Expedited Review SHEET – Initial Review

|  |  |
| --- | --- |
| **Reviewer Name:      Primary  Secondary** | VCU IRB #: |
| **Review Begin Date:         (optional)** |  |
| PROTOCOL TITLE: | |

The Expedited Review Sheet is designed to guide the review process and serve as documentation of a completed expedited review.

*Reminders and suggestions for expedited reviewers:*

* Submission of this completed review sheet (to the panel’s IRB Coordinator) is *required* for documentation of the review and *approval* of research submitted *for expedited review* at VCU.
* Use the electronic version of this document to access hyperlinks for clarifying definitions, policies, and guidance.
* Print this document to serve as a worksheet or facilitate note-taking during your review process.
* Review the expedited review process prior to initiating your review [(WPP# VIII-2: Expedited Review).](http://www.research.vcu.edu/irb/wpp/flash/VIII-2.htm)
* Inclusion of children, pregnant women, and prisoners can only be approved IF the reviewer finds justification given protocol-specific findings AND also completes the Review Sheet for each corresponding vulnerable population to be approved ([*Special Population Review Sheets*](http://www.research.vcu.edu/irb/guidance.htm)).
* Navigate this document in it’s entirety or by the following sections header links:

1. [Risk Evaluation](#I_RiskEvaluation)
2. [Exceptions to Expedited Review](#II_Exceptionsfromexpreview)
3. [Expedited Categories](#III_ExpedCategories)
4. [PI Qualifications, COI, and Grant Considerations](#IV_PIqual)
5. [Expedited Research Review Criteria](#V_Expeditedreviewcriteria)
6. [Review of Informed Consent Elements](#VI_ReviewofICElements)
7. [Identification of Informed Consent Methods](#VII_IdentificationofICMethods)
8. [Waiver or Alteration of Consent and Waiver of Alteration/Signature](#VIII_Waiveroralterationofinformedconsent)
9. [Additional Review Considerations](#IX_Additional)
10. [Continuing Review Schedule](#X_ContinuingReview)
11. [Reviewer Action](#Xi_Reviewer_Action)
12. Risk Evaluation:

In order to qualify for expedited review, the research must pose no greater than [minimal risk](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102) to research participants.

|  |
| --- |
| Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [[**45 CFR 46.102(i)**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102)]. |

*Is the research no greater than minimal risk?*

Yes *(Expedited review continues)*

No *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

II. Exceptions to Expedited Review:

The expedited review procedure may not be used:

* Where identification of the participants or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
* Where the research is classified and involves human participants.
* Where the research involves prisoners (unless the research would otherwise qualify under and exempt category, were it not for the inclusion of prisoners).

*Do any of the above exceptions apply?*

No *(Expedited review will continue)*

Yes *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

III. Expedited Categories:

Select one or more of the following *6 Expedited Categories* [[45 CFR 46.110](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.110)] or select “none apply”.

|  |
| --- |
| Note: Research activities should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. For more information, see [VCU IRB WPP#; VIII-2.](http://www.research.vcu.edu/irb/wpp/flash/VIII-2.htm) |

***CATEGORY 1:*** Research on drugs or devices where an IND or IDE is not required (or device will be used as approved. **(**[Category 1](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm) guidance). ***Indicate (a) OR (b), below:***

***(a)*** Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

***(b)*** Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

***CATEGORY 2:*** Collection of blood samples (finger/heel/ear stick or venipuncture) in accordance with prescribed limits**. (**[Category 2](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm) **guidance). *Indicate (a) OR (b), below:***

***(a)*** From healthy, non-pregnant adults, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.

***(b)*** From other adults and children, considering the age, weight, health of the subjects, collection procedure, the amount of blood and frequency of collection. The amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

***CATEGORY 3:*** Prospective collection of biological specimens for research purposes by noninvasive means. ([Category 3](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm) guidance).

|  |
| --- |
| **(**[Category 3](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)**)** Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;(f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization. |

***CATEGORY 4:*** Collection of data through noninvasive procedures, routinely employed in clinical practice, excluding procedures involving general anesthesia, sedation, x-rays, and microwaves. **(**[Category 4](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)guidance**).**

|  |
| --- |
| **(**[Category 4](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)**)** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual. |

***CATEGORY 5:*** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes**. (**[Category 5](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)guidance**).**

|  |
| --- |
| **(**[Category 5](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)**)** Non-research purposes include medical treatment and/or diagnosis. NOTE: Some research in this category may be exempt. This category refers only to research that is not otherwise exempt (under [Exempt Category 4](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101)). |

***CATEGORY 6:*** Collection of data from voice, video, digital, or image recordings made for research purposes. ([Category 6](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm) guidance).

