FUll Board Review SHEET – Initial Review

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

The Full Board Review Sheet is designed to guide the primary and secondary reviewers in preparation for leading the discussion during the IRB board meeting.

*Reminders and suggestions for reviewers:*

* *How to begin:* Review the full board review process prior to initiating your review [(VCU IRB WPP# VIII-3: Full Board Review).](http://www.research.vcu.edu/irb/wpp/flash/VIII-3.htm)
* *About vulnerable populations:* Inclusion of *children*, *pregnant women, and prisoners* can only be approved IF the reviewer finds justification which is documented by protocol-specific findings (within the minutes). Use the Children, Pregnant Women, and/or Prisoner Review Sheets, as appropriate, to document these protocol-specific findings and lead the discussion points during the meeting (link: [*Special Population Review Sheets*](http://www.research.vcu.edu/irb/guidance.htm)).
* *About this document:* Preparation of this document prior to the meeting greatly facilitates efficient discussion and documentation. Use the electronic version of this document to access hyperlinks to definitions, policies, and guidance. ‘Fillable’ areas are provided for documentation purposes. Plan to provide a printed copy of this document to the panel’s IRB Coordinator to aide in the documentation of comments within the minutes. Navigate to specific review areas using the following section header links:

1. [PI Qualifications, COI, and Grant Considerations](#I)

1. [Full Board Review Criteria](#II)
2. [Additional Review Considerations](#III)
3. [Informed Consent Process Plan](#IV)
4. [Review of Elements of Informed Consent](#V)
5. [Consent Process/Document Edit Notes](#VI)
6. [Identification of Informed Consent Method](#VII)
7. [Waiver or Alteration of Consent and Waiver of Documentation/Signature](#VIII)
8. [Continuing Review Schedule](#IX)
9. [Reviewer Action](#X)

I. PI Qualifications, COI, and Grant Considerations:

*A.* Is the PI qualified by training and experience to carry out the responsibilities of this protocol, as described, and to supervise the other responsibilities of this protocol as described?

Yes

No: Comment:

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| *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:

Yes: Comment:

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| *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 disclosed.

None outstanding

Yes/Possibly: Comment:

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| *Note:* Non-financial conflicts of interest should be evaluated by the IRB as part of the human subject protection program. |

*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: Comment:

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| *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. |

II. Full Board Research 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: Comment:

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| *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.* What is the overall level of risk to the research participants [[§46.111(a)(2)](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111)]?

Slight increase over minimal risk.

Significant increase over minimal risk.

Minimal risk (where the research does not otherwise qualify for Expedited or Exempt Review). Comment:

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| *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. |

1. 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: Comment:

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| ***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.In evaluating risks and benefits, the reviewer/IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The reviewer/IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.  A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences. (Ref: [NIH Risk/Benefit Model](http://ohsr.od.nih.gov/irb/protocol.html)). |

1. 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: Comment:

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| *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). |

*E.* 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: Comment:

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

*F.* 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: Comment:

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| **Note:** See description in the Research Plan to assess privacy provisions. Keep in mind that privacy is about respecting the identity and protecting the person of 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? |

*G.* 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: Comment:

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| 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. |

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

Yes

No: Comment:

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| *Note:* The individual(s) carrying out the recruitment process should be appropriately trained and knowledgable about the study. 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) Compensation should not be coercive. |

*I.* 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\*: Comment:

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| *Note:* *\**Principal Investigators are required to submit a Form Supplement for the inclusion of each vulnerable population listed above. Reviewers should use these submitted Form Supplements to assist with the completion of the Review Sheets for each special population requested. |

III. Additional Review Considerations:

A. *Radiation Safety:* Is ionizing radiation used for research purposes within this protocol (not medically indicated)?

No

Yes: RSC approval IS documented.

Yes: RSC approval NOT documented\*: Comment:

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| *Note:* VCU Radiation Safety Committee (RSC) approval must be documented where ionizing radiation is proposed for research use only (not for the benefit of the research participant or otherwise medically/clinically indicated). See also the [**VCU Guidelines for IRB Protocols Involving the Use of Ionizing Radiation**](http://www.vcu.edu/oehs/radiation/humanuseguide.pdf). |

B. *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? (See[*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 – Agreements are needed. Comment:

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

Yes

No: Comment:

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| *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: Comment:

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| *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). |

IV. FDA-Regulated Research:

FDA-Regulated drugs, devices, or biologics (research data will be collected for new, new indications, or approved uses of drugs, devices or biologics)

No FDA-Regulated drugs, devices, or biologics (SKIP TO SECTION V).

A. If the research involves a new drug/device/biologic (or the use of a marketed drug/device/biologic for a new indication), is *documentation* provided in the form of an IND, IDE, or waiver from the FDA?

Not Applicable (FDA-products are NOT involved as described above)

Yes: Appropriate documentation is provided.

No – Documentation is missing or incomplete: Comment:

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| *Note:* The drug dosage and route of administration must be appropriately described and match the market application. Prior safety and efficacy data must be sufficient to warrant the proposed phase of testing for the drug or device. See VCU IRB WPP [***XVI-6: Requirements for an IND***](http://www.research.vcu.edu/irb/wpp/flash/XVI-6.htm) |

B*.* 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: Comment:

C. If the research involves a new device, the IRB must make its own determination of the level of risk of the device, as follows:

Not Applicable (investigational device is not involved in the research)

Non-Significant Risk (NSR) Device

Significant-Risk (SR) Device

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| *Note:* A SR device study is defined [21 CFR 812.3(m)] as a study of a device that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. A NSR device investigation is one that does not meet the definition for a significant risk study. See VCU IRB WPP [*XVI-1: Review of Devices.*](http://www.research.vcu.edu/irb/wpp/flash/XVI-1.htm)See also FDA Guidance titled [**Medical Devices**](http://www.fda.gov/oc/ohrt/irbs/devices.html). |

V. Review of Informed Consent Elements:

*Note:* In addition to indicating the status of each element below, the primary and secondary reviewers are responsible for:

* Determining if the information presented is clear and comprehensive, presented in a language understandable to the research participant (or representative).
* Evaluating 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.
* Ensuring that the consent process does not include exculpatory language (through which the subject or the representative appears to waive any legal rights, releases, or appears to release the investigator, the sponsor, the institution from liability for negligence.
* Ensuring 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).
* Identifying any edits necessary to the informed consent document required or recommended.

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| 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) |
|  |  | 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). |

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| 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). |

VI. Consent Document/Process Edit Notes:

*Reviewer Notes Regarding Suggested Edits to the Informed Consent Document (notes may also be made directly on the consent document):*

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* *VIII*, Go to *Section IX* 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):

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| *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:

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| ***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. Has the PI requested a *waiver or alteration of SOME of the required elements* of informed consent?

Yes: Complete the Waiver Justification Chart, below.

No.

1. Has the PI requeted 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:*

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| 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 determine that the information provided in the research plan supports 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; **Notes:** |
| **Yes** | | **46.116(d)(2):** The waiver or alteration will not adversely affect the rights and welfare of the subjects; **Notes:** |
| **Yes** | | **46.116(d)(3):** The research could not practicably be carried out without the waiver or alteration; and **Notes:** |
| **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. *[Both findings must be documented by protocol-specific information as part of the review process].*

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

*Waiver of Signed Consent Chart:*

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| *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 ORSP is required in order to consider allowance for waiver of signed consent under 21 CFR 50.24.*

Notes:

IX. 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:

X. Reviewer Action:

Meeting date:

Secondary Reviewer:

Notes regarding contact with the principal investigator::