VCU Research and Innovation

HRP-401 | 02/01/2024

CHECKLIST: Pre-Review

The purpose of this checklist is to provide support for IRB Staff conducting Pre-review. This checklist is to be completed by the IRB staff, signed, dated, and retained.[1]

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

Regulatory Oversight *(Check all that apply)*

☐ **Common Rule Requirements prior to January 21, 2019**

☐ **Common Rule Requirements as of January 21, 2019**

☐ DHHS

☐ FDA

☐ OCR

☐ DOD

☐ DOE

☐ NSF

☐ DOJ

☐ ED

☐ Tribal Law

☐ EPA

☐ VA

☐ EU GDPR

[1] This document satisfies AAHRPP elements I.1.A, I.1.E, I.6.A, I.6.B, I.7.A, I.7.C. I-9, II.3.G, II.4.B, III.2.C

☐ Other Federal Agency

☐ None

☐ ICH-GCP

Restrictions (Check if applicable)

☐ Principal Investigator is Restricted

Special Determinations (Check all that apply)

☐ Children - HRP-416

☐ Wards - HRP-416

☐ Pregnant women - HRP-412

☐ Prisoners - HRP-415

☐ Students/Employees

☐ Not significant risk device (FDA) - HRP-418

☐ Non-viable neonates - HRP-413

☐ Neonates of uncertain viability - HRP-414

☐ Individuals with impaired decision-making capacity - HRP-417

☐ Waiver/alteration of the consent process - HRP-410

☐ Waiver of HIPAA authorization - HRP-441

☐ Waiver of consent documentation - HRP-411

☐ Waiver of consent for planned emergency research - HRP-419

Protocol Tracking (Check all that apply)

☐ Social/Behavioral/Education

☐ Single-Site Study

☐ Deception

☐ Certificate of Confidentiality

☐ Biomedical/Clinical

☐ Collaborative Study (Lead Site)

☐ Collaborative Study (Participating Site)

☐ Other

☐ Clinical Trial

☐ Multi-Site Study (Lead Site)

☐ Multi-Site Study (Participating Site)

Notes

Click or tap here to enter text.

STUDY CLOSURE

☐ Research can be closed.

Reviewer Signature

Date of Signature: Click or tap here to enter text.

VCU Research and Innovation

HRP-402 | 02/01/2024

CHECKLIST: Non-Committee Review

The purpose of this checklist is to provide support for Designated Reviewers conducting Non-Committee Review. This checklist is to be completed by the Designated Reviewer, signed, dated, and retained.[1]

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

Type of submission:

☐ Initial Review

☐ Modification

☐ Continuing Review

☐ Request for Human Research or engagement determination

☐ Review of Modifications Required to Secure Approval

1. Reviewer Criteria (Check if "**Yes**." **Otherwise, sign the form, and return all materials**.)

☐ I do **not** have a Conflicting Interest

2. Review Level (Select one of the following)

☐ Not Human Research (use HRP-310 - WORKSHEET - Human Research Determination)

☐ Human Research Not Engaged (use HRP-311 - WORKSHEET - Engagement Determination)

[1] This document satisfies AAHRPP elements I.1.A, I.6.B, I.7.A, I-9, II.1.D, II.2.A-II.2.C, II.2.F-II.2.F.3, II.5.A, II.5.B

□ Exempt (use HRP-312 - WORKSHEET - Exemption Determination, HRP-319 - WORKSHEET - Limited IRB Review)

- □ (1) Educational settings
- □ (2)(i) Tests, surveys, interviews, or observation (non-identifiable)
- □ (2)(ii) Tests, surveys, interviews, or observation (low risk)
- □ (2)(iii) Tests, surveys, interviews, or observation (identifiable); and for which limited IRB review was conducted via expedited review
- □ (3)(i)(A) Benign behavioral interventions (non-identifiable)
- □ (3)(i)(B) Benign behavioral interventions (low risk)
- □ (3)(i)(C) Benign behavioral interventions (identifiable); and for which limited IRB review was conducted via expedited review
- □ (4) Secondary research on data or specimens (no consent required)
- □ (5) Demonstration projects
- □ (6) Taste and food quality
- □ (7) Storage or maintenance of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review
- □ (8) Secondary research use of data or specimens (broad consent required); and for which limited IRB review was conducted via expedited review

□ Expedited (use HRP-313 - WORKSHEET - Expedited Review, HRP-314 - WORKSHEET - Criteria for Approval)

- □ Minor modifications to previously approved research
- □ (1)(a) Drug studies
- □ (1)(b) Device studies
- □ (2)(a) Blood samples from healthy, non-pregnant adults
- □ (2)(b) Blood samples from others
- □ (3) Noninvasive biological specimens
- □ (4) Noninvasive procedures
- □ (5) Data, documents, records, or specimens

☐ (6) Voice, video, digital, or image recordings

☐ (7)(a) Behavioral research

☐ (7)(b) Social science methods

☐ (8)(a) Long-term follow-up

☐ (8)(b) No subjects enrolled

☐ (8)(c) Data analysis

☐ (9) Convened IRB determined Minimal Risk

☐ HUD continuing review

3. Determination (Select one of the following)

☐ Meets criteria

☐ Modifications required to meet criteria

☐ Send to convened IRB

4. Additional Information

Describe modifications required to secure approval, if required in section 3 above. Or, if review must be sent to the convened IRB, provide rationale for this determination (e.g. describe why research cannot be approved via expedited review, explain why research appearing on the expedited review list is actually more than Minimal Risk, etc.):

Click or tap here to enter text.

5. Continuing Review (select one of the following)

☐ Status update only required (expedited studies reviewed under revised 2018 Common Rule regulatory authority and exempt studies).

☐ Continuing review required. Rationale: Click or tap here to enter text.

Reviewer Signature

Attach any required completed checklists and documentation of protocol-specific findings justifying regulatory determinations.

X _____

Date of Signature: Click or tap here to enter text.

VCU Research and Innovation

HRP-410 | 02/01/2024

CHECKLIST: Waiver or Alteration of Consent Process

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver or alteration of the consent process. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer uploads this checklist in the "Administrative Documents" tab. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Use a separate checklist for each waiver or alteration determination for a study.

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Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

The research must meet one of the following four sets of criteria:

1. Waiver or Alteration of Consent Process[2] (Check if **"Yes."** All must be checked)

☐ The research is **NOT** FDA-regulated.

☐ The research does **NOT** involve non-viable neonates.

[1] This document satisfies AAHRPP elements I-9, II.3.G, II.5.A, II.5.B, III.1.F

[2] 45 CFR §46.116(f)

☐ The research involves no more than Minimal Risk to the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research could **NOT** practicably be carried out without the waiver or alteration.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If the research involves using Identifiable Private Information or Identifiable Biospecimens, the research could **NOT** practicably be carried out without using such information or biospecimens in an identifiable format.

☐ **NA if research does not use identifiable private information or biospecimens, or if the research is not subject to the 2018 Rule.**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The waiver or alteration will **NOT** adversely affect the rights and welfare of the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Waiver of consent for the storage, maintenance, or secondary research use of the Identifiable Private Information or Identifiable Biospecimens cannot be granted for those who refused to provide broad consent.

☐ **NA if broad consent not used for the research, or if the research is not subject to the 2018 Rule.**

☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent.[3]

☐ **NA if waiving informed consent, or if the research is not subject to the 2018 Rule.**

2. Waiver or Alteration of Consent Process[4] (Check if **"Yes."** All must be checked)

☐ The research **IS** FDA-regulated.

☐ The clinical investigation involves no more than Minimal Risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects.[5]

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

[3] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

[4] https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf

[5] A survey of patient records to determine sufficient number or preliminary review of the patient's record and recording of limited information is considered preparation for a clinical investigation, does not fall within the definition of a clinical investigation, and, therefore, does not require informed consent. *FDA's Informed Consent Guidance for IRBs, Clinical Investigators, and Sponsors (August 2023)* https://www.fda.gov/media/88915/download.

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The clinical investigation could not practicably be carried out without the waiver or alteration.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

3. Waiver or Alteration of Consent Process[6] (Check if **"Yes."** All must be checked)

☐ The research is **NOT** FDA-regulated.

☐ The research does **NOT** involve non-viable neonates.

☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. One must be checked)**

☐ Public benefit or service programs.

☐ Procedures for obtaining benefits or services under those programs.

☐ Possible changes in or alternatives to those programs or procedures.

☐ Possible changes in methods or levels of payment for benefits or services under those programs.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research could **NOT** practicably be carried out without the waiver or alteration.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Waiver of consent for the storage, maintenance, or secondary research use of the Identifiable Private Information or Identifiable Biospecimens cannot be granted for those who refused to provide broad consent.

☐ **NA if broad consent not used for the research, or if the research is not subject to the 2018 Rule.**

☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent.

☐ **NA if waiving informed consent, or if the research is not subject to the 2018 Rule.**

[6] 45 CFR §46.116(e)

4. Waiver of the Consent Process for FDA-Regulated Research Involving Anonymous Tissue Specimens[7] (Check if **"Yes."** All must be checked)

☐ The research does not involve Human Subjects as Defined by DHHS.

☐ The study involves an in vitro diagnostic device investigation.

☐ The testing is noninvasive.

☐ 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 device is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

☐ For a product in the laboratory research phase of development, and not represented as an effective in vitro diagnostic product, all labeling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures."

☐ For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labeling bears the statement, prominently placed: "For Investigational Use Only. The performance characteristics of this product have not been established."

☐ The study uses one of more of the following: **(Check all boxes that are true. One must be checked.)**

- ☐ Specimens collected for routine clinical care or analysis that would have been discarded.
- ☐ Specimens obtained from specimen repositories.
- ☐ Leftover specimens that were previously collected for other research purposes.

☐ The identity of the subject is not known to the investigator or any other individuals associated with the investigation, including the sponsor meaning neither the investigator nor any other individuals associated with the investigation, including the sponsor can readily ascertain the identity of the subject.

☐ One of the following is true: **(Check all boxes that are true. One must be checked.)**

- ☐ Specimens are not coded where "Coded" means that 1) a number, letter, symbol, or combination thereof (i.e., the code) has replaced identifying information (such as name or social security number) that would enable the investigator or any other individuals associated with the investigation, including the sponsor to readily ascertain the identity of the individual to whom the specimen pertains; and 2) a key to decipher the code exists, enabling linkage of the identifying information to the specimen.

[7] Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable – April 25, 2006

☐ Neither the investigator(s) nor any other individuals associated with the investigation or the sponsor can link the specimen to the subject from whom the specimen was collected, either directly or indirectly through coding systems.

☐ One of the following is true: **(Check all boxes that are true. One must be checked.)**

☐ The specimens are not accompanied by clinical information.

☐ Clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor.

☐ The individuals caring for the patients are different from those conducting the investigation and do not share information about the patient with those conducting the investigation.

☐ The specimens are provided to the investigator(s) without identifiers.

☐ The supplier of the specimens has established policies and procedures to prevent the release of personal information.

5. Waiver of Informed Consent for Planned Emergency Research[8]

☐ The research meets the criteria in **HRP-419 - CHECKLIST - Waiver of Consent for Emergency Research**.

