



Policy	P15
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Created:	September 2, 2011
Edited	
Version	P15.1

Utilizing the NCI CIRB

PURPOSE - The purpose of this Standard Operating Procedure (SOP) is to outline the procedures for utilization of the National Cancer Institute's (NCI) Central Institutional Review Board (CIRB) using facilitated review. *Facilitated Review* is the process by which the WSU IRB reviews a proposed study from the local context, decides if it is appropriate for referral to the CIRB, and then oversees local performance, which includes the review of the protocol and all documents given to local study participants, as well as monitoring of all local unanticipated problems and serious adverse events. The NCI CIRB was designed to 1) improve access to NCI-sponsored Cooperative Group clinical trials for potential study participants and their physicians by enabling local IRBs to rapidly approve clinical trials through the use of a facilitated review process; 2) enhance the protection of study participants by providing consistent expert IRB review at the national level; and 3) reduce the administrative burden for local IRBs and research staff. Since Wright State University has completed enrollment in the CIRB Initiative by submitting a completed CIRB Application, submitting two signed Authorization Agreements, and including the CIRB on the Institution's FWA, the WSU IRB and investigators may take advantage of the CIRB's reviews.

POLICY - It is the policy of the WSU IRB to perform a facilitated review of NCI-sponsored Cooperative Group studies approved through the NCI CIRB in which the Dayton Clinical Oncology Group (DCOP) wishes to participate. The IRB will decide on an individual study basis whether to accept the CIRB review or to perform full IRB review of the study.

RESPONSIBILITY – If the CIRB's review is accepted, the CIRB becomes the IRB of Record for the study and is responsible for reviews of amendments, continuing reviews, review of adverse events distributed by the Cooperative Group coordinating the study, and review of information distributed by the Cooperative Group coordinating the study intended for use by current or prospective study participants. The WSU IRB will maintain responsibility for consideration of local context and oversight of local performance for these studies (including local serious adverse events and unanticipated problems).

PROCEDURE FOR INITIAL REVIEW

When DCOP wishes to open a Cooperative Group clinical trial that has been approved by the NCI CIRB, the following steps must be followed to conduct a facilitated review:

- A. DCOP staff will submit one hard (paper) copy and one e-mail copy of the study protocol obtained from the CIRB Website (www.ncicirb.org) to the WSU IRB
- B. In addition to the study information from the CIRB website, DCOP will also submit the following:
 1. WSU IRB petition for facilitated review of research
 2. DCOP-specific consent document (containing DCOP/WSU-specific boilerplate information and HIPAA Authorization language)

- C. All new CIRB protocols listed for review will have a facilitated review performed by the WSU IRB chair, vice-chair, or another member of the WSU IRB. The reviewer will consider local context issues when reviewing the study and informed consent document.

Local context issues include, but are not limited to: local and state laws; institutional policies; local investigator credentials; and demographics/cultural issues of the local population. Minor word substitutions and/or additions to the informed consent document to aid in comprehension by the local population are permitted so long as the changes do not alter the meaning of the text. **These should be avoided unless they are clearly necessary.** Deletions are not allowed. If the reviewer requires text changes that alter the meaning of the text, the protocol will require full board review by the WSU IRB, facilitated review may not be used, and the CIRB cannot serve as the IRB of record for the protocol at the local site.

- D. The reviewer shall determine whether to accept the CIRB review of the study or whether to require that the study be submitted for full review by the WSU IRB. Results of the review will be recorded on the WSU IRB Facilitated Review Form (see form at end of procedure). Reviewer comments, if any, and the decision to either accept or not accept the CIRB review shall be sent to the IRB Coordinator via email within 7 business days of review.
- E. The WSU IRB Coordinator will notify the CIRB Administrative Office of facilitated review acceptance via the website within 24 hours of notification of the reviewer's decision. The WSU IRB coordinator will also communicate the decision to DCOP. If modifications are requested, these will be communicated to DCOP by the WSU IRB coordinator. Once the requests for modification have been addressed by DCOP, the WSU IRB Coordinator will notify the CIRB Administrative Office of facilitated review acceptance.
- F. The IRB Coordinator will list the study on the upcoming IRB agenda in the "IAA/Facilitated Review" category. Studies designated for full IRB review will be listed on the following month's agenda for such review.
- G. The expiration date of CIRB studies will be the CIRB expiration date.
- H. For CIRB studies accepted by the IRB, the CIRB will become the IRB of record for the protocol, and the CIRB will be responsible for continuing review as well as review of subsequent amendments and non-local, serious adverse events as notified by the cooperative group.
- I. Documentation of the facilitated review acceptance by the IRB Reviewer of a new CIRB study will be noted in the IRB minutes.
- J. A copy of the documents (Petition, DCAP Consent, and study protocol) and review sheet will be maintained in the IRB study file (along with any later submitted reports of local serious adverse events or unanticipated problems).

