INFORMATION SHEET ON PROCEDURES FOR NIH IRBS AND INVESTIGATORS REVIEWING AND IMPLEMENTING RESEARCH PROTOCOLS INVOLVING THE NIH AND WALTER REED NATIONAL MILITARY MEDICAL CENTER (WRNMMC)

Introduction

The National Institutes of Health (NIH) and Walter Reed National Military Medical Center (WRNMMC) have entered into a reliance agreement for NIH to conduct Institutional Review Board (IRB) review of research protocols developed by the NIH Intramural Program and implemented at the NIH and WRNMMC.

There are two categories of collaborations that are covered by this agreement:

1. Protocols may be implemented in their entirety, in parallel, at NIH and WRNMMC. These protocols will be led by Principal Investigators (PIs) who are employees of each institution. The PI with overall responsibility will be known as the “Lead PI” and the other PI as a “Site PI”.

2. Alternatively, collaborations may involve NIH and WRNMMC investigators working on aspects of the same protocol. These protocols will be led by a PI who is an NIH employee and will have a “Lead Associate Investigator” employed by WRNMMC.

Note that for the remainder of this information sheet, the term “Lead Investigator” will refer to the “Site PI” or the “Lead Associate Investigator” from WRNMMC.

Framework for Collaborations

This agreement represents a new working relationship between WRNMMC and the NIH and sets out guidelines for operationalizing these collaborations for NIH IRBs and Investigators.

The underlying expectation is that when NIH IRBs review collaborations under this reliance that they will apply the human subject regulations and policies that they normally apply when reviewing NIH research and when being relied upon by another institution. WRNMMC is responsible for ensuring that DoD regulations and policies have been addressed for WRNMMC investigators and/or resources involved in the research. The procedures for this process are laid out below. Please note that these procedures are provisional and may be revised in the future as we gain a better understanding of how the reliance agreement is implemented.

Applicable Regulations and Policies

The review of research will fall under the regulatory framework of 45 C.F.R. 46 (DHHS Common Rule) which is nearly identical to the Department of Defense (DoD) adoption

of the Common Rule i.e., 32 C.F.R. 219. Per the agreement, reviewing NIH IRBs will apply 45 C.F.R. 46 and FDA regulations when applicable during its review and this review will meet the human subject protection requirements of WRNMMC's OHRP-approved FWA.

NIH staff will follow applicable NIH Human Research Protections Program (HRPP) policies. WRNMMC staff will follow NIH HRPP Standard Operating Procedures (SOPs) pertaining to IRB actions after approval of a protocol at the NIH, specifically:

SOP 9	Continuing Review by the Convened IRB;
SOP 10	Amendments to IRB-approved Research;
SOP 11	Suspensions and Terminations of IRB Approval and Administrative Holds;
SOP 11A	Closure of an IRB-approved Protocol;
SOP 16	Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations; and
SOP 16A	Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP).

In addition, WRNMMC staff will follow applicable WRNMMC HRPP policies. Specific requirements found in DoD Instruction 3216.02 (DoDI 3216.02) and 10 U.S.C. 980 will be addressed by WRNMMC during administrative reviews of the protocol packet, pre and post NIH IRB review, which will take place prior to the enrollment of any subjects at WRNMMC. WRNMMC has sole responsibility for assuring compliance with DoDI 3216.02, 10 U.S.C. 980 and any other applicable DoD-specific policy and law.

Confirming coverage of non-exempt human subjects research activities under this agreement

When thinking about collaborating with WRNMMC, whether a new or existing protocol, we ask that you consult the NIH Office of Human Subjects Research Protections (OHSRP) first to ensure that you can obtain coverage under the program-wide reliance agreement. Provide a memo about the proposed collaboration including a detailed description of the research activities, their location(s), the identity of the lead investigator at WRNMMC with whom you intend to collaborate, whether the project will involve NIH or WRNMMC personnel, and required WRNMMC resources (e.g., facilities, staff, funding.) Please also confirm that scientific review has taken place prior to submitting this memo to OHSRP, or provide a rationale for why it is not required.

OHSRP will consider the request and confirm, subject to WRNMMC's agreement during pre-review (see below), whether the collaboration can in principle be covered under this agreement. OHSRP will perform this review within 10 working days. The OHSRP Director has authority to determine that dual IRB review is more appropriate for a specific protocol.

Pre-review by WRNMMC

Prior to submitting the protocol to the NIH IRB (either for initial review or as an amendment adding WRNMMC as a site), WRNMMC must conduct a pre-review to ensure that the research activities set forth in the protocol and consent(s) comply with WRNMMC regulations and policies.

The NIH PI must prepare a protocol packet for the WRNMMC lead investigator to submit to the Department of Research Programs (DRP) at WRNMMC. The packet should include the protocol and informed consent form(s) as well as the NIH IRB Initial Review Local Context Worksheet (Appendix 2) for completion by WRNMMC. NIH investigators are encouraged to work closely with their counterpart investigator(s) at WRNMMC to ensure that research protocols capture all required elements for the WRNMMC pre-review provided they do not conflict with NIH requirements. The WRNMMC Project Review Sheet (Appendix 1) outlines the requirements that will be considered in the DRP's review of the NIH protocol and should be used as a guide in preparing the protocol packet.

The WRNMMC DRP will conduct a pre-review of the research protocol packet within 30 days of receipt to ensure the proposed research is compliant with applicable DoD-specific policies and laws. As part of the pre-review process, WRNMMC may provide a local context addendum to the protocol for the purposes of providing guidance to the NIH IRB beyond the NIH IRB local context worksheet.

