



Exempt Reviewer Form

| | | | |
|-------------------------|--|------------------|--|
| Principal Investigator: | | | |
| IRB #: | | Submission Date: | |
| Study Title: | | | |

REVIEW RECOMMENDATIONS: It is recommended to first review the Summary & Purpose section and Background Procedures section of the eProtocol submission, then review all remaining information.

| Protocol Information- Summary & Purpose section | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Is the proposed start date appropriate? (i.e., not before IRB review and approval) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the summary and Purpose clear and concise? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Does the purpose and proposed research activities fall within the definition of human subject's research? | <input type="checkbox"/> | <input type="checkbox"/> | |

If No, complete the Not Human Participants Research (HPR) steps below.

Not Human Participants Research

(a) Request review by the IRB Education Coordinator to determine not HPR.

or

(b) Send submission back to IRB with not HPR justification recommending not HPR and submission withdrawal. Email your reviewer sheet to IRBReview@wayne.edu informing the IRB of withdrawal.

Change Review Type: Requires resubmission of a research project that would be reviewed and approved under an expedited or full board review process. Provide justification and submit justification in eProtocol. If assigned as the expedited reviewer the Expedited Initial Reviewer form must be completed.

Full Board Review or **Expedited Review**

Reviewer's Signature: _____

Sign here when Not HPR or changing the Review Type

STOP THE FORM IS COMPLETE

Notes: Submit notes via eProtocol

Background, Rationale, Data Analysis, and Procedures

Note Section A is not required for exempt submissions

Section B: PROCEDURES

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| ITEM b: Are the research activities and interventions described? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM c: Is a description provided regarding who will conduct research activities, where, and when? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

| | | | |
|---|--------------------------|--------------------------|--------------------------|
| ITEM d: Is the frequency of study visits and total duration of study participation (total time commitment) provided? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|--------------------------|

IF SECONDARY DATA COLLECTION (E.G. RETROSPECTIVE CHART REVIEW) SELECT N/A AND GO SECTION C.

Notes: Submit notes via eProtocol

Section C: DATA COLLECTION

| | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| ITEM b: If data collection instruments are not in the public domain has appropriate permissions been addressed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Personnel Information & COI

| | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| If the Principal Investigator has the role of "Student/Resident/Fellow" is a Faculty Sponsor/Mentor listed? <i>(The Faculty Sponsor cannot also be the authorized signatory)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| COI SECTION: Have any key personnel indicated a conflict of interest? | <input type="checkbox"/> | <input type="checkbox"/> | |
| COI SECTION: If yes, is the management plan attached? See Attachments section. If N/A go next section. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

COI Management Plan: (i) If there is a management plan, are there any additional conditions that should be added to the management plan? Yes No
If yes, include with your eProtocol comments.

(ii) Does the management plan include information that should be added to the consent/assent? Yes No
If yes has that information been added? Yes No

Notes: Submit notes via eProtocol

Participant Checklist

| | Yes | No | N/A |
|--|--------------------------|--------------------------|-----|
| Based on review of the summary/purpose and study procedures have all applicable populations been selected? | <input type="checkbox"/> | <input type="checkbox"/> | |

Note: Vulnerable Population Addenda are not required for Exempt and does not appear in eProtocol for an Exempt ONLY. CITI Training is still required. PRISONERS CANNOT BE INCLUDED FOR EXEMPT RESEARCH

Notes: Submit notes via eProtocol

| Study Location & Data Collection | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| If research activities include online activities, does the Location section state “Online/Virtual/Remote” and the Online/Virtual/Remote platform? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are there any non-WSU sites or sites included outside of the PI’s assigned Department? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If: (a) Non-WSU Site or (b) site outside of PI’s department, are Letters of support included? (see the Protocol Information-Attachments section)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| DMC, Karmanos, McLaren, JDVAMC (CIC), or Psychiatry are locations | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol

| COORDINATING CENTER APPLICATION | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| If not applicable Select N/A and go to next section <input type="checkbox"/> N/A | | | |
| If WSU is the Coordinating Center for this study is the Coordinating Center Form attached? (If yes, complete the coordinating center reviewer form) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If International site, see International Addendum & see International Research checklist. | | | |

| VAMC Checklist | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| If not applicable Select N/A and go to next section <input type="checkbox"/> N/A | | | |
| Is the John D. Dingell Veterans Administration indicated as a study location? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes, has the reviewer completed the VAMC reviewer Checklist? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PLEASE COMPLETE THE IRB REVIEWER FORM FOR VAMC AND SUBMIT WITH THIS REVIEWER CHECKLIST. | | | |