PROCEDURE FOR CONTINUING REVIEW OF A CIRB-APPROVED STUDY

The CIRB conducts continuing review for all studies on its menu. The WSU-IRB does not have to conduct a continuing review for studies for which the CIRB is the IRB of record.

PROCEDURE FOR AMENDMENT REVIEW OF A CIRB-APPROVED STUDY

The CIRB reviews amendments for all studies on its menu. Amendments to a CIRB-approved study will not be reviewed by the WSU-IRB. When changes in an amendment include changes in the informed consent document, the investigator/research staff will submit one copy of the updated informed consent document to the WSU-IRB for date stamping.

PROCEDURE FOR SERIOUS ADVERSE EVENT REVIEW

Serious adverse events or unanticipated problems that do not involve study participants from DCOP should not be submitted to the WSU IRB. Serious adverse events or unanticipated problems involving a study participant from this Institution should be submitted and reviewed in the usual manner per WSU Standard Operating Procedures.

TRANSFER OF STUDIES CURRENTLY APPROVED BY LOCAL IRB TO CIRB

Cooperative Group studies currently approved by WSU IRB may be transferred to the CIRB. The following process will be followed to transfer the protocols.

1. Notice of intent to refer a currently approved study will be sent to the WSU IRB with a request for facilitated review.
2. A facilitated review of the study will be performed by the IRB Chair or designee using the materials already available in the IRB folder for the study.
3. If the review indicates that the study may be transferred to the CIRB, the WSU IRB Coordinator will notify the CIRB via the website as described above.
4. The IRB Coordinator will document the transfer in the WSU protocol study file.
5. Any currently enrolled study participants will NOT need to be reconsented.

LOCAL CLOSURE OF CIRB STUDIES

Should DCOP desire to close a study currently active through the CIRB, they will notify the WSU IRB Administrator by memo of their intention (note: this is most likely to be done if there has been no enrollment in a study and it appears unlikely that patients will be enrolled). The WSU Administrator will inform the CIRB of the desire to close the study locally.

Wright State University-Specific Language for NCI Protocols

The following wording has been suggested for consent documents that will be undergoing facilitated review for the NCI Central IRB. This language does not need to be used in every protocol, but has been approved for use when appropriate.

Purpose	Suggested Wording or Formatting
Identification of the local PI and site. To follow title on consent document	Principal Investigator: Howard M. Gross, M.D. <i>(or other name as appropriate for study)</i> Sites: Dayton Clinical Oncology Program (DCOP) and Affiliates
Identification of reproductive risks (standard statement)	Reproductive Risks: You should not become pregnant <i>(or father a baby nor donate sperm)</i> while on this study or during the first 3 months after the completion of therapy because the drugs <i>(add “and radiation” if appropriate)</i> in this study can affect an unborn baby. Some of the drugs <i>(add “and radiation” if appropriate)</i> used in the study may make you unable to have children in the future. If you are capable of becoming pregnant <i>(or fathering children if appropriate)</i> you must discuss your pregnancy plans with the study doctors before enrolling in the study; you must also agree that you will not become pregnant <i>(or father a baby)</i> while you are receiving treatment in this study. When you have completed treatment on this study, discuss with your doctor when it might be safe to become pregnant <i>(or father a baby)</i> . Abstinence (not having sex) is the only thing that is completely effective in preventing pregnancy.
HIPAA and Confidentiality Information (example)	<p>The United States Government has issued a privacy rule to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Privacy Rule is designed to protect the confidentiality of your personal health information. This portion of the consent document you are reading, called an “Authorization”, describes your rights and explains how your health information will be used and disclosed (shared).</p> <p>In working with the sponsor, the study doctor will use and share personal health information about you. This is information about your health that also includes you name, address, telephone number or other facts that could identify the health information as yours. This includes information in you medical record and information created or collected during the study. This information may include your medical history, physical exam and laboratory test results. Some of these tests may have been done as part of your regular care. The study doctor will use this information about you to complete this research. <i>(note; modify this section as needed to include the protected health information that is being used during the study).</i></p> <p>In most cases, the study doctor will use your initials and assign a code number to your information that is shared with the sponsor. The sponsor and its representatives may review or copy your personal health information at the study site. Regulatory authorities</p>

