐ 3(i). Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met[5]:

☐ (A) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects cannot readily be ascertained, directly or indirectly, through identifiers linked to the subjects; OR

☐ (B) Any disclosure of the Human Subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; OR

☐ (C) The information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or indirectly, through identifiers linked to the subjects; AND an IRB conducts limited IRB review[6]. **(See HRP-319 – WORKSHEET – Limited IRB Review)**

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

☐ (i) The identifiable private information or identifiable biospecimens are publicly available; OR

[5] SACHRPP guidance regarding interpreting exempt category 3: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-august-2-2017.html

[6] For VA Research, the limited IRB review must be completed prior to approval by the R&D committee.

☐ (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR

☐ (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR part 160 and 164 (HIPAA), subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); OR

☐ (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ 5. Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine: public benefit or service programs, including procedures for obtaining benefits or services under those programs[7] [8]

☐ (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision This research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ 6.[9]Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives and consumed or (ii) if a food is consumed that contains a food ingredient at or below the level

[7] Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

[8] When following Veterans Administration (VA) regulations and guidance, the determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 must be made by the Under Secretary for Health on behalf of the Secretary of VA, after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate.

[9] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).

and for a use found to be safe, or agriculture chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.

The following exemption categories are not applied at VCU

☐ 7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts limited IRB review[10] **(See HRP-319 - WORKSHEET - Limited IRB Review) NOT APPLIED AT VCU**

☐ 8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use. **(See HRP-319 - WORKSHEET - Limited IRB Review)[11] NOT APPLIED AT VCU**

Pre-2018 Requirements

NOTE: If this study is subject to 2018 Common Rule requirements[12], complete section 3 above.

4. One of the following is true:

☐ **The research is DOJ Regulated.**

5. The research falls into one or more of the following categories (one or more categories must be checked)

☐ 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (Both the procedures involve normal education practices and the objectives of the research involve normal educational practices.)

☐ 2. Research involving the use of educational tests[13] (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that Human Subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the Human Subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. In addition:

☐ If the research involves children and is conducted, funded, or subjects to regulation by DHHS, **Dept. of Defense (DOD), Dept. of Education (ED), Veterans Administration (VA), or the**

[10] For VA Research, the limited IRB review must be completed prior to approval by the R&D committee.

[11] For VA Research, the limited IRB review must be completed prior to approval by the R&D committee.

[12] Exempt modification submissions initially reviewed under pre-2018 requirements will be moved to 2018 Common Rule requirements unless DOJ-regulated.

[13] Includes cognitive, diagnostic, aptitude, and achievement tests

Environmental Protection Agency (EPA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed and (2) the use of educational tests. **("NA" if the research does not involve children or is not conducted, funded, or otherwise subject to by these agencies.)**

☐ 3. Research involving the use of educational tests survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the Human Subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

☐ 4. [14]Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. (**For research conducted, funded, or otherwise subject to regulation by any federal agency "existing" means "existing at the time the research is proposed." Otherwise, it means "existing at the time the research is proposed or will exist in the future for non-research purposes."**)

☐ 5. Research and demonstration projects which are conducted by or subject to the approval of Dept. or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs. In addition: (Check if "**Yes**". All must be checked)

☐ The program under study delivers a public benefit[15] or service.[16]

☐ The research or demonstration project is conducted pursuant to specific federal statutory authority.

☐ There is no statutory requirement that the project be reviewed by an IRB.

☐ The project does not involve significant physical invasions or intrusions upon the privacy of subjects.

☐ The funding agency concurs with the exemption.

☐ 6. [17]Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found

[14] "If these sources are publicly available" was removed because public data cannot be private, and if there is no collection of private identifiable data, there can be no Human Subjects.

[15] For example, financial or medical benefits as provided under the Social Security Act

[16] For example, social, supportive, or nutrition services as provided under the Older Americans Act

[17] Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization's policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1).

to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the Dept. of Agriculture.

VCU Research and Innovation

HRP-313 | 02/01/2024

WORKSHEET: Expedited Review

The purpose of this worksheet is to provide support for Designated Reviewers conducting reviews using the expedited procedure. It does not need to be completed or retained.[i]

---

1. Humanitarian Use Device (HUD) (Check if "**Yes**" or "**NA**". Must be checked)

☐ Continuing review of non-research Humanitarian Use Device (HUD) using the expedited procedure.[ii] ("**NA**" if not HUD) ☐ **NA**

2. Research Involving Prisoners[iii] (Must be checked)

☐ There are no prisoners as subjects OR the study is minimal risk and there is no prisoner interaction OR for modifications that do not involve interaction with prisoners. (VCU research involving interactions with prisoners is reviewed by the convened IRB, including the prisoner representative, regardless of whether the study is minimal risk.)

3. Minor Modifications (Check if "**Yes**" or "**NA**". All must be checked)

☐ The modifications do not affect the design of the research.

☐ The modifications add no more than Minimal Risk to subjects.

☐ All added procedures fall into categories (1)-(7) below. ("**NA**" if no added procedures) ☐ **NA**

4. Initial Review, Continuing Review, or Modifications (Check if "**Yes**" or "**NA**". All must be checked)

☐ The research activities (or remaining research activities) present no more than Minimal Risk to Human Subjects. (**"NA"** if the research falls into category (8)(b))

☐ Identification of the subjects or their responses (or the remaining procedures involving identification of subjects or their responses) will **NOT** reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than Minimal Risk. (**"NA"** if the research falls into category (8)(b))

☐ The research is **NOT** classified.[iv]

☐ The research (or remaining research) falls into one or more of the following categories: **(Check all that apply)**

☐ (1)(a) Clinical studies of drugs when an IND is not required.

☐ (1)(b) Clinical studies of medical devices when an IDE is not required, or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ (2)(a) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from healthy, non-pregnant adults who weigh ≥110 pounds where the amount drawn is ≤550 ml[v]/8 week period and collection occurs at most 2 times/week.

☐ (2)(b) Collection of blood samples[vi] by finger stick, heel stick, ear stick, or venipuncture from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected (50 ml or 3 ml/kg,[vii] whichever is less, per 8 week period), and the frequency with which it will be collected (at most 2 times/week).

☐ (3) Prospective collection of biological specimens for research purposes by noninvasive[viii] means.[ix]

☐ (4) Collection of data through noninvasive procedures[x] (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing.[xi]

☐ (5) Research involving materials (data, documents, records, or specimens) that have been collected for any purpose, or will be collected solely for non-research purposes.

☐ (6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ (7)(a) Research on individual or group characteristics or behavior.[xii]

☐ (7)(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

> For research approved on or after 1/21/2019, this does not include scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected; this is deemed not to be research per 45 CFR 46. 102(l)(1).

☐ (8)(a) Continuing review of research previously approved by the convened IRB where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects.[xiii] (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (8)(b) Continuing review of research previously approved by the convened IRB where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.[xiv]

☐ (8)(c) Continuing review of research previously approved by the convened IRB where the remaining research activities are limited to data analysis. (For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.)

☐ (9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than Minimal Risk and no additional risks have been identified.[xv] [xvi]

---

[i] This document satisfies AAHRPP elements I-9, II.2.F-II.2.F.3, II.5.A.

[ii] Humanitarian Device Exemption (HDE) Program Guidance for Industry and Food and Drug Administration Staff Document issued on September 6, 2019 states, "For continuing review [of the HUD], an IRB may use an expedited review procedure in which a chairperson or one or more experienced reviewers carries out the review, similar to the expedited review procedure described at 21 CFR 56.110(b)."

[iii] AAHRPP Tip Sheet 18: Review of Research involving Prisoners and the Role of the Prisoner Representative; OHRP Prisoner Research FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/prisoner-research/index.html.

[iv] Classified information is sensitive information to which access is restricted by law or regulation to particular groups of persons. A formal security clearance is required to handle classified documents or access classified data. In the United States classified research involving human subjects is where the protocol, information required by the IRB for review and oversight, or information provided by the research subjects includes classified information, as defined in Executive Order 13526, "Classified National Security Information," December 29, 2009.

[v] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[vi] Collection of blood samples from other adults and children may include a draw from an existing peripheral indwelling catheter; however, all draws from central lines are considered to be greater than minimal risk. Per correspondence with OHRP dated April 2023.

[vii] Volume pertains to amount collected for research purposes; does not include volume drawn for clinical care purposes. *Per correspondence with OHRP dated October 2019.*

[viii] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares (refer to 21 CFR 812.3).

[ix] Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum-base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

[x] Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares (refer to 21 CFR 812.3).

[xi] Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

[xii] Examples: Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.

[xiii] Long term follow up includes research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol. Long term follow-up excludes research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk.

[xiv] OHRP recommends that IRBs use their discretion "to determine otherwise" under §46.109(f)(1) to determine that continuing review of research should be conducted at intervals appropriate to their degree of risk, but not less than once per year for research that is subject to the 2018 Requirements for expedited categories (8)(b) and (9). OHRP 2018 Requirements FAQs https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html.

[xv] Ibid.

[xvi] A nonsignificant risk (NSR) study that is determined to be minimal risk by a convened board would be eligible for expedited review for continuing review under Category 9 (per OC GCP correspondence from FDA dated January 2015).

VCU Research and Innovation

HRP-314a | 03/01/2024

WORKSHEET: Criteria for Approval-Reviewer Summary

The purpose of this worksheet is to provide support for IRB members reviewing research. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative").[1]

1. General Considerations (Check if **"Yes"** or **"NA"**. All must be checked)

☐ The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise.

☐ For initial review the principal investigator is qualified and not prohibited from conducting the research. **("NA if not initial review) NA:** ☐

☐ Materials are complete.

2. Criteria for Approval (Check if "**Yes**" or "**NA**". all must be checked) (Applies to initial, continuing, and modifications) *If you cannot check "Yes" or "NA" use the fillable field to indicate the changes that need to be made to satisfy the criterion.*

☐ Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk. Click or tap here to enter text.

☐ Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **("NA" if none) NA:** ☐ Click or tap here to enter text.

☐ Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.[2] Click or tap here to enter text.

☐ Selection of subjects is equitable.[3] (Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures.) Click or tap here to enter text.

☐ The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **("NA" if ≤ Minimal Risk) NA:** ☐ [4] Click or tap here to enter text.

[1] This document satisfies AAHRPP elements I.1.E, I.1.F, I.7.C, I-9, II.1.E, II.2.E-II.2.E.2, II.2.F-II.2.F.3, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, III.1.F

[2] In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

[3] In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

[4] When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the

☐ There are adequate provisions to protect the privacy of subjects.[5] Click or tap here to enter text.

☐ There are adequate provisions to maintain the confidentiality of data. [6] Click or tap here to enter text.

☐ Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. **("NA" if no vulnerable subjects) NA:** ☐ Click or tap here to enter text.