WRNMMC may recommend changes in the research protocol packet to the lead WRNMMC investigator. If the WRNMMC investigator, in collaboration with the NIH PI, determines that the recommended changes are reasonable then these should be incorporated into the draft research protocol packet. The packet should then be resubmitted to the WRNMMC DRP for additional consideration.

When WRNMMC is satisfied that the research protocol packet meets all DoD requirements and is ready to be submitted to the NIH IRB, it will issue an endorsement letter confirming this to the lead WRNMMC investigator who will then provide it to the NIH PI. The NIH PI will include the endorsement letter in the research protocol packet when submitting to the NIH IRB for review.

NIH IRB Review

When the NIH IRB conducts the pre-IRB review of a protocol submission, the NIH IRB should:

1. Confirm receipt of the Endorsement Letter from WRNMMC;
2. Confirm receipt of the completed NIH IRB initial review local context worksheet; and
3. Work with the Chair to determine whether a non-voting, DoD consultant should attend the IRB meeting to help ensure that all aspects of the study are

adequately assessed. This representative will provide technical assistance and should be knowledgeable about DoD policies and laws as they pertain to human subjects research protections. This may be advisable when NIH IRBs are reviewing DoD research for the first time. To obtain a consultant, the NIH IRB Office should contact the DRP at WRNMMC (see contact information at the end of this information sheet).

At the time of review, the NIH IRB should consider local context considerations as outlined in the NIH IRB Local Context Worksheet /NIH IRB Continuing Review Local Context Worksheet, and any local addendum attached to the protocol.

Upon initial and subsequent approvals of the protocol:

1. The NIH IRB will provide the NIH PI all documents related to the IRB's review and determination;
2. The NIH PI will provide these documents via email to the WRNMMC lead investigator, and the DRP at WRNMMC; and
3. WRNMMC should have the opportunity to conduct a post-review (a DoD component level administrative review) of the research protocol packet following all determinations made by the NIH IRB.

Commencement of research at the NIH

Research activities taking place at NIH can begin once a protocol has NIH IRB approval and is compliant with all additional NIH institutional requirements e.g., completion of ancillary reviews.

Post-review by WRNMMC

Following the review and approval of the protocol packet by an NIH IRB, the lead investigator at WRNMMC will submit the documentation to a post-review (component-level administrative review) to ensure that the human subjects research in which WRNMMC is engaged continues to be compliant with applicable DoD-specific policies and laws. This WRNMMC review will be conducted within 30 days of receiving the NIH IRB-approved research protocol packet from the WRNMMC lead investigator.

If no further changes to the IRB-approved research protocol packet are required by WRNMMC, WRNMMC will issue an approval letter to the WRNMMC lead investigator who will then provide it to the NIH PI. The NIH PI will provide the approval letter to the NIH IRB. The issuance of the approval letter serves to confirm that the protocol is in compliance with DoD regulations and policies. DoD-supported research may begin once this approval letter is issued.

If the post-review suggests changes to the NIH IRB-approved research protocol packet, the WRNMMC investigator, in collaboration with the NIH PI, will determine if these changes can be incorporated into the research protocol packet and, if so, the NIH PI will submit them as an amendment to the NIH IRB. If the NIH IRB approves the

amendment, the revised research protocol packet will be provided to WRNMMC for a further opportunity to review. Any additional requests for changes, if appropriate, will be submitted to the NIH IRB as an amendment. Once an IRB-approved research protocol packet satisfies WRNMMC, an approval letter will be issued to the WRNMMC lead investigator. The NIH PI will provide the approval letter to the NIH IRB. The issuance of the approval letter serves to confirm that the protocol is in compliance with DoD regulations and policies. DoD-supported research may begin once this approval letter is issued.

Commencement of research at WRNMMC

WRNMMC supported-activities, such as the involvement of WRNMMC personnel or use of their facilities at the WRNMMC site, can only commence after approval is secured from both the NIH IRB and WRNMMC's component-level administrative review.

See Figure 1 – Flowchart for Initiating Collaboration between the NIH and WRNMMC for an outline of the above process.

Requirements for the management of Amendments

Pre-review

A pre-review of proposed amendments may be required by WRNMMC prior to submission to the NIH IRB. To determine this, the NIH PI should provide a proposed amendment to the lead WRNMMC investigator who will submit it to the WRNMMC DRP. The WRNMMC DRP will consider the amendment and inform the WRNMMC lead investigator by email within 3 working days (72 hours) if a pre-review is required. The DRP's decision should be promptly communicated from the WRNMMC lead investigator to the NIH PI.

If a pre-review is not required, the NIH PI can proceed with submitting the amendment to the NIH IRB and append a copy of the email from the WRNMMC DRP confirming that a pre-review is not required.

If a pre-review is required, WRNMMC will conduct a pre-review within 14 days of receiving the amendment submission packet. When satisfied that the proposed amendment meets all applicable DoD requirements, the WRNMMC DRP will issue a determination letter to the lead WRNMMC investigator. The determination letter should then be passed on to the NIH PI by the WRNMMC lead investigator. The NIH PI will submit the determination letter to the proposed amendment confirming to the NIH IRB that WRNMMC's local requirements have been satisfied.

As above, NIH may implement the amended NIH research activities upon receipt of NIH IRB approval.

Post-review

Following review and approval of the amendment by the NIH IRB, the lead investigator at WRNMMC will submit the amendment approval packet to a post-review (component-level administrative review) to ensure that the human subjects research in which WRNMMC is engaged continues to be compliant with applicable DoD-specific policies and laws. This WRNMMC review will be conducted within 30 days of receiving the NIH IRB approved research protocol packet.