***CATEGORY 7:*** Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. ([Category 7](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm) guidance).

|  |
| --- |
| ([Category 7](http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm)) Examples include (but are not limited to) research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior. NOTE: Some research in this category may be exempt. This category refers only to research that is not otherwise exempt (under Exempt Categories 2 and 3). |

*NONE of the Above Initial Review Expedited Criteria Apply: (Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

IV. PI Qualifications, COI, and Grant Considerations:

*A.* Is the PI qualified by training and experience to carry out the responsibilities of this protocol described for the PI and to supervise the responsibilities of this protocol described/delegated for others?

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#XI_ReviewerAction) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* The ORSP has already ensured that the PI has successfully completed required CITI training. Consultants or other personnel may be included in support of the PI when considering qualifications. |

**B.** Are there any outstanding financial conflicts of interest to consider in the review of this protocol?

No potential conflict disclosed.

None outstanding.

|  |
| --- |
| *Note:* COI Committee Review is concurrent with VCU IRB Review. If no potential COI is disclosed, then submission to the COI Committee is not necessary. |

**C*.***Are there any outstanding non-financial conflicts of interest to consider in the review of this protocol?

No non-financial conflicts of interest to disclosed.

None outstanding.

*D.* Is the protocol congruent with the grant application?

No grant application submitted.

Yes, the protocol is designed to meet the objectives and appropriately represents the grant application submitted for IRB review.

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* The protocol must be designed to meet the objectives described in the grant application, appropriately representing the risks, benefits, procedures, and research subject populations described in the grant application. |

V. Expedited Review Criteria:

In the review of the research protocol, the IRB must consider the following review criteria [[45 CFR 46.111(a-b)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]:

*A.* Are the risks to subjects minimized through sound research design and the use of diagnostic or treatment data (whenever appropriate)? [[§46.111(a)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* The hypothesis of the research must be clearly stated, adequate preliminary data should be considered as necessary to justify the research, and the study design should be adequate to address the hypothesis. |

*B.* Are the risks to subjects reasonable in relation to anticipated benefits to subjects (if any) and the importance of the knowledge that may reasonably be expected to result? [[§46.111(a)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* Risks and benefits must be adequately identified, evaluated, and described. The rationale and details of all research procedures must be accurately described and acceptable. Appropriate efforts must be taken to minimize the potential risks and maximize the likelihood of benefits. |

*C.* Is the planned selection of subjects equitable, including appropriate inclusion and exclusion criteria? [[§46.111(a)(3)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* In making this assessment the reviewer/IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons [**§46.111(a)(3) and 46.111(b)**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111). Recruitment methods should be defined and equitable, allowing for a fair distribution of research risks and benefits among a cross-section of the community (as appropriate). Compensation should not be coercive. |

*D.* Does the research plan include adequate monitoring of data collected to ensure the safety of the subjects? [[§46.111(a)(6)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* The plans for data and statistical analysis should be defined and justified. The rationale for the proposed number of subjects should be described. |

*E.* Are adequate provisions described to protect the privacy of the subjects ([§46.111(a)(7)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111))?

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| **Note:** See description in the Research Plan to assess privacy provisions. Keep in mind that privacy is about respecting the identity and protecting the subject and his/her defined community. Will subject/community be provided with adequate privacy regarding their participation in the research activities? Are provisions adequate to prevent violations of privacy? |

*F.* Are adequate provisions described to maintain the confidentiality of data ([§46.111(a)(7)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111))?