[8] 21 CFR §50.24 and 45 CFR §46 Waiver of Informed Consent Requirements in Certain Emergency Research – November 1, 1996

VCU Research and Innovation

HRP-411 | 02/01/2024

CHECKLIST: Waiver of Written Documentation of Consent

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves the waiver of written documentation of consent. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

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Use a separate checklist for each waiver or alteration determination for a study.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

The research must meet one of the following sets of criteria:

1. Waiver of Written Documentation of Consent[2] (Check if **"Yes."** All must be checked)

☐ The written script of the information to be provided orally (if consent is obtained in person) and all written information to be provided or electronically displayed include all required and appropriate additional

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

[2] 21 CFR §56.109(c)(1) and 45 CFR §46.117(c)(1)(ii)

elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in HRP-314 - WORKSHEET - Criteria for Approval.

☐ The research presents no more than Minimal Risk of harm to subjects.

☐ The research involves no procedures for which written consent is normally required outside of the research context.

Select one of the following: **(One must be checked)**

- ☐ Written information describing the research **is to be provided** to the subject or the subject's Legally Authorized Representative (LAR).
- ☐ Written information describing the research **does not need to be provided** to the subject or the subject's LAR.

2. Waiver of Written Documentation of Consent[3] (Check if **"Yes."** All must be checked)

☐ The research is not FDA-regulated.

☐ The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in HRP-314 - WORKSHEET: Criteria for Approval**.**

☐ The only record linking the subject and the research would be the consent document.

☐ The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.

☐ Each subject or Legally Authorized Representative (LAR) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Select one of the following: **(One must be checked)**

- ☐ Written information describing the research **is to be provided** to the subject or the subject's LAR.
- ☐ Written information describing the research **does not need to be provided** to the subject or the subject's LAR.

3. Waiver of Written Documentation of Consent[4] (Check if **"Yes."** All must be checked)

☐ The research is not FDA-regulated.

☐ The research is subject to the 2018 Rule.

[3] 45 CFR §46.117(c)(1)(i)

[4] 45 CFR §46.117(c)(1)(iii)

□ The written script of the information to be provided orally and all written information to be provided include all required and appropriate additional elements of consent disclosure in **Section 7: ELEMENTS OF CONSENT DISCLOSURE** in HRP-314 - WORKSHEET- Criteria for Approval**.**

□ The subjects or subject's Legally Authorized Representative (LAR) are members of a distinct cultural group or community in which signing forms is not the norm.

□ The research presents no more than Minimal Risk of harm to subjects.

□ There is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select one of the following: **(One must be checked)**

□ Written information describing the research **is to be provided** to the subject or the subject's LAR.

□ Written information describing the research **does not need to be provided** to the subject or the subject's LAR.

VCU Research and Innovation

HRP-412 | 02/01/2024

CHECKLIST: Pregnant Women

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves pregnant women as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) [1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer uploads this checklist in the "Administrative Documents" tab. The IRB Office retains this checklist in the protocol file.
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Submission Information

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Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

Research must meet one of the following three sets of criteria in Section 1-3.

1. Minimal Risk Research (Check if "Yes". All must be checked)

☐ The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS, Veterans Administration (VA), or the Environmental Protection Agency (EPA).

☐ The research involves no more than Minimal Risk to pregnant women and fetuses.

[1] This document satisfies AAHRPP elements I.1.D, I-9, II.4.A, II.4.B, II.5.A, II.5.B

☐ The research is not funded by Department of Defense, OR is funded by DOD but does not involve interventions/invasive procedures to the woman or fetus and does not involve fetuses or neonates as subjects.

2. Research Involving Pregnant[2] Women[3] (Check if "**Yes**". All must be checked)

☐ Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses. **(NA if not scientifically appropriate.) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ One of the following is true: **(Check box that is true)**

☐ The risk to the fetus[4] is caused solely by Interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus.

☐ There is no prospect of benefit to the fetus, the risk to the fetus is **NOT** greater than Minimal Risk, and the purpose of the research is the development of important biomedical[5] knowledge which cannot be obtained by any other means

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Any risk is the least possible for achieving the objectives of the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is NOT greater than Minimal Risk and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent of the mother is obtained. **(NA if research does not hold out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus.) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained, except that the father's consent need NOT be obtained if he is unable to consent

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[2] "Pregnancy" encompasses the period of time from implantation until delivery. A woman shall be assumed to be pregnant if she exhibits any of the pertinent presumptive signs of pregnancy, such as missed menses, until the results of a pregnancy test are negative or until delivery.

[3] 45 CFR §46.204

[4] "Fetus" means the product of conception from implantation until delivery.

[5] For Department of Defense (DOD) research, the phrase "biomedical knowledge" can be replaced with "generalizable knowledge."

because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. **(NA if research does not hold out the prospect of direct benefit to the fetus.) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D. **(NA if research does not enroll children who are pregnant.) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ No inducements, monetary or otherwise, will be offered to terminate a pregnancy.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

3. **Research Involving Pregnant Women that is NOT Otherwise Approvable**[6](All must be "**Yes**")

☐ The research does **NOT** meet the requirements of 45 CFR §46.204.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

[6] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B of 45 CFR §46 and the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Deputy Institutional Official has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

VCU Research and Innovation

HRP-413 | 02/01/2024

CHECKLIST: Non-Viable Neonates

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves non-viable neonates as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) [1]

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Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

The research must meet one of the following two sets of criteria.

1. Research Involving Non-Viable[2] Neonates[3] (Check if **"Yes."** All must be checked)

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

[2] "Viable," as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

[3] 45 CFR §46.205

☐ Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Vital functions of the neonate will not be artificially maintained.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research will not terminate the heartbeat or respiration of the neonate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ There will be no added risk to the neonate resulting from the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The legally effective informed consent of both parents of the neonate is obtained, unless one parent is unable to consent because of unavailability, incompetence, or temporary incapacity and the consent of the father need not be obtained if the pregnancy resulted from rape or incest.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The consent of a Legally Authorized Representative (LAR) of either or both of the parents of a nonviable neonate will not be obtained.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

2. Research Involving Neonates that is Not Otherwise Approvable [4] (Check if **"Yes."** All must be checked)

☐ The research does **NOT** meet the requirements of §46.205.

[4] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B or Part 45CFR46; the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Deputy institutional Official (IO/DIO) has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

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CHECKLIST: Neonates of Uncertain Viability

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves neonates of uncertain viability as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) [1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer uploads this checklist in the "Administrative Documents" tab. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

The research must meet one of the following two sets of criteria.

1. Neonates[2] of Uncertain Viability[3] (Check if "**Yes**". All must be checked)

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

[2] "Viable," as it pertains to the neonate, means being able, after delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heartbeat and respiration.

[3] 45 CFR §46.205

☐ Where scientifically appropriate, pre-clinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Individuals engaged in the research will have no part in determining the viability of a neonate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ One of the following is true: **(Check box that is true)**

☐ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving that objective.

☐ The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the neonate. **("NA" if the consent process is waived) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent's Legally Authorized Representative (LAR) is obtained in accord with the regulations, except that the consent of the father or his LAR need not be obtained if the pregnancy resulted from rape or incest. **("NA" if the consent process is waived) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

2. Research Involving Neonates of Uncertain Viability that is Not Otherwise Approvable [4] (Check if "**Yes**". All must be checked)

☐ The research does **NOT** meet the requirements of §46.205.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

[4] 45 CFR §46.207. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD), the research may proceed when the DoD institutions demonstrate to the Senior Designated Official (SDO) that the IRB has fulfilled its duties in accordance with Subpart B or Part 45CFR46; the SDO must receive explicit written approval from the DoD Office of Human Research Protections (DOHRP). For all other research, the research may proceed only after the Institutional Official/Deputy Institutional Official (IO/DIO) has conducted a review in accordance with HRP-044 - SOP - Not Otherwise Approvable Research and approved the research.

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CHECKLIST: Prisoners

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves Prisoners as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.) [1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer attaches this checklist to "Submit Non-Committee Review" activity. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

The research must meet one of the following three sets of criteria in Section 1-3

1. Non-DHHS-Regulated Research Where a Subject Becomes Incarcerated (Check if "**Yes**". All must be checked)

☐ The research is **NOT** conducted or funded by DHHS or Veterans Administration (VA).

☐ The subject was not incarcerated at the time of enrollment and subsequent incarceration was unexpected.

☐ The incarceration does not put the rights and wellbeing of the subject in jeopardy.

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

☐ The Prisoner representative has been consulted.

☐ The terms of the subject's confinement does not inhibit the ethical conduct of the research.

☐ There are no other significant issues preventing the research from continuing as approved.

☐ This approval is limited to the individual subject and does not allow recruitment of Prisoners.

☐ One of the following is true: **(Check all that are true)**

- ☐ The subject will be at increased risk of harm if withdrawn from the research.
- ☐ The research presents no more than Minimal Risk[2] and no more than inconvenience to the subjects.

2. Non-DHHS Regulated Minimal Risk Research (Check if "Yes". All must be checked)

☐ The research is **NOT** conducted, funded, or otherwise subject to regulation by DHHS or Veterans Administration (VA).

☐ The research does not involve interaction with prisoners (e.g. existing data, record review).

☐ The research presents no more than Minimal Risk.[3]

☐ The research is reviewed by the expedited procedure.

3. Research Involving Prisoners[4] as Subjects (Check if "**Yes**" or "**NA**". All must be checked)

☐ The research under review represents one of the following categories of research: **(At least one must be checked.)**

- ☐ Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than Minimal Risk[5] and no more than inconvenience to the subjects.
- ☐ Study of prisons as institutional structures or of Prisoners as incarcerated persons, provided that the study presents no more than Minimal Risk and no more than inconvenience to the subjects.
- ☐ Research on conditions particularly affecting Prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).

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[2] "*Minimal risk*" for research involving prisoners is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.
[3] Ibid.
[4] "Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
[5] Ibid.

☐ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject where one of the following is true: **(One box must be checked)**

☐ All groups may benefit from the research.

☐ Prisoners are assigned to control groups which may not benefit from the research.

☐ Epidemiologic studies in which the sole purpose is to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, the research presents no more than Minimal Risk and no more than inconvenience to the subjects, and Prisoners are not a particular focus of the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Any possible advantages accruing to the Prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The risks involved in the research are commensurate with risks that would be accepted by non-Prisoner volunteers.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Procedures for the selection of subjects within the prison are fair to all Prisoners and immune from arbitrary Intervention by prison authorities or Prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available Prisoners who meet the characteristics needed for that particular research project.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The information is presented in language which is understandable to the subject population. **("NA" if no prisoner interaction) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Adequate assurance exists that parole boards will not take into account a Prisoner's participation in the research in making decisions regarding parole, and each Prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole. **("NA" if no prisoner interaction) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If the IRB finds there may be a need for follow-up examination or care of subjects after the end of their participation, adequate provision has been made for such examination or care, taking into account the

varying lengths of individual Prisoners' sentences, and for informing subjects of this fact. **("NA" if no prisoner interaction) ☐ NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ A Prisoner representative reviewed the research focusing on the requirements of this checklist.[6] **("NA" if no prisoner interaction[7]) ☐ NA**

☐ The Prisoner representative received all materials pertaining to the research. **("NA" if no prisoner interaction[8]) ☐ NA**

☐ For convened IRB review, the Prisoner representative presented either orally or in writing at the meeting or for review using the expedited procedure the Prisoner representative concurred that the research involves no more than Minimal Risk to the Prisoner subjects. **("NA" if no prisoner interaction[9]) ☐ NA**

☐ If the research is DHHS-regulated, the research may proceed only after the institution has certified to OHRP that the duties of the Board under this section have been fulfilled. If the research is conducted or funded by the Department of Defense (DOD), the research may proceed only after the institution has demonstrated to the Senior Designated Official that the IRB has fulfilled its duties under this section. **Check if NA: ☐**

[6] For review using the expedited procedure, the prisoner representative may be the Designated Reviewer or may serve as a consultant to the Designated Reviewer.