Notes: Submit notes via eProtocol

| Protocol Checklist |
|--|
| Does the research include the following? |
| <input type="checkbox"/> In-Person Activities: <i>If conducted at non WSU site/affiliate sites check for letters of support</i> |
| <input type="checkbox"/> Questionnaires/Survey: <i>Check attachments section for the questionnaire/survey</i> |
| <input type="checkbox"/> Interview: <i>Check attachments section for script/questions/outline</i> |
| <input type="checkbox"/> Focus Group: <i>Check attachments section for questions/outline</i> |
| <input type="checkbox"/> Internet: <i>Check for completion of Internet Use in Research Addendum for eProtocol.</i> |
| <input type="checkbox"/> International: <i>Check for completion of International Research Addendum for eProtocol.</i> |
| <input type="checkbox"/> Record Review: <i>Check for waivers of consent/waiver of HIPAA, if applicable.</i> |
| <input type="checkbox"/> Thesis or dissertation project: <i>Check Personnel Information section for faculty sponsor/mentor</i> |
| Waivers & Data Agreements: |
| <input type="checkbox"/> Waivers of Consent or Waiver of written documentation of consent: <i>Check Consent Information section for completed waiver.</i> |
| <input type="checkbox"/> Waivers of Consent to screen for eligibility: <i>Check Consent Information section for completed waiver.</i> |

- HIPAA-** Use or collection of PHI: *must select HIPAA Authorization and complete HIPAA section*
- Data Use Agreement or Limited Data Set:** *In comments inform the PI that they will need to contact mtainfo@wayne.edu for assistance. The agreement does not need to be attached to the IRB submission.*

Notes: Submit notes via eProtocol

| Funding | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Is the study funded? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the study supported by the U.S. Department of Defense (DOD) or U.S. Department of Energy? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes for DOD funding, DOD Addendum must be completed (also see DOD reviewer checklist to complete review). | | | |
| If sponsored by the Department of Energy (DOE) did the PI provide the DOE Checklist for IRBs to Use in Verifying that Human Subjects Research Protocols are in Compliance with Department of Energy (DOE) Requirements? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Check the Protocol Information-Attachments Tab | | | |
| Notes: Submit notes via eProtocol | | | |

| Exempt Application | | | |
|--|--|--------------------------|-------------------------------|
| Note items A, B, & C: USER MUST SELECTS "NO" IN ORDER TO QUALIFY FOR EXEMPT | | | |
| | Yes | No | |
| Item D: Is item D completed with all risks identified? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> None |
| The risks selected must be included for the consent/assent forms. | | | |
| *Concurrence of Exempt Categories | | | |
| <input type="checkbox"/> | Category 1 Consent Types: <ul style="list-style-type: none"> • Adult Participants: Research Information Sheet <ul style="list-style-type: none"> ○ <input type="checkbox"/> Waiver of written documentation of consent with use of Research Information Sheet • Child Participants: Parental Permission obtained with a School Parent Supplemental Letter | | |

- This requires a request for waiver of documentation of Parental Permission
- School Parent Supplemental Information Letter
- Assent Research Information Sheet for age-appropriate assent

Category 2 (THIS CATEGORY CAN ONLY INCLUDE CHILDREN IF THE FOLLOWING CRITERIA ARE MET)

- (i) educational tests and/or
- (ii) the observation of public behavior (as long as the investigator(s) do not participate in the activities being observed)

Consent Types:

- Adult Participants: Research Information Sheet
 - Waiver of written documentation of consent
- Child Participants: Parental Permission obtained with a School Parent Supplemental Letter if criteria met above
 - This requires a request for waiver of documentation of Parental Permission
 - Research Information Sheet for age-appropriate assent

If collecting identifiable data Limited IRB review is required, item 2(a) should be “Yes” and Limited IRB Review is completed for the Procedures to Maintain Confidentiality section.