☐ The informed consent process meets one of these sections or checklists:

- ☐ **Section 5: Consent Process**
- ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
- ☐ **Permanently closed to enrollment**

☐ The informed consent documentation meets one of these sections, worksheets, or checklists:

- ☐ **Section 6: Long Form**
- ☐ **HRP-317 - WORKSHEET - Short Form**
- ☐ **HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent**
- ☐ **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**
- ☐ **Permanently closed to enrollment**

☐ Additional applicable criteria[7] are met **("NA" if none) NA:** ☐ Click or tap here to enter text.

3. Additional Considerations (Check all that apply.)

☐ Does the research involve no more than Minimal Risk to subjects?

☐ Does the research require Continuing review? (**Note that for FDA or DOJ[8] overseen research there is no option not to require Continuing review.**)

The research does not require Continuing review if one of the following apply:

- ☐ The research is eligible for expedited review. **(See HRP-313 – WORKSHEET - Expedited Review)**
- ☐ The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information

specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5)

[5] The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be "sensitive" or "private." The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects' potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought. (AAHRPP Tip Sheet #5 section 2b-c)

[6] The Secretary of HHS will, after consultation with the Office of Management and Budget's privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data. In the interim, the IRB will consider it appropriate to make adequate provisions to maintain confidentiality of data any time confidentiality is promised by the investigator, or when there are legal/ethical requirements to maintain data confidentiality. The IRB will determine whether there are adequate provisions to maintain the confidentiality of that data based on a review of the procedures that are in place to meet those promises or legal/ethical requirements (e.g. What information is included in the data, how it is stored, how long it will be stored, who will have access to it, and who will be responsible for receiving/transmitting it.) (AAHRPP Tip Sheet #4 section 2b-c)

[7] HRP-315 - WORKSHEET - Advertisements; HRP-316 - WORKSHEET - Payments; HRP-318 - WORKSHEET - Additional Federal Agency Criteria; HRP-412 - CHECKLIST - Pregnant Women; HRP-413 - CHECKLIST - Non-Viable Neonates; HRP-414 - CHECKLIST - Neonates of Uncertain Viability; HRP-415 - CHECKLIST - Prisoners; HRP-416 - CHECKLIST - Children; HRP-417 - CHECKLIST - Cognitively Impaired Adults; HRP-418 - CHECKLIST - Non-Significant Risk Device.

[8] VCU applies the 2018 Revised Common Rule to all research unless a provision does not apply because the agency(ies) funding or regulating the research (e.g., DOJ) is not a signatory of the Revised Common Rule.

or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

☐ Should review take place more often than annually?[9] If so, specify period. Click or tap here to enter text.

☐ Is verification needed from sources other than the investigator that no material changes have occurred since prior review?[10] **("NA" if initial) NA: ☐**

☐ Does information need to be provided to subjects because it may affect their willingness to continue participation? **("NA" if initial) NA: ☐**

4. Primary Reviewer Criteria for Initial Review (Check if "**Yes**" or "**NA**". all must be checked; May be determined by a primary reviewer)

☐ The research has the resources necessary to protect subjects. (Time to conduct and complete the research; adequate facilities, subject pool, and medical/psychosocial resources; qualified investigators and research staff; appropriate qualifications for international research.)

☐ The plan for communication among sites is adequate to protect subjects. **("NA" if not a Multi-Site Study where PI is the lead or not initial) NA: ☐**

Complete remaining items when applicable

5. Consent Process[11] (Check if "**Yes**". All must be checked)

☐ The investigator will obtain the legally effective informed consent of the subject or LAR[12].

☐ The circumstances of consent provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate.

☐ The circumstances of consent minimize the possibility of coercion or undue influence.

☐ Information to be given to the subject or LAR will be in language understandable[13] to the subject or LAR.

☐ The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

☐ Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate.

---

[9] Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB's experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures.

[10] Implement when the veracity of the information provided is questioned.

[11] VCU applies the 2018 Common Rule requirements around consent process and documentation to all research, regardless of funding. This includes FDA-only and DOJ-regulated studies.

[12] (LAR = "subject's Legally Authorized Representative")

[13] "Understandable" means the information presented to prospective subject is in a language and at a level the subjects can comprehend (including an explanation of scientific and medical terms) *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download.

☐ There is no exculpatory language[14] through which the subject or LAR is made to waive or appear to waive the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence.

☐ Consent will disclose the elements in **Section 7: Elements of Consent Disclosure**

6. Long Form of Consent Documentation (Check if "**Yes**" or "**NA**". All must be checked.)

☐ The written consent document is accurate, complete, and consistent with the protocol.

☐ The written consent document embodies the elements in **Section 7: Elements of Consent Disclosure**

☐ The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed.

☐ The subject or LAR will sign and date the consent document.

☐ The person obtaining consent will sign and date the consent document.

☐ A copy of the signed and dated consent document will be given to the person signing the document.

☐ If there is a LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **("NA" if no signature line) NA: ☐**

☐ When a subject or LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or LAR, and that consent was freely given. **("NA" if all subjects are able to read) NA: ☐**

7. Elements of Consent Disclosure[15] (Check if "**Yes**" or "**NA**". All must be checked.)

Required Elements

*(*Can be omitted if there are none.)*

☐ The study involves research.

☐ The purposes of the research.

☐ The expected duration of the subject's participation.

☐ The procedures to be followed.

☐ Identification of any procedures, which are experimental.*

☐ Any reasonably foreseeable risks or discomforts to the subject.*

[14] FDA considers exculpatory language to be language that has the general effect of freeing or appearing to free an individual or an entity from malpractice, negligence, blame, fault, or guilt *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

[15] For additional guidance for FDA-regulated research on the elements of consent (including examples and recommendations on language), please see *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download.

☐ Any benefits to the subject or to others, which may reasonably be expected from the research.*[16]

☐ Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.*

☐ The extent, if any, to which confidentiality of records identifying the subject will be maintained.*

☐ How to contact the research team for questions, concerns, or complaints about the research.

☐ How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.

☐ Whom to contact in the event of a research-related injury to the subject.

☐ Participation is voluntary.

☐ Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.

☐ The subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

☐ One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

- ☐ A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or
- ☐ A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Required for More than Minimal Risk Research

☐ Whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.

☐ Whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

[16] If payments, including reimbursement for research-related expenses incurred by subjects due to participation, are provided, the consent process should not identify them as benefits *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

Required for Clinical Trials that Follow ICH-GCP

NA: ☐

☐ The approval of the IRB.

☐ The probability for random assignment to each treatment.

☐ The subject's responsibilities.

☐ When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.

☐ The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject

☐ When there is no intended clinical benefit to the subject, a statement to this effect.

☐ The monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.

☐ If the results of the trial are published, the subject's identity will remain confidential.

Required for FDA-Regulated Research[17]

NA: ☐

☐ The possibility that the Food and Drug Administration may inspect the records and should not state or imply that FDA needs permission from the subject for access to the records.[18]

☐ The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.

☐ The investigator should ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.

[17] The FDA generally recommends against including statements such as "FDA has given permission for the clinical investigation to proceed" or "FDA has approved the clinical investigation" in the informed consent process, because such statements may suggest to subjects that the investigation has FDA's endorsement. *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

[18] *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download

☐ For controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

Additional

☐ The particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.

☐ If the subject is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable.

☐ Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.

☐ Any additional costs to the subject that may result from participation in the research.

☐ The consequences of a subject’s decision to withdraw from the research.

☐ Procedures for orderly termination of participation by the subject.

☐ Significant new findings developed during the course of the research, which may relate to the subject’s willingness to continue participation will be provided to the subject.

☐ Approximate number of subjects involved in the study.

☐ Amount and schedule of all payments.

☐ A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.

☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

☐ For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

☐ Any additional information which should be given to subjects when in the IRB’s judgement the information would meaningfully add to the protection of the rights and welfare of subjects.[19]

[19] 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

☐ When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).

8. Additional Considerations for Electronic Consent (Check if "Yes" or "NA". All must be checked) ☐ NA

☐ Electronic consent document includes all elements in **Section 7-Elements of Consent Disclosure**

☐ The date of the electronic signature will be captured.

(NA if waiver of documentation of consent is requested and justified) NA: ☐

☐ Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures.

☐ Electronic consent process includes age-appropriate materials to facilitate comprehension.

☐ Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject's needs.

☐ Electronic consent document/process allows subjects to proceed forward or backward or pause for review later.

☐ Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents.

☐ Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures.

☐ The informed consent process outlines in detail how any included documents will be utilized.

☐ Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team.

☐ For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child's assent, procedures are in place to verify the child's identify and assent when the child initially presents to the investigator.

(NA if the research is not a FDA-Regulated Clinical Trial) NA: ☐

9. Summary Recommendations

SUMMARY OF STUDY:

a. Using lay terminology so all members of the panel will understand, provide a brief description of the study, including the hypothesis/aims, procedures and target population.

Click or tap here to enter text.

b. Make your motion consistent with HRP-041 - SOP - IRB Meeting Conduct.

Click or tap here to enter text.

c. Confirm that the criteria of 21 CFR 56.111 and/or 45 CFR 46.111 are met / will be met after the outlined changes have been made / are not met.
Criteria are only met if there are no unanswered questions and no open-ended reviewer notes.

☐ Criteria of approval (21 CFR 56.111 and/or 45 CFR 46.111) are met
☐ Changes are required: Click or tap here to enter text.

d. This research involves no more than minimal risk / greater than minimal risk.
If the study is no greater than minimal risk, make a recommendation as to whether future reviews should be done at the expedited level or remain at the full board. If being kept at the full board, explain why.

Click or tap here to enter text.

e. Confirm special determination review and approval criteria are met / will be met after the outlined changes have been made / are not met.

Special determinations (enter each checklist completed): Click or tap here to enter text.
☐ Criteria of approval are met
☐ Changes are required: Click or tap here to enter text.

VCU Research and Innovation

HRP-315 | 03/01/2024

WORKSHEET: Advertisements

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating advertisements meant to be seen or heard by subjects.[1]

1. Context (Check if **"Yes"**. All must be checked)

☐ The application describes the mode of communication.

☐ For printed advertisements, the final copy is being reviewed.

☐ For audio/video tape, the tape is the final version

2. The advertisement: (Check if **"Yes"**. All must be checked)

☐ Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.

☐ Does NOT promise "free treatment," when the intent is only to say subjects will not be charged for taking part in the research.

☐ Does NOT include exculpatory language.

☐ Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type

☐ The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as:

- The name and address of the investigator or research facility
- The condition under study or the purpose of the research
- In summary form, the criteria that will be used to determine eligibility for the study
- A brief list of participation benefits, if any
- The time or other commitment required of the subjects
- The location of the research and the person or office to contact for further information.

3. For FDA-Regulated research, the Advertisement: (Check if **"Yes"**. All must be checked)

☐ Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.

[1] This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E

☐ Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device.

☐ Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.