	<p>and the Wright State University Institutional Review Board (IRB) may also review or copy your information to make sure that the study is done properly or for other purposes required by law.</p> <p>By signing this consent document, you allow the study doctor to use your personal health information to carry out and evaluate this study. You also allow the study doctor to share your personal health information with: <i>(list appropriate agencies or groups for study)</i>.</p> <p>Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, these groups are committed to keeping your personal health information confidential. Nonetheless, complete confidentiality cannot be guaranteed.</p> <p>You have the right to see and get a copy of your records related to the study for as long as the study doctor has this information. However, by signing this consent you agree that you might not be able to review or receive some of your records related to the study until after the study has been completed.</p> <p>You may choose to withdraw this Authorization at any time, but you must notify the study doctor in writing. Send your written withdrawal notice to: Howard M. Gross, M.D. Dayton Clinical Oncology Program 3123 Research Blvd., Suite 150 Dayton, OH 45420 Daytime Telephone Number: 937-775-1350</p> <p>If you withdraw from the study and withdraw your Authorization, no new information will be collected for study purposes unless the information is needed to preserve the scientific integrity of the study or concerns an adverse event (a bad effect) related to the study. If an adverse event occurs, your entire medical record may be reviewed. All information that has already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the study sponsor.</p> <p>If you withdraw from the study, but do not withdraw your Authorization to use your protected health information, new personal health information may be collected until this study ends.</p> <p>This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. Your study doctor will keep this authorization for at least 6 years.</p> <p>If you do not sign this consent (which contains this Authorization), you cannot participate in this research study or receive study-related</p>
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	<p>treatment. If you withdraw this Authorization in the future, you will no longer be able to participate in this study. Your decision to withdraw your Authorization or not to participate will not result in any penalty or loss of access to treatment or other benefits to which you are entitled.</p> <p>By signing this consent you grant the Dayton Clinical Oncology Program (DCOP) permission to copy all your medical records and to gather information pertinent to this research protocol in-line with federal guidelines.</p>
Local information for participants' questions about the research or their rights as a research subject.	You can contact Sidney Pinkus at the Dayton Clinical Oncology Program (937-775-1351) or Howard M. Gross (937-832-1093) or, after hours at 937-223-0990, for answers to questions about the research, research subject's right and research related injury. In addition, you may contact the IRB Coordinator, Institutional Review Board, Wright State University at 937-775-4462, for information regarding patient's rights in research studies..
GINA statement (for research involving genetic studies)	A federal law (Genetic Information Non-Discrimination Act, GINA) will help lower the risk from health insurance or employment discrimination on the basis of genetic information. The federal law does not include other types of misuse by life insurance, long-term care or disability insurance. If you want to learn more about the GINA Law, you can find information about it on the internet or ask the study staff. In addition to the federal law, some states have laws that also help protect against genetic discrimination.

Wright State University Facilitated Review Checklist FRSP # _____

Reviewer Name _____ Date _____

Instructions to reviewer: This DCOP study is receiving WSU facilitated review to allow the NCI CIRB to become the IRB of record for the study. WSU will retain responsibility for overseeing local performance of the study, including serious adverse events and unanticipated problems. WSU must also determine if there are local factors that may affect the decision to allow the CIRB to become the IRB for this study. Local context issues include, but are not limited to: local and state laws; institutional policies; local investigator credentials; and demographics/cultural issues of the local population.

During your review, **changes to the informed consent should be avoided if possible**. Minor word substitutions and/or additions to the informed consent document to aid in comprehension by the local population are permitted so long as the changes do not alter the meaning of the text. Deletions are not allowed. If you, as the reviewer, require text changes that alter the meaning of the text, the protocol will require full board review by the WSU IRB, facilitated review may not be used, and the CIRB cannot serve as the IRB of record for the protocol at the local site.

For the facilitated review, please indicate the following:

_____ The CIRB study protocol was included in the packet

_____ The DCOP informed consent was included and reviewed. Appropriate local information was included (e.g. WSU IRB contact information for questions about rights as a research subject, information about who to contact with questions about the research or research-related injuries etc.)

_____ The DCOP-specific HIPAA consent information was included as a part of the consent document and was reviewed

_____ The WSU petition for facilitated review research was included and was reviewed

Please indicate any modifications that are required on the DCOP consent or WSU petition for research.