Once an IRB-approved amendment packet satisfies WRNMMC, an approval letter will be issued to the WRNMMC lead investigator. The NIH PI will promptly provide the approval letter to the NIH IRB. The issuance of the approval letter serves to confirm that the protocol is in compliance with DoD regulations and policies. Changes to DoD-supported research can commence once this approval letter is issued.

As above, WRNMMC may implement the amended WRNMMC research activities upon receipt of NIH IRB approval and completion of the post-review.

See Figure 2 – Flowchart for Amendment Review for NIH and WRNMMC Collaborations for an outline of the above process.

Requirements for the management of Continuing Reviews (CR)

NIH PIs should work closely with counterparts at WRNMMC to ensure that there is adequate time to collect information from the WRNMMC site, if applicable, and for the submission of materials to the NIH IRB before the Continuing Review (CR) deadline. This includes providing the lead WRNMMC investigator with a copy of the NIH IRB CR local context worksheet to facilitate the updating of information concerning local considerations (Appendix 3). When completed, this should be submitted by the NIH PI to the NIH IRB with the CR packet.

When the NIH IRB approves the CR of a protocol it should provide all documents related to the IRB's review and determination to the NIH PI. The NIH PI will provide those documents to the lead WRNMMC investigator and the DRP at WRNMMC.

On-going management of protocols

As part of ensuring safe and appropriate performance of research, the NIH has the authority to observe any aspect of the research process at WRNMMC, including observing the consent process. The NIH IRB retains the authority to request such oversight when necessary.

The OHSRP will:

- Report any suspension or termination of NIH IRB approval to OHRP, the FDA (if applicable), and the Signatory Official for WRNMMC;

- Report any unanticipated problem and/or serious or continuing noncompliance determination to OHRP, the FDA (if applicable), and the Signatory Official for WRNMMC.
- Notify WRNMMC in advance of any reporting to OHRP, the FDA and/or other oversight entities of unanticipated problems, serious or continuing non-compliance determinations, or the findings of an investigation, if WRNMMC personnel are involved.
- When feasible, NIH will provide WRNMMC the opportunity to review and comment on the report before it is sent to OHRP, the FDA or others, provided that WRNMMC provides its comments promptly.

Communications

The appropriate point of contact at NIH and WRNMMC will likely vary depending on the specific protocol under review and/ or item at issue. However, a guiding principle is that the NIH PI is the conduit for communications with the NIH and the lead investigator at WRNMMC, is the conduit for NIH communications to WRNMMC.

On a protocol-by-protocol basis, the NIH IRB local context worksheet requests the contact details of a regulatory point of contact at WRNMMC should the NIH IRB have any questions about the institution or need to request the attendance of a DoD consultant at an IRB meeting. If WRNMMC suggests that this identified point of contact may serve as a designee for the WRNMMC DRP, this should be confirmed in writing. Copies of this should be retained by the NIH PI and IRB. Additionally, the contact details of the regulatory point of contact can be updated through an administrative amendment or at the time of CR using the NIH IRB CR local context worksheet.

Further Assistance

For questions about the process outlined above or the implementation of this agreement, please contact:

Office of Human Subjects Research Protections (OHSRP)
Building 10, Room 2C-146, Bethesda, MD 20892
Main Phone: 301-402-3444
Email: ohsr_nih_ddir@od.nih.gov

If your query relates to a specific WRNMMC practice or issue, please contact:

Mr. Robert Roogow MS, CIM
Director of IRB Operations
Department of Research Programs
Walter Reed National Military Medical Center, Bethesda, MD
Direct line: 301-319-7736
Email: Robert.Roogow.civ@mail.mil