Category 3 (THIS CATEGORY EXCLUDES CHILDREN & CANNOT INCLUDE DECEPTION)

Consent Types:

- Adult Participants: Research Information Sheet
 - Waiver of written documentation of consent

If collecting identifiable data Limited IRB review is required, item 3(b) should be “Yes” and Limited IRB Review is completed for the Procedures to Maintain Confidentiality section.

Category 4

- Only applicable if there will be no contact with participants.
- Collection of identifiable data that does not fall under the protection of HIPAA regulations is not permitted under this category (Expedited category 5 applies in this case).

Consent Types:

- Waiver of Consent and Waiver of Written Documentation of Consent
- Waiver of HIPAA Authorization is required when medical records are being accessed

Category 5

- Adult Participants: Research Information Sheet
 - Waiver of written documentation of consent

Category 6

- Adult Participants: Research Information Sheet
 - Waiver of written documentation of consent

Notes: Submit notes via eProtocol

Background, Rationale, Data Analysis, and Procedures
SECTION B: USE OF DECEPTION

If secondary data collection, Select N/A and go to next section **N/A**
Exempt Category 3 is not allowed

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Is a rationale for use of deception provided? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

See the consent information section for the debriefing script & alteration of consent

Notes: Submit notes via eProtocol

SECTION B: AUDIO/VIDEO RECORDING & PHOTOGRAPHY

If secondary data collection (e.g., retrospective chart review) Select N/A and go to next section N/A

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| ITEM (iv): Is the context of use for the audio/video/photography described as it relates to the research? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM (iv) Does the description of the collection process include a mechanism for the participant to prospectively agree to the intervention and information collection? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

If Yes, then Exempt Category 3 must apply with at least one of the following:

- (a) The information obtained is recorded by the investigator in such a manner that the identity of the participant cannot readily be ascertained, directly or through identifiers linked to the participants
- (b) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation.
- (c) The information obtained is recorded by the investigator in such a manner that the identity of the participants' can be readily ascertained, directly or through identifiers linked to the participants, Limited IRB must be conducted to examine the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Notes: Submit notes via eProtocol

Participant Population

| Section A | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| Is the expected age range and description of participants been provided? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Has the number of records/charts/specimens been provided? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Section C: STUDENTS INCLUDED AS RESARCH PARTICIPANTS | Yes | No | N/A |
| If there is a relationship between the PI/recruitment personnel and the students? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the rationale appropriate for enrolling students (grade school and WSU higher education)? | | | |
| Are there measures to minimize risk of undue influence (noted as coercion)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Section D: EMPLOYEES | Yes | No | N/A |
| If enrolling WSU/WSU affiliate employees/staff is the PI the direct supervisor of the WSU/WSU affiliate employees/staff? If yes, the recruiting procedures must be revised. See the WSU IRB Policy on Vulnerable Populations: Students, Trainees, and Employees | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the rationale appropriate for enrolling WSU/WSU affiliate employees/staff? | | | |

| | | | |
|--|--------------------------|--------------------------|--------------------------|
| Are there measures to minimize risk of undue influence (noted as coercion)? | | | |
| Section E: NON-ENGLISH-SPEAKING PARTICIPANTS & STUDY SCREENING | Yes | No | N/A |
| If Non-English speaking participants will be included as participants: Check the Consent/Assent sections for translated consent/assent documents. Check the Attachments section for translated data collection tools and recruitment materials, if applicable. See WSU IRB's Informed Consent for Non-English Speaking Participants policy for information regarding non-English speaking participants. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If there are screening procedures, determine whether a waiver of consent/assent is required (see consent information or assent information sections) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Section F: PRINCIPAL INVESTIGATOR'S EXPERTISE | Yes | No | N/A |
| Does the PI have the appropriate expertise to conduct the study? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If the PI is a student/resident/fellow does the faculty sponsor/mentor have the appropriate expertise to provide oversight of the conduct of research activities? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol
Please include any notes if there are concerns regarding Students or Employee participants.