[7] For research that does not involve interaction with prisoners (e.g. existing data, record review) review by a prisoner representative is not required (AAHRPP Tip Sheet 18).

[8] For research that does not involve interaction with prisoners (e.g. existing data, record review) review by a prisoner representative is not required (AAHRPP Tip Sheet 18).

[9] For research that does not involve interaction with prisoners (e.g. existing data, record review) review by a prisoner representative is not required (AAHRPP Tip Sheet 18).

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HRP-416 | 02/01/2024

CHECKLIST: Children

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves children as subjects. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)[1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer uploads this checklist in the "Administrative Documents" tab. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Use a separate checklist for each child determination for a study.

1. Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

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

2. Pediatric Risk Determination - 21 CFR §50.51-50.54 and/or 45 CFR §46.404-46.407

The research falls into one of the following categories of research involving children.[2] One determination must be checked and documented.

☐ **Option 1 – Minimal Risk:** Research involving children under 21 CFR §50.51/45 CFR §46.404 (Check if "**Yes**". All must be checked)

☐ No greater than Minimal Risk to children is presented.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ **Option 2 – Greater than Minimal Risk with Direct Benefit to Subjects:** Research involving children under 21 CFR §50.52/45 CFR §46.405 (Check if "**Yes**". All must be checked)

☐ The research involves greater than Minimal Risk to subjects

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research presents the prospect of direct benefit to the individual subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ One of the following is true. **(Check box that is true)**

☐ The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.

☐ The risk to children is presented by a monitoring procedure that is likely to contribute to the subject's well-being.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The risk is justified by the anticipated benefit to the subjects.

*Provide protocol specific findings justifying this determination:*Click or tap here to enter text.

☐ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ **Option 3 – Minor Increase over Minimal Risk with Generalizable Knowledge:** Research involving children under 21 CFR §50.53/45 CFR §46.406 (Check if "**Yes**". All must be checked)

☐ The research involves greater than Minimal Risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject.

[2] Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The risk represents a minor increase over Minimal Risk where the researcher has presented sufficient evidence that the procedures, population, and the qualifications of research personnel support all of the following to be true[3]: **(Check boxes that are true. All must be checked.)**

☐ The increase in the probability and magnitude of harm is only slightly more than minimal risk.

☐ Any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period).

☐ There is no, or an extremely small probability, that participants will experience as severe the potential pain, discomfort, stress, or harm associated with the procedure.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

*Provide protocol specific findings justifying this determination:*Click or tap here to enter text.

☐ The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ **Option 4 – Not otherwise approvable research:** Not otherwise approvable research involving children under 21 CFR §50.54/45 CFR §46.407 (Check if "**Yes".** All must be checked) Follow HRP-044 - SOP - Not Otherwise Approvable Research as applicable.

☐ The research does not meet the requirements of Options 1, 2, or 3.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

[3] Where "minor increase over minimal risk" is based on SACHRP *Recommendations regarding risk in research involving children*; 18-Apr-2005.

3. Research Involving Wards of the State (Check **one** option below. One determination must be checked and documented.)

☐ **Option 1:** This research does NOT involve Wards of the State (Check if "**Yes**")

☐ **Option 2:** This research does involve Wards of the State or any other agency, institution, or entity under 21 CFR §50.56/45 CFR §46.409 and one of the following risk levels is checked in Section 2: Option 1 (21 CFR §50.51/45 CFR §46.404) or Option 2 (21 CFR §50.52/45 CFR §46.405). (Check if "**Yes**")

☐ **Option 3:** This research does involve Wards of the State or any other agency, institution, or entity under 21 CFR §50.56/45 CFR §46.409 and Option 3 (21 CFR §50.53/45 CFR §46.406) or Option 4 (21 CFR §50.52/45 CFR §46.407) is checked in **Section 2**.(Check if "**Yes**" and **complete table below**.)

Check if "Yes"	**Wards of the State: Option 3 Criteria** (***All of the following must be checked and documented)*:**	**Provide protocol specific findings justifying this determination**
☐	One of the following is true: **(Check box that is true)** ☐ The research is related to their status as wards. ☐ The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.	Click or tap here to enter text.
☐	An advocate will be appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis for research approved under §50.53 or §50.54/§46.406 or §46.407.	Click or tap here to enter text.
☐	The advocate will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child's participation in the research.	Click or tap here to enter text.
☐	The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.	Click or tap here to enter text.

4. Adequate Provisions To Solicit the Assent[4] of Children (Check if **"Yes".** All must be checked)

☐ **Assent will be obtained from:** (Check box that is true.)

☐ **All children**. (Check if "**Yes**." One of the following options for documentation of assent must be checked.)

☐ Investigator will document assent in the consent signature block.

☐ Other (NOTE: The protocol needs to describe the process of assent documentation)

☐ **None of the children.** (Check if "**Yes**" and **complete the Table for Waiver of Assent** to document the reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c).)

☐ **Some children.** (Check is "**Yes**" and **complete the Table for Waiver of Assent** below to document the reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c) The protocol needs to describe which children will not be asked for assent.)

☐ Investigator will document assent in the consent signature block.

☐ Other (NOTE: The protocol needs to describe the process of assent documentation)

Check if "Yes"	**Table for Waiver of Assent** **Reason Why Assent is Not Necessary** **45 CFR §46.408(a)/21 CFR §50.55(c)** *One or more of the following are true. (Check all boxes that are true.)*
☐	The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be consulted.
☐	The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research
☐	Assent is waived using the following criteria 45 CFR §46.408(a)/45 CFR §46.116(f)/21 CFR §50.55(d): ☐ The research involves no more than Minimal Risk to the subjects. ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

[4] "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent, 45 CFR §46.402(b).

	☐ The research could not practicably be carried out without the waiver or alteration ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation. ☐ If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. **(NA if research is FDA regulated, is subject to Pre-2018 Requirements OR if does not use identifiable private information or biospecimens) ☐ NA**
☐	Waiver of Child Assent under 45 CFR §46.408(a)/45 CFR §46.116€ (Check if "**Yes**". All must be checked) ☐ The research is not FDA-regulated. ☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials ☐ The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check all boxes that are true. At least one must be checked.) ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. ☐ The research could not practicably be carried out without the waiver or alteration.

5. Adequate Provisions Are Made for Soliciting the Permission of Parents or Guardians[5] (Check if **"Yes". <u>One</u>** of the following must be checked)

☐ Permission is to be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

[5] "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

☐ Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. (**Cannot be selected for the following Pediatric risk levels**: Section 2, Option 3 - 21 CFR §50.53/45 CFR §46.406 or Section 2, Option 4 - 21 CFR §50.54/45 CFR §46.407)

☐ Parental permission is waived (Complete documentation in Section 6)

6. Waiver of Parental Permission (To be completed only if a parental waiver was checked in Section 5. **One** of the following must be checked and documented.)

☐ **Waiver of Parental Permission under 45 CFR §46.408(c)** (Check if "**Yes**". All must be checked.)

☐ The research is not FDA-regulated.

☐ The research does not involve non-viable neonates.

☐ The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The waiver is not inconsistent with Federal, State, or local law.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ **Waiver of Parental Permission under 45 CFR §46.116(f)** (Check if "**Yes**". All must be checked.)

☐ The research is not FDA-regulated.

☐ The research does not involve non-viable neonates.

☐ The research involves no more than Minimal Risk to the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research could not practicably be carried out without the waiver or alteration

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. (N/A if research is subject to Pre-2018 Requirements OR if research does not use identifiable private information or biospecimens) ☐ **NA**

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Waiver of consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens cannot be granted for those who refused to provide broad consent. **(NA if research is subject to Pre-2018 Requirements OR broad consent not used for the research) ☐ NA**

☐ Alteration of the consent process can only omit or alter the basic and/or additional elements of consent[6]. **(NA if research is subject to Pre-2018 Requirements OR if waiving informed consent) ☐ NA**

☐ **Waiver of Parental Permission under FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects"[7]** (Check if "**Yes**." All must be checked.)

☐ The research **IS** FDA-regulated.

☐ The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research could not practicably be carried out without the waiver or alteration

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

☐ **Waiver of Parental Permission under 45 CFR §46.408(c)/45 CFR §46.116(e)** (Check if "**Yes**". All must be checked.)

[6] An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 45 CFR 46.116(b) and (c). An IRB may not omit or alter any of the requirements described in 45 CFR 46.116(a). If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 45 CFR 46.116(d).

[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/irb-waiver-or-alteration-informed-consent-clinical-investigations-involving-no-more-minimal-risk.

☐ The research is not FDA-regulated.

☐ The research does not involve non-viable neonates.

☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials.

☐ Public benefit or service programs.

☐ Procedures for obtaining benefits or services under those programs.

☐ Possible changes in or alternatives to those programs or procedures.

☐ Possible changes in methods or levels of payment for benefits or services under those programs.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research could not practicably be carried out without the waiver or alteration.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

CHECKLIST: COGNITIVELY IMPAIRED ADULTS

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when both of the following are true:

1. The research involves cognitively impaired adults as subjects, AND
2. The research involves a consent process or other intervention or interaction with the cognitively impaired subject(s).

This checklist must be used for all reviews where a consent process is required per the protocol, or where the interventions or interactions will be required with the subjects (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure).[1] This checklist does not need to be used for reviews where the research qualifies for waiver or alteration of consent processes per **HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process**, and where there will be no interventions or interactions with the subjects.

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer uploads this checklist in the "Administrative Documents" tab. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

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

All research must meet the criteria in Sections 1 or 2

1. Research involving cognitively impaired adults with anticipated direct benefit to the subject (Check if "**Yes**". All must be checked)

☐ One of the following is true: **(Check box that is true)**

☐ Subjects have a disease or condition for which the procedures involved in the research hold out a prospect of direct benefit to the individual subject that is unavailable outside the research context.

☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Risks to subjects are reasonable in relation to the anticipated benefits to subjects.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The trial is not prohibited by law.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Subjects will be particularly closely monitored.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Subjects will be withdrawn if they appear to be unduly distressed.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The proposed plan for the assessment of the capacity to consent is adequate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The subject will be informed about the research to the extent compatible with the subject's understanding.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Assent will be obtained from: **(One of the following must be checked)**

☐ All subjects.

☐ Some subjects, specify: Click or tap here to enter text.

☐ None of the subjects.

☐ The consent document includes a signature line for a Legally Authorized Representative (LAR).

☐ If capable, the subject will sign and personally date the written informed consent.