☐ Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

4. For Veterans Administration (VA)-Regulated research, the advertisement: (Check if “Yes”. All must be checked)

☐ Does NOT use the VA Facebook page as a method of advertising non-VA studies at VA facilities.

☐ If the research is non-VA research being conducted at a VA facility, the advertisement includes a clear and legible disclaimer that states:

- The research is not VA research.
- The research will not be conducted by the VA.
- The research has not been reviewed by VA’s Institutional Review Board.

  The research is not endorsed by VA.

VCU Research and Innovation

HRP-316 | 10/23/2024

WORKSHEET: Payments

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating payments to subjects or their Legally Authorized Representatives.[1]

1. Requirements for Payments[2] (Check if "**Yes**". All must be checked)

☐ All payments are described in the protocol including: (Check if "Yes". All must be checked)

- ☐ Amount
- ☐ Method
- ☐ Reason/purpose (e.g., their time, inconvenience, discomfort, or some other consideration)
- ☐ Timing of disbursement

☐ Credit for payment accrues as the study progresses.

☐ Payment is not contingent upon completing the entire study.

☐ The amount of payment and the proposed method and timing of disbursement is neither coercive nor presented undue influence.

☐ Any amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn and is evaluated in context of any reimbursement or compensation payment included in the study.

☐ All information concerning payment, including the amount and schedule of payments, is in the informed consent document.

☐ The information sheet or consent document contains required VCU institutional language for payments over $50 as included in HRP-502 - TEMPLATE CONSENT DOCUMENT.[3]

☐ Compensation does not include a coupon good for a discount on the purchase price of the product once it has been approved.

[1] This document satisfies AAHRPP elements II.3.C-II.3.C.1, III.1.E

[2] FDA Information Sheet, "Guidance for Institutional Review Boards and Clinical Investigators, Payment and Reimbursement to Research Subjects" January 2018

[3] https://procurement.vcu.edu/i-want-to/pay-an-individual/compensate-a-research-participant/

VCU Research and Innovation

HRP-317 | 02/01/2024

WORKSHEET: Short Form of Consent Documentation

The purpose of this worksheet is to provide support for IRB members or Designated Reviewers using HRP-314 - WORKSHEET - Criteria for Approval when reviewing research involving the short form of consent documentation. (LAR = "subject's Legally Authorized Representative") [1]

1. Short Form of Consent Documentation (Check if **"Yes"**. All must be checked)

☐ The written consent document states that the elements of consent have been presented orally to the subject or the subject's LAR.

☐ There is written summary of what is to be said to the subject or LAR that embodies the required and appropriate additional elements in Section 7: ELEMENTS OF CONSENT DISCLOSURE in HRP-314 - WORKSHEET - Criteria for Approval.

☐ The consent document and summary are accurate and complete.

☐ An impartial witness[2] is present during the entire consent discussion.

☐ For subjects who do not speak English the witness is conversant in both English and the language of the subject or the subject's LAR.

☐ The subject or the subject's LAR will sign and date the short form consent document.

☐ The witness will sign and date the short form consent document and the summary.

☐ The person obtaining consent will sign and date the summary.

☐ When a subject or the subject's LAR is unable to read: An impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's LAR, and that consent was freely given.

☐ A copy of the signed and dated summary will be given to the person signing the document.

☐ A copy of the signed and dated consent document will be given to the person signing the document.

---

[1] This document satisfies AAHRPP elements II.3.F, III.1.F

[2] The FDA recommends "…that an impartial third party not otherwise connected with the clinical investigation (for example, clinical staff not involved in the research, a patient advocate or an independent interpreter) serve as the witness. The witness must be present physically or by some other means, for example, by phone or video conference, during the oral presentation, not just the signing of the consent form (21 CFR 50.27(b)(2))." *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download.

☐ If there is a signature line for a LAR or parent, the IRB has approved inclusion of adults unable to consent or children.

VCU Research and Innovation

HRP-318 | 10/9/2024

WORKSHEET: Additional Federal Agency Criteria

The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies. It does not need to be completed or retained.[1]

1. Additional Criteria for Veterans Administration (VA) Research (Check if "**Yes**" or "**NA**". All must be checked)

☐ The research does not involve the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289g(b)).

☐ The research is not an Intervention involving neonates.

☐ The research is not classified.

☐ The research is not planned emergency research that involves a waiver of the consent process.

☐ The protocol and consent document are consistent with the HIPAA authorization.

☐ The consent process and document will disclose:

- ☐ A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85.

When applicable:

- ☐ A statement that VA research subjects and/or their insurance will not be charged any costs related to the research except that some veterans are required to pay co-payments for medical care and services provided by VA and that these co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.
- ☐ Information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio recordings will be used for the research, and whether the photographs, video, and/or audio recordings will be disclosed outside VA.
- ☐ The required VA PREP Act statement for research studying a drug, biological product, device, or vaccine designed to treat, diagnose, cure or prevent COVID-19. [2]

☐ If the research includes broad consent (NOTE: Broad consent is not applied at VCU):

[1] This document satisfies AAHRPP elements I.1.A, I.1.D, I.1.F, I-2, I-3, I-9, II.2.D, II.2.F-II.2.F.3, II.2.I, II.3.B, II.3.C-II.3.C.1, II.3.E, II.3.F, II.3.G, II.4.A, II.4.B, II.4.C, III.1.C, III.1.E, III.1.F, III.2.C, III.2.D

[2] The verbatim VA PREP Act consent form language can be found in the Veterans Health Administration (VHA) Office of Research and Development (ORD) Guidance: Implementation of the Public Readiness and Emergency Preparedness Act (PREP Act) for COVID-19 Research Activities).

☐ Broad consent can only be obtained for the use of information or biospecimens that are collected initially for research purposes.

☐ Documentation of informed consent for broad consent cannot be waived by the IRB.

The broad consent process and document will disclose:

☐ A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations.

☐ When applicable: A statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research.

☐ If the research involves pregnant women as subjects, the VA medical facility Director must certify that the medical facility has sufficient expertise in women's health to conduct the research if the research includes interventional studies or invasive monitoring of pregnant women as subjects.

☐ The research does not involve clinical interventions with the potential of greater than Minimal Risk for children who are pregnant.

☐ If the research involves biological specimens and data obtained from children, it is considered research involving children even if de-identified.

☐ If the research involves neonates, the VA medical facility Director must certify that the medical facility has sufficient expertise in neonatal health to conduct the proposed research.

☐ If the research involves fetal tissue, it meets the requirements of the NIH Reminder of Legal Requirements Regarding the Acquisition and Use of Human Fetal Tissue for Research Purposes and NIH Policy on Informed Consent for Human Fetal Tissue Research.

☐ If the research involves stems cells, it meets the requirements of the NIH Guidelines for Stem Cell Research.

☐ If the research involves Prisoners as subjects, a waiver shall be granted by the Chief Research and Development Officer.

☐ If the research involves children as subjects, the research must not present greater than minimal risk and the VA medical facility Director must approve participation in the research.

☐ If the research is international research, approval has been granted from the VA medical facility Director and an approval document signed by the VA medical facility Director is provided.

☐ If the research is an international Cooperative Studies Program activity, it has been approved by the Chief Research and Development Officer.

☐ If the research includes taking a photograph, video and/or audio recording, the informed consent cannot be waived by the IRB.

☐ If the research is exempt and involves Interaction with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally:

- Permission to participate can be withdrawn;
- Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and
- Contact information for the VA Investigator.

2. Additional Criteria for Veterans Administration (VA) Research for Multi-Site Research When the Investigator is the Multi-Site Study PI for All Participating Facilities and the VA Central IRB is Not Being Used (Check if "**Yes**" or "**NA**". All must be checked)

☐ Each Participating Site (pSite) has an active FWA.

☐ Each pSite has provided documentation of all relevant approvals, including approval of its IRB of record.

☐ The IRB has approved the study-wide protocol and sample informed consent document to be provided to each pSite.

☐ The study-wide protocol contains a mechanism for ensuring that any differences in the protocol or informed consent at engaged local pSites are justified by the local site investigators, and that they are approved by the principal investigator before being implemented.

☐ There are clear Adverse Event reporting requirements, a data monitoring committee if applicable (or other reliable monitoring mechanism) with clear procedures and requirements, and a clearly defined feedback loop to the investigator's or study sponsor's IRB.

☐ The PI's plan for communicating appropriate critical information (e.g., reports of data and safety monitoring) to engaged pSites is adequate.

☐ The principal investigator and all local site investigators will obtain written approvals from the relevant local VA facilities' IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements.

☐ Research will not be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local associate chief of staff for research and development.

☐ Confidentiality and information security requirements are met for information storage at and transmission to statistical or coordinating centers.

☐ Data monitoring committees will provide reports to the IRB.

3. Additional Criteria for Veterans Administration (VA) when Serving as the sIRB Reviewing VA Collaborative Research (Check if **"Yes"** or **"NA"**. All must be checked)

☐ For reliance agreements, records of an IRB are addressed in the MOU for the VA Facility's use of another entity's IRB. The MOU ensures that all applicable Federal and VA regulations are met.[3]

☐ The protocol or other documentation submitted to the VA IRB of Record must clearly delineate which research activities will be conducted as the VA portion of the overall Collaborative Research study (e.g., by VA researchers on VA time or VA property).

☐ The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA's portion of the study.

☐ Each institution engaged in the collaborative research must use the informed consent document required by its respective institutional policies for participants recruited from that institution, or procedures requiring participation of the participants at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA's auspices and which will be performed under a non-VA institution's auspices.

☐ The protocol, addendum, and/or IRB of Record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed, and/or further disclosed and to whom. This includes data from individual participants as well as other data developed during the research such as the analytic data and the aggregate data.

☐ Refer to HRP-833 - WORKSHEET - Considerations for Serving as the sIRB for considerations when serving as the sIRB for VA research.

4. Additional Criteria for Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prisons (BOP) (Check if "**Yes**" or "**NA**". All must be checked)

☐ The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research within the BOP.

☐ The project does not involve medical experimentation, cosmetic research, or pharmaceutical testing.

☐ The research design is compatible with both the operation of prison facilities and protection of human subjects.

☐ The investigator will observe the rules of the institution or office in which the research is conducted.

☐ Investigators who are not BOP employees have signed a statement agreeing to adhere to the requirements of 28 CFR 512.

[3] VHA Directive 1200.05(2) section 16.a.(9) and VHA Directive 1058.03

☐ All research proposals will be reviewed by the BOP IRB.

☐ The project has an adequate research design and will contribute to the advancement of knowledge about corrections.

☐ The selection of subjects within any one organization is equitable.

☐ Incentives will not be offered to help persuade inmate subjects to participate. Soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are no longer in BOP custody and are participating in authorized research being conducted by BOP employees or contractors.

☐ If a non-employee of the BOP will receive records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has been provided to the agency.