FIGURE 1 - FLOWCHART FOR INITIATING COLLABORATION BETWEEN THE NIH AND WRNMMC

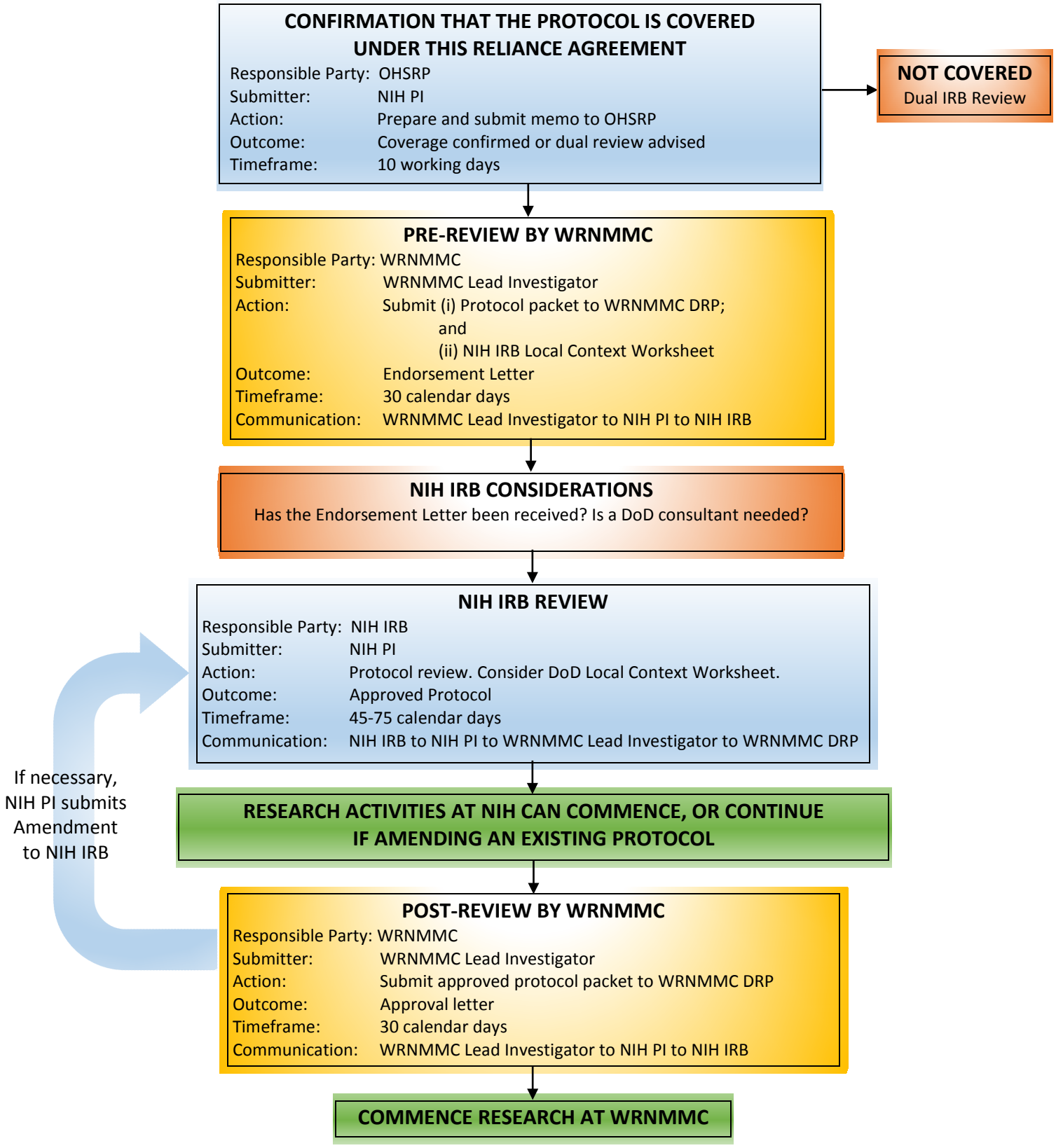
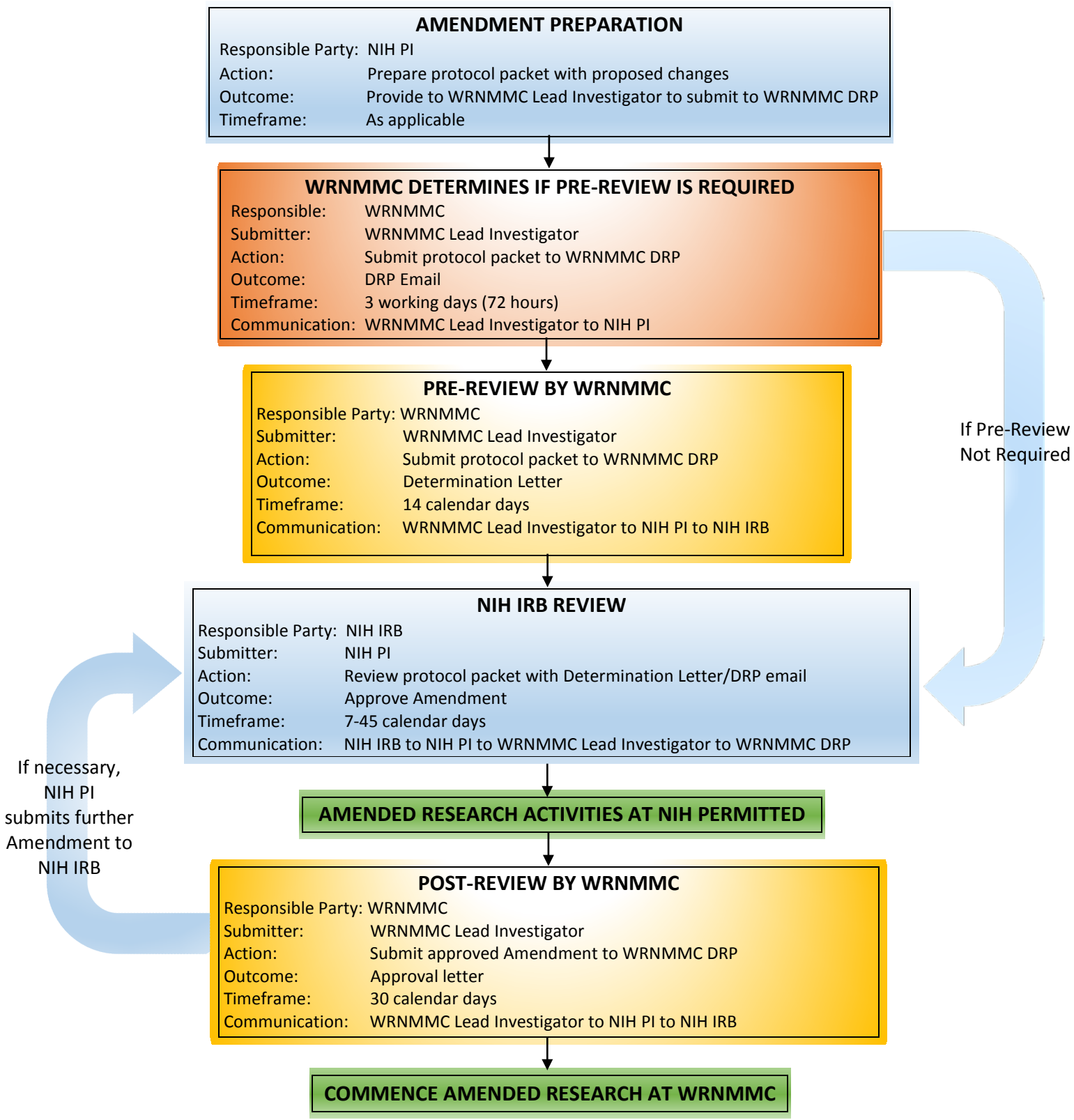