2. Research involving cognitively impaired adults with NO anticipated direct benefit to the subject (Check if "Yes". All must be checked)

☐ Subjects have a disease or condition for which the procedures involved in the research are intended.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The objectives of the trial cannot be met by means of study of subjects who can give consent personally.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The foreseeable risks to the subjects are low.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The negative impact on the subject's well-being is minimized and low.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The trial is not prohibited by law.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Subjects will be particularly closely monitored.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Subjects will be withdrawn if they appear to be unduly distressed.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The proposed plan for the assessment of the capacity to consent is adequate.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The subjects will be informed about the research to the extent compatible with the subject's understanding.

☐ Assent will be obtained from: **(One of the following must be checked)**

- ☐ All subjects.
- ☐ Some subjects, specify: Click or tap here to enter text.
- ☐ None of the subjects.

☐ The consent document includes a signature line for a (LAR).

□ If capable, the subject will sign and personally date the written informed consent.

VCU Research and Innovation

HRP-418 | 02/01/2024

CHECKLIST: Non-Significant Risk Device

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves an abbreviated IDE This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB). [1]

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

1. SIGNIFICANT RISK DEVICE STUDY (Check if "**Yes**." If any are checked, the device is a significant risk device.)

☐ Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject.

☐ Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.

[1] This document satisfies AAHRPP elements II.5.A, II.5.B

☐ Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

2. NON-SIGNIFICANT RISK DEVICE STUDY (Check if "**Yes**.")

☐ Meets none of the above criteria.

3. RATIONALE (Describe)

IRB Considerations[2]*:*

- *The risk determination is based on the proposed use of a device in an investigation, and not on the device alone.*
- *Consider the potential harm any additional procedures the subject will need to undergo as part of the investigational study (e.g., surgical procedure)*

Click or tap here to enter text.

[2] Information Sheet Guidance For IRBs, Clinical Investigators, and Sponsors, Significant Risk and Nonsignificant Risk Medical Device Studies, January 2006, https://www.fda.gov/media/75459/download

VCU Research and Innovation

HRP-419 | 02/01/2024

CHECKLIST: Waiver of Consent Process for Emergency Research

The purpose of this checklist is to provide support for IRB members or the Designated Reviewer following HRP-314 - WORKSHEET - Criteria for Approval when research involves waiver of consent for planned emergency research. This checklist must be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure). [1]

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, the Designated Reviewer completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations. The Designated Reviewer uploads this checklist in the "Administrative Documents" tab. The IRB Office retains this checklist in the protocol file.
- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this checklist made on the previous review have changed, one of the following two options may be used:
  1. The convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol specific findings justifying those determinations, in which case this checklist does not need to be completed or retained.
  2. The convened IRB completes this checklist to document determinations required by the regulations along with protocol specific findings justifying those determinations and the IRB Office uploads this checklist in the "Administrative Documents" tab and retains this checklist in the protocol file.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.
Person Completing Checklist (Name):	Click or tap here to enter text.
Date Checklist Completed:	Click or tap here to enter text.

1. Waiver of the Informed Consent Process for Planned Emergency Research (Check if **"Yes."** All must be checked)

☐ The research is **NOT** subject to regulation by a Common Rule agency other than DHHS.

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

☐ The research does **NOT** involve prisoners as subjects.

☐ The research does **NOT** involve pregnant women, fetuses, non-viable neonates, or neonates of uncertain viability.

☐ The IRB has reviewed and approved consent procedures and a consent document in accordance with HRP-314 - WORKSHEET - Criteria for Approval.

☐ The Human Subjects are in a life-threatening situation.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Available treatments are unproven or unsatisfactory.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Obtaining informed consent is not feasible because the subjects will not be able to give their informed consent as a result of their medical condition.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Obtaining informed consent is not feasible because the intervention under investigation must be administered before consent from the subject's Legally Authorized Representative (LAR) is feasible.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Obtaining informed consent is not feasible because there is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Participation in the research holds out the prospect of direct benefit to the subjects because they are facing a life-threatening situation that necessitates intervention.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subject.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The research could not practicably be carried out without the waiver.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a LAR for each subject within that window of time and, if feasible, to asking the LAR contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact LARs and make this information available to the IRB at the time of continuing review.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the research will be conducted and from which the subjects will be drawn.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include public disclosure to the communities in which the research will be conducted and from which the subjects will be drawn, prior to initiation of the research, of plans for the investigation and its risks and expected benefits.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include public disclosure of sufficient information following completion of the research to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Additional protections of the rights and welfare of the subjects will include establishment of an independent data monitoring committee to exercise oversight of the research.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If obtaining informed consent is not feasible and a LAR is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a LAR, and asking whether he or she objects to the subject's participation in the research. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ Procedures are in place to inform, at the earliest feasible opportunity, each subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the research, the details of the investigation and other information contained in the informed consent document.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ There is a procedure to inform the subject, or if the subject remains incapacitated, a LAR of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If a LAR or family member is told about the research and the subject's condition improves, the subject is also to be informed as soon as feasible.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If a subject is entered into research with waived consent and the subject dies before a LAR or family member can be contacted, information about the research is to be provided to the subject's LAR or family member, if feasible.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The investigator will interpret "family member" to mean any one of the following legally competent persons: spouses; parents; children (including adopted children); brothers, sisters, and spouses of brothers and sisters; and any individual related by blood or affinity whose close association with the subject is the equivalent of a family relationship.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the research consistent with this waiver.

Provide protocol specific findings justifying this determination: Click or tap here to enter text.

☐ If the research is FDA-regulated, the protocol is being performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies this protocol as including subjects who are unable to consent (even if an IND for the same drug product or an IDE for the same device already exists).

☐ **NA if not FDA-regulated.**

☐ If the research is FDA-regulated, a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the research has concurred with the above findings.

☐ **NA if not FDA-regulated.**

☐ If the research is NOT FDA-regulated, the research is also not subject to regulations codified by the FDA at title 21 CFR part 50.

☐ **NA if not FDA-regulated.**

If an IRB determines that it cannot approve a protocol because it does not meet the criteria in the exception or because of other relevant ethical concerns, the IRB must document its findings and provide these findings promptly (no longer than within 30 days) in writing to the investigator and the sponsor.

CHECKLIST: Investigator Quality Improvement Assessment

The purpose of this checklist is to allow investigators to conduct a quality improvement self-assessment and for IRB staff to conduct a quality improvement assessment of investigators. (LAR = "subject's Legally Authorized Representative)[1]

General Research (Not Clinical Trials)

Basic Information	Quality Improvement Details
Principal Investigator	Click or tap here to enter text.
Protocol Name	Click or tap here to enter text.
Name of Person Completing Checklist	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. Regulatory Documentation for Each Study

Response	Regulatory Document
☐ Yes ☐ No ☐ NA	Grant
☐ Yes ☐ No ☐ NA	Annual progress reports for grant
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved protocol
☐ Yes ☐ No ☐ NA	Previously IRB approved versions of the protocol
☐ Yes ☐ No ☐ NA	IRB approved amendments to the protocol
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Previous versions of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Most recent versions of the IRB approved information provided to subjects
☐ Yes ☐ No ☐ NA	Previous versions of IRB approved information provided to subjects
☐ Yes ☐ No ☐ NA	Currently approved recruitment materials

[1] This document satisfies AAHRPP elements I.5.A, I.5.B, I.5.D, I-9

☐ Yes ☐ No ☐ NA	Previous versions of approved recruitment materials
☐ Yes ☐ No ☐ NA	IRB roster associated with each approval letter
☐ Yes ☐ No ☐ NA	Correspondence with the IRB on file: (look for signature and date when needed for submission)
☐ Yes ☐ No ☐ NA	Initial IRB application
☐ Yes ☐ No ☐ NA	Continuing review applications. **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Modification applications: **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Initial IRB approval
☐ Yes ☐ No ☐ NA	Continuing review approvals
☐ Yes ☐ No ☐ NA	Modification approvals
☐ Yes ☐ No ☐ NA	Interim reports
☐ Yes ☐ No ☐ NA	Notifications of IRB disapproval, deferral, modifications required to secure approval
☐ Yes ☐ No ☐ NA	Responses to IRB actions
☐ Yes ☐ No ☐ NA	Suspension of IRB Approval or Termination of IRB Approval
☐ Yes ☐ No ☐ NA	Copies of email correspondence with the IRB
☐ Yes ☐ No ☐ NA	Other communications with the IRB
☐ Yes ☐ No ☐ NA	Records of investigator and staff training
☐ Yes ☐ No ☐ NA	Signed agreements/contracts between parties
☐ Yes ☐ No ☐ NA	Correspondences to and from the funding agency

2. Document Retention

Response	Retention Requirement

☐ Yes ☐ No ☐ NA	Consent documents are retained for 3 years after completion of the research.
☐ Yes ☐ No ☐ NA	Records for sponsors are retained until the sponsor authorizes destruction of the records.

3. Informed Consent

Response	Informed Consent Requirement
☐ Yes ☐ No ☐ NA	An investigator seeks consent only under circumstances that provide the prospective subjects or the LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
☐ Yes ☐ No ☐ NA	The information given to the subjects or the LAR is in language understandable to the subject or the LAR.
☐ Yes ☐ No ☐ NA	Investigators do not disclose any exculpatory language, through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.
☐ Yes ☐ No ☐ NA	Investigators disclose to the subject the information in the consent document.
☐ Yes ☐ No ☐ NA	Investigators give either the subject or LAR adequate opportunity to read the consent document before it is signed.
☐ Yes ☐ No ☐ NA	A copy of the signed and dated consent document is given to the person signing the document.
☐ Yes ☐ No ☐ NA	Investigators provide the prospective subject or the LAR 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. **(NA if research is subject to Pre-2018 Requirements) ☐ NA**
☐ Yes ☐ No ☐ NA	The Informed consent document begins with a concise and focused presentation of the key information that is most likely to assist a prospective subjects or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. **(NA if research is subject to Pre-2018 Requirements) ☐ NA**
☐ Yes ☐ No ☐ NA	Informed consent as a whole presents 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. **(NA if research is subject to Pre-2018 Requirements) ☐ NA**

4. Informed Consent Disclosures

Informed Consent Requirement	Response
Required (*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.* ☐ Any benefits to the subject or to others, which may reasonably be expected from the research.* ☐ 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. (**NA if research is subject to Pre-2018 Requirements) NA: ☐**
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.
Additional: (Include when appropriate.)	☐ 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. (**NA if research is subject to Pre-2018 Requirements)**

	□ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (**NA if research is subject to Pre-2018 Requirements)** □ 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). (**NA if research is subject to Pre-2018 Requirements)** □ 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.[2] □ When the study involves genetic testing, a statement that outlines the protections afforded to the subject under the Genetic Information Nondiscrimination Act (GINA).

[2] 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.