Please indicate if there are any concerns related to local context that need to be addressed in any of the documents

Recommended Action:

_____ Acceptance (CIRB may become the IRB for this study)

_____ Acceptance with modifications listed above

_____ Rejection (the protocol must be submitted to the WSU IRB for full review)

**Petition for Facilitated Review and Approval of NCI CIRB Research from DCOP
Wright State University Office of Research and Sponsored Programs**

Date:

For RSP use only

IRB Assignment Number:

Title of Research Project:

☐ Check here to indicate that Principal Investigators/Advisor (exempt protocols) or all investigators/advisor (expedited and full board) have completed the required human subjects protection training offered by Collaborative Institutional Training Initiative (CITI)—see <http://www.citiprogram.org/> and IRB Policy P.5. (found in the IRB Standard Operating Procedures at http://www.wright.edu/rsp/IRB/irb_charter.html).

RISK ASSESSMENT:

1. Does the study involve any risk to the subjects? Examples of risks/discomforts include: dizziness, nausea, embarrassment, social stigma (shame or disgrace), psychological distress, loss of employment, invasion of privacy and breach of confidentiality. ☐ Yes ☐ No

If yes:

- a. Indicate where these risks are described in the protocol and consent form/cover letter.
- b. Are the risks/discomforts reasonable in relation to anticipated benefits (if any)? ☐ Yes ☐ No
- c. Indicate how risks to subjects have been minimized where possible. For example:
 - ☐ Subjects have received 24-hour emergency phone numbers
 - ☐ More frequent health exams or diagnostic tests are being performed to monitor for known or anticipated risks
 - ☐ Emergency equipment is available for use if needed
 - ☐ Specimens/samples already collected for standard treatment are used for research purposes whenever possible
 - ☐ Other (please specify)

SAFETY MONITORING:

A plan for data safety monitoring should be provided in any situation in which participants might be at greater than minimal risk of harm, including when a drug or device is being tested for safety or effectiveness for marketing approval, or in placebo-controlled trials, or when marketing drugs are being tested for another indication or compared for safety or effectiveness. A plan is required for all clinical trials, including the development or evaluation of clinical laboratory tests (e.g. imaging or diagnostic tests) if the test will be used for medical decision-making for the subject, or if the test itself imposes more than minimal risk for subjects. Guidelines regarding drafting this plan can be found in Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, of the U.S. Department of Health and Human Services Public Health Service Grant Application (PHS 398) instructions at < <http://grants.nih.gov/grants/forms.htm>>.

2. Does the protocol require a safety data monitoring plan? ☐ Yes ☐ No. If yes:

- a. Will the research be monitored by a Data Safety Monitoring Board? ☐ Yes ☐ No
- b. If no, please explain how safety will be monitored
- c. Will all local serious adverse events and unanticipated problems be reported promptly to the WSU IRB?
☐ Yes ☐ No

3. When applicable, will medical or psychological resources be made available to participants after their completion of the study, if the research produces consequences in which these services are required? ☐ Yes ☐ No ☐ N/A.

CONFIDENTIALITY AND PRIVACY:

4. Indicate the procedure for assuring confidentiality of the data (e.g. responses kept in locked safe, restricted access to information, etc.) or for assuring the anonymity of the subjects (e.g. no names on instrument(s), no personal identifiers linked to instrument(s), no in-person interviews/videos, etc.) Please note that student investigators must store study records or data in a Wright State location (i.e. not at home). ☐

5. Indicate the procedure for assuring that method(s) used during data collection protect the privacy of the participants (for example, recruitment, obtaining of consent, or obtaining of data will be done in a private location or manner). Note: this does not refer to the confidentiality of the data. ☐

6. Does the protocol involve immediate or future testing of genetic material and/or pedigree studies?

☐ Yes ☐ No

If yes, standard wording must be added to the consent document that cautions prospective subjects about the hazards of identifiable genetic findings toward future insurability and/or employability. See suggested wording in "Cover Letter/Consent Form Guidelines" (http://www.wright.edu/rsp/IRB/Consent_Guide.doc). In addition, wording should be added indicating compliance with the Genetic Information Nondiscrimination Act (GINA). See <http://www.wright.edu/rsp/IRB/GINA.pdf> for further information. Has appropriate wording been added to the consent document? ☐ Yes ☐ No If No, provide further information. ☐

7. Have adequate safeguards been taken to protect against identifying, directly or indirectly, any individual subject in any report of the research project? ☐ Yes ☐ No If No, provide further information. ☐