☐ Except as noted in the consent statement to the subject, the investigator will not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.

☐ Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person will not be stored in, or introduced into, an electronic retrieval system.

☐ Required elements of disclosure include all of the following:

- ☐ Anticipated uses of the results of the research.
- ☐ A statement that participation is completely voluntary and that the subject may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- ☐ A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.
- ☐ Identification of the investigators.
- ☐ A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a investigator may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.

☐ The investigator has academic preparation or experience in the area of study of the proposed research.

☐ The IRB application includes a statement regarding assurances and Certification required by federal regulations, if applicable.

☐ The investigator will assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Researcher.

5. Additional Criteria for Department of Justice (DOJ) Research Funded by National Institute of Justice (NIJ) (Check if "**Yes**" or "**NA**". All must be checked)

☐ The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research funded by NIJ.

☐ Projects have a privacy certificate approved by the NIJ human subjects protection officer.

☐ All investigators and research Staff have signed employee confidentiality statements, which are maintained by the investigator.

☐ Identification of the funding agency(ies).

☐ A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by the NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.

☐ Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.

☐ A copy of all data will be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

- ☐ At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
- ☐ At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall not include an abstract in the report of findings.
- ☐ In any publication of results, the research shall acknowledge the Bureau's participation in the research project.
- ☐ The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

☐ Prior to submitting for publication the results of a research project conducted under this subpart, the research shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

6. Additional Criterion for the Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency (Check if "**Yes**" or "**NA**". All must be checked)

☐ The research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance.

☐ If the results of research involving an intentional exposure of human subjects are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA) the IRB's determinations and approval will be submitted to the Environmental Protection Agency (EPA) Human Subjects Research Review official for final review and approval before the research can begin.

☐ If the research involves children, the research must either be:

☐ observational research not involving greater than Minimal Risk or

☐ observational research involving greater than Minimal Risk but presenting prospect of direct benefit.

☐ If the research involves intentional exposure of subjects to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function.

☐ If the research involves the use of Broad Consent, the research can only be Exempt under category 7 (NOTE: Broad consent is not applied at VCU): Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of Identifiable Private Information or Identifiable Biospecimens for potential secondary research.

7. Additional Criteria for Department of Energy (DOE) Research (Check if "Yes" or "NA". All must be checked)

☐ For research that involves Personally Identifiable Information (PII) or Protected Health Information (PHI), the protocol addresses the following DOE requirements:

- Keeping PII/PHI confidential.
- Protecting PII/PHI during storage and transmission.
- Releasing PII/PHI, when required, only under a procedure approved by the responsible IRB and DOE.
- Using PII/PHI only for purposes of the IRB-approved project.
- Handling and marking documents containing PII/PHI as "containing PII or PHI."
- Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII/PHI.
- Making no further use or disclosure of the PII/PHI except when approved by the responsible IRB and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project, as required by Office of

Management and Budget Circular No. A-133; (d) when required by law; or (e) with the consent of the participant/guardian.

- Protecting PII/PHI data stored on removable media (CD, DVD, USB Flash Drives, etc.), network drives and stand-alone computers using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified.
- Using passwords to protect PII/PHI used in conjunction with FIPS 140-2 certified encryption products that meet the current DOE password requirements:
    - Minimum of twelve (12) non-blank characters
    - Must contain a lowercase letter
    - Must contain an uppercase letter
    - Must contain a number or special character
    - Must contain a nonnumeric in the first and last position
    - Must not contain the user ID
- Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped.
- Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products.
- Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer.
- Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter.
- Using TLS 1.1 encryption methods or higher for websites established for the submission of information that includes PII.
- Using two-factor authentication for logon access control for remote access to systems and databases that contain PII/PHI. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63).
- Reporting the loss or suspected loss of PII/PHI immediately upon discovery to (1) the DOE funding office program manager, or, if funded by a DOE laboratory, the DOE laboratory Program Manager and (2) the DOE HSP Program Manager and the NNSA HSP Program Manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1-866-941-2472, by fax at 702-932-0189, or by e-mail at circ@jc3.doe.gov. For additional information, see: http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting.
- Classified projects that use PII/PHI must also comply with all requirements for conducting classified research.

☐ For classified human subjects research (in whole or in part):

- Exemptions (as per 10 CFR §745.104) and expedited review cannot be used. If the research meets a particular exemption or expedited category it may be noted, but full IRB review is required.
- A waiver of informed consent may only be granted by the convened IRB for minimal risk research that qualifies for exemption under 10 CFR §745.104.
- The identity of the sponsoring Federal agency will be disclosed to subjects, unless the sponsor requests that it not be done, because doing so could compromise intelligence sources or methods; the research involves no more than Minimal Risk to subjects; and the IRB determines that by not disclosing the identity, the investigators will not adversely affect the subjects.

- The informed consent document will state that the project is classified, what that means for the purposes of that project, and what part of the research that applies to.
- The IRB must determine whether the potential human subjects need access to classified information to make a valid informed consent decision.
- Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, Director of the Office of Science and Technology Policy (OSTP) or designee, and then the Director of National Intelligence (ODNI) or designee, in that order. The Director of OSTP (or designee), or the Director of National Intelligence (or designee) will review and approve or disapprove the research, or will convene or designate an IRB that is, to the extent possible, made up of unaffiliated members with the appropriate qualifications and clearance to approve or disapprove the research.
- Information on each project that is classified must be submitted annually (or in accordance with the directions and schedules provided by the appropriate HSP program manager) by the responsible HSP program managers.
- If the IRB believes that the project, in whole or in part, can be thoroughly reviewed in an unclassified manner, a request for a waiver from some or all of the requirements of classified HSR can be submitted. The study-specific waiver request must be signed by the IRB Chair, and reviewed and approved by the appropriate HSP Program Manager (and if the waiver request relates to an intelligence-related project, also the DOE Office of Intelligence and Counterintelligence (IN)). A list of waiver requests and the actions taken will be provided.
- HSR that is classified, in whole or in part, must not be initiated without IRB approval. After IRB approval, the DOE IO reviews and determines whether he/she will approve/disapprove the project or brief the Secretary about the project prior to his/her approval/disapproval.

☐ For research involving protected classes:

- Prisoners, children, and individuals with impaired decision making [sic] must be conducted in accordance with the appropriate Subpart(s) of 45 CFR §46.
- Proper protections are in place for DOE/NNSA federal and/or contractor employees who may be subject to coercion or undue influence. DOE and DOE site employees are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team) and that data collected about them is kept confidential.

8. Additional Criterion for Department of Education (ED) Research (Check if "Yes" or "NA". All must be checked)

☐ If prior consent [4] or written documentation of consent or parental permission is waived, the research does NOT involve gathering information about any of the following:

- Political affiliations or beliefs of the student or the student's parent
- Mental or psychological problems of the student or the student's family
- Sex behavior or attitudes
- Illegal, anti-social, self-incriminating, or demeaning behavior
- Critical appraisals of other individuals with whom respondents have close family relationships

[4] Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any survey, analysis, or evaluation funded by the Department of Education.

- Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
- Religious practices, affiliations, or beliefs of the student or student's parent
- Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)

9. Additional Criteria for Department of Defense (DOD) Research (Check if "Yes" or "NA". All must be checked)

☐ The investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements.

☐ The review has considered (and will document) the scientific merit of the research; within consideration of scientific merit, feasibility, of study completion should be considered. [5]

☐ For research that involves DOD-affiliated personnel, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.

☐ For research that takes place on a DOD facility, the key investigator must receive approval from the command or DOD Component HRPP or its delegate responsible for the facility.

☐ The research does NOT involve Prisoners of war or detainees as subjects. [6]

☐ The research does not involve the testing of chemical or biological agents, which is prohibited, pursuant to Section 1520a of Title 50, U.S.C, unless exceptions for research for prophylactic, protective, or other peaceful purposes apply,

☐ Explicit written approval from DOHRP was obtained prior to the initiation of excepted testing of chemical or biological agents involving HSR.

☐ Military personnel will not be paid for research conducted while on duty. [7]

[5] The IRB may rely on outside experts to provide an evaluation of the scientific merit.

[6] This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person, and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions when the purpose is for diagnosis or treatment of a medical condition in a patient. Such treatment (e.g., an investigational new drug) may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and only when the same product may be available to DOD-affiliated personnel consistent with established medical practice.

[7] Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

☐ If the research involves DOD-affiliated personnel as subjects, when applicable, the following is required: (Check if "Yes." Or "NA". All must be checked):

- ☐ If the research includes risks to their fitness for duty (e.g. health, availability to perform job, data breach), then informed consent form must inform DOD-affiliated personnel about these risks and that they should seek command or Component HRPP guidance before participating.
- ☐ Research involves greater than Minimal Risk and recruitment will occur in a group setting: The IRB has appointed an ombudsperson [8] who does not have a conflict of interest with the research or be a part of the research team, and will be present during the recruitment to explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. The ombudsman should be available to address concerns about participation.
- ☐ If the study involves Large-scale genomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required:
    - The research is subject to DOD Component security review and DOHRP approval.
    - The research will apply an HHS Certificate of Confidentiality
    - Administrative, technical, and physical safeguards are considered, as the disclosure of the data may pose a risk to national security.

☐ If the research is subject to Section 980 of Title 10, U.S.C., consent will be obtained unless waived by the DOHRP.[9] The IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks).

☐ The key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) for research that requires a waiver of informed consent pursuant to Paragraph (b) of Section 980 of Title 10, U.S.C.

☐ If consent is obtained from the experimental subjects legal representative (for cognitively impaired subjects), the intention of the research must be to be beneficial to the subject[10] .

☐ Military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research.[11]

---

[8] A person who acts as an impartial and objective advocate for human subjects participating in research.

[9] Section 980 of Title 10, U.S.C. applies to research financed by DOD appropriated funds. The requirement for consent may be waived by the DOHRP if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. Research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects.

[10] Section 980 of Title 10, U.S.C.

[11] If applicable, excluded superiors or those in the chain of command may participate in separate human subjects research recruitment sessions.

☐ Military and civilian supervisors, officers, and others in the chain of command will not be present at any recruitment sessions or during the consent process for any DoD-affiliated personnel.

☐ When a subject is a Service member, all Research Component, and/or National Guard members in a federal duty status are considered to be adults. If a Service Member, Research Component, or Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such member as a human subject is considered during IRB review.

☐ The disclosure regarding provisions for research-related injury follows the requirements of the DOD component.

☐ When conducting multi-site research a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities.

☐ Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.

- Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:
  - May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
  - Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.
- The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

and the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.[12]

☐ If the research involves emergency medicine research, the DOHRP, on behalf of the Secretary of Defense, must approve a waiver of the advance informed consent in accordance with provision 10 USC 980.

☐ If the research involves Human Subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, its territories, and its possessions: **(Check if "Yes" or "NA". All must be checked.)**

☐ Applicable national laws and requirements of the foreign country will be followed.