Clinical Trials

Basic Information	Quality Improvement Details
Principal Investigator	Click or tap here to enter text.
Protocol Name	Click or tap here to enter text.
Name of Person Completing Checklist	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

5. Regulatory Documentation for Each Study

Response	Regulatory Documentation Category
☐ Yes ☐ No ☐ NA	Grant
☐ Yes ☐ No ☐ NA	Annual progress reports for grant
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved protocol
☐ Yes ☐ No ☐ NA	Previously IRB approved versions of the protocol
☐ Yes ☐ No ☐ NA	IRB approved amendments to the protocol
☐ Yes ☐ No ☐ NA	Most recent version of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Previous versions of the IRB approved consent document
☐ Yes ☐ No ☐ NA	Most recent versions of the IRB approved information provided to subjects
☐ Yes ☐ No ☐ NA	Previous versions of IRB approved information provided to subjects
☐ Yes ☐ No ☐ NA	Currently approved recruitment materials
☐ Yes ☐ No ☐ NA	Previous versions of approved recruitment materials
☐ Yes ☐ No ☐ NA	IRB roster associated with each approval letter
☐ Yes ☐ No ☐ NA	Correspondence with the IRB on file: (look for signature and date when needed for submission)
☐ Yes ☐ No ☐ NA	Initial IRB application

☐ Yes ☐ No ☐ NA	Continuing review applications. **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Modification applications: **Number:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Initial IRB approval
☐ Yes ☐ No ☐ NA	Continuing review approvals
☐ Yes ☐ No ☐ NA	Modification approvals
☐ Yes ☐ No ☐ NA	Interim reports
☐ Yes ☐ No ☐ NA	Notifications of IRB disapproval, deferral, modifications required to secure approval
☐ Yes ☐ No ☐ NA	Responses to IRB actions
☐ Yes ☐ No ☐ NA	Suspension of IRB Approval or Termination of IRB Approval
☐ Yes ☐ No ☐ NA	Copies of email correspondence with the IRB
☐ Yes ☐ No ☐ NA	Other communications with the IRB
☐ Yes ☐ No ☐ NA	Records of investigator and staff training
☐ Yes ☐ No ☐ NA	Signed agreements/contracts between parties
☐ Yes ☐ No ☐ NA	Subject screening log **Number screened:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Subject identification code list
☐ Yes ☐ No ☐ NA	Subject enrollment log **Number enrolled:** Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Record of retained body fluids/tissue samples
☐ Yes ☐ No ☐ NA	Correspondences to and from the sponsor or CRO
☐ Yes ☐ No ☐ NA	Letters
☐ Yes ☐ No ☐ NA	Meeting notes
☐ Yes ☐ No ☐ NA	Notes of telephone calls
☐ Yes ☐ No ☐ NA	CVs or other relevant documents evidencing qualifications of PI, co-investigators, and all study personnel
☐ Yes ☐ No ☐ NA	CVs or other relevant information have been updated within the past two years

☐ Yes ☐ No ☐ NA	CVs or other relevant information are signed and dated
☐ Yes ☐ No ☐ NA	Instructions for handling of investigational product(s) and trial-related materials (if not in protocol or investigator's brochure)
☐ Yes ☐ No ☐ NA	Decoding procedures for blinded trials
☐ Yes ☐ No ☐ NA	Normal lab values
☐ Yes ☐ No ☐ NA	Updates to normal lab values
☐ Yes ☐ No ☐ NA	Lab certification (e.g., CLLIA)?
☐ Yes ☐ No ☐ NA	Updates to lab certification (e.g., CLIA)?
☐ Yes ☐ No ☐ NA	Lab director's CV
☐ Yes ☐ No ☐ NA	Updates to lab director's CV
☐ Yes ☐ No ☐ NA	Monitoring/auditing log. How often is monitoring taking place: Click or tap here to enter text.
☐ Yes ☐ No ☐ NA	Site Initiation report or visit documentation
☐ Yes ☐ No ☐ NA	Study close-out report or visit documentation
☐ Yes ☐ No ☐ NA	DSMB reports
☐ Yes ☐ No ☐ NA	Staff signature log
☐ Yes ☐ No ☐ NA	Signature log reflects current staff working on the study
☐ Yes ☐ No ☐ NA	Staff working on the study are IRB approved
☐ Yes ☐ No ☐ NA	Delegation of responsibility (The Investigator maintains a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.)
☐ Yes ☐ No ☐ NA	Most recently approved sample case report forms (CRF)
☐ Yes ☐ No ☐ NA	For marketed products, a package insert/product information

6. Study Records (IND studies)

Response	Study Record Category
☐ Yes ☐ No ☐ NA	A signed current FDA 1572

☐ Yes ☐ No ☐ NA	Previous signed versions of FDA 1572
☐ Yes ☐ No ☐ NA	A current signed financial disclosure form submitted to the sponsor
☐ Yes ☐ No ☐ NA	Previous versions of signed financial disclosure forms submitted to the sponsor
☐ Yes ☐ No ☐ NA	Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement
☐ Yes ☐ No ☐ NA	Current investigator brochure
☐ Yes ☐ No ☐ NA	Previous versions of or updates to the investigator brochure
☐ Yes ☐ No ☐ NA	There is shipping log for each drug. These include:
☐ Yes ☐ No ☐ NA	Date shipment received
☐ Yes ☐ No ☐ NA	Shipment number from packing slip study drug or device
☐ Yes ☐ No ☐ NA	Batch number, lot number, code mark
☐ Yes ☐ No ☐ NA	Expiration date
☐ Yes ☐ No ☐ NA	Number of boxes, kits, or devices per lot number
☐ Yes ☐ No ☐ NA	Number of bottles, vials, inhalers, or devices per box or kit
☐ Yes ☐ No ☐ NA	Condition of study drug or device shipment (Intact, damaged)
☐ Yes ☐ No ☐ NA	Receiver's name
☐ Yes ☐ No ☐ NA	There is an accountability log for each drug under investigation. These include:
☐ Yes ☐ No ☐ NA	Subject ID number, initials, or name
☐ Yes ☐ No ☐ NA	Lot or kit number
☐ Yes ☐ No ☐ NA	Number of bottles, vials, etc.
☐ Yes ☐ No ☐ NA	Amount of study drug per bottle, vial, etc..
☐ Yes ☐ No ☐ NA	Total amount dispensed
☐ Yes ☐ No ☐ NA	Initials
☐ Yes ☐ No ☐ NA	Date dispensed

☐ Yes ☐ No ☐ NA	Number of bottles, vials, etc. returned
☐ Yes ☐ No ☐ NA	Total amount returned
☐ Yes ☐ No ☐ NA	Balance: number dispensed less number returned
☐ Yes ☐ No ☐ NA	Comments: subject lost, discarded, etc.
☐ Yes ☐ No ☐ NA	Person who dispensed the drug
☐ Yes ☐ No ☐ NA	The investigator furnishes all reports to the sponsor of the drug
☐ Yes ☐ No ☐ NA	An investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse effect immediately.
☐ Yes ☐ No ☐ NA	An investigator shall provide the sponsor with an adequate report shortly after completion of the investigator's participation in the investigation.

7. Study Records (IDE studies)

Response	Study Record Category
☐ Yes ☐ No ☐ NA	A signed Investigator Statement
☐ Yes ☐ No ☐ NA	Previous versions of signed Investigator Statements
☐ Yes ☐ No ☐ NA	A current signed financial disclosure form submitted to the sponsor
☐ Yes ☐ No ☐ NA	Previous versions of signed financial disclosure forms submitted to the sponsor
☐ Yes ☐ No ☐ NA	Valid licensure for each investigator/staff member listed on the 1572 or in the Investigator Statement
☐ Yes ☐ No ☐ NA	There is shipping log for each device. These include:
☐ Yes ☐ No ☐ NA	Date shipment received
☐ Yes ☐ No ☐ NA	Shipment number from packing slip study device
☐ Yes ☐ No ☐ NA	Batch number, lot number, code mark
☐ Yes ☐ No ☐ NA	Expiration date
☐ Yes ☐ No ☐ NA	Number of boxes, kits, or devices per lot number
☐ Yes ☐ No ☐ NA	Number of bottles, vials, inhalers, or devices per box or kit

☐ Yes ☐ No ☐ NA	Condition of study drug or device shipment (Intact, damaged)
☐ Yes ☐ No ☐ NA	Receiver's name
☐ Yes ☐ No ☐ NA	There is an accountability log for each device under investigation. These include:
☐ Yes ☐ No ☐ NA	Subject ID number, initials, or name
☐ Yes ☐ No ☐ NA	Study device lot, batch number, or code mark
☐ Yes ☐ No ☐ NA	Date dispensed
☐ Yes ☐ No ☐ NA	Device disposition
☐ Yes ☐ No ☐ NA	Comments, such as malfunctions, device failure, disposition of unused devices (returned to sponsor or destroyed) or any other pertinent information concerning the device.
☐ Yes ☐ No ☐ NA	Person who dispensed the device
☐ Yes ☐ No ☐ NA	Correspondence with another investigator, an IRB, the sponsor, a monitor, or FDA, including required report
☐ Yes ☐ No ☐ NA	Reports of unanticipated adverse device effects. The investigator submits to the sponsor and to the reviewing IRB a report of any unanticipated adverse device effect occurring during an investigation as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
☐ Yes ☐ No ☐ NA	Reports of withdrawal of IRB approval. The investigator reports to the sponsor, within 5 working days, a withdrawal of approval by the reviewing IRB of the investigator's part of an investigation.
☐ Yes ☐ No ☐ NA	Progress reports. The investigator submits progress reports on the investigation to the sponsor, the monitor, and the reviewing IRB at regular intervals, but in no event less often than yearly.
☐ Yes ☐ No ☐ NA	Reports of deviations from the investigational plan. The investigator notifies the sponsor and the reviewing IRB of any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. Such notice is given as soon as possible, but in no event later than 5 working days after the emergency occurred. Except in such an emergency, prior approval by the sponsor is required for changes in or deviations from a plan, and if these changes or deviations may affect the scientific soundness of the plan or the rights, safety, or welfare of human subjects, FDA and IRB is required.
☐ Yes ☐ No ☐ NA	Reports of use of the device without informed consent. If the investigator uses a device without obtaining informed consent, the investigator reports such use to the sponsor and the reviewing IRB within 5 working days after the use occurs.

☐ Yes ☐ No ☐ NA	Final report. The investigator, within 3 months after termination or completion of the investigation or the investigator's part of the investigation, submits a final report to the sponsor and the reviewing IRB.

8. Document Retention

Response	Requirement
☐ Yes ☐ No ☐ NA	An investigator retains records required to be maintained under this part for a period no less than 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. All data retention and disposal complies with institutional policy issued by VCU Technology Services.

9. Document Retention (IND studies)

Response	Requirement
☐ Yes ☐ No ☐ NA	An investigator retains records required to be maintained under this part for a period no less than 2 years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. All data retention and disposal complies with institutional policy issued by VCU Technology Services.

10. Document Retention (IDE studies)

Response	Requirement
☐ Yes ☐ No ☐ NA	An investigator or sponsor shall maintain the records required by this subpart during the investigation and for a period no less than 2 years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol. All data retention and disposal complies with institutional policy issued by VCU Technology Services.

11. Informed Consent Disclosures

Both the informed consent discussion and the written informed consent form and any other written information to be provided to subjects includes explanations of the following:

Informed Consent Requirement	Response
Required (*Can be omitted if there are none.)	☐ The form begins with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. (**NA if research is subject to Pre-2018 Requirements) NA:** ☐ ☐ 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.* ☐ Any benefits to the subject or to others, which may reasonably be expected from the research.* ☐ 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. (**NA if research is subject to Pre-2018 Requirements) NA: ☐**
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.
Required for Clinical Trials that Follow ICH-GCP	☐ 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	☐ The possibility that the Food and Drug Administration may inspect the records. ☐ 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. ☐ For controlled drug or 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: (Include when appropriate.)	☐ 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. (**NA if research is subject to Pre-2018 Requirements)** ☐ A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (**NA if research is subject to Pre-2018 Requirements)** ☐ 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). (NA if research is subject to Pre-2018 Requirements)

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

12. Study Conduct (IND studies)

Response	Study Conduct Category
☐ Yes ☐ No ☐ NA	Investigators are responsible for the control of drugs under investigation.
☐ Yes ☐ No ☐ NA	Investigators administer the drug only to subjects under their personal supervision or under the supervision of a sub-investigator responsible to the investigator.
☐ Yes ☐ No ☐ NA	Investigators do not supply the investigational drug to any person not authorized to receive it.