FIGURE 2 - FLOWCHART FOR AMENDMENT REVIEW FOR NIH AND WRNMMC COLLABORATIONS



APPENDIX 1 – WRNMMC PROJECT REVIEW SHEET

NOTE TO NIH PI:
This checklist outlines the requirements that will be considered in the WRNMMC Department of Research Program (DRP) Review of the protocol. Work with the WRNMMC lead investigator to ensure that the elements listed below are satisfied as far as they are able to in the protocol and provided that they do not conflict with NIH requirements. Consult with OHSRP if concerned that there is a conflict.

WALTER REED NATIONAL MILITARY MEDICAL CENTER
RESEARCH REVIEWER NEW PROJECT REVIEW SHEET

DRP Review Sheet – Version 5.0
IRBNet #_____ PI: _____
Title:_____

_____

Completed by: **Date:**

1. INVESTIGATORS *Be sure to check Training and Credentials	**YES**	**NO**	**N/A**
If funding is not available, direct the investigator to the Chief, Development Office for assistance in securing funding. If funding is not available, defer further review until secured			
a. The PI and all AIs are eligible to serve in this capacity i. Dated CV with rank and place of employment ii. Human Subjects Protections training (CITI) within 3 years iii. GCP Training if FDA regulated research			
b. COI disclosure if the study is funded by other than DoD			
c. Roles and Responsibilities information is provided			
d. Verification from credentials if non-WRNMMC billeted personnel are interacting with subjects in a clinical capacity? (check the credentials listing found on the Intranet)			
e. Signatures of AI/PI			
f. Signature of Research Monitor (if applicable)			
g. Department Chief signature			
h. Signatures from supporting services (or appropriate impact statements)			
Comments:			

2. PURPOSE AND BACKGROUND	**YES**	**NO**	**Pg**	**N/A**
a. Literature review is provided with citations				
b. Clear statement of the reason for this project (how will this further the understanding of what is being studied)				
c. Specific aims of the research are clearly stated				

d. Justification is provided for the involvement of human subjects				
Comments:				
3. METHODOLOGY	**YES**	**NO**	**Pg**	**N/A**
a. Step by step description of all activities involving human subjects i. Processes for screening and recruitment clearly outlined ii. If long term follow up is needed, all future contact methods are addressed				
b. Enrollment section clearly describes Who/What/Where/When/How				
c. Clear explanation of the frequency and duration of each research activity				
d. Screening forms, data collection forms, case report forms, questionnaires, and any other instruments are provided (Check for any possible copyright issues)				
e. Clear distinction is made between research and standard of care activities				
f. Roles and responsibilities description addresses all of the tasks presented				
g. Tissue Banking Policy is provided for non-WRNMMC facilities and Banking of Human Biological Specimen section in the protocol is completed				
Comments:				
4. CONSENT Process	**YES**	**NO**	**Pg**	**N/A**
a. Waiver/alteration of Consent				
b. Informed Consents are provided for all populations to be studied i.e. assent for minors, parental permission, consent version for controls, for optional components, LAR consent				
c. Consent Checklist is completed				
d. If study involves children, assent form included				
Comments:				
5. HIPAA DOCUMENTATION: Completed at least one of the following documents	**YES**	**NO**	**Pg**	**N/A**
a. HIPAA Authorizations that meet regulatory requirements are provided for all study participants				
b. Waiver or Alteration of HIPAA Authorization populations				
c. Required Representations for Research on Decedents Only				
d. Required Representations for Review Preparatory to Research				
Comments:				
6. RISKS AND BENEFITS	**YES**	**NO**	**Pg**	**N/A**
a. Risks are stated, accurate, and consistent with the master protocol/IB				
b. Alternative treatments or choices are discussed				

c. For more than minimal risk studies, a Research Monitor is named, current CV/CITI provided, and COI statement provided if applicable				
d. For more greater than minimal risk studies, a data monitoring plan (i.e. interim analysis, stopping rules) to protect subjects safety.				
e. Research monitor responsibilities are specified				
f. If subjects will be exposed to radiation specifically for research purposes (CT, X-ray, radioactive medication, fluoroscopy), review by radiation safety committee requested i. IBC Review is required as well				
g. If data will be shared outside the institution, AMRDEC Web Application is being used or IT has approved the SSV (Also verify that an appropriate agreement is being developed with ORTA/legal)				
h. Plans for storing and securing PHI are stated				
i. Plans for disposition or destruction of PHI (including master links) are stated				
j. Benefits to subjects are addressed (Note: compensation is not a benefit!)				
1. If **children** are subjects, and GTMR, the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches				
2. If **pregnant women** or **viable fetuses** are subjects, the risk to the fetus is caused by interventions that could benefit the woman or the fetus **or** the risk to the fetus is not greater than minimal and the purpose of the research is the development of knowledge which cannot be obtained otherwise				
3. If **fetus (not viable) outside of the uterus** is the subject, all requirements of 45 CFR 46.209 are met				
k. If being used as an 'experimental subject' per DoD definition, an intent to benefit each subject has been identified per 10 USC 980				
Comments:				
7. INVESTIGATIONAL AGENTS	**YES**	**NO**	**Pg**	**N/A**
a. FDA approval status is addressed for all medications and devices used for research				
b. Are any drugs or devices (including software) being used.				
If YES, Review the DRUG or DEVICE algorithm; is an IND/IDE required?				
c. IND required documents are provided 1572, Investigator Brochure, plans for product accountability Pharmacy impact statement				
d. IDE required documents are provided Device manual, plans for maintenance/training Medical maintenance concurrence				

e. Risk determination for device performed by sponsor, PI, or FDA as applicable				
f. If IND or IDE, a sponsor monitoring plan is in place				
Comments:				