☐ When a DoD-affiliated person who is also a citizen of the host nation is a research subject, where differences in applicable standards exist between the United States and the host nation, the standard that is most protective of human subjects will be applied.

☐ Take into consideration the cultural sensitivities in the setting where the research will take place [13].

[12] See: http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g (This is the enabling statute for 45 CFR 46.205. Compliance with Subpart B complies with this statute.) See also: http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-1, and http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-2

[13] SECNAVINST 3900.39E 29 MAY 2018, Section 3.d.

☐ For research that is conducted in a foreign country, unless it is conducted by a DOD overseas institution, or involves subjects who are DOD-affiliated personnel that are U.S. citizens, the key investigator must receive approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) to conduct the research.

☐ When Broad Consent is used, DOHRP notification is required. (NOTE: Broad consent is not applied at VCU)

☐ Refer to HRP-833 - WORKSHEET - Considerations for Serving as the sIRB for considerations when serving as the sIRB for a DOD institution.

10. Additional Criteria for Department of Defense (DOD) Research Involving Classified Information [14] (Check if "Yes" or "NA". All must be checked)

☐ The convened IRB approved the research.

☐ Waivers of consent are prohibited.

☐ Approval from the DOD-affiliated personnel's command or DOD Component Human Research Protection Program (HRPP) and DOHRP approval will be obtained.[15]

☐ No DoD agency within the Intelligence Community may sponsor, contract for, or conduct non-exempt HSR except in accordance with Paragraph 2.10 of Executive Order 12333 and DoD 5240.01.

[14] DOD-supported research is considered classified when:

- Classified information is required for IRB review and oversight of the research.
- Classified information must be provided to human subjects, or their guardians, during the HSR recruitment or informed consent process in order to achieve fully effective legal consent.
- Classified information is provided to, or by, research subjects.

DOD-conducted or -supported research is not considered classified when:

- The research is a part of a classified program, but the research itself is not classified; if the information required in the research protocol is not classified; if the information needed by the IRB is not classified; or if the information required by the human subject is not classified. For the purposes of the annual report for classified research, unclassified HSR that falls into the criteria listed in this paragraph should be included in the report.
- Research that requires subjects to hold a clearance as a means of creating ease of entry or access to controlled spaces where the research will occur does not constitute classified HSR unless one of the conditions described in Sections 3.13.b.(1) or (3) also exist.
- If the research constitutes an authorized operation activity, then it is not HSR.

[15] The DOHRP is the final approval authority for all DoD-conducted or DoD-supported classified HSR. The SDO prospectively conducting or supporting the HSR must submit a package to the DOHRP for approval to conduct the classified HSR.

VCU Research and Innovation

HRP-319 | 03/01/2024

WORKSHEET: Limited IRB Review

The purpose of this worksheet is to provide support for IRB members performing limited IRB reviews[1]. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative (LAR)")[2]

Method for limited IRB review: (check one)

☐ Limited IRB review, for research as a condition of exemption, conducted via expedited review[3]

☐ Limited IRB review, for research as a condition of exemption, performed by the convened IRB.

1. The research falls into one the following exempt categories: (One or more categories must be checked)

☐ Category 2 (iii): Research that only includes Interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording) where the information obtained is recorded by the investigator in such a manner that the identity of the Human Subjects can readily be ascertained, directly or through identifiers linked to the subjects. The following must be true[4]: (**Check if "Yes"**)

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

☐ Category 3 (i)(C): Research involving benign behavioral Interventions[5] in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the Intervention and information collection and the information obtained is recorded by the investigator in such a manner that the identity of the Human

---

[1] For VA Research,
- If an exempt activity requires a limited IRB review, the limited IRB review must be completed prior to approval by the R&D Committee.
- Research that has undergone limited IRB review and determined to be exempt requires approval by the R&D Committee and requires continuing review by the R&D Committee unless it is under the oversight of another subcommittee (e.g., Safety Review Subcommittee).

[2] This document satisfies AAHRPP elements II.2.A, II.2.B, II.2.C, II.3.F, II.3.G

[3] 45 CFR §46.110(b)(1)

[4] 45 CFR §46.111(a)(7)

[5] For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

Subjects can readily be ascertained, directly or through identifiers linked to the subjects. The following must be true [6] [7]:**(Check if "Yes")**

☐ There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

[6] 45 CFR §46.111(a)(7)

[7] If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

VCU Research and Innovation

HRP-320 | 03/01/2024

WORKSHEET: Scientific or Scholarly Review

The purpose of this worksheet is to provide support for individuals responsible for the scientific review of research. Use this worksheet to determine whether the research has scientific or scholarly validity. IRB members conducting scientific or scholarly review are to use this worksheet but do not need to complete or retain it. Consultants providing scientific or scholarly review are to complete this worksheet and provide it to IRB staff who will retain it in the files.[1]

1. Overall Scientific and Scholarly Validity - for all research (Check if **"Yes"**. All must be checked). If no, please refer to Scientific Review Committee.

☐ The protocol accurately describes the research in a clear, detailed protocol in terms of:

- Objectives
- Background
- Setting
- Procedures
- Data and safety monitoring plan
- Risks
- Potential benefits
- Alternatives to participation

☐ There is no other way to do this research that would reduce risks to subjects and still answer the scientific question.

☐ There are no other monitoring procedures needed that would reduce risks to subjects and not affect the science.

☐ The research is likely to answer its proposed question.

☐ The protocol fairly portrays the knowledge expected to result.

2. Clinical Trials (Check if "**Yes**" or "**NA**". All must be checked if the research is a Clinical Trial.

☐ The available nonclinical and clinical information on an investigational product is adequate to support the Clinical Trial.

☐ The investigator has demonstrated (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.

☐ The investigator has sufficient time to properly conduct and complete the trial within the agreed trial period.

[1] This document satisfies AAHRPP elements I.1.F, I-9, II.2.E-II.2.E.2, II.3.A

☐ The investigator has available an adequate number of qualified staff and adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely.

☐ The investigator will ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.

☐ A qualified physician (or dentist, when appropriate), who is an investigator or a sub-investigator for the trial, will be responsible for all trial-related medical (or dental) decisions.

3. Comments

Comment on the above:

Click or tap here to enter text.

VCU Research and Innovation

HRP-321 | 03/01/2024

WORKSHEET: Review of Information Items

The purpose of this worksheet is to provide support for the convened IRB reviewing Serious Non-Compliance, Continuing Non-Compliance, Unanticipated Problem Involving Risks to Subjects or Others, Suspension of IRB Approval, and Termination of IRB Approval[1].

1. Considerations

☐ Modify the protocol.

☐ Modify the information disclosed during the consent process.

☐ Provide additional information to current subjects (whenever the information may relate to the subject's willingness to continue).

☐ Provide additional information to past subjects.

☐ Have current subjects to re-consent.

☐ Increase the frequency of continuing review.

☐ Observe the research.

☐ Observe the consent process.

☐ Require additional training of the investigator.

☐ Notify investigators at other sites.

☐ Terminate IRB approval.

☐ Suspend IRB approval.

☐ Lift prior suspension of IRB approval.

☐ Transfer subjects to another investigator.

☐ Make arrangements for clinical care outside the research.

☐ Allow continuation of some research activities under the supervision of an independent monitor.

☐ Require follow-up of subjects for safety reasons.

☐ Require adverse events or outcomes to be reported to the IRB and the sponsor.

☐ Obtain additional information.

☐ Consider whether changes without prior IRB review and approval were consistent with ensuring the subject's continued welfare.

☐ Other: Click or tap here to enter text.

[1] This document satisfies AAHRPP elements I.5.A, I.5.D, I-9, II.2.G

VCU Research and Innovation

HRP-322 | 11/26/2024

WORKSHEET: Emergency Use

The purpose of this worksheet is to provide support for investigators conducting an emergency use of an unapproved drug, biologic, or device in a life-threatening situation, and to provide support for Designated Reviewers reviewing such uses. This worksheet is to be used when overseeing such uses. (LAR = "subject's Legally Authorized Representative")[1]

Emergency Use of an Unapproved Drug or Biologic [2]

1. Exemption Criteria for Emergency Use of an Unapproved Drug or Biologic (Check if "**Yes**". All must be checked)

☐ The patient is (was) confronted by a disease or condition that is (was) either:

- ☐ Life-threatening (diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and diseases or conditions with potentially fatal outcomes, where the end point of clinical trial analysis is survival).
- ☐ Severely debilitating (diseases or conditions that cause major irreversible morbidity).

☐ The situation necessitates (necessitated) the use of the investigational drug or biologic.

☐ No generally acceptable alternative for treating the patient is (was) available.

☐ There is (was) insufficient time to obtain IRB approval.

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ The FDA has (had) issued an IND or will authorize (has authorized) shipment of the test article in advance of the IND submission.

☐ The use is (was) **NOT** subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination.

Section 2 or 3 must be met

[1] This document satisfies AAHRPP element I.7.C

[2] Emergency use of an unapproved drug or biologic is a clinical investigation and must comply with 21 CFR §50 and 21 CFR §56.102(d) and 104(c).

2. **Consent criteria** (Check if "**Yes**". All must be checked)

☐ Informed consent will be (was) sought from the patient or the patient's LAR, in accordance with and to the extent required by 21 CFR §50. See HRP-314 - WORKSHEET - Criteria for Approval.

☐ Informed consent will be (was) documented using HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access in accordance with and to the extent required by 21 CFR §50.27. See HRP-314 - WORKSHEET - Criteria for Approval.

3. Exception Criteria for Consent (Check if "Yes". All must be checked)

☐ The patient is (was) confronted by a life-threatening situation necessitating the use of the test article.

☐ Informed consent cannot (could not) be obtained from the patient because of an inability to communicate with, or obtain legally effective consent from, the patient.

☐ Time is (was) insufficient to obtain consent from the patient's LAR.

☐ There is (was) no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the patient.

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ A physician uninvolved in the clinical Investigation will certify (has certified) in the medical record that the above findings were met.

☐ If certification took place after the use of the drug or biologic, all of the following are true: **("NA" if certification took place before the use)**

- ☐ Immediate use of the test article is (was), in the investigator's opinion, required to preserve the life of the patient.
- ☐ Time is (was) insufficient time to obtain the independent determination a physician uninvolved in the clinical Investigation.
- ☐ The treating physician will document (has documented) in the medical record that the above findings were met.
- ☐ The treating physician' report to the IRB within 5 working days will document that the above findings were met.

Emergency Use of an Unapproved Device[3]

4. Criteria for Emergency Use of an Unapproved Device (Check if "**Yes**" or "**NA**". All must be checked)

☐ The patient is (was) confronted by a life-threatening disease or a serious condition requiring immediate use of the device.

☐ The situation necessitates (necessitated) the immediate use of the device.

☐ No generally acceptable alternative for treating the patient is (was) available.