13. Study Conduct (IDE studies)

Response	Study Conduct Category
☐ Yes ☐ No ☐ NA	Investigators permit an investigational device to be used only with subjects under the investigator's supervision.
☐ Yes ☐ No ☐ NA	Investigators do not supply an investigational device to any person not authorized to receive it.
☐ Yes ☐ No ☐ NA	Upon completion or termination of a clinical investigation or the investigator's part of an, or at the sponsor's investigation request, investigators return to the sponsor any remaining supply of the device or otherwise dispose of the device as the sponsor directs.
☐ Yes ☐ No ☐ NA	If the investigation is terminated, suspended, discontinued, or completed, investigators return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug as authorized by the sponsor.
☐ Yes ☐ No ☐ NA	If an investigational drug is subject to the Controlled Substances Act, investigators take adequate precautions, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.

[3] 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.

	Investigators prepare and submit the following reports to the sponsor:
☐ Yes ☐ No ☐ NA	Any unanticipated adverse device effect occurring during an investigation. (Within 5 working days.)
☐ Yes ☐ No ☐ NA	Withdrawal of approval by the reviewing IRB of the investigator's part of an investigation. (Within 5 working days.)
☐ Yes ☐ No ☐ NA	Progress reports on the investigation. (At least yearly.)
☐ Yes ☐ No ☐ NA	Any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.)
☐ Yes ☐ No ☐ NA	Use of a device without obtaining informed consent (within 5 working days after the use occurs).
☐ Yes ☐ No ☐ NA	A final report. (Within 3 months after termination or completion of the investigation or the investigator's part of the investigation.)
	Investigators prepare and submit the following reports to the IRB:
☐ Yes ☐ No ☐ NA	Any unanticipated adverse device effect occurring during an investigation. (As soon as possible, but in no event later than 10 working days after first learning of the effect.)
☐ Yes ☐ No ☐ NA	Progress reports on the investigation. (At least yearly.)
☐ Yes ☐ No ☐ NA	Any deviation from the investigational plan to protect the life or physical well-being of a subject in an emergency. (As soon as possible, but in no event later than 5 working days after the emergency occurred.)
☐ Yes ☐ No ☐ NA	Use of a device without obtaining informed consent (within 5 working days after the use occurs).
☐ Yes ☐ No ☐ NA	A final report (within 3 months after termination or completion of the investigation or the investigator's part of the investigation).
	Investigators prepare and submit the following reports to the study monitor:
☐ Yes ☐ No ☐ NA	Progress reports on the investigation. (At least yearly.)

14. IND Sponsor-Investigator Requirements

Response	Requirement
☐ Yes ☐ No ☐ NA	The investigator submits a completed Form FDA 3454 attesting to the absence of financial interests and arrangements for all participating clinical investigators.

☐ Yes ☐ No ☐ NA	For any participating clinical investigator for whom the investigator does not submit a completed Form FDA 3454, the investigator submits a completed Form FDA 3455 (Disclosure Statement).
☐ Yes ☐ No ☐ NA	The investigator maintains on file information pertaining to the financial interests of clinical investigators for 2 years after the date of approval of the application.
☐ Yes ☐ No ☐ NA	The investigator selects qualified investigators.
☐ Yes ☐ No ☐ NA	The investigator provides participating investigators with the information they need to conduct an investigation properly.
☐ Yes ☐ No ☐ NA	The investigator ensures that the investigation(s) is conducted in accordance with the general investigational plan and protocols contained in the IND.
☐ Yes ☐ No ☐ NA	The investigator maintains an effective IND with respect to the investigations.
☐ Yes ☐ No ☐ NA	The investigator ensures that FDA is promptly informed of significant new adverse effects or risks with respect to the drug.
☐ Yes ☐ No ☐ NA	The investigator ensures that all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug.
☐ Yes ☐ No ☐ NA	The investigator selects only investigators qualified by training and experience as appropriate experts to investigate the drug.
☐ Yes ☐ No ☐ NA	The investigator ships investigational new drugs only to investigators participating in the investigation.
☐ Yes ☐ No ☐ NA	Before permitting an investigator to begin participation in an investigation, the investigator obtains the following:
☐ Yes ☐ No ☐ NA	A signed investigator statement (Form FDA-1572).
☐ Yes ☐ No ☐ NA	A curriculum vitae or other statement of qualifications of the investigator showing the education, training, and experience that qualifies the investigator as an expert in the clinical investigation of the drug for the use under investigation.
☐ Yes ☐ No ☐ NA	Sufficient accurate financial information to allow the investigator to submit complete and accurate certification or disclosure statements.
☐ Yes ☐ No ☐ NA	The investigator selects a monitor qualified by training and experience to monitor the progress of the investigation.
☐ Yes ☐ No ☐ NA	The investigator provides each participating clinical investigator an investigator brochure.
☐ Yes ☐ No ☐ NA	The investigator ensures, as the overall investigation proceeds, that each participating investigator is informed of new observations discovered by or reported to the investigator on the drug, particularly with respect to adverse effects and safe use.

☐ Yes ☐ No ☐ NA	The investigator monitors the progress of all clinical investigations being conducted under the IND.
☐ Yes ☐ No ☐ NA	If the investigator discovers that an investigator is not complying with the signed agreement (Form FDA-1572), the general investigational plan, or other applicable requirements; the investigator promptly either secures compliance or discontinues shipment of the investigational new drug to the investigator and ends the investigator's participation in the investigation.
☐ Yes ☐ No ☐ NA	If the investigator's participation in the investigation is ended, the investigator ensures that the investigator dispose of or returns the investigational drug and notifies the FDA.
☐ Yes ☐ No ☐ NA	The investigator reviews and evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigator(s).
☐ Yes ☐ No ☐ NA	If the investigator determines that the investigational drug presents an unreasonable and significant risk to subjects, the investigator:
☐ Yes ☐ No ☐ NA	Ensures discontinuation of those investigations that present the risk.
☐ Yes ☐ No ☐ NA	Notifies the FDA, all institutional review boards, and all investigators who have at any time participated in the investigation of the discontinuance.
☐ Yes ☐ No ☐ NA	Ensures the disposition of all stocks of the drug outstanding.
☐ Yes ☐ No ☐ NA	Furnishes the FDA with a full report of the investigator's actions.
☐ Yes ☐ No ☐ NA	The investigator maintains adequate records showing the receipt, shipment, or other disposition of the investigational drug, including, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment.
☐ Yes ☐ No ☐ NA	The investigator retains these records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified.
☐ Yes ☐ No ☐ NA	The investigator retains reserve samples of any test article and reference standard identified in and used in any bioequivalence or bioavailability studies and release the reserve samples to the FDA upon request.
☐ Yes ☐ No ☐ NA	The investigator retains each reserve sample for a period of at least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at least 5 years following the date of completion of the bioavailability study.
☐ Yes ☐ No ☐ NA	The investigator permits, upon request from any properly authorized officer or employee of the Food and Drug Administration, at reasonable times, such officer or

	employee to have access to and copy and verify any records and reports relating to a clinical investigation being conducted under the IND.
☐ Yes ☐ No ☐ NA	The investigator submits, upon written request by the FDA, the records or reports (or copies of them) to the FDA.
☐ Yes ☐ No ☐ NA	The investigator discontinues shipments of the drug to any investigator who has failed to maintain or make available records or reports of the investigation as required.
	If an investigational new drug is a substance listed in any schedule of the Controlled Substances Act (21 U.S.C. 801; 21 CFR part 1308), the investigator ensures:
☐ Yes ☐ No ☐ NA	Upon the request of a properly authorized employee of the Drug Enforcement Administration of the Department of Justice, all records concerning shipment, delivery, receipt, and disposition of the drug, which are required to be kept be made available by the investigator to whom the request is made, for inspection and copying.
☐ Yes ☐ No ☐ NA	That adequate precautions are taken, including storage of the investigational drug in a securely locked, substantially constructed cabinet, or other securely locked, substantially constructed enclosure, access to which is limited, to prevent theft or diversion of the substance into illegal channels of distribution.
☐ Yes ☐ No ☐ NA	The investigator ensures the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated.

15. Significant Risk IDE Sponsor-Investigator Requirements

Response	Requirement
☐ Yes ☐ No ☐ NA	The investigator ensures that no part of the investigation begins until the IRB and FDA have both approved the application or supplemental application.
☐ Yes ☐ No ☐ NA	The investigator selects other investigators qualified by training and experience to investigate the device.
☐ Yes ☐ No ☐ NA	The investigator selects monitors qualified by training and experience to monitor the investigational study in accordance with the IDE and other applicable FDA regulations.
☐ Yes ☐ No ☐ NA	The investigator ships investigational devices only to qualified investigators participating in the investigation.
☐ Yes ☐ No ☐ NA	The investigator obtains a signed agreement from each participating investigator that includes:
☐ Yes ☐ No ☐ NA	The participating investigator's curriculum vitae,

☐ Yes ☐ No ☐ NA	A statement of the participating investigator's relevant experience, including the dates, location, extent, and type of experience, where applicable,
☐ Yes ☐ No ☐ NA	An explanation of the circumstances that led to termination of a study if the participating investigator was involved in an investigation or other research that was terminated,
☐ Yes ☐ No ☐ NA	A statement of the participating investigator's commitment to: ● Conduct the investigation in accordance with the agreement, the investigational plan, the IDE and other applicable FDA regulations, and conditions of approval imposed by the reviewing IRB or FDA, ● Supervise all testing of the device involving human subjects, and ● Ensure that the requirements for obtaining informed consent are met.
☐ Yes ☐ No ☐ NA	The investigator maintains sufficient accurate financial disclosure information to submit a complete and accurate certification or disclosure statement as required under 21 CFR 54, Financial Disclosure by Clinical Investigators.
☐ Yes ☐ No ☐ NA	The investigator obtains a commitment from clinical investigators to promptly update this information if any relevant changes occur during the course of the investigation and for one year following completion of the study. (The financial certification or disclosure is submitted in the PMA or Premarket Notification 510(k) application. It should not be submitted in the IDE application.)
☐ Yes ☐ No ☐ NA	The investigator supplies all participating investigators with copies of the investigational plan and a report of prior investigations of the device.
☐ Yes ☐ No ☐ NA	Securing Compliance: If the investigator discovers that a participating investigator is not complying with the signed agreement, the investigational plan, the IDE requirements, any other applicable FDA regulations, or any conditions of approval imposed by the reviewing IRB or FDA, the investigator promptly either secures compliance, or discontinues shipments of the device to the investigator and terminates the investigator's participation in the investigation. A sponsor must also require that the investigator dispose of or return the device, unless this action would jeopardize the rights, safety, or welfare of a subject.
☐ Yes ☐ No ☐ NA	Unanticipated Adverse Device Effects: The investigator immediately conducts an evaluation of any unanticipated adverse device effect. An investigator who determines that an unanticipated adverse device effect presents an unreasonable risk to subjects terminates all investigations or parts of the investigations presenting that risk as soon as possible. Termination must occur no later than 5 working days after the sponsor makes this determination and no later than 15 working days after the sponsor first received notice of the effect.
☐ Yes ☐ No ☐ NA	Resumption of Terminated Studies: For significant risk device investigations, an investigator may not resume a terminated investigation without IRB and FDA approval.