| | | | |
|---|--------------------------|--------------------------|--------------------------|
| Recruitment Process, Participant Compensation & Costs | | | |
| If secondary data collection ONLY (e.g., retrospective chart review), Select N/A and go to next section <input type="checkbox"/> N/A | | | |
| Section A: RECRUITMENT PROCESS | Yes | No | N/A |
| ITEM (i): Are recruitment procedures clearly described? Note: it is clear when, where, and how recruitment procedures are taking place. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM (ii): <ul style="list-style-type: none"> If DMC, VAMC, KCI, McLaren are selected check the attachments section for approvals. If a non-WSU or non-WSU affiliate site will provide direct access to prospective participants has this entity been listed for "Other"? <input type="checkbox"/> Yes <input type="checkbox"/> No Check the Attachments sections for letter(s) support from these entities. Direct access includes the PI/study team directly recruiting participants from the site or directly sending recruitment materials. | | | |
| For the item " <i>Please identify planned recruitment materials and or methods</i> " are any materials or methods selected? If yes, check the attachment section for any of the items listed (flyers, email, social media posts/statements, advertisements, presentations etc.) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Notes: Submit notes via eProtocol | | | |
| Section B: PARTICIPANT COMPENSATION | | | |

If No compensation, then select N/A and go to next section N/A

| | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| Will participants be compensated for their time? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes, does the Compensation meet IRB policy guidelines ? <ul style="list-style-type: none"> • Minimally invasive studies: \$5-\$50 per study visit • Moderately, Extremely Invasive or Time-Consuming Study Procedures: \$50-\$250 per study visit • Total Compensation for Multiple Visits: \$100-\$1000 total • Transportation Costs Regardless of Type of Study: • \$10-\$50 for transportation to performance sites that are distant from the participant's home. Compensation for actual travel expenses (or similar costs such as childcare) could be offered in addition to compensation to participate in the study procedures. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Section C: STUDY COSTS | Yes | No | N/A |
| Are there any costs to participants? <i>If yes, this must be stated for the consent/assent forms.</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol

| Procedures to Maintain Confidentiality section | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Has the appropriate data type been selected (identifiable, anonymous, de-identified, or coded)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM a: If information will be disclosed outside of the research team, is there a description of whom the information will be shared? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, is this indicated for the Consent Form's Confidentiality section? <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| ITEM b: If PHI will be used, has the HIPAA section been completed? If yes, HIPAA must be selected for the Protocol Checklist and then complete the HIPAA section | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM c: Are there measures to protect privacy of participants? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM d: Are there measures to maintain confidentiality of data? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM g: If identifiable data will be collected and released (video, audio, photo) does the response state how permission will be obtained to release identifiable data? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM j: Is there an adequate plan for storage (including audio or video recordings)? IRB guidance recommends storage of all research data on an encrypted server. Password protection ONLY is not adequate. For use of PHI: user must follow the hospitals/clinical care facilities HIPAA compliant storage procedures. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM i: Is there an appropriate plan to dispose of data (a secure way to shred/delete data)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol

Procedures to Maintain Confidentiality section

LIMITED IRB REVIEW (FOR EXEMPT CATEGORIES 2 & 3 ONLY)

If not applicable, Select N/A and go to next section N/A

| | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| ITEM 1: Does the described risks include possibility of criminal or civil liability or include damaging participants' financial standing, employability, educational advancement, or reputation? <p style="text-align: center;">Note if yes, the study cannot be Exempt.</p> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM 1(a): Are there appropriate security controls in place to protect confidentiality of data and deter risk of information being lost, stolen, or compromised? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM 2(a): Is the de-identification of data being conducted by individuals that are listed as key Personnel for the Personnel Information section or personnel/entity included as part of a data agreement? The IRB does not process/review the agreement, response should address the agreement. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM 2(b): Is there a description to de-identify data prior to sharing with any outside party? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> Reviewer Limited IRB Review Acknowledgement: The IRB reviewer acknowledges that limited IRB review has been conducted and has determined that there are adequate provisions in place to protect participants' privacy and confidentiality of data. Reviewers Initials: _____ | | | |
| Notes: Submit notes via eProtocol | | | |