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| Note: See description in the Research Plan to assess confidentiality. Keep in mind that confidentiality refers to the subject’s understanding as to how private, identifiable data will be maintained and shared. Are reasonable and appropriate measures in place so that the risk of breaching confidentiality is no greater than minimal? This is particularly important if identification of the subject or his/her private information, or the defined community, may reasonably place the subject at risk or criminal or civil liability or be damaging or stigmatizing to the subject or community. |

*G.* Are the procedures for recruitment and any proposed participant remuneration appropriate?

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *of this document to upgrade to full board review).*

Comments:

|  |
| --- |
| *Note:* The individual(s) performing conducting recruitment should be appropriate. All written recruitment materials and/or scripts must be submitted with the application and reviewed to ensure that they are not coercive (and to ensure that they comply with the VCU IRB guidelines at [**VCU IRB WPP XVII-2.**](http://www.research.vcu.edu/oeco/fedreg-info/VCUIRBWPP.doc) |

*H.* Has the investigator planned to enroll pregnant women, prisoners, or children (under the age of 18) in the research [[§46.111(b)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]?

No

Yes\*: (The reviewer must also complete corresponding review sheets for each vulnerable population included, justifying the inclusion of these populations with protocol-specific findings, or require the investigator to exclude them from his or her protocol).

|  |
| --- |
| *Note:* *\**Investigators are required to submit a Form Supplement for the inclusion of each vulnerable population listed above. VCU IRB [Review Sheets](http://www.research.vcu.edu/irb/guidance.htm) are available for the review of the inclusion of each of these vulnerable populations. Each review sheet will guide the reviewer through a series of additional considerations for the involvement of this population. Note, research involving prisoners typically does not qualify for expedited review unless the research would qualify for exemption (were it not for the inclusion of prisoners). |

VI. Review of Informed Consent Elements:

*Note:* In addition to indicating the status of each element below, the reviewer must also:

* Determine if the information presented is clear and comprehensive, presented in a language understandable to the research participant (or representative). Edits necessary prior to securing approval should be communicated to the PI directly, and then verified through receipt and review of an updated consent document/protocol.
* Evaluate the consent process to ensure that circumstances provide the prospective subject or the representative with sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.
* Ensure that no informed consent, whether oral or written, includes any exculpatory language through which the subject or the representative 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.
* Ensure that the approved protocol clearly describes the complete process/plan for informed consent in accordance with [§46.111(a)(4-5)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111), including methods for ensuring ongoing informed consent (as appropriate).

|  |  |  |
| --- | --- | --- |
| BASIC ELEMENTS (Required): | | |
| Included | **Waived or altered** | Check that each of the following basic elements is either included or wavier or altered. Basic elements, which are waived or altered, require justification with protocol-specific information [**§46.116(a)(1-8)**](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). Note that many elements can be combined into a single statement or phrase and that the degree of thoroughness should be appropriate for the research. If the element does not apply to the research context (e.g., due to the level of risk), this may be indicated as justification for waiver. |
|  |  | A statement that the study involves research [§46.116(a)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | An explanation of the purposes of the research [§46.116(a)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | The expected duration of the subject's participation [§46.116(a)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A description of the procedures to be followed [§46.116(a)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | Identification of any procedures which are experimental [§46.116(a)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A description of any reasonably foreseeable risks or discomforts to the subject [§46.116(a)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A description of any benefits to the subject or to others which may reasonably be expected from the research [§46.116(a)(3)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject [§46.116(a)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained [§46.116(a)(5)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). Indicate record review by VCU/VCU Health System, Sponsor, DHHS, and FDA (if research is FDA-regulated). |
|  |  | For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained [§46.116(a)(6)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116) *[NOTE: Expedited research will NOT be greater than minimal risk.]* |
|  |  | An explanation of whom to contact for answers to pertinent questions about the **research and research subjects’ rights** and an explanation of whom to contact in the event of a research-related **injury** to the subject [§46.116(a)(7)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled [§46.116(a)(8)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |

|  |  |  |
| --- | --- | --- |
| ADDITIONAL ELEMENTS (Should be included, as applicable): | | |
| Included | **Not**  **Applicable** | Include all additional elements of informed consent as they apply to the research (see VCU IRB Biomedical and Social Behavioral Informed [Consent Templates](http://www.research.vcu.edu/forms/vcuirb.htm) for additional guidance regarding when inclusion of each of these elements becomes necessary). |
|  |  | A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable [§46.116(b)(1)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent [§46.116(b)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | Any additional costs to the subject that may result from participation in the research [§46.116(b)(3)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject [§46.116(b)(4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | A statement that 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 [§46.116(b)(5)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |
|  |  | The approximate number of subjects involved in the study [§46.116(b)(6)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116). |