☐ There is (was) insufficient time to use existing procedures to obtain FDA approval of an IDE.

☐ There is (was) substantial reason to believe that benefits will (would) exist.

☐ The treating physician will document (has documented) in the medical record that the above findings were met.

☐ The treating physician will report (has reported) the use to the IRB within 5 working days with documentation that the above findings were met.

☐ A physician uninvolved in the emergency use will certify (has certified) in the medical record that the above findings were met.

☐ One of the following is true:

- ☐ There is (was) no IDE.
- ☐ The treating physician wants (wanted) to use the device in a way not approved under an existing IDE.
- ☐ The treating physician is (was) not part of the IDE study.

☐ One of the following is true:

- ☐ There is an IDE and the treating physician has (had) authorization from the sponsor.
- ☐ There is no IDE and the treating physician will notify (has notified) FDA of the emergency use within 5 working days.

☐ The treating physician will follow (has followed) the procedures below if time permits (check all that apply):

[3] FDA does not consider the emergency use of an unapproved device to be clinical investigation and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at http://www.fda.gov/downloads/Training/CDRHLearn/UCM180888.pdf, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

□ Concurrence of the IRB Chair.

□ Informed consent from the patient or LAR (use HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access).

□ Clearance from the institution as specified by policy.

□ The use is (was) **NOT** subject to DHHS regulation See (HRP-310 - WORKSHEET - Human Research Determination).

VCU Research and Innovation

HRP-323 | 02/01/2024

WORKSHEET: Criteria for Approval for HUD

The purpose of this worksheet is to provide support for the convened IRB when evaluating an initial application to use a Humanitarian Use Device (HUD), and for Designated Reviewers when evaluating a continuing review submission. (LAR = "subject's Legally Authorized Representative"). This worksheet does not have to be completed or retained.

1. Humanitarian Use Device: (Check if **"Yes"**. All must be checked)

☐ The FDA has issued an approved Humanitarian Device Exemption (HDE) for this device.

☐ The HUD is **not** being used to evaluate its safety and effectiveness. **(If the HUD is being used to evaluate its safety and effectiveness complete HRP-314 - WORKSHEET - Criteria for Approval)**

2. General Considerations (Check if **"Yes**". All must be checked)

☐ The convened IRB (or Designated Reviewer) has adequate expertise to review this HUD application. **(If "No", obtain consultation.)**

☐ Materials are complete. **(If "No," the HUD application cannot be approved.)**

3. Criteria For Approval Of HUD: (Check if **"Yes**". All must be checked) Applies to all reviews: initial, continuing, and modifications.

☐ Risks to patients are minimized by using procedures, which do not unnecessarily expose patients to risk.

☐ Risks to patients are reasonable in relation to the proposed use of the device.

☐ There are adequate provisions to protect the privacy of patients.

☐ There are adequate provisions to maintain the confidentiality of patient data.

☐ The proposed use of the HUD is within the scope of the indication approved in the HDE.

☐ The institution has approved the use of the HUD as a clinical service.

4. Additional Considerations (Check all that apply)

☐ **For Initial Review:** Should there be any limitations on the use of the HUD? (e.g., Limitations based on one or more measures of disease progression, prior to use and failure of any alternative treatment modalities, reporting requirements to the IRB or IRB chair, or appropriate follow-up precautions and evaluations.)

☐ **For Continuing Review and Modifications:** Is there information that needs to be provided to current patients because it may affect their willingness to receive/use the HUD?

5. Consent Process (Check if **"Yes"**. All must be checked)

☐ The HUD labeling states that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

☐ Patients or their LAR will be informed of the patient labeling provided by the manufacturer.

☐ Patients or their LAR will be given sufficient opportunity to consider whether or not to receive/use the HUD; or when HUD is used in emergent situations, patients or their LAR will be given information about the HUD after its use/receipt.

☐ Information regarding the HUD will be communicated in language understandable to the patient.

VCU Research and Innovation

HRP-325 | 02/01/2024

WORKSHEET: Compassionate Use of an Unapproved Medical Device

The purpose of this worksheet is to provide support for investigators conducting non-emergency individual patient/small group expanded access for an unapproved medical device (commonly known as Compassionate Use) and to provide support for Designated Reviewers reviewing such uses. This worksheet is to be used when overseeing such uses. It does not need to be completed or retained. (LAR = "subject's Legally Authorized Representative")[1]

Compassionate Use of an Unapproved Device[2]

1. **Criteria for Compassionate Use of an Unapproved Device** (Check if "**Yes**." All must be checked.)

☐ The patient is confronted by a serious disease or condition.

☐ No generally acceptable alternative for treating, diagnosing, or monitoring the patient is (was) available.

☐ The probable risk to the patient is not greater than the probable risk from the disease.

☐ The patient does not meet the inclusion criteria for an IDE study.

☐ The treating physician will document in the medical record that the above findings were met.

☐ The treating physician has/will obtain approval from FDA for the use.

☐ If an IDE exists for the device, the sponsor has authorized its use.

☐ An independent assessment from an uninvolved physician will be included in the submission to FDA.

☐ All institutional clearances have been obtained.

☐ Concurrence of an IRB Chair has been (will be) obtained.

☐ The treating physician will report any problems as a result of the device use to the IRB and sponsor.

☐ The treating physician will provide follow-up information (if applicable) of the use and give it to the sponsor, the FDA and the IRB.

☐ The use is **NOT** research subject to DHHS regulation See HRP-310 - WORKSHEET - Human Research Determination.

2. **Consent criteria** (Check if "**Yes**". All must be checked)

[1] This document satisfies AAHRPP element I.7.C

[2] FDA does not consider the compassionate use of an unapproved device to be a clinical investigation and FDA does not require compliance with 21 CFR §50 and 21 CFR §56. The requirements are based on FDA guidance at https://www.fda.gov/medical-devices/investigational-device-exemption-ide/expanded-access-medical-devices, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm051345.htm#compassionateuse, and http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM127067.pdf.

☐ Informed consent will be sought from the patient or the patient's LAR.[3]

☐ Informed consent will be documented using HRP-506 - TEMPLATE CONSENT DOCUMENT - Expanded Access.[4]

[3] FDA does not require the consent process to follow the informed consent requirements at 21 CFR §50.

[4] FDA does not require the documentation of consent to follow the informed consent requirements at 21 CFR §50.27.

VCU Research and Innovation

HRP-326 | 03/01/2024

WORKSHEET: Performance Evaluation for IRB Chairs

The purpose of this worksheet is to provide support for the Institutional Official/ Deputy Institutional Official (IO/DIO) or designee when evaluating the performance of the IRB Chair(s) as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP. This worksheet does not need to be completed and retained.[1]

1. Considerations when evaluating IRB Chairs

Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Chair to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

- ☐ Number of meetings attended and chaired out of total number of meetings
- ☐ Number of protocols reviewed via Non-Committee Review
- ☐ Number of protocols reviewed that went to the convened IRB
- ☐ Number of reviews completed as the primary reviewer
- ☐ Timeliness of reviews
- ☐ Completion of required checklists
- ☐ Completion of educational requirements
- ☐ Attendance at educational sessions

2. Consideration when evaluating IRB Chairs

Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Chair to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

- ☐ Leadership of the IRB
- ☐ Ability to lead meetings
- ☐ Preparedness for meetings
- ☐ Knowledge of regulations and identification of areas for improvement
- ☐ Communication with investigators
- ☐ Communication with organizational officials
- ☐ Communication with IRB staff

[1] This document satisfies AAHRPP element I.1.E

☐ Ability to work with IRB staff

☐ Ability to help investigators

☐ Issues related to being a general IRB member

3. Notes

Click or tap here to enter notes.

VCU Research and Innovation

HRP-327 | 03/01/2024

WORKSHEET: Performance Evaluation for IRB Members

The purpose of this worksheet is to provide support for the IRB Chair or IRB Manager when evaluating the performance of the IRB Members and Alternates as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP. This worksheet does not need to be completed and retained.[1]

1. Considerations when evaluating regular and alternate IRB members

Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Member or Alternate to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

☐ Number of meetings attended out of total number of meetings

☐ Number of exempt determinations made

☐ Number of protocols reviewed via Non-Committee Review

☐ Number of protocols reviewed that went to the convened IRB

☐ Number of reviews completed as the primary reviewer

☐ Timeliness of reviews

☐ Completion of required checklists

☐ Completion of educational requirements

☐ Attendance at educational sessions

☐ Number of educational sessions conducted

2. Considerations when evaluating regular and alternate IRB members

Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB Member or Alternate to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

☐ Preparedness for meetings

☐ Contribution to IRB meetings

☐ Quality of reviews

☐ Knowledge of regulations and identification of areas for improvement

[1] This document satisfies AAHRPP element I.1.E

☐ Knowledge of organizational policies and procedures and identification of areas for improvement

☐ Communication with investigators

☐ Communication with IRB staff

☐ Ability to work with IRB staff

3. Notes

Click or tap here to enter notes.

VCU Research and Innovation

HRP-328 | 03/22/2024

WORKSHEET: Performance Evaluation for IRB Staff

The purpose of this worksheet is to provide support for the IRB Chair or IRB Manager when evaluating the annual performance of the IRB staff as part of the annual HRPP evaluation conducted in HRP-060 - SOP - Annual Evaluations of the HRPP. This worksheet does not need to be completed and retained. [1]

1. Considerations when evaluating IRB staff

Objective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB staff member(s) to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

☐ Workload – handles workload efficiently

☐ Number of protocols reviewed via Non-Committee Review

☐ Number of protocols processed

☐ Timeliness of processing materials

☐ Completion of checklists and documentation

☐ Prepares agendas in a timely manner

☐ Prepares convened IRB minutes in a timely manner

☐ Completion of educational requirements

☐ Attendance at educational sessions

☐ Number of educational sessions conducted

☐ Attainment and maintenance of certification (e.g., CIM or CIP)

2. Considerations when evaluating IRB staff

Subjective Criteria (Check if satisfactory or not applicable. If needed, work with the IRB staff member(s) to develop a plan to address any unchecked items per HRP-060 - SOP - Annual Evaluations of the HRPP.)

☐ Preparedness for meetings

☐ Quality of pre-reviews

☐ Completes and maintains convened IRB minutes and records efficiently and correctly

[1] This document satisfies AAHRPP element I.1.E

☐ Knowledge of regulations and identifications of areas for improvement

☐ Knowledge of organizational policies and procedures and identification of areas for improvement

☐ Communication with IRB chairs, IRB staff, investigators, and study staff

☐ Ability to help investigators

3. Notes

Click or tap here to enter notes.

VCU Research and Innovation

HRP-330 | 03/01/2024

WORKSHEET: HIPAA Authorization

The purpose of this checklist is to provide support for IRB staff when evaluating whether a HIPAA authorization is valid. IRB staff are to consult this worksheet to review HIPAA authorizations. This worksheet does not need to be completed or retained.