| Consent/Assent Information & Procedures | | Yes | No | N/A |
|---|---|--------------------------|--------------------------|--------------------------|
| If secondary data collection, select N/A and go to next section <input type="checkbox"/> N/A If Children are included review the Assent section. | | | | |
| ITEM 10(a): Is the consent or assent process clearly defined? | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| ITEM 10(c): Are all individuals referenced obtaining consent/assent listed for the Personnel Information section. | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the appropriate type of consent/assent/information sheet provided? Use of the WSU IRB's consent templates is highly recommended | | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Check that the following information has been addressed for the consent/assent documents: | | | | |
| <input type="checkbox"/> | Statement that the research is voluntary. | | | |
| <input type="checkbox"/> | States the activities involves research. | | | |
| <input type="checkbox"/> | Description of ALL the study procedures, duration of procedures, & total duration of participation Request and description of audio & video recording. | | | |
| <input type="checkbox"/> | Risks are stated, if applicable (Compare the eProtocol Exempt Paragraph Risks section). | | | |
| <input type="checkbox"/> | Benefits are stated, if applicable or no direct benefit indicated | | | |
| <input type="checkbox"/> | The Research Related Injuries section has been removed, if appropriate | | | |
| <input type="checkbox"/> | Confidentiality/storage of data is described (including audio, video, photographs). | | | |
| <input type="checkbox"/> | Compensation is described, if applicable or a statement that there is no compensation | | | |
| <input type="checkbox"/> | Contact information of the Principal Investigator and IRB has been provided. | | | |
| IF NO, PLEASE REQUEST REVISIONS via eProtocol. | | | | |

Notes: Submit notes via eProtocol

Consent Information/Assent Information (waivers and/or alterations of consent)

See exempt category notes regarding consent types

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Waiver of Consent and/or Parental Permission | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Waiver for written documentation of consent Use of Research Information Sheet (RIS) or Verbal Consent Script | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Waiver of consent and waiver of written document of consent to screen | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Alteration of informed consent <i>(Removing elements of consent from the RIS or use of deception)</i> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The PI has provided specific justifications for the waiver statements | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| USE OF DECEPTION | N/A | | |
| An alteration of consent has been completed and is appropriate. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The study ONLY includes adult participants. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| There is a prospective agreement that informs the participant that they will be unaware or misled regarding the nature or purpose of the research. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| A debriefing script has been provided (check attachments). | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol

| HIPAA | If not applicable Select N/A and go to next section <input type="checkbox"/> N/A | Yes | No | N/A |
|---|--|--------------------------|--------------------------|--------------------------|
| If identifiable information from medical records, clinical databases, specimen or tissue banks, repositories, will be accessed for research are there any HIPAA concerns? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is a waiver of HIPAA Authorization requested? Waiver of HIPAA Authorization is required when medical records are being accessed for exempt category 4 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If a waiver of HIPAA Authorization is requested, is a waiver of consent also requested (see Consent Information section)? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Notes: Submit notes via eProtocol | | | | |

| Protocol Information-Attachments Checklist | | | |
|---|--------------------------|--------------------------|--------------------------|
| | Yes | No | N/A |
| PI's CV/Resume is attached | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| All Data Collection Tools (questionnaires, surveys, etc.) are provided. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are data collection tools in easy-to-understand appropriate language? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Recruitment Materials (flyers, advertisements, scripts etc.) are provided | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Does the recruitment materials meet the IRB's Criteria for Advertising? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Advertising Criteria: (Flyers/Advertisements, recruitment emails, and scripts) <ul style="list-style-type: none"> Indicates that this is a Research Study Potential benefits of participation are not coercive or misleading. Compensation is not overly emphasized, coercive, or misleading. Free of deception and exculpatory language Font size or other visual effect is not coercive or misleading. Language and terminology is appropriate for the intended audience <hr/> Recruitment materials/advertisements DO NOT: <ul style="list-style-type: none"> Imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent. Include exculpatory language (e.g., releasing the investigator or sponsor from liability) Perceive to be coercive or imply undue pressure. <hr/> The following items may be included in advertisements (the inclusion of all of the listed items is not required): <ol style="list-style-type: none"> The name and address of the clinical investigator and the identity of the research facility. The condition under study and/or the purpose of the research. The criteria, in summary form, that will be used to determine eligibility for the study. A brief list of the benefits or incentives of participation, if any. The time or other commitment required of the participants. The name of the person or office to contact for further information. | | | |
| Attachments (section) continued | Yes | No | N/A |