VII. Identification of Informed Consent Method:

*Informed Consent Process Plan:*

List the consent document(s) (and special waivers or processes) submitted and reviewed for this protocol.

Click here to enter text.

*Standard Documents:*

Research Participant Consent Form *(with all required elements of informed consent) –* Skip Section VII, Go to Section VIII of this review sheet.

*Consent Procedures Involving Waivers:*

*Waiving Elements:* Regarding the required elements of informed consent, if any are missing, please indicate if only some are waived or all are waived:

SOME elements of informed consent will be waived.

All elements of informed consent will be waived *[Note:* In prospective research, it is exceedingly rare NOT to verbally inform the participant that the activity is research. Must NOT be FDA-regulated research].

WAIVING DOCUMENTATION: Do either of the above procedures involve waiver of *the requirement to obtain a signature (also known as a waiver of documentation)* of informed consent?

Yes, waiver of documentation (or consent document signature) is requested. (Note: If no consent document is planned, a written script of the verbal consent statement must be submitted).

No, all research subjects will be required to sign a consent document.

*Consent Materials for Certain Vulnerable Populations:*

Consent Form for Prisoner/Subjects (See also Prisoner Review Sheet)

Parental Permission Form (See also Children Review Sheet)

Waiver of Parental Permission (Must NOT be FDA-regulated research).

Assent Form (Children or Applicable Adults) – (See also Children Review Sheet)

Waiver of Assent (no assent for children and/or applicable adults)

Translated Consent Documents (intended for subjects with Limited English Proficiency) - See [VCU IRB WPP# XVII-1: Research Subjects with Limited English Proficiency](http://www.research.vcu.edu/irb/wpp/flash/XVII-1.htm))

Use of a Legally Authorized Representative (LAR serves on behalf of the research participant). See [IRB WPP #XI-3: Legally Authorized Representative (Inclusion in Consent Process)](http://www.research.vcu.edu/irb/wpp/flash/XI-3.htm) for information about use of an LAR in, and outside of, Virginia. If use of an LAR is planned clearly indicate that the additional required criteria are met (using the chart below):

|  |
| --- |
| *Criteria for allowing LAR to provide initial informed consent on behalf of an adult:*  (1) The PI plans to/has requested to enroll adults who are not capable of providing consent  (2) The PI indicates that an appropriate Legally Authorized Representative will be asked to give consent on behalf of the incapacitated adult  (3) The PI indicates that all eligible subjects will require an LAR OR that some subjects may be able to provide assent or even consent for themselves  (4) The PI describes a plan and includes documents to assess capacity and solicit the consent for continued participation for adult subjects who will or may regain decision making capacity. Consider use of the VCU Informed Consent Evaluation Tool at <http://www.research.vcu.edu/forms/ICEval.doc>, as appropriate.  (5) A written or script-supported consent document (or other information relevant to the research) will be provided to the research participant accompanied by a consent conversation, as applicable  (6) The circumstances of the consent process provides the prospective participant or the LAR sufficient opportunity to consider whether to participate  (7) The circumstances of the consent process minimize the possibility of coercion or undue influence  (8) The person communicating information to the participant or the LAR during the consent process will provide that information in language understandable to the participant or the representative.  (9) The informed consent document contains a line for LAR signature ONLY if permission from an LAR is appropriate. |

VIII. Waiver or Alteration of Consent *AND* Waiver of Documentation/Signature:

|  |
| --- |
| ***Guidance:***   * [WPP #XI-2 Informed Consent Documentation, Waiver of Documentation, and Required Signatures](http://www.research.vcu.edu/irb/wpp/flash/XI-2.htm) * [WPP # XI-1 Consent Process, Elements, Waiver of Element(s), and Modification](http://www.research.vcu.edu/irb/wpp/flash/wpp_guide.htm)**.** |

1. Is the PI requesting a *waiver or alteration of SOME of the required elements* of informed consent?

Yes: Complete the Waiver Justification Chart, below.