1. CORE ELEMENTS (Check if "**Yes**". All must be checked)

☐ A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion.

☐ The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure.

☐ The name or other specific identification of the person(s), or class of persons, to whom the covered entity may make the requested use or disclosure.

☐ A description of each purpose of the requested use or disclosure.

☐ An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure. (The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.)

☐ Signature of the individual and date. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

2. REQUIRED STATEMENTS (Check if "**Yes**". All must be checked)

☐ The individual's right to revoke the authorization in writing.

☐ The authorization either:

- Describes the exceptions to the right to revoke the authorization.
- References the Notice for Privacy Practices for Protected Health Information which describes the exceptions to the right to revoke the authorization.

☐ The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either of the following:

- The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization.

- The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

☐ The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this authorization.

3. OTHER REQUIREMENTS (Check if "**Yes**". All must be checked)

☐ The authorization is written in plain language.

☐ The individual will be provided with a copy of the signed authorization.

☐ If the marketing involves direct or indirect remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.

☐ The authorization is either a separate document or incorporated into the written consent document for research.

☐ No material information in the authorization is known to be false.

VCU Research and Innovation

HRP-331 | 03/01/2024

WORKSHEET: FERPA Compliance

The purpose of this worksheet is to provide support for the FERPA officer determining whether personally identifiable information can be released from student education records [1] or personal education information from an education program (defined as: any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education). IRB staff may also reference the criteria in this worksheet. This worksheet does not need to be completed or retained.[2]

Requirements for Disclosure (one of the following categories must be met)

☐ The parent or eligible student will provide a signed and dated written consent that discloses:

- ☐ The records that may be disclosed;
- ☐ The purpose of the disclosure
- ☐ The party or class of parties to whom the disclosure may be made
- ☐ If a parent or adult student requests, the school will provide him or her with a copy of the records disclosed
- ☐ If the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

☐ The disclosure is to other school officials, including teachers, within the agency or institution whom the agency or institution has determined to have legitimate educational interests. A contractor, consultant, volunteer, or other party to whom an agency or institution has outsourced institutional services or functions may be considered a school official under this paragraph provided that the outside party—

- Performs an institutional service or function for which the agency or institution would otherwise use employees;
- Is under the direct control of the agency or institution with respect to the use and maintenance of education records; and
- Is subject to the requirements of §99.33(a) governing the use and redisclosure of personally identifiable information from education records.

☐ The disclosure is, subject to the requirements of 34 CFR §99.34, to officials of another school, school system, or institution of postsecondary education where the student seeks or intends to enroll, or where the

[1] The term "education records" is defined to mean, with certain exceptions, those records that are: (1) directly related to a student, and (2) maintained by an educational agency or institution or by a party acting for the agency or institution. 20 U.S.C. § 1232g(a)(4)(A); 34 CFR § 99.3 (definition of "education records"). For instance, a student's health records, including immunization records, maintained by an educational agency or institution (such as by an elementary or secondary school nurse) would generally constitute education records subject to FERPA. Joint Guidance on the Application of the Family Educational Rights and Privacy Act (FERPA) And the Health Insurance Portability and Accountability Act of 1996 (HIPAA) To Student Health Records

[2] This document satisfies AAHRPP elements II.3.G, II.4.B, III.2.C

student is already enrolled so long as the disclosure is for purposes related to the student's enrollment or transfer.

☐ The disclosure is, subject to the requirements of 34 CFR §99.35, to authorized representatives of—

- The Comptroller General of the United States;
- The Attorney General of the United States;
- The Secretary; or
- State and local educational authorities.

☐ The disclosure is in connection with financial aid [3] for which the student has applied or which the student has received, if the information is necessary for such purposes as to:

- Determine eligibility for the aid;
- Determine the amount of the aid;
- Determine the conditions for the aid; or
- Enforce the terms and conditions of the aid.

☐ The disclosure is to State and local officials or authorities to whom this information is specifically—

- Allowed to be reported or disclosed pursuant to State statute adopted before November 19, 1974, if the allowed reporting or disclosure concerns the juvenile justice system and the system's ability to effectively serve the student whose records are released; or
- Allowed to be reported or disclosed pursuant to State statute adopted after November 19, 1974, subject to the requirements of 34 CFR §99.38. (A State from further limiting the number or type of State or local officials to whom disclosures may be made.)

☐ The disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to: Develop, validate, or administer predictive tests; Administer student aid programs; or Improve instruction. Where:

- ☐ The study is conducted in a manner that does not permit personal identification of parents and students by individuals other than representatives of the organization that have legitimate interests in the information;
- ☐ The information is destroyed when no longer needed for the purposes for which the study was conducted
- ☐ The school enters into a written agreement with the organization that:
  - ☐ Specifies the purpose, scope, and duration of the study or studies and the information to be disclosed
  - ☐ Requires the organization to use personally identifiable information from education records only to meet the purpose or purposes of the study as stated in the written agreement;

[3] Financial aid means a payment of funds provided to an individual (or a payment in kind of tangible or intangible property to the individual) that is conditioned on the individual's attendance at an educational agency or institution.

☐ Requires the organization to conduct the study in a manner that does not permit personal identification of parents and students, as defined in this part, by anyone other than representatives of the organization with legitimate interests

☐ Requires the organization to destroy or return to the school all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and specifies the time period in which the information must be returned or destroyed

☐ The disclosure is to accrediting organizations to carry out their accrediting functions.

☐ The disclosure is to parents, as defined in 34 CFR §99.3, of a dependent student, as defined in section 152 of the Internal Revenue Code of 1986.

☐ The disclosure is to comply with a judicial order or lawfully issued subpoena where one of the following is true:

☐ The school makes a reasonable effort to notify the parent or eligible student of the order or subpoena in advance of compliance, so that the parent or eligible student may seek protective action, unless the disclosure is in compliance with—

- A Federal grand jury subpoena and the court has ordered that the existence or the contents of the subpoena or the information furnished in response to the subpoena not be disclosed;
- Any other subpoena issued for a law enforcement purpose and the court or other issuing agency has ordered that the existence or the contents of the subpoena or the information furnished in response to the subpoena not be disclosed; or
- An ex parte court order obtained by the United States Attorney General (or designee not lower than an Assistant Attorney General) concerning investigations or prosecutions of an offense listed in 18 U.S.C. 2332b(g)(5)(B) or an act of domestic or international terrorism as defined in 18 U.S.C. 2331.

☐ The disclosure is to the court when the school initiates legal action against a parent or student

☐ The disclosure is to the court when a parent or eligible student initiates legal action against the school,

☐ The disclosure is in connection with a health or safety emergency, under the conditions described in §99.36.

☐ The disclosure is information the school has designated as “directory information”, under the conditions described in §99.37.

☐ The disclosure is to the parent of a student who is not an eligible student or to the student.

☐ The disclosure, subject to the requirements in 34 CFR §99.39, is to a victim of an alleged perpetrator of a crime of violence or a non-forcible sex offense. The disclosure may only include the final results of the disciplinary proceeding conducted by the institution of postsecondary education with respect to that alleged crime or offense. The institution may disclose the final results of the disciplinary proceeding, regardless of whether the institution concluded a violation was committed.

□ The disclosure [4] is to a parent of a student at an institution of postsecondary education regarding the student's violation of any Federal, State, or local law, or of any rule or policy of the institution, governing the use or possession of alcohol or a controlled substance if—

- The institution determines that the student has committed a disciplinary violation with respect to that use or possession; and
- The student is under the age of 21 at the time of the disclosure to the parent.

□ The disclosure concerns sex offenders and other individuals required to register under section 170101 of the Violent Crime Control and Law Enforcement Act of 1994, 42 U.S.C. 14071, and the information was provided to the school under 42 U.S.C. 14071 and applicable Federal guidelines.

□ The disclosure is of records in which the school or other party has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information. “Not personally identifiable” means information that includes none of the following:

- Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
- Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

□ The disclosure is of records in which are de-identified student level data from education records for the purpose of education research by attaching a code to each record that may allow the recipient to match information received from the same source, provided that—

- The school or other party that releases de-identified data does not disclose any information about how it generates and assigns a record code, or that would allow a recipient to identify a student based on a record code;
- The record code is used for no purpose other than identifying a de-identified record for purposes of education research and cannot be used to ascertain personally identifiable information about a student; and
- The record code is not based on a student's social security number or other personal information.

[4] This section does not supersede any provision of State law that prohibits an institution of postsecondary education from disclosing information.

VCU Research and Innovation

HRP-332 | 03/01/2024

WORKSHEET: NIH GDS Institutional Certification

The purpose of this worksheet is to allow the HRPP Director or designee to evaluate whether an investigator's genomic data sharing plan meets the criteria for submission to an NIH-designated data repository.

1. Institutional Certification Requirements (ALL must be checked "Yes")

Yes or No?	Institutional Certification Requirement
☐ Yes ☐ No	The data submission is consistent, as appropriate, with applicable national, tribal, and state laws and regulations as well as relevant institutional policies.
☐ Yes ☐ No	Limitations on the research use of the data, as expressed in the informed consent documents, are delineated. ☐ **NA for submission to an unrestricted-access database.**
☐ Yes ☐ No	The identities of research participants will not be disclosed to NIH-designated data repositories.
☐ Yes ☐ No	The protocol for collection of genomic and phenotype data is consistent with 45 CFR §46.
☐ Yes ☐ No	Data submission and subsequent data sharing for research purposes are consistent with the informed consent and explicitly disclosed to study participants from whom the data were or will be obtained. [1]
☐ Yes ☐ No	Consideration was given to risks to individual participants and their families associated with the data submitted to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
☐ Yes ☐ No	To the extent relevant and possible, consideration was given to risks to groups or populations associated with submitting data to NIH-designated data repositories and subsequent sharing, including unrestricted access to genomic summary results.
☐ Yes ☐ No	The investigator's plan for de-identifying datasets is consistent with the standards outlined in Section IV.C.1 of the NIH Final Genomic Data Sharing Policy. (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html)

If you cannot select "Yes" to all items above, then stop. You cannot certify that the data submission criteria have been met. Communicate with the investigator to let her or him know that you cannot proceed with the Institutional Certification process without changes to the investigator's data sharing plan.

[1] For studies using data from specimens collected before the effective date of the GDS Policy, January 25, 2015, review should ensure the data submission is not *inconsistent* with the informed consent provided by the research participant. NIH will accept data derived from de-identified cell lines or clinical specimens lacking consent for research use that were created or collected before the effective date of the GDS Policy. After the Policy effective date, NIH expects *explicit* consent for broad sharing and for data that will be submitted to unrestricted-access data repositories. https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html

2. Unrestricted- or Controlled-Access Database

Choose the type of database to which the investigator will submit:

☐ Unrestricted-Access Database[2] ☐ Controlled-Access Database[3]

Check if applies:

☐ Sensitive genomic summary results[4] are only to be made available through controlled-access.