8. FACILITIES AND RESOURCES	**YES**	**NO**	**N/A**
a. Budget information adequate to indicate the source of required funds			
b. Itemized budget for all funded projects on cost calculator			
c. Signed Impact statements are provided from any required supporting services (For example PAD, nursing, pharmacy, radiology, pathology, laboratory, recruitment locations)			
d. Letters of support from all collaborators			
e. If outside funding, ORTA (Office of Research and Technology Application) has been notified			
f. If compensation offered, requirements for on/off duty Federal employees have been addressed according to DODI 3216.02			
Comments:			
9. MISCELLANEOUS	**YES**	**NO**	**N/A**
a. Information consistent between the DMRN coversheet, CFs, Protocol			
b. Project proposal, master protocol included, if applicable			
c. Project clearly describes collaboration with another institution(s)			
d. This IRB being proposed as the IRB of record for other study sites i. if yes, is the project set up as a multicenter study in IRBNet ii. if yes, is there an IAIR in place with the engaged institution that is relying			
e. Documentation of thorough scientific review endorsed by the SRC/TBSRC Chair is provided If not, forward package to SRC workspace after admin review complete			
f. Versions are numbered and dated, pages are numbered, font is readable			
Comments:			

Overall Comments:

WALTER REED NATIONAL MILITARY MEDICAL CENTER
CONSENT FORM CHECK LIST

Project # _____ PI: _____

ARE THE FOLLOWING STATEMENTS PRESENT ON THE INFORMED CONSENT?	YES	NO	N/A
1. Statement that the study involves research.			
2. Statement that participation is voluntary and that refusal to participate will involve no loss of benefits to which the subject is otherwise entitled			
3. Explanation of the purpose of the research in understandable lay terms as well as the rationale for conducting the study			
4. Expected duration of the subject's participation.			
5. Description of the procedures to be followed (Identification of procedures or medications which are experimental or above standard of care) in understandable lay terms			
6. Approximate number of subjects to be involved in the project.			
7. Description of any reasonably foreseen risks or discomforts to the subject in understandable lay terms			
8. Description of any benefits to the subject or to others which may reasonably be expected from the research in understandable lay terms.			
9. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject in understandable lay terms.			
10. Statement indicating whether a Certificate of Confidentiality has been obtained, if applicable			
11. Statement describing the manner in which identifiable records will be secured, stored and destroyed			
12. Statement noting the possibility that the Food and Drug Administration and other DoD and Federal Agencies may inspect the records (if applicable.)			
13. Explanation as to whether any compensation and an explanation if medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. (required for GTMR studies)			
14. Explanation of who to contact for answers to pertinent questions about a) the research (PI, study team) b) research subject's rights (HPA, DRP) c) research-related injury to the subject (SJA)			

15. Statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.			
16. Consequences of loss of DoD health care beneficiary status.			
17. Consent addresses banking/storage of specimens, as applicable			
18. Consent addresses future use			
19. Consent addresses genetic testing, as applicable. Restrictions of GINA law to military personnel is addressed			
When appropriate, one or more of the following elements of information shall also be provided to each subject:	**YES**	**NO**	**N/A**
1. If required by the FDA, does the consent state "a description of this clinical trial will be available on , as required by U.S. Law Examples include FDA regulated trials of drugs and biologics (i.e. other than phase I trials), trials of devices (i.e. pediatric post-market surveillance)			
2. Is a statement added that already collected data about the subject will be retained and analyzed until the study closes even if the subject chooses to withdraw from the research if the data is necessary to maintain the integrity of the study			
3. Statement that the particular treatment or procedures may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable.			
4. Is information included on how to avoid pregnancy or for how long after the study to prevent pregnancy?			
5. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.			
6. Additional costs to the subject that may result from participation in the research.			
7. If compensation is offered, considerations related to compensating on/off duty Federal employees (including Active Duty Military) have been addressed			
8. Consequences of a subject's decision to withdraw from the research and procedures for orderly conclusion of participation by the subject.			
9. 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.			
10. Statement that the possibility of blood/tissue samples may have commercial value.			

11. Statement that blood/tissue samples are being stored for future research use			
12. Statement that explains prospect of benefit to a vulnerable subject population if GTMR.			