No.

1. Is the PI requesting a *waiver or alteration of ALL of the required elements* of informed consent?

Yes: Complete the Waiver Justification Chart, below.  *[Note:* It is exceedingly rare (in prospective research) not to, as a minimum standard, verbally inform the participant that the activity is research].

No.

*Waiver Justification Chart:*

|  |  |  |
| --- | --- | --- |
| The IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent (above), or waive the requirements to obtain informed consent, provided the IRB finds and documents that ***EITHER*** [*§46.116(c)(1-2)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116) ***OR*** [*§46.116(d)(1-4)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116) ***apply.*** As part of the review process, the reviewer must confirm the PI has provided protocol-specific information to support these findings. | | |
| [§46.116(c)(1-2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116): Both of the following 2 FINDINGS must be documented [46.116(c)(1-2)]. | | |
| **Yes** | **46.116(c)(1):** The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine:  (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and **Notes:** | |
| **Yes** | **46.116(c)(2):** The research could not practicably be carried out without the waiver or alteration. **Notes:** | |
| [§46.116(d)(1-4)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116): ****ALL of the following 4 FINDINGS must be documented [46.116(d)(1-4)].**** | | |
| **Yes** | | **46.116(d)(1):** The research involves no more than minimal risk to the subjects; |
| **Yes** | | **46.116(d)(2):** The waiver or alteration will not adversely affect the rights and welfare of the subjects; |
| **Yes** | | **46.116(d)(3):** The research could not practicably be carried out without the waiver or alteration; and |
| **Yes** | | **46.116(d)(4):** Whenever appropriate, the subjects will be provided with additional pertinent information after participation. **Notes:** |

1. Is the PI requesting a *waiver of the requirement to obtain a signed consent form (documentation of informed consent)*?

Yes: Complete the Waiver of a Signed Consent Chart, below. *[The PI must have documented in the protocol adequate justifications to meet the criteria.]*

No: Skip to [Section IX](#IX_Additional)**.**

*Waiver of Signed Consent Chart:*

|  |  |  |  |
| --- | --- | --- | --- |
| *Indicate ONE of the following conditions* in order to approve the ***waiver of a signed consent document***. Please note, In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. | | | |
|  | ***Condition 1*** [*46.117(C)(1)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117)  **Yes**  **Yes**  **Yes**  **Yes**  **Yes**  **Yes** | The consent document is the only record linking the subject and the research, where the principle risk is potential harm resulting from breach of confidentiality. (*Note:* This condition does not apply FDA-regulated research.)   1. Is the consent document the only record linking the participant and the research? 2. Is potential harm resulting from a breach of confidentiality the principal risk? 3. Will participants be asked whether they want documentation linking them to the research? 4. Does the researcher provide an adequate explanation in the research plan to justify the waiver? 5. Will the investigator provide the participants with a written statement regarding the research? 6. Is the study subject to FDA regulations? (if YES, waiver cannot be granted)   **Notes:** | |
|  | ***Condition 2***  [*46.117(C)(2)*](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.117)  [*21 CFR 56.109(c)(1)*](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.109)  **Yes**  **Yes**  **Yes**  **Yes**  **Yes** | | That the research presents **no more than minimal risk** of harm to subjects, and involves no procedures, for which written consent is normally required outside of the research context. (Note: This condition does apply to FDA-regulated research as per 21 CFR 56.109(c)(1)).   1. Is the research no greater than minimal risk? 2. The research does not involve procedures that would normally require written consent outside of the research context. 3. Does the researcher provide an adequate explanation in the research plan to justify the waiver? 4. Will the investigator provide the participants with a written statement regarding the research? 5. Is the study subject to FDA regulations? (if YES, waiver cannot be granted)   **Notes:** |

*Note: If this is FDA-regulated emergency research, prior consultation with the OECO is required in order to consider allowance for waiver of signed consent under 21 CFR 50.24.*

IX. Additional Review considerations:

A. *Involvement of Non-VCU Institutions/Sites:*  If the research involves a *direct Federal award* made to VCU (or application for a Federal award), are there non-VCU institutions/sites *engaged* in the research activity? (*Guidance Link:* [*VCU IRB WPP: XVII-6*](http://www.research.vcu.edu/irb/wpp/flash/XVII-6.htm)).

