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| **Expedited and Full Review Checklist** | | | | | |
| Section 1: Project Characteristics | | | | | |
| IRB#: |  | PI name: |  | | |
| Meeting date: |  | Reviewers: |  |  | |
| Study Title: |  | | | | |
| Characteristics: (check all that apply) | New  Continuation  Amendment | | Funded Federal Sponsor  Unfunded Commercial Sponsor  Grant included/congruent | | Minimal Risk  Greater than minimal risk |

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| Section 2: Research Study Checklist | | | |
| Yes | No\* | N/A |  |
|  |  |  | If this is a continuation of a previously approved study, has **progress-to-date** been adequately reported? |
|  |  |  | Are the scientific **training/qualifications/credentialing** and privileges of PI and research staff outlined and adequate? [Criteria 46.111(1)] |
|  |  |  | Have all **conflicts of interest** been identified and addressed? |
|  |  |  | The research has the resources necessary to protect subjects including time to conduct and complete the research; adequate facilities, subject pool and medical/psychosocial resources. |
|  |  |  | Are **risks to subjects minimized** by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk? [Criteria 46.111(1)] |
|  |  |  | If the study involves an **investigational drug/device/biologic** have appropriate controls been identified? |
|  |  |  | If the research involves a **new device**, has the level of risk been determined? |
|  |  |  | If the research involves a **new drug/device/biologic** (or marketed drug/device/biologic for new indication), is documentation of IND, IDE or waiver from FDA included? |
|  |  |  | If ionizing **radiation** is used for research purposes is RSC approval documented? |
|  |  |  | If **Non-VCU Institutions/Sites** are involved, is VCU oversight needed (direct federal award to VCU)? |
|  |  |  | If applicable, have **surveys/questionnaires/measures** been provided and reviewed? [Criteria 46.111(1)] |
|  |  |  | If the study involves PHI, have all appropriate HIPAA pathway(s) for access/use been identified? |
|  |  |  | If the research involves the development of or contribution to a **data registry or specimen bank**, have the additional requirements been met? |
|  |  |  | If the research involves **DNA testing** or other **genetic analysis,** have the additional requirements been met? |
|  |  |  | Are there adequate safeguards for **privacy (person) & confidentiality (data)**? [Criteria 46.111(7)] |
|  |  |  | If **vulnerable populations** (pregnant women, children, prisoners, diminished capacity, others) will be included, are adequate protections in place? [Criteria 46.111(3)] |
|  |  |  | Are the **procedures for recruitment** and **incentives for participation** appropriate & not coercive? [Criteria 46.111(2)] |
|  |  |  | Is **subject selection** equitable? [Criteria 46.111(3)] |
|  |  |  | Have **recruitment materials**, ads, and subject information (letters, etc.) been provided and reviewed? |
|  |  |  | Do the anticipated **benefits** outweigh the expected **risks**? [Criteria 46.111(2)] |
|  |  |  | If there is **no direct benefit** to the participants, are the benefits to future subjects or knowledge to be gained mentioned? [Criteria 46.111(2)] |
|  |  |  | If the research is > minimal risk OR is a NIH funded clinical trial, is there a **Data and Safety Monitoring Plan** and/or formal DSMB? [Criteria 46.111(1),(6)] |
|  |  |  | Are there any exemptions/**waiver of consent**/**waiver of documentation of consent** (verbal consent) or waiver of any other elements that require special attention? [Criteria 46.111(5)] |
|  |  |  | Have all **ancillary approvals** been included with the submission (e.g. RSC, IBC, PMRC, School Board, etc.)? |
|  |  |  | If applicable, have additional regulatory requirements been met for DoD, DoJ, DoEd? |

\*For items checked “No”, make an entry in the Research Study Issues Needing Clarification or Revision section on page 3.