ARE THE FOLLOWING CORE ELEMENTS AND STATEMENTS PRESENT IN THE HIPAA AUTHORIZATION?	**YES**	**NO**	**N/A**
1. Description of PHI to be used or disclosed (identifying the information in a specific and meaningful manner)			
2. A statement indicating the specific identification of the person or class of persons within the MHS that the individual authorizes to make the requested use or disclosure			
3. The name(s) or other specific identification of the person(s) or class of person to whom the MHS may make the requested use or disclosure			
4. A description of each purpose of the requested use or disclosure that is study specific and/or that is a reasonable description of any use or disclosure of PHI for future studies, including a description of the person or class of persons who may receive the PHI for future research studies.			
5. Authorization expiration date or event that relates to the individual or to the purpose of the use or disclosure (the terms “end of the research study” or “none” may be used for research, including for the creation and maintenance of a research database or research repository).			
6. Signature of the individual and date			
7. If the Authorization is signed by an individual’s personal representative, a description of the representative’s authority to act for the individual			
8. The individual’s right to revoke his/her Authorization in writing and either (1) the exceptions to the right to revoke and a description of how the individual may revoke the Authorization or (2) reference to the corresponding section(s) of the MHS’s Notice of Privacy Practices			
9. Notice of DoD’s ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the Authorization, including research-related treatment, and if applicable, any consequences of refusing to sign the Authorization			
10. The potential for the PHI to be re-disclosed by the recipient and no longer protected by the HIPAA Privacy Rule. This statement does not require an analysis of risk for re-disclosure; rather, it may be a general statement that the HIPAA Privacy Rule may no longer protect health information			
11. If the authorization is for research related treatment, there is an opt-in provision for using PHI for other types of research activities			

involved in the study. (Other research activities may be creating a database or future studies).			

APPENDIX 2 – NIH IRB INITIAL REVIEW LOCAL CONTEXT WORKSHEET

Please complete a copy of this worksheet for each relying institution. This form should be completed by the Site Principal Investigator (PI)/Lead Investigator with the local context representative. The local context representative is typically an individual with knowledge of the institutional human research protection program and its policies as well as state and local law. Answers pertain to the implementation of the protocol named below at your institution.

Date of Submission: _____ (DD/MM/YY)

Site PI/ Lead Investigator	
Protocol Title	
Protocol #	
Institution Relying on NIH for IRB Review (signatory institution):	
Local Context Representative	
Title of Local Context Representative	
Attestation by Site PI/Lead Investigator	I attest to the accuracy of the responses provided below and to having confirmed these with the Local Context Representative listed above. _____ _____ Site PI/ Lead Investigator signature Date

☐ The Endorsement Letter from your institution is attached confirming that pre-review has taken place and that the research protocol packet meets all applicable DoD requirements.

SUBJECT SELECTION

1. Does the selection and recruitment process for this protocol comply with local laws and your institutional policies?
   ☐ Yes
   ☐ No *(If no, please attach an explanation to this form.)*

2. Do you find the selection and recruitment methods in this protocol acceptable in the context of your local area?
   ☐ Yes

☐ No *(If no, please attach an explanation to this form.)*

3. Is there anything else the NIH IRB should know about the anticipated study population at your institution?
   ☐ Yes *(If yes, please attach an explanation to this form.)*
   ☐ No

VULNERABLE POPULATIONS

4. Check all vulnerable populations from which you intend to enroll in this protocol. Will there be vulnerable groups among the study population?
   ☐ Children
   ☐ Pregnant women, human fetuses, and neonates
   ☐ Prisoner
   ☐ Adults with impaired decision making capacity
   ☐ Emancipated minors, mature minors
   ☐ Wards of the state
   ☐ Other special populations. An example may include enrolling employees of the relying institution as research subjects. Please describe:

5. Will non-English speakers be enrolled?
   ☐ Yes
   ☐ No *(If no, please attach an explanation to this form.)*

INFORMED CONSENT PROCESS

6. Does the consent/assent process for this protocol comply with local laws and your institution's consent policies?
   ☐ Yes
   ☐ No *(If no, please attach an explanation to this form.)*

7. Do the consent/assent documents (and/or waiver of consent of documented consent) for this protocol comply with local laws and your institution's policies regarding informed consent?
   ☐ Yes
   ☐ No *(If no, please attach an explanation to this form.)*

8. According to the protocol, who will provide consent or parental permission? *(check all that potentially apply)*
   ☐ Potential study participant
   ☐ Parent of potential pediatric study participant
   ☐ Legally Authorized Representative (LARs)
   ☐ Other: Please describe:

9. If non-English speakers will be enrolled, describe how the recruitment and informed consent process will be conducted? *(If applicable, an attachment may be added e.g. copy of the relevant institutional policy.)*

COMPENSATION

10. Will you provide compensation to participants enrolled in this protocol?
    - ☐ Yes
    - ☐ No *(If no, please attach an explanation to this form.)*

11. Is the participant compensation described in the protocol consistent with local laws and your institution's policies?
    - ☐ Yes
    - ☐ No *(If no, please attach an explanation to this form.)*

PRIVACY AND CONFIDENTIALITY

12. Are the privacy and confidentiality provisions of the protocol consistent with the resources and practices available at your institution?
    - ☐ Yes
    - ☐ No *(If no, please attach an explanation to this form.)*

13. Are the privacy and confidentiality provisions of the protocol consistent with local laws, institutional policies, and HIPAA (if applicable)?
    - ☐ Yes
    - ☐ No *(If no, please attach an explanation to this form.)*

14. Are there any other sections of the protocol which are inconsistent with local laws or your institution's policies?
    - ☐ Yes *(If so, please attach an explanation to this form.)*
    - ☐ No

COMMUNITY DESCRIPTORS

15. Given the nature of this particular research study, are there any additional factors particular to this study site or the community (community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area?
    - ☐ Yes *(If so, please attach an explanation to this form.)*
    - ☐ No

16. Does the community have a positive attitude toward the conduct of research?
    - ☐ Yes
    - ☐ No *(If no, please attach an explanation to this form.)*

STATE AND LOCAL LAW

17. List the states from which you will be recruiting and provide the age of majority for each state. (*If applicable, an attachment may be added.)*

18. If consent will be provided by LARs, describe your state and local law, and corresponding institutional policy regarding LARs. Describe who may serve as an LAR according to state laws and institutional policies. (*If applicable, an attachment can be added.)*

19. If children or adults who are decisionally impaired will be enrolled, describe your state, local, and corresponding institutional policies regarding assent by children or adults who are unable to provide consent. (*If applicable, an attachment can be added.)*

20. If mature or emancipated minors will be enrolled, please describe the circumstances under which they will be able to provide consent to their own participation and describe any applicable state, local, and institutional policies.