Explanation: Click or tap here to enter text.

If Controlled-Access Database selected above, specify one of the data use limitations[5] below for appropriate secondary use. These limitations must be included in the GDS Institutional Certification to the NIH.

☐ General Research Use: Use of the data is limited only by the terms of the Data Use Certification: these data will be added to the dbGaP Collection.

☐ Health/Medical/Biomedical: Use of the data is limited to health/medical/biomedical purposes, does not include the study of population origins or ancestry.

☐ Disease-specific: Use of the data must be related to the specific disease.

List disease: Click or tap here to enter text.

☐ Other: Click or tap here to enter text.

Additional modifiers, if appropriate (check all that apply):

☐ IRB Approval Required	☐ Publication Required	☐ Collaboration Required	☐ Not-for-profit Use Only	☐ Methods Development Research	☐ Genetic Studies Only

[2] Data made publicly available to anyone.

[3] Data made available for secondary research only after investigators have obtained approval from NIH to use the requested data for a particular project.

[4] Genomic summary results (GSR) are results from primary analyses of genomic research that convey information relevant to genomic associations with traits or diseases across datasets rather than data specific to any one individual research participant (e.g., genotype counts and frequencies; allele counts and frequencies; effect size estimates and standard errors; likelihoods; and p-values). GSR may be considered to have particular sensitivities related to individual privacy or potential for group harm.

[5] Standard NIH data use limitations: https://osp.od.nih.gov/wp-content/uploads/standard_data_use_limitations.pdf. Additional modifiers to standard data use limitations may be indicated if appropriate and should have a basis in the informed consent from the participants or in special knowledge of the preferences of the original study population.

VCU Research and Innovation

HRP-333 | 03/01/2024

WORKSHEET: Certificate of Confidentiality

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating whether a Certificate of Confidentiality is required or appropriate for a study.[1]

1. Considerations for Certificate of Confidentiality (Check if "**Yes**")

☐ The research is funded by the National Institutes of Health (NIH) and is biomedical, clinical, or other research.[2] If "**Yes**," a COC is automatically issued through the award. Other HHS agencies provide a CoC for funded research upon request.[3]

☐ The research is health-related biomedical, behavioral, clinical, or other research that is not funded by HHS.[4]

If "**Yes**," answer the following:

☐ The research is collecting personally identifiable information.

☐ The research is sensitive.[5]

☐ The research is collecting information that if disclosed could significantly harm or damage the participant.

2. Certificate of Confidentiality for Research Language is included in Consent (If "Yes" in #1, must be "**Yes**")

☐ The consent document includes information describing the CoC and its purpose and its applicability to the research.

[1] This document satisfies AAHRPP element II.3.E

[2] NOT-OD-17-109: Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality; https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

[3] To identify appropriate HHS agency for CoC request; https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step1

[4] Online Certificate of Confidentiality System; https://public.era.nih.gov/commonsplus/public/coc/request/init.era

[5] Examples of sensitive research activities include but are not limited to the following: collecting genetic information; collecting information on psychological well-being of subjects; collecting information on subjects' sexual attitudes, preferences, or practices; collecting data on substance abuse or other illegal risk behaviors' studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).

VCU Research and Innovation

HRP-351 | 03/01/2024

WORKSHEET: Protocol-Specific Emergency/Disaster Risk Mitigation Planning

The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to modify research during an emergency/disaster situation impacting the investigator's ability to ensure the ongoing safety of research subjects. Challenges to study conduct may arise, for example, from:

- Extreme weather events.
- Natural disasters
- Man-made disasters
- Infectious disease outbreaks

These challenges may lead to difficulties in conducting protocol-specified procedures, including administering or using test articles or adhering to protocol-mandated visits and tests. The following worksheet contains various considerations when investigators are responsible for protocol-specific emergency/disaster risk mitigation planning.[1]

1. General Exclusions: If any of the following are true, development of a protocol-specific risk mitigation plan for research may not be needed.

☐ Research does not involve in-person interaction with research subjects.

☐ Research can be conducted as written while adhering to additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event.

☐ Research is externally sponsored, and the sponsor has developed a protocol-specific risk mitigation plan for the research.

☐ Research has been voluntarily placed on hold for recruitment and all research procedures (except for necessary follow-up procedures to be done consistently with additional institution-level and HRPP-level guidance and requirements regarding the emergency/disaster event).

2. General Considerations for Creating a Protocol-Specific Emergency/Disaster Risk Mitigation Plan. The following are additional considerations for investigators when determining the various elements of their research that must be modified to ensure the ongoing safety of research subjects during an emergency/disaster situation. The considerations below do not represent an exhaustive list and are intended to serve as a starting point to guide an ongoing discussion between investigators, study staff,

[1] This document satisfies AAHRPP elements I.1.H

sponsors and institutional review boards (IRBs) in their efforts to address the new risks to research subjects and others posed by current or anticipated emergencies/disasters.

☐ Modifications to Recruitment and Enrollment Processes (Select any that are appropriate for the research.):

- ☐ Temporarily discontinue study recruitment efforts and initiatives.
- ☐ Temporarily discontinue enrollment of new research subjects.
- ☐ Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to recruitment and enrollment (e.g., for infectious disease outbreaks).
- ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

☐ Additional Modifications to Minimize Risk (Select any that are appropriate for the research.):

- ☐ Withdraw some or all current research subjects from the research.
- ☐ Modify study visit procedures so that visits can be completed via phone.
- ☐ Modify study visit procedures so that visits can be completed virtually.
- ☐ Modify study visit procedures so that visits can be completed at subjects' local lab, clinical or imaging center.
- ☐ Incorporate additional screening procedures for research subjects or study personnel that will be completed prior to in-person visits (e.g., for infectious disease outbreaks).
- ☐ Incorporate other additional safety monitoring procedures. Describe: Click or tap here to enter text.
- ☐ If planned on-site monitoring visits are no longer possible, consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites.
- ☐ Modify timing and scope of specific study visits to account for essential versus nonessential study procedures.
- ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

☐ For FDA-Regulated Research: Modifications to Investigational Drug/Biologic/Device Access and Administration (Select any that are appropriate for the research.):

- ☐ For any investigational products that can typically be distributed for self-administration, modify the protocol to allow for alternative secure delivery methods (e.g., investigational product can be shipped to the subject's residence).
- ☐ For any investigational products that are normally administered in a healthcare setting, consult FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel).
- ☐ Other relevant actions should be taken. Describe: Click or tap here to enter text.

3. Research Record and Study Documentation Considerations when implementing Emergency/Disaster-Specific Study Modifications: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects in emergency/disaster situations.

☐ For protocol wide study restrictions or modifications necessitated by the emergency/disaster situation, documentation related to any of the following elements are included in the research record where applicable and appropriate to the research:

- ☐ Changes in study conduct
- ☐ Duration of those changes
- ☐ Which trial participants were impacted
- ☐ How those trial participants were impacted
- ☐ Other relevant actions that were taken. Describe: Click or tap here to enter text.

☐ For FDA-regulated research where there are individual instances when efficacy endpoints are not collected, the research record includes documentation related to the reasons for failing to obtain the efficacy assessment (e.g., identifying the specific limitation imposed by the emergency/disaster leading to the inability to perform the protocol-specified assessment).

- ☐ Specific information in case report forms explains the basis of any missing data, including the relationship to the emergency/disaster for missing protocol-specified information.

☐ For FDA-regulated research where changes in the protocol include any of the following, the research record includes documentation that changes were made in consultation with the applicable FDA review division where feasible and appropriate:

- ☐ Amendments to data management and/or statistical analysis plans
- ☐ Alternative administration of investigational products that are normally administered in a healthcare setting (e.g., home nursing or alternative sites by trained but non-study personnel)
- ☐ Protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments and alternative collection of research-specific specimens

4. Communication Plan to Subjects: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during emergency/disaster situations.

☐ A research subject communication plan describing the study-specific modifications being made to ensure the ongoing safety of research subjects during the emergency/disaster situation has been developed for implementation with all current (and where applicable, prospective) research subjects. This plan includes:

- ☐ What information will be communicated to current (and where applicable, prospective) research subjects

☐ Who will communicate the information

☐ When the information will be communicated

☐ How the information will be communicated

5. IRB Notification and Approval (Where Applicable): One of the following must be true.

☐ If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB within five business days following the standard pathway to submit reportable new information.

☐ For all other study modifications made to ensure the ongoing safety of research subjects throughout an ongoing emergency/disaster situation, a study amendment is submitted to the IRB

VCU Research and Innovation

HRP-352 | 03/01/2024

WORKSHEET: Additional Emergency-Disaster Review Considerations

The purpose of this worksheet is to provide IRB members with additional considerations that may become relevant when reviewing Human Research during an emergency/disaster situation. These additional considerations may provide additional and necessary flexibility for study teams while continuing to assure research subject safety during the emergency/disaster. This worksheet is to be used when directed to do so by the IRB Chair or staff. It does not need to be completed or filed.

1. More widespread use of waivers of documentation of consent for minimal risk research: Additional use of waivers of documentation of consent may be appropriate if the following items are true. (Check if "Yes." All must be checked)

☐ The research involves no more than Minimal Risk to the subjects.

☐ The research involves only interaction, not intervention, with subjects.

☐ The emergency/disaster may create additional challenges in notifying participants of changes to consent documents.

☐ The research meets one of the eligibility categories for waiver of written documentation of consent listed in HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent.

2. Alternate mechanisms for safety monitoring. (Check if "Yes." All must be checked)

☐ The research involves protocol-specified visits to the investigational site.

☐ Research subjects may not be able to come to the investigational site for protocol-specified visits due to the emergency/disaster.

☐ Alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) are available.

☐ Alternative methods for safety assessments can feasibly be implemented.

☐ Alternative methods for safety assessments) would be sufficient to assure the safety of trial participants.

3. Additional flexibility in oversight of research not subject to federal regulations. (Check if "Yes." All must be checked)

☐ The research is not covered by federal regulations.

☐ One or more of the following options is feasible and appropriate during an emergency/disaster to provide necessary flexibility for study teams while continuing to assure research subject safety:

☐ Extend continuing review dates during the anticipated period of an emergency.

☐ Allow minor changes to be reported to the IRB or EC without requiring IRB or EC approval prior to implementation.

4. Other mechanisms for additional flexibility not described above. In addition to the options above, additional considerations in providing added flexibility to study teams during emergency/disaster situations may be appropriate where any of the following is true. (Check if "Yes")

☐ Additional institution-level information related to emergency/disaster planning (and not otherwise specified above) provides additional guidance in providing additional flexibility or support to study teams managing research during and emergency/disaster.

☐ Federal guidance or communications related to managing research during the emergency/disaster is issued and provides additional flexibility or resources.