	The investigator must maintain accurate and complete records relating to the investigation. These records include:
☐ Yes ☐ No ☐ NA	All correspondence including required reports,
☐ Yes ☐ No ☐ NA	Records of receipt, use or disposition of a device that relate to: ● The type and quantity of the device, the dates of its receipt, and the batch number or code mark. ● The names of all persons who received, used, or disposed of each device. ● Why and how many units of the device have been returned to the sponsor, repaired, or otherwise disposed of.
☐ Yes ☐ No ☐ NA	Signed investigator agreements including financial disclosure information,
☐ Yes ☐ No ☐ NA	Records concerning complaints and adverse device effects whether anticipated or not,
☐ Yes ☐ No ☐ NA	Any other records that FDA requires to be maintained by regulation or by specific requirement for a category of investigation or a particular investigation.
	The investigator provides the following reports in a timely manner to FDA, the IRBs, and/or the investigators.
☐ Yes ☐ No ☐ NA	Unanticipated Adverse Device Effects
☐ Yes ☐ No ☐ NA	Withdrawal of IRB Approval
☐ Yes ☐ No ☐ NA	Withdrawal of FDA Approval
☐ Yes ☐ No ☐ NA	Current list of Investigators
☐ Yes ☐ No ☐ NA	Progress Reports
☐ Yes ☐ No ☐ NA	Recalls and Device Disposition
☐ Yes ☐ No ☐ NA	Final Report
☐ Yes ☐ No ☐ NA	Informed consent
☐ Yes ☐ No ☐ NA	Significant Risk Device Determination
☐ Yes ☐ No ☐ NA	Other Reports
☐ Yes ☐ No ☐ NA	The investigational device or its immediate package bears a label with the following information:

	● The name and place of business of the manufacturer, packer, or distributor; ● The quantity of contents, if appropriate; and ● The statement, "CAUTION -- Investigational device. Limited by Federal (or United States) law to investigational use."
☐ Yes ☐ No ☐ NA	The label describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions.
☐ Yes ☐ No ☐ NA	The labeling of an investigational device does not contain any false or misleading statements nor imply that the device is safe or effective for the purposes being investigated.
☐ Yes ☐ No ☐ NA	The investigator provides detailed information on device labeling in the investigational protocol. This information may vary depending on the device and the nature of the study. Product labeling should be sufficient to ensure stability of the test article for the duration of the study (storage requirements, calibration procedures), bear sufficient directions for proper administration, and detail procedures to follow in the event of patient injury.
☐ Yes ☐ No ☐ NA	The investigator, or any person acting for or on behalf of the investigator does not: ● Promote or test market an investigational device, until after FDA has approved the device for commercial distribution. ● Commercialize an investigational device by charging the subjects or investigators a higher price than that necessary to recover costs of manufacture, research, development, and handling. ● Unduly prolong an investigation. If data developed by the investigation indicate that premarket approval (PMA) cannot be justified, the sponsor must promptly terminate the investigation. ● Represent that an investigational device is safe or effective.
☐ Yes ☐ No ☐ NA	Advertisements have been reviewed and approved by the IRB to assure that they are not unduly coercive and do not promise a certainty of cure beyond what is outlined in the consent and the protocol. No claims are made, either explicitly or implicitly, that the device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other device.

16. **Abbreviated IDE Sponsor-Investigator Requirements**

Response	**Requirement**
☐ Yes ☐ No ☐ NA	The device is labeled with the name and place of business of the manufacturer. *21 CFR §812.2(b)(1)(i)*
☐ Yes ☐ No ☐ NA	The device is labeled with the following statement: “CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.” *21 CFR §812.2(b)(1)(i)*

☐ Yes ☐ No ☐ NA	The labeling describes all relevant contraindications, hazards, adverse effects, interfering substances or devices, warnings, and precautions. *21 CFR §812.2(b)(1)(i)*
☐ Yes ☐ No ☐ NA	The investigator has obtained IRB review and approval of the research. *21 CFR §812.2(b)(1)(ii)*
☐ Yes ☐ No ☐ NA	The protocol includes a brief explanation of why the device is not a significant risk device. *21 CFR §812.2(b)(1)(ii)*
☐ Yes ☐ No ☐ NA	The IRB has determined that the device is not a significant risk device. *21 CFR §812.2(b)(1)(ii)*
☐ Yes ☐ No ☐ NA	The IRB has documented that determination in the minutes along with the IRB's rationale for making that determination. *FDA Information Sheets for IRBs*
☐ Yes ☐ No ☐ NA	The investigator has obtained informed consent of each subject in accordance with 21 CFR §50. *21 CFR §812.2(b)(1)(iii).*
☐ Yes ☐ No ☐ NA	Unless waived by the IRB, the investigator has documented informed consent of each subject in accordance with 21 CFR §50. *21 CFR §812.2(b)(1)(iii).*
☐ Yes ☐ No ☐ NA	The investigator monitors the investigation for compliance. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	The investigator immediately conducted an evaluation of any unanticipated adverse device effect. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	If the investigator terminated all investigations or parts of investigations presenting that risk as soon as possible, not later than 5 working days after making this determination. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	If the investigator determined whether each unanticipated adverse device effect presented an unreasonable risk to subjects, the investigator has to terminate all investigations or parts of investigations presenting that risk as soon as possible, not later than 5 working days after the investigator makes this determination. *21 CFR §812.2(b)(1)(iv)*
☐ Yes ☐ No ☐ NA	**The investigator maintains the following records consolidated in one location and available for FDA inspection and copying: *21 CFR §812.2(b)(1)(v)-(vi)***
☐ Yes ☐ No	A statement of the extent to which the good manufacturing practice regulation in part 820 will be followed in manufacturing the device. *21 CFR §812.140(b)(4)(v)*
☐ Yes ☐ No	The name and intended use of the device and the objectives of the investigation. *21 CFR §812.140(b)(4)(i)*
☐ Yes ☐ No	A brief explanation of why the device is not a significant risk device. *21 CFR §812.140(b)(4)(ii)*

☐ Yes ☐ No	The name and address of each investigator. *21 CFR §812.140(b)(4)(iii)*
☐ Yes ☐ No	The name and address of each IRB that has reviewed the investigation. *21 CFR §812.140(b)(4)(iv)*
☐ Yes ☐ No	Records concerning adverse device effects (whether anticipated or unanticipated) and complaints. *21 CFR §812.140(b)(5)*
☐ Yes ☐ No	Records of each subject's case history and exposure to the device. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Case report forms and supporting data. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Signed and dated consent forms. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Documents evidencing informed consent. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No ☐ NA	For any use of a device by the investigator without informed consent, any written concurrence of a licensed physician and a brief description of the circumstances justifying the failure to obtain informed consent. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	Documentation that informed consent was obtained prior to participation in the study. 21 CFR §812.140(a)(3)(i)
☐ Yes ☐ No	**The investigator makes the following reports to FDA: *21 CFR §812.2(b)(1)(v)***
☐ Yes ☐ No ☐ NA	Unanticipated adverse device effects. An evaluation of an unanticipated adverse device effect under §812.46(b) was reported to FDA and the IRB within 10 working days after the sponsor first receives notice of the effect. Thereafter the investigator submitted additional reports concerning the effect as FDA requested. *21 CFR §812.140(a)(1); 21 CFR §812.150(b)(1)*
☐ Yes ☐ No ☐ NA	Withdrawal of IRB approval. The investigator notified FDA of any withdrawal of approval of an investigation or a part of an investigation by the IRB within 5 working days after receipt of the withdrawal of approval. *21 CFR §812.140(a)(2); 21 CFR §812.150(b)(2)*
☐ Yes ☐ No ☐ NA	Withdrawal of FDA approval. The investigator notified the IRB and participating investigators of any withdrawal of FDA approval of the investigation, and did so

	within 5 working days after receipt of notice of the withdrawal of approval. *21 CFR §812.150(b)(3)*
☐ Yes ☐ No ☐ NA	Progress reports. At regular intervals, and at least yearly, the investigator submitted progress reports to the monitor and the IRB. *21 CFR §812.140(a)(3); 21 CFR §812.150(b)(5)*
☐ Yes ☐ No ☐ NA	Recall and device disposition. The investigator notified FDA and the IRB of any return, repair, or disposal of any units of a device. Such notice occurred within 30 working days after the request was made and stated why the request was made. *21 CFR §812.150(b)(6)*
☐ Yes ☐ No ☐ NA	The investigator submitted a final report to the IRB within 6 months after termination or completion. *21 CFR §812.150(b)(7)*
☐ Yes ☐ No ☐ NA	Informed consent. The investigator submitted to FDA and the IRB a copy of any use of a device without obtaining informed consent, within 5 working days of receipt of notice of such use. *21 CFR §812.140(a)(5); 21 CFR §812.150(b)(8)*
☐ Yes ☐ No ☐ NA	Significant risk device determinations. If the IRB determined that a device was a significant risk device, the investigator submitted to FDA a report of the IRB's determination within 5 working days after first learning of the IRB's determination. *21 CFR §812.150(b)(9)*
☐ Yes ☐ No ☐ NA	Other. The investigator, upon request by the IRB or FDA, provided accurate, complete, and current information about any aspect of the investigation. *21 CFR §812.150(b)(10)*
☐ Yes ☐ No	**The investigator does not:**
☐ Yes ☐ No	Promote or test market the device. *21 CFR §812.7(a)*
☐ Yes ☐ No	Commercialize the device by charging the subjects a price larger than that necessary to recover costs of manufacture, research, development, and handling. *21 CFR §812.7(b)*
☐ Yes ☐ No	Unduly prolong an investigation. *21 CFR §812.7(c)*
☐ Yes ☐ No	Represent that an investigational device is safe or effective. *21 CFR §812.7(d)*

Clinical Trials Case History

Basic Information	Study and Subject Details
Principal Investigator	Click or tap here to enter text.
Protocol Name	Click or tap here to enter text.
Subject Code	Click or tap here to enter text.
Name of Person Completing Checklist	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. Subject selection

Response	Requirement
☐ Yes ☐ No ☐ NA	There is a completed eligibility checklist.
☐ Yes ☐ No ☐ NA	The eligibility criteria checklist includes dated signature/initials of the person obtaining the information.

2. Consent

Response	Requirement
☐ Yes ☐ No ☐ NA	For subjects who did not meet eligibility (e.g. screen-failures), identifiable information was destroyed or authorization obtained to keep subject information.
☐ Yes ☐ No ☐ NA	Original copies of all consent forms signed by subjects are on file.
☐ Yes ☐ No ☐ NA	There is a current consent form on file.
☐ Yes ☐ No ☐ NA	All previous consent forms are on file.
☐ Yes ☐ No ☐ NA	Valid IRB-approved consent forms were used.
☐ Yes ☐ No ☐ NA	The consent forms on file are the *original* signed and dated version (not a photocopy).
☐ Yes ☐ No ☐ NA	All pages of the consent forms are on file for each subject.
☐ Yes ☐ No ☐ NA	All yes/no or similar options on the consent forms are completed/initiated.
☐ Yes ☐ No ☐ NA	Consent forms are free of any handwritten changes/corrections.