8. If identifiable medical information is being collected, indicate agreement to follow the HIPAA requirements published in the "Cover Letter/Consent Form Guidelines" (see http://www.wright.edu/rsp/IRB/Consent_Guide.doc). ☐ Yes ☐ No ☐ N/A

If no, is a waiver of the HIPAA privacy rule being requested? (Note: this is most commonly requested with studies limited to chart review) ☐ Yes ☐ No

If a waiver is being requested, all of the following questions must be completely answered:

- a. Explain why the research cannot reasonably be conducted without the waiver of authorization. ☐
- b. Explain why the research cannot reasonably be conducted without access to and use of identifiable health information. ☐
- c. Briefly describe the PHI (Protected Health Information) for which use and/or disclosure has been determined necessary. ☐
- d. Describe the reasonable safeguards to protect identifiable information from unauthorized use or re-disclosure. ☐
- e. Describe the reasonable safeguards to protect against identification, directly or indirectly, any patient in any report of the research. ☐
- f. Describe the plan to destroy the identifiers at the earliest opportunity, consistent with the research. If there is a health or research justification for retaining identifiers, or if the law requires you to keep such identifying information, please provide this information as well. ☐

- g. Provide written assurance that identifiable information will not be reused/disclosed to any other person or entity, unless such use is required by law, for oversight of the research study, or for other research permitted by law. ☐
9. Will a Certificate of Confidentiality be requested from NIH? ☐ Yes ☐ No
- a. If yes, does the Consent Form advise the subjects of situations where the PI may voluntarily comply with state laws? ☐ Yes ☐ No
- b. If yes, has the standard confidentiality statement been modified to be consistent with Confidentiality Certificate protections? See <http://grants.nih.gov/grants/policy/coc/index.htm>. ☐ Yes ☐ No

STUDY SITE RESOURCES:

10. Please describe how the study will be locally administered by answering the following questions.
- a. State where you will be conducting the research study (e.g. Wright State University (WSU), Good Samaritan Hospital (GSH), etc.). Include the address for any site not affiliated with WSU
- Name of site(s): ☐
 - If other than WSU, Dayton Clinical Oncology Program (DCOP) or hospital facility, describe the facility where the study will be conducted ☐
- b. How will the PI ensure that all research staff for the study are adequately informed of the research-related duties and functions? ☐
- c. Are there adequate resources to complete the research study? ☐ Yes ☐ No
- d. Is there access to a population that will allow recruitment of the required number of participants?
☐ Yes ☐ No If no, explain how subjects will be recruited in item 17., below.

RECRUITMENT:

11. Will this research study recruit any subjects from the following “Vulnerable” categories? Check all that apply.

- ☐ Cognitively Impaired
- ☐ Fetuses
- ☐ Pregnant Women
- ☐ Prisoners
- ☐ Healthy Volunteers (applies only to more than minimal risk protocols)
- ☐ Others vulnerable to coercion (e.g. employee of research site or sponsor, students of investigator).

Describe:

☐

- ☐ Minors (<18 years of age)

For research involving minors, please indicate which of the categories listed below accurately describes this protocol (refer to the appropriate section of 45CFR46, Subpart D)

- ☐ Not involving greater than minimal risk (46.404)
- ☐ Involving greater than minimal risk but of direct benefit to individual subjects (46.405)
- ☐ Involving greater than minimal risk, no direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject disorder or condition (46.406)
- ☐ Involving research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of minors (46.407)

12. Describe the population from which the researcher will recruit (or data source from which data will be obtained): ☐. Note: if subjects are being recruited at a non-WSU site (e.g. local schools, prisons etc.) provide a copy of the permission to use that site signed by an institutional official, or, equivalently, approval from their IRB.

13. How will participants be recruited for this study? Attach copies of any materials given to prospective subjects and/or scripts of any oral communication used to recruit subjects.

14. What type of advertising will be used for this study? Check all that apply.

Note: If an advertisement is to be used, WSU policy requires prior written approval from the PI's department chair and dean. A copy of the advertisement with approval of the chair or dean must be submitted with this application for IRB review.