| | | | |
|---|---|--|--------------------------|
| Letters of Support provided (Non-Affiliate Sites & Outside of PI's Department) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Ancillary Reviews/Approvals are required | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Ancillary Reviews include: | | | |
| <input type="checkbox"/> DMC | <input type="checkbox"/> PRMC-Protocol Review and Monitoring Committee (KCI/Cancer Studies) | <input type="checkbox"/> VA Clinical Investigation Committee (CIC) | |
| <input type="checkbox"/> Department of Psychiatry | <input type="checkbox"/> Radiation Safety Committee (RSC) | <input type="checkbox"/> Institutional Biosafety Committee (IBC) | |
| <input type="checkbox"/> Export Control (International Research) | <input type="checkbox"/> Dean of Students (WSU Campus wide student recruitment) | <input type="checkbox"/> McLaren Approval & Authorization | |
| Notes: If revisions are required for these documents, submit notes via eProtocol | | | |

| eProtocol Internet Addendum Checklist | | | |
|--|--------------------------|--------------------------|---|
| | | | If not applicable, select N/A and go to next section <input type="checkbox"/> N/A |
| | Yes | No | N/A |
| Internet Addendum is completed. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Recruitment conducted via internet. If yes, procedures are described. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Data Collection conducted via internet. If yes, procedures are described. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Are social media platforms being used? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If yes, check the attachments for site administrator(s) approval(s) has been provided from social media platforms that are being used. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Notes: Submit notes via eProtocol | | | |

eProtocol International Addendum Checklist

If not applicable, Select N/A and go to next section N/A

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| International Addendum is completed. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Approval from Export control is provided (Check the Protocol Information Attachments) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Local IRB review/approval provided. (Check the Protocol Information Attachments) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If local IRB review is not available, has the researcher provided documentation of the following: (1) lack of local IRB review and (2) plans for observing local ethical standards? DOD research requires local ethics review. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Letters of Support provided (Check the Protocol Information Attachments) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Investigator and research staff are qualified for conducting research in respective country. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Informed consent/assent/questionnaires/surveys are written both in English and the in the native language of the proposed research site. | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Risks are minimized | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol

Additional Reviewer Checklists

Please complete the following additional checklists if applicable.

Please submit with this initial reviewer checklist to the IRB Administrator.

All IRB reviewer forms are available on the [IRB Reviewer Forms and Tools website](#)

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Coordinating Center Reviewer Checklist | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| NIH Genomic Data Sharing | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Other: <input style="width: 60%; height: 20px;" type="text"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Criteria for Approval

Criteria for approval must be met to provide Concurrence of Exemption

| | Yes | No | N/A |
|---|--------------------------|--------------------------|--------------------------|
| Is the research more than minimal risk to participants? If yes, study is not eligible for exempt review. | <input type="checkbox"/> | <input type="checkbox"/> | |
| Is the selection of participants equitable? | <input type="checkbox"/> | <input type="checkbox"/> | |
| Are there adequate provisions to maintain participant privacy and confidentiality? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Is the consent & assent process appropriate? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Notes: Submit notes via eProtocol

Reviewer Determination

Concurrence of Exemption Granted

Exemption category revised from PI's selection.
State Revised Category

Specific Minor Revisions

Submit comments in eProtocol

Date Revisions Requested:

Date Revisions Completed:

Notes:

Submit notes via eProtocol

Concurrence of Exemption Period (select all that apply)

**Status Check-In
Every 3 years**

**Status Check-In with Limited IRB Review
Every 3 years**

Reviewer's Signature:

Date:

Email completed reviewer sheets to: IRBReview@wayne.edu

*Exempt Categories NOTE: The WSU IRB has elected to opt out of the optional categories #7 and #8 as described in 45CFR 46.104. These categories involve research with biospecimens in which broad consent is obtained. Any study with broad consent will not be eligible for exempt review under this policy.