☐ Yes ☐ No ☐ NA	The subject signed his/her own consent forms. (Exceptions: IRB-approved surrogate or parental consent)
☐ Yes ☐ No ☐ NA	The subject received a copy of the signed and dated consent form.
☐ Yes ☐ No ☐ NA	The subject's receipt of a copy of the signed and dated consent form is documented.

3. Prompt Reporting Requirements

Response	Requirement
☐ Yes ☐ No ☐ NA	All prompt reporting requirements have been fulfilled.

4. Data Collection Source Documents

☐ Yes ☐ No ☐ NA	Data collection complete/accurate for each subject. (e.g. no blank fields/missing data)
☐ Yes ☐ No ☐ NA	Source documentation is available to support data entry.
☐ Yes ☐ No ☐ NA	The source documentation/CRF for each subject includes dated signature/initials of the person obtaining the information for each subject.
☐ Yes ☐ No ☐ NA	Changes/cross-outs, additional comments (if any) in subject files routinely initialed and dated.
☐ Yes ☐ No ☐ NA	For any changes/cross-outs being made, the original entry is still legible. (e.g. use of white-out or pencil erased entries is not acceptable)

VCU Research and Innovation

HRP-431 | 02/01/2024

CHECKLIST: Minutes Quality Improvement Assessment

The purpose of this checklist is to allow individuals to conduct a quality improvement self-assessment of IRB minutes.

Minutes Information

Minutes Information	Response
IRB Number	Click or tap here to enter text.
Meeting Date	Click or tap here to enter text.
Name of Person Completing Checklist	Click or tap here to enter text.
Date Completed	Click or tap here to enter text.

1. General Minutes Requirements

Response	Requirement
☐ Yes ☐ No	Does the "Attendance Table" record each voting member (regular members and alternates) present at the meeting at any time?
☐ Yes ☐ No	Does the "Attendance Table" record any member in attendance who did not vote at any time?
☐ Yes ☐ No	Does the "Attendance Table" record each member's name?
☐ Yes ☐ No	Does the "Attendance Table" record which members were chairs or vice chairs?
☐ Yes ☐ No	Does the "Attendance Table" record each member's status as an unaffiliated member or affiliated member?[i]
☐ Yes ☐ No	Does the "Attendance Table" record each member's status as a scientific member or non-scientific member?
☐ Yes ☐ No	When a member is a representative of a vulnerable population, does the "Attendance Table" record that member's representative capacity? (Prisoners, children, cognitively impaired adults)
☐ Yes ☐ No	Does the "Attendance Table" record for each alternate member the name of IRB member for whom alternate is substituting.
☐ Yes ☐ No	Does the "Attendance Table" record whether any members were present by teleconference and if so indicate them by name?
☐ Yes ☐ No	Do the minutes record the total number of members present on the current IRB roster excluding alternate IRB members?
☐ Yes ☐ No	Do the minutes correctly record the number of members required for a quorum? (Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the roster, then 10/2 = 5 and the next

	whole number is 6. If there 11 IRB members on the roster, then 11/2=5.5 and the next whole number is 6.)
☐ Yes ☐ No ☐ NA	Do the minutes indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions? (NA if no members were present by teleconference)
☐ Yes ☐ No	Do the minutes record the meeting start time?
☐ Yes ☐ No	Do the minutes record the meeting end time?
☐ Yes ☐ No	Do the minutes record a summary of each business item that was discussed?

2. Requirements for Each Protocol Reviewed

Response	Requirement
☐ Yes ☐ No	Do the minutes record a protocol ID?
☐ Yes ☐ No	Do the minutes record a protocol title?
☐ Yes ☐ No	Do the minutes record an investigator name?
☐ Yes ☐ No	Do the minutes record a type of review as either initial review, continuing review, or review of modifications to previously approved research?
☐ Yes ☐ No ☐ NA	If the minutes record a consultant report, does it summarize the key information provided the consultant. (NA if there were no consultant reports)
☐ Yes ☐ No	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) or indicate “None”?
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues, does what is recorded qualify as a “Controverted Issue” and “Resolution”? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues does the controverted issue include a resolution or a statement that there was no resolution? (NA if there were no controverted issues)
☐ Yes ☐ No	Do the minutes record a motion as one of the following: Approved, Modifications Required to Secure Approval, Deferred, Disapproved?
☐ Yes ☐ No ☐ NA	For initial or continuing review do the minutes record the period of approval for the motion?
☐ Yes ☐ No ☐ NA	Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused?
☐ Yes ☐ No ☐ NA	Do the minutes list the names of IRB members who were absent or recused?
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)

☐ Yes ☐ No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table?
☐ Yes ☐ No	Do minutes document the level of risk determined by the convened IRB as either Minimal Risk or more than Minimal Risk?
☐ Yes ☐ No ☐ NA	If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, prisoners, or cognitively impaired adults do the minutes either say “See IRB Records” or include one of more of the “Determination/Protocol Specific Findings” tables in HRP-501 - TEMPLATE - MINUTES? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	If the minutes say “See IRB records for this protocol” is the corresponding completed checklist(s) in the IRB records? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	If the minutes include one of more of the “Determination/Protocol Specific Findings” tables, is the table completed? (NA if no research requiring documented findings was reviewed)
☐ Yes ☐ No ☐ NA	Do minutes justify any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document? (NA if a DHHS-approved sample consent form was not reviewed)
☐ Yes ☐ No ☐ NA	Do minutes document the rationale for a significant/non-significant device determination? (NA if abbreviated IDE devices were not reviewed.)
☐ Yes ☐ No ☐ NA	Do minutes document modifications required to secure approval? (NA if there were no modifications required to secure approval) Otherwise, include the “Modifications Required to Secure Approval Table” in HRP-501 - TEMPLATE - MINUTES.
☐ Yes ☐ No ☐ NA	When minutes document modifications required to secure approval is the “Modifications Required to Secure Approval Table” included? (NA if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ NA	When minutes document modifications required to secure approval does the “Modifications Required to Secure Approval Table” include a reason (basis) for each modification? (NA if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ NA	When minutes document modifications required to secure approval does the “Modifications Required to Secure Approval Table” describe the required modifications in such a way that an IRB staff member can determine whether an investigator has made the required changes without judging whether a change meets the regulatory criteria for approval? (NA if there were no modifications required to secure approval)
☐ Yes ☐ No ☐ NA	If a protocol was tabled, do the minutes indicate this and provide the reason for tabling? (NA if there were no tabled protocols)
☐ Yes ☐ No ☐ NA	If a protocol was deferred or disapproved do the minute document the reasons? (NA if there were no deferred or disapproved protocols)
☐ Yes ☐ No ☐ NA	If a protocol was deferred do the minute document recommended changes? (NA if there were no deferred or disapproved protocols)

3. Requirements for Each Problem Reviewed (☐ NA if no problems were reviewed)

Response	Requirement
☐ Yes ☐ No	Do the minutes describe the problem?
☐ Yes ☐ No	Do the minutes describe whether the problem was serious or continuing non-compliance, an Unanticipated Problem Involving Risks to Subjects or Others, or a Suspension of IRB Approval or Termination of IRB Approval?
☐ Yes ☐ No ☐ NA	Do the minutes record a protocol ID? (NA if there was no specific protocol involved)
☐ Yes ☐ No ☐ NA	Do the minutes record a protocol title? (NA if there was no specific protocol involved)
☐ Yes ☐ No ☐ NA	Do the minutes record an investigator name? (NA if there was no specific investigator involved)
☐ Yes ☐ No	Do the minutes record controverted issues (when the IRB members express a difference of opinion among themselves) and their resolution or indicate "None"?
☐ Yes ☐ No	If the minutes record controverted issues, does what is recorded qualify as a "Controverted Issue" and "Resolution"? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues does the information sufficiently describe the controverted issue? (NA if there were no controverted issues)
☐ Yes ☐ No ☐ NA	If the minutes record controverted issues does the "Controverted Issue" include a resolution or a statement that there was no resolution? (NA if there were no controverted issues)
☐ Yes ☐ No	Do the minutes document the motion?
☐ Yes ☐ No	Do the minutes record the vote as the number of members for, against, abstaining, absent, or recused?
☐ Yes ☐ No ☐ NA	Do the minutes list the names of IRB members who were absent or recused?
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes record the vote of just one? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No ☐ NA	If both a regular IRB member and the alternate IRB member are present at the meeting do the minutes indicate which voted? (NA if both a regular IRB member and the alternate IRB member were not present at the meeting)
☐ Yes ☐ No	Is the sum total of the number of members for, against, abstaining, absent, or recused constant among votes and equal to the number of people listed in the attendance table?

4. Minutes Efficiency

Indicate the number of days between the meeting and the finalization of the minutes: Click or tap here to enter text.

[i] For ease of review, OHRP and FDA recommend that attendance information be listed at the beginning of the minutes and include the full name and representative capacity (e.g., scientist, nonscientist, unaffiliated) of each IRB member present at the convened meeting.

This IRB may choose to append a current IRB membership roster to the minutes to avoid having to repeat certain information (e.g., representative capacity for each IRB member).

VCU Research and Innovation

HRP-441 | 03/01/2024

CHECKLIST: HIPAA Waiver of Authorization

The purpose of this checklist is to provide support for the Privacy Board Member designated to conduct Privacy Board Reviews to document a waiver or alteration of HIPAA authorization using the expedited procedure or at committee review. This checklist needs to be completed, signed, dated, and retained.

Submission Information

Basic Information	Submission Details
IRB Number:	Click or tap here to enter text.
Study Title:	Click or tap here to enter text.
Short Title:	Click or tap here to enter text.
Investigator:	Click or tap here to enter text.

1. SCOPE (Check all that apply)

☐ Waiver of HIPAA authorization for recruitment

☐ Waiver of HIPAA authorization for conduct of study

☐ Alteration of HIPAA authorization to not require signature of the individual and date (e.g., verbal)

☐ Alteration of HIPAA authorization (include specifics of alteration below in "Notes" section; refer to HRP-330 - WORKSHEET - HIPAA Authorization)

2. DOCUMENTATION OF WAIVER APPROVAL (Check if **"Yes."** All must be checked)

☐ The description of the PHI for which use or access is included in the protocol summary and is necessary for the research.

☐ The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements: (Check if **"Yes."** All must be checked)

- ☐ An adequate plan to protect the identifiers from improper use and disclosure.
- ☐ An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law.
- ☐ Adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

☐ The research could **NOT** practicably be conducted without the waiver or alteration.

☐ The research could **NOT** practicably be conducted without access to and use of the protected health information.

Notes

Click or tap here to enter text.

Signature

Using the expedited review procedure the designated privacy board member signing below has determined that the above requirements are met, access to the protected health information described in the protocol is necessary, and waived or altered the requirement for authorization.

SIGNATURE OF MEMBER

X _____

Date: Click or tap here to enter text.