☐ No advertising will be used

☐ Newspaper

☐ Poster

☐ Brochure

☐ Web Site

☐ Patient Recruitment Letter

☐ Internet

☐ E-mail

☐ Radio or TV (script)

☐ Other (describe)

15. State the approximate expected number and age range of participants to be enrolled. List each group, arm, cohort, etc. if applicable, including control groups, on separate lines. If only one group, description would be "All." Check "N/A" if the only data used in the study will come from a previously existing, deidentified data source. N/A ☐ (Note: This applies to exempt studies only)

Group	NUMBER OF SUBJECTS						AGE RANGE OF SUBJECTS					
	All sites for which you are the PI			All other sites			All sites for which you are the PI			All other sites		

- a. Are subjects who might otherwise benefit from the research excluded from participation?
☐ Yes ☐ No. If yes, provide scientific and ethical reasons for excluding these subjects
.
- b. Is the subject population representative of the population base from which subjects could be selected with respect to gender representation (see NIH guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).
☐ Yes ☐ No. If no, please explain. .
- c. Is the subject population representative of the population base from which subjects could be selected with respect to minority representation (see NIH guidelines at http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).
☐ Yes ☐ No. If no, please explain. .

16. Will subjects be paid or otherwise compensated? ☐ Yes ☐ No ☐ N/A. If yes:

- a. What is the amount of the compensation?
- b. If not monetary, what will be used for compensation?
- c. What is the reason for compensation?
- d. If subjects are to be remunerated, indicate how this remuneration will be prorated over the course of their participation.

17. Will the research involve the intentional use, of or introduction into, subjects of:

- a. Biohazards (e.g. rDNA, microorganisms, biological toxins) requiring approval by the Institutional Biosafety Committee?

- ☐ Yes ☐ No
- b. Radioisotopes, radiation, or x-rays requiring approval by the Radiation Safety Committee:
☐ Yes ☐ No
- c. Hazardous chemicals (not covered elsewhere in this petition) requiring approval of Environmental Health and Safety?
☐ Yes ☐ No

18. Does the protocol involve exposure to human blood or body fluids by study personnel? ☐ Yes ☐ No

If yes, have study personnel received appropriate training? ☐ Yes ☐ No (If no, describe the steps that will be taken to ensure that training occurs).

INFORMED CONSENT:

19. Indicate who will be signing the informed consent (indicate all that may apply):

- ☐ Participant (adult)
☐ Legally authorized representative for participant

20. Please indicate if all elements of informed consent and HIPAA authorization are included in the consent document(s) ☐ Yes ☐ No. If no, explain why not.

21. Describe the process by which informed consent will be obtained and documented.

- a. The consent interview will be conducted by:
☐ Study staff ☐ Investigator or co-investigator ☐ Other (describe)
☐ N/A (e.g. if the consent process does not involve an interview)
- b. Is there a waiting period between the consent discussion and the signing of the consent document?
☐ Yes ☐ No ☐ N/A
- c. Will participants be allowed to review the document at home prior to signing? ☐ Yes ☐ No
☐ N/A
- d. Are there procedures in place to minimize the possibility of coercion or undue influence?
☐ Yes ☐ No. If no, please explain: ☐ N/A
- e. Will the language to be used in the informed consent document and/or consent interview be understood by the potential participants? ☐ Yes ☐ No ☐ N/A
- f. If consent will be obtained from adults who are cognitively impaired on a temporary basis at the beginning of the research, is there an opportunity (if appropriate) for these participants to provide consent after recovery of cognitive function? ☐ Yes ☐ No ☐ N/A
- g. Will a copy of the informed consent document be given to the participant?
☐ Yes ☐ No ☐ N/A

22. Are there anticipated costs to study participants? ☐ Yes ☐ No ☐ N/A. If yes, describe and justify the costs:

SIGNATURES AND CERTIFICATIONS

By signing and submitting this application, the Principal Investigator agrees that he/she:

1. Accepts responsibility for the scientific conduct of the project, and that the research will be conducted in full compliance with WSU policies and federal regulations.
2. Has provided the IRB with all the information on the research project necessary for its facilitated review.

3. Will submit all CIRB-initiated modifications of the consent to the IRB for inclusion in the study folder
4. Will submit local unanticipated problems (including adverse events) to the IRB for review in a timely manner.
5. Will not put this research project into effect until IRB approval for facilitated review is received.
6. Has completed the required modules in the CITI training program, which can be found at <http://www.citiprogram.org/> (see also IRB Policy P.5.)

Signature of Principal Investigator Date

All other Investigators listed on the cover of this petition (if any) must sign to acknowledge their participation in this project:

Signature of Co-Investigator Date

Signature of Co-Investigator Date

Signature of Co-Investigator Date

Signature of Co-Investigator Date