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| Section 3: Informed Consent Checklist | | | | | | | |
| IRB#: | | | |  | PI name: |  | |
| Meeting date: | | | |  | Reviewers: |  |  |
| Yes | No\* | N/A | Does the consent document(s) contain the following **REQUIRED** ELEMENTS? | | | | |
|  |  |  | | A clear statement that the study is **research** | | | |
|  |  |  | | All of the research **purposes** (ie., protocol objectives) are clearly stated | | | |
|  |  |  | | Expected **duration** of the volunteer’s involvement | | | |
|  |  |  | | **Procedures or treatments** to be done and explanation which procedure(s) or treatment(s) are experimental | | | |
|  |  |  | | Reasonably foreseeable **discomforts and risks** | | | |
|  |  |  | | Reasonably expected **benefits** to volunteer and others | | | |
|  |  |  | | **Alternatives** to participation | | | |
|  |  |  | | Description of how **confidentiality** of data will be maintained. | | | |
|  |  |  | | Statement of who **will have access** to research records (VCU/VCUHS, Sponsor, DHHS, FDA) | | | |
|  |  |  | | Financial considerations: **extra costs of, or compensation for**, participation | | | |
|  |  |  | | Availability of medical care and any other compensation for **research-related injury** (if > minimal risk). | | | |
|  |  |  | | Statement of who a volunteer should **contact for injury or adverse event** | | | |
|  |  |  | | Statement of who will **answer questions** about the research itself | | | |
|  |  |  | | Contact information for ORIE office for **questions about volunteer’s rights** | | | |
|  |  |  | | **Non-coercion disclaimer**. E.G., "Participation in research is entirely voluntary. | | | |
|  |  |  | | Statement that the treatments or procedures “may involve **risks that are currently unforeseeable**” to subject or to the embryo or fetus, if the subject is or may become pregnant. | | | |
|  |  |  | | Description of circumstances where researcher may **terminate a volunteer’s participation** without their consent | | | |
|  |  |  | | Procedures for **orderly termination** of a volunteer’s participation | | | |
|  |  |  | | Consequences of a volunteer’s **withdrawal** from the research | | | |
|  |  |  | | Plan to **inform** volunteers of significant research findings relevant to their continued participation | | | |
|  |  |  | | Description of how, why, and how many prospective volunteers will be **selected** | | | |
|  |  |  | | If the study is a **clinical trial**, the following language must be included : *“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 Website will include a summary of the results. You can search this Web site at anytime.”* | | | |
|  |  |  | | The appropriate **signature** lines (e.g. PI, LAR, multiple parents, etc.) are indicated on consent documents. | | | |
| Yes | No\* | N/A | ADDITIONAL ELEMENTS | | | | |
|  |  |  | | Has **assent** been appropriately obtained and documented? | | | |
|  |  |  | | **Other elements** a reasonable person would want to know | | | |
|  |  |  | | For sponsored studies, the **sponsor is identified**? | | | |
|  |  |  | | If the study involves retention of data or samples for future research (**research registry**), the consent clearly explains options. | | | |
|  |  |  | | Where collaborators will **receive data or samples** (including for future research), is this clearly stated? | | | |
|  |  |  | | Valid **translations of consent** have been provided | | | |
|  |  |  | | The consent does not contain any **exculpatory language** that holds harmless the sponsor or researcher | | | |
|  |  |  | | The consent documents are written in a language no higher than an **8th grade reading level**. | | | |
|  |  |  | | If the research includes governmental departments (e.g. DOD, DOJ, DOE, etc.) have the required elements been met? | | | |
| Yes | No\* | N/A | | CONSENT PROCESS | | | |
|  |  |  | | The consent discussion will be conducted by a qualified individual and provide sufficient opportunity to ask questions and consider whether or not to participate. | | | |
|  |  |  | | The circumstances of consent minimize the possibility of coercion or undue influence. | | | |
|  |  |  | | Information to be given to the subject or LAR will be in language understandable to them. | | | |
|  |  |  | | Opportunities for ongoing consent are appropriate and adequate. | | | |

\*For items checked “No”, make an entry in the Informed Consent Changes Needed section on page 4.

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| Section 4: Suggested Review Presentation Format | | | | | |
| IRB#: |  | PI name: | |  | |
| Meeting date: |  | Reviewers: | |  |  |
| 1. Primary objective of the study: | | | | | |
| 2. Target subject population(s) / Current study enrollment & progress (for continuations): | | | | | |
| 3. Brief description of main study intervention / Description of changes (for amendments): | | | | | |
| 4. Research Study issues needing clarification or revision: (these should be noted as Reviewer Notes in RAMS-IRB) | | | | | |
| 46.111 Criterion  1(i) - Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.  1(ii) - Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.  2 - Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.  3 – Selection of subjects is equitable.  6 – When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.  7(i) – When appropriate, there are adequate provisions to protect the privacy of subjects.  7(ii) – When appropriate, there are adequate provisions to maintain the confidentiality of data.  8 – When some or all of the subjects are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects. | | |  | | |

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| Section 4 continued: Suggested Review Presentation Format | | | | | |
| IRB#: |  | PI name: | |  | |
| Meeting date: |  | Reviewers: | |  |  |
| 5. Informed Consent changes needed: (these should be noted as Reviewer Notes in RAMS-IRB) | | | | | |
| 46.111 Criterion  4 – Informed consent will be sought from each prospective subject or the subjects legally authorized representative, in accordance with, and to the extent required by the regulations.  5 – Informed consent will be appropriately documented, in accordance with, and to the extent required by the regulations. | | |  | | |
| 6. Overall Recommendation: Approval Conditional Approval Table Disapprove | | | | | |