Not applicable (no direct Federal award or application)

Yes: Does each non-VCU institution/site engaged: (1) have an OHRP Federalwide Assurance *OR* (2) has an IRB Authorization Agreement been signed between VCU and the non-VCU institution/site?  Yes;  No: STOP – FWA or Authorization Agreement needed to continue.

Comments:

B*. Investigational Drugs and Devices:* If this study involves an investigational drug or device, is there a plan for control of the investigational drugs, biologics, or device, including inventory and dispensing of the drug, biologic, or device? (Note: Plan should be described within the research synopsis).

Yes

Not Applicable

No: *(Expedited review ends – Go to* [*Section XI*](#Xi_Reviewer_Action) *to upgrade to full-board review, if needed).*

Comments:

|  |
| --- |
| *Note:* Expedited Category 1 allows restricted use of investigational drugs or devices. See [**WPP XVI-7: Control of Investigational Drugs, Devices, and Biologics**](http://www.research.vcu.edu/irb/wpp/flash/XVI-7.htm) for information about safe handling. |

C*. Research Setting and Resources:* Dothe research setting and resources available facilitate the protection of research participants and minimization of risk?

Yes

No: *(Expedited review ends – Go to* [*Section XI*](#XI_ReviewerAction) *to upgrade to full-board review, if needed).*

Comments:

|  |
| --- |
| *Note:* Consideration should be given the following items (as applicable): 1) access to a population that would allow recruitment of the necessary number of participants, 2) sufficient time to conduct and complete the research, 3) adequate numbers of qualified staff, 4) adequate facilities, 5) a process to ensure that all persons assisting with the research were adequately informed about the protocol and their research-related functions, 6) availability of medical or psychological resources that participants might require as a consequence of the research. |

*D. Research Registries/Specimen Banks:* If this research involves the development of or contribution to a data registry or specimen bank, are the plans for protection of privacy and confidentiality of data adequate as described?

Yes

Not Applicable

No: *(Expedited review ends – Go to* [*Section XI*](#XI_ReviewerAction) *to upgrade to full-board review, if needed).*

Comments:

|  |
| --- |
| *Note:* The information provided about access and control, data protections, access for registry use, and informed consent considerations should offer subject protections based on the kind of information/data being collected and stored. For additional guidance on research registries or data banks, as well as protocols intending to use such registries, see [WPP XVII-4 Research Involving Data Registries/ Specimen Banks](http://www.research.vcu.edu/irb/wpp/index.htm#XVII-4.htm). |

X. Continuing Review Schedule:

Continuing review is standard at least annually. Is a more frequent review schedule necessary for this study?

No, *annual continuing review* is adequate.

Yes: A more frequent review schedule is recommended, as follows:

XI. Reviewer Action:

Select one of the following 2 possible review results (and follow the instructions given for communicating your decision):

Approve via Expedited Review **in accordance with 45 CFR 46.110 and 45 CFR 46.111. The research poses no greater than minimal risk.**

***How to communicate approval:* Send an email to your IRB Panel Coordinator with the following attachments:**

1. this completed Expedited Review Sheet
2. All Vulnerable Populations Review Sheets (as applicable for Children, Pregnant Women, and/or Prisoners); and,
3. All documents related to the protocol that have been modified during the review process.

**Upgrade to Full Board Review** (based upon issues identified in the review process)

***How to upgrade this review to full board review:***

1. Inform the PI and IRB Coordinator that the review is being upgraded to full board review.
2. Continue the review using the full board review sheet.

***Reminder:***Research cannot be disapproved via the expedited process (must be referred for full board discussion).