21. If wards of the state or other special populations (child or adult) will be enrolled, describe any applicable state, local, or institutional policies if they have requirements that go beyond what is required in the corresponding subparts of 45 CFR 46. (*If applicable, an attachment can be added.)*

22. What are the other state and local laws that govern the conduct of research at your institution? (*If applicable, an attachment can be added.)*

ADDITIONAL INFORMATION

23. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research. (*If applicable, an attachment may be added.)*

24. a. Describe how the relying institution gathers and evaluates the PI and research staff for financial conflicts of interest. (*If applicable, an attachment may be added.)*

    b. Confirm that the applicable COI policy has, and will be, followed for the protocol in question, during the entire time period (initial review, continuing review, amendments) that an NIH IRB will be the IRB of Record.

    ☐ Yes

☐ No *(Individuals not in compliance with local COI requirements may not participate in the protocol being reviewed by the NIH)*

c. Please describe your institution's requirements for human subjects protections training for PIs and other staff engaged in research.

a. Confirm that the investigators involved in the research are in compliance with local training requirements.

☐ Yes
☐ No *(If so, please attach an explanation to this form.)*

d. Provide the boilerplate language that is specific to your institution. This is standard language required by your institution that is added to the research-specific text of an informed consent document, such as: birth control language, coverage of research injury, required phone numbers for the PI or study representative, and a person unaffiliated with the study who can answer general study questions, etc. (*If applicable, an attachment may be added.)*

e. Provide the institutional letterhead used for the informed consent document. (*If applicable, an attachment may be added.)*

f. Provide any other institutional requirements for informed consent documents. For example, if the relying institution has identified a conflict of interest, does the relying institution's management plan require a change in the informed consent document? *(If applicable, an attachment may be added.)*

g. Is there anything else the NIH IRB should know about the institution's local context or institutional policies?

☐ Yes
☐ No

h. Confirm that the institution has the adequate training, experience, facilities and resources to conduct the proposed research procedures. (*If applicable, an attachment may be added.)*

☐ Yes
☐ No

i. If the IRB has any questions, please identify the regulatory point of contact at your institution:

Name:
Title:
Phone number:
Email:

j. Add any additional comments that will help the NIH IRB in its review process: (*If applicable, an attachment may be added.)*

APPENDIX 3 - NIH IRB CONTINUING REVIEW LOCAL CONTEXT WORKSHEET

Please complete a copy of this worksheet for each relying institution. This form should be completed by the Site PI/ Lead Investigator with the local context representative. The local context representative is typically an individual with knowledge of the institutional human research protection program and its policies as well as state and local law. The topics listed below reflect those asked on the Initial Review Local Context Worksheet that was previously submitted for the protocol named below. Indicate for each topic whether or not there are changes from the information previously provided. If there are changes, please describe. Attachments in support of changes may be added.

Date of Submission: _____ (DD/MM/YY)

Site PI/ Lead Investigator	
Protocol Title	
Protocol #	
Institution Relying on NIH for IRB Review (signatory institution):	
Local Context Representative	
Title of Local Context Representative	
Attestation by Site PI/Lead Investigator	I attest to the accuracy of the responses provided below and to having confirmed these with the Local Context Representative listed above. _____ _____ Site PI/Lead Investigator signature Date

1. **SUBJECT SELECTION** (Questions 1-3 on the NIH IRB Initial Review Local Context Worksheet)
   - ☐ No change
   - ☐ Changed

   If changed, please describe:

2. **VULNERABLE POPULATIONS** (Questions 4-5 on the NIH IRB Initial Review Local Context Worksheet)
   - ☐ No change
   - ☐ Changed

If changed, please describe:

3. **INFORMED CONSENT PROCESS** (Questions 6-9 on the NIH IRB Initial Review Local Context Worksheet)

☐ No change
☐ Changed

If changed, please describe:

4. **COMPENSATION** (Questions 10-11 on the NIH IRB Initial Review Local Context Worksheet)

☐ No change
☐ Changed

If changed, please describe:

5. **PRIVACY AND CONFIDENTIALITY** (Questions 12-14 on the NIH IRB Initial Review Local Context Worksheet)

☐ No change
☐ Changed

If changed, please describe:

6. **COMMUNITY DESCRIPTORS** (Questions 15-16 on the NIH IRB Initial Review Local Context Worksheet)

☐ No change
☐ Changed

If changed, please describe:

7. **STATE AND LOCAL LAW** (Questions 17-22 on the NIH IRB Initial Review Local Context Worksheet)

☐ No change
☐ Changed

If changed, please describe:

8. **ADDITIONAL INFORMATION** (Questions 23-32 on the NIH IRB Initial Review Local Context Worksheet)

☐ No change
☐ Changed

If changed, please describe:

9. If the regulatory point of contact has changed at your institution, please update below:
   Name:
   Title:
   Phone number:
   Email: