IRB Administration Office
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Full Board & Expedited Reviewer Form

Principal Investigator's Name:	
IRB #:	**Submission Date:**
Study Title:	
☐ **Full Board Submission**	**Full Board Meeting Date:**
☐ ***Expedited Submission**	**Expedited Category:**
Primary Reviewer	**Secondary Reviewer (not applicable for Expedited Review)**

Review Recommendations: It is recommended to first review the Summary & Purpose section and Background & Rationale section of the eProtocol submission. Please also refer to the Protocol/Proposal document. Then review all remaining eProtocol tabs.

Summary & Purpose	**Yes**	**No**	**N/A**
Is the proposed start date appropriate? (i.e not before IRB review and approval)	☐	☐	☐
Is the summary of the scope of work provided in non-technical terms (lay terms)?	☐	☐	☐
Is the summary and Purpose clear and concise?	☐	☐	☐
Notes: Submit notes via eProtocol			

Background, Rationale	**Yes**	**No**	**N/A**
PROCEDURES			
Is relevant background information provided?	☐	☐	☐
Is the sample size justification provided?	☐	☐	☐

Are there alternatives to study participation?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Personnel Information & COI	**Yes**	**No**	**N/A**
If the Principal Investigator has the role of "Student/Resident/Fellow" is a Faculty Sponsor/Mentor listed? *(Faculty sponsor cannot also be the authorized signatory, must be listed as one or the other)*	☐	☐	☐
COI SECTION: Have any key personnel indicated a conflict of interest?	☐	☐	
COI SECTION: If yes, is the management plan attached? **See Attachments section**	☐	☐	☐

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, background, and protocol/proposal etc. have all applicable populations been selected?	☐	☐	

For Vulnerable Populations, the Vulnerable Populations Addenda for eProtocol must be completed

Notes: **Submit notes via eProtocol**

Study Location	**Yes**	**No**	**N/A**
Is the correct study location indicated?	☐	☐	☐
If research activities include online activities, does the Location section state "Online/Virtual/Remote" and the Online/Virtual/Remote platform?	☐	☐	☐
Are there any non-WSU sites?	☐	☐	☐
Are sites included that are outside of the PI's Department?	☐	☐	☐
If : (a) Non-WSU Site or (b) site outside of PI's department Are Letters of support included? (**see the Protocol Information-Attachments section**)?	☐	☐	☐

If taking place at DMC, Karmanos, McLaren, JDVAMC (CIC), or Psychiatry are the appropriate approval letters included? (**see the Protocol Information-Attachments section**)?	☐	☐	☐
Notes: **Submit notes via eProtocol**			
If International Site, see International Addendum & see International Research checklist.			
COORDINATING CENTER APPLICATION **If not applicable Select N/A and go to next section** ☐ **N/A**	**Yes**	**No**	**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)	☐	☐	☐

VAMC Checklist **If not applicable Select N/A and go to next section** ☐ **N/A**	**Yes**	**No**	**N/A**
Is the John D. Dingell Veterans Administration indicated as a study location?	☐	☐	☐
If Yes, has the reviewer completed the VAMC reviewer Checklist?	☐	☐	☐
Please complete the IRB Reviewer Form for VAMC and submit with this reviewer checklist			
Notes: **Submit notes via eProtocol**			

Protocol Checklist	**Yes**	**No**	**N/A**
Will in-person activities take place?	☐	☐	☐
If flexible review is selected, does the submission meet the flexible review criteria listed?	☐	☐	☐

Does the research include the following?

☐ Questionnaires/Survey
☐ Interview
☐ Focus Group

If yes, go to the Background Rationale section for a description of procedures.
Check Protocol Information-Attachment sections for surveys/questionnaires/scripts/interview guides.

☐ Internet-Check for completion of Internet Use in Research Addendum for eProtocol.
☐ International-Check for completion of International Research Addendum for eProtocol.
☐ Record Review (etc, retrospective chart medical record review, education record review) check for waivers of consent/HIPAA, if applicable

Waivers:

☐ Waivers of Consent or Waiver of Written documentation of consent
☐ Waivers of Consent to screen for eligibility

Check that the waiver is completed for the Consent Information section.
If HIPAA applies (use of medical records of databases) review HIPAA section

Notes: **Submit notes via eProtocol**

Funding	Yes	No	N/A
Is the study funded?	☐	☐	☐
Is the study supported by the U.S. Department of Defense (DOD) or U.S. Department of Energy?	☐	☐	☐
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? **Check the Protocol Information-Attachments Tab**	☐	☐	☐

Notes: **Submit notes via eProtocol**

Background, Rationale, Data Analysis, and Procedures

Section B: PROCEDURES

	Yes	No	N/A
Are the research activities and interventions described?	☐	☐	☐
Does the research site and/or the study include public health pandemic mitigation procedures? If No, is appropriate justification provided? ☐ Yes ☐ No	☐	☐	☐
Is a description provided regarding who will conduct research activities, where, and when?	☐	☐	☐
Is the frequency of study visits and total duration of study participation (total time commitment) provided? **If secondary data collection (e.g. retrospective chart review) Select N/A and go to next section**	☐	☐	☐

Notes: **Submit notes via eProtocol**

Section C: DATA COLLECTION

	Yes	No	N/A
If there are data collection instruments, are all instruments, surveys and/or educational materials included for the Protocol Information-Attachments section?	☐	☐	☐
If participants will complete the survey/questionnaire or review the materials, are they in easy to understand language?	☐	☐	☐

Notes: Submit notes via eProtocol

AUDIO/VIDEO RECORDING

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

	Yes	No	N/A
If yes, is audio/video recording information listed in consent/research information sheet with a statement regarding when recordings will be destroyed?	☐	☐	☐
If audio/visual recording, is there information regarding audio and video recording included for the consent/assent forms?	☐	☐	☐

Notes: Submit notes via eProtocol

USE OF DECEPTION

If secondary data collection, Select N/A and go to next section ☐ N/A

	Yes	No	N/A
When there is a potential for deception or experimental manipulation, is protocol-specific scientific justification provided and does the reviewer agree?	☐	☐	☐
If yes, the study must meet the criteria for an alteration to informed consent. ***An alteration of consent must be completed for the Consent Information section of the application.***	☐	☐	☐
There is an acceptable plan to debrief participants.	☐	☐	☐

Notes: Submit notes via eProtocol

Participant Population

Section A:	**Yes**	**No**	**N/A**
Does the number of total participants match with what is indicated for the consent and assent documents (if applicable)?	☐	☐	☐
Section B:	**Yes**	**No**	**N/A**
Pregnant women are excluded from the study with appropriate scientific justification.	☐	☐	☐

Research Participation is based on gender and/or race/ethnicity with appropriate scientific justification.	☐	☐	☐
VULNERABLE POPULATIONS INCLUDED (If no, go to next section)			
	Yes	**No**	
Children	☐	☐	
Pregnant women	☐	☐	
Fetuses/Neonates	☐	☐	
Non-Consenting Participants	☐	☐	
Terminal Illness	☐	☐	
Cognitively Impaired (Appendix D is attached to the Protocol information Tab under attachments)	☐	☐	
	Yes	**No**	**N/A**
If any of the vulnerable populations listed above are included, is appropriate scientific justification provided? (*If, no be sure to include your comments in eProtocol*)	☐	☐	☐
COERCION OR UNDUE INFLUENCE Is there potential for coercion or undue influence of potential participants?	☐	☐	☐
If yes, sufficient safeguards are in place to minimize risks or potential harms?	☐	☐	☐
Section C	**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	☐	☐	☐
Section D	**Yes**	**No**	**N/A**
Are WSU students being recruited campus wide (not only in the PI's department and/or college)? If yes, has WSU Dean of Students approval been provided (see Attachments section)? ☐ Yes ☐ No	☐	☐	☐
Section E	**Yes**	**No**	**N/A**
If Non-English speaking participants will be included as participants check the Consent/Assent sections for translated consent 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.	☐	☐	☐
If there are screening procedures, determine whether a waiver of consent/assent is required (see consent Information or assent information sections)	☐	☐	☐
Section F:	**Yes**	**No**	**N/A**
Does the PI have the appropriate expertise to conduct the study?	☐	☐	☐
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?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Please also include any notes if there are concerns regarding Students or Employee participants.

Recruitment Process, Participant Compensation & Costs

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

Section A: RECRUITMENT PROCESS	Yes	No	N/A
Recruitment procedures are clearly defined.	☐	☐	☐
If use of recruitment materials is indicated, those materials (i.e., flyers, notices, advertisements, verbatim scripts, etc. are included for the eProtocol Information-Attachments tab.	☐	☐	☐
If recruitment materials are used, materials meet the IRB's Adverting policy standards (see standards at the end of this form)	☐	☐	☐

Notes: Submit notes via eProtocol

Section B: PARTICIPANT COMPENSATION	Yes	No	N/A
Will participants be compensated for their time?	☐	☐	☐
If yes, does Participant Compensation meet IRB policy guidelines? • **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.	☐	☐	☐

Section C: STUDY COSTS	Yes	No	N/A
If participants will incur additional costs, is the information clearly stated?	☐	☐	☐

Notes: Submit notes via eProtocol

Risks	Yes	No	N/A
Are all known potential risks to participants (physical, psychological, legal, economics, social, breach of confidentiality) stated?	☐	☐	☐
Are the risks to participants more than minimal? If yes, the study does not qualify for expedited review	☐	☐	☐
Are all activities that could potentially result in identification of child abuse, reportable diseases, criminal activities addressed? If secondary data collection, Select N/A and go to next section	☐	☐	☐
Are risks to participants minimized and safeguards in place? Risks are minimized when appropriate by using procedures already being performed on the participants for diagnostic procedures, treatment or educational purposes.	☐	☐	☐
Are there reasonable and appropriate measures to minimize risks to privacy and confidentiality? For more information see the WSU IRB Guidance Tool for Privacy and Confidentiality	☐	☐	☐
Are the risks described accurately and included in the consent/assent/information sheet forms? If secondary data collection, Select N/A and go to next section	☐	☐	☐

Notes: Submit notes via eProtocol

Data Safety Monitoring Plan	Yes	No	N/A
Will conduct of the research require use of a data safety monitoring board (DSMB) or other designated safety oversight committee that is not provided in the protocol?	☐	☐	☐

Is a monitoring plan sufficient and not a committee or board? Whether the proposed plan is commensurate with the nature, size, and complexity of the clinical trial, as well as the degree of risk involved in the study.	☐	☐	☐
If a plan only, is the plan in place adequate?	☐	☐	☐
Does the plan or monitoring committee need to be independent from the	☐	☐	☐
Is a monitor provided with the appropriate expertise?	☐	☐	☐
Are the intervals of monitoring appropriate to ensure safety of participants?	☐	☐	☐
Does the plan or data safety monitoring committee need to be independent of the PI and research team?	☐	☐	☐
Note If WSU is the Lead Institution in a multi-site study or the PI provides services such as data coordination, the IRB must determine whether the PI has submitted an adequate plan to communicate information among the sites that may affect the health or safety of participants or their willingness to continue to participate in the study. Examples include: unexpected problems and adverse events, protocol modifications, and interim study results.			
For additional information regarding Data Safety Monitoring see the WSU IRB's Data Safety and Monitoring in Research Policy			
Notes: Submit notes via eProtocol			

Benefits	If not applicable, Select N/A and go to next section ☐ **N/A**		
	Yes	**No**	**N/A**
Are the benefits accurately stated, if any?	☐	☐	☐
Are the benefits, if any, also described in the consent/assent/information sheet?	☐	☐	☐
Are the benefits to society, if any, clearly described?	☐	☐	☐
Notes: Submit notes via eProtocol			

Procedures to Maintain Confidentiality	Yes	No	N/A
Are the measures to maintain confidentiality clearly stated?	☐	☐	☐
Is there an adequate plan for storage and disposal of data (including audio or video recordings)?	☐	☐	☐
Are there adequate provisions to protect the personal privacy interests of the participant(s)?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Consent Information (Procedures) If secondary data collection, select N/A and go to next section ☐ N/A	Yes	No	N/A
Item#10(a) Is the consent process clearly defined?	☐	☐	☐
Item #10(c) Are the individuals listed as obtaining consent also included under the Personnel information section as key personnel?	☐	☐	☐
Is the appropriate type of consent/assent/information sheet selected and included with the submission? **Use of the WSU IRB's consent templates is highly recommended**	☐	☐	☐

Notes: **Submit notes via eProtocol**

Consent Document Checklist

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

Required Elements of Consent

		Yes	No	N/A
1	A statement that the study involves research & that the research is voluntary.	☐	☐	☐
2	Consent document begins with a clear and concise presentation of "Key Information".	☐	☐	☐
3	An explanation of the proposed research.	☐	☐	☐
4	An explanation of the expected duration of participants' participation.	☐	☐	☐
5	Statement of appropriate number of participants expected to be involved in the study.	☐	☐	☐
6	A description of the procedures to be followed.	☐	☐	☐
7	Identification of any procedures that are experimental (may be omitted if none).	☐	☐	☐
8	Statement that the participant's bio-specimens (even if identifiers are removed) may be used for commercial profit and whether the participant will or will not share in this commercial profit.	☐	☐	☐
9	Statement regarding whether clinically relevant research results, including individual research results will be disclosed to participants and if so under what conditions.	☐	☐	☐
10	Statement regarding whether the research (if known) will or might include whole genome sequencing of bio-specimens (i.e. sequencing of human germline or somatic specimen with the intent to generate the genome or exome sequence of the specimen).	☐	☐	☐
10(a)	Genetic Information Nondiscrimination Act (GINA) language included (Only required if study involves genetic work)	☐	☐	☐
11	A description of any reasonable foreseeable risks or discomforts to the participant.	☐	☐	☐
12	Statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable (*look for when research involves investigational drugs or devices, novel procedures involving risks or where a goal of the research is to define safety*).	☐	☐	☐
13	State if the participant is or becomes pregnant, the particular treatment or procedure may involve risk to the embryo or fetus, which are currently unforeseeable (*look for when research involves pregnant women or women of childbearing potential and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy*).	☐	☐	☐
14	Description of any benefits to the participant or to others which may reasonably be expected from the research.	☐	☐	☐
15	A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the participant including their important potential benefits and risks (may be omitted if there are none).	☐	☐	☐
16	Statement describing any additional costs to the participant that may result from participating in the research (*look for when additional costs are expected*).	☐	☐	☐
17	Statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.	☐	☐	☐
18	Statement that notes the possibility that the FDA and/or OHRP, WSU, DMC, KCI, etc, may inspect the records. This should also include the monitor, auditor, IRB, and any other applicable regulatory clause. May not be applicable if an Information Sheet is being used.	☐	☐	☐
19	An explanation of whether compensation is available if injury occurs and, if appropriate the WSU indemnification clause.	☐	☐	☐
20	If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained.	☐	☐	☐
		Yes	No	N/A

21	Explanation as to whether any medical treatments are available if injury occurs.	☐	☐	☐
21(a)	If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be omitted.	☐	☐	☐
22	An explanation of whom to contact for answers to: • Pertinent questions about the research • Pertinent questions about the research participants' rights	☐	☐	☐
23(a)	An explanation of whom to contact (usually the PI) in the event of a research related injury to the participant *(may be omitted if the research involves no more than minimal risk and the reviewer concurs with the PI's rationale for the omission*).	☐	☐	☐
23(b)	If Research-Related Injury section is being omitted from the consent or the information sheet: ☐ The Study is no more than minimal risk ☐ The reviewer concurs with the PI's justification	☐	☐	☐
24	A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled.	☐	☐	☐
25	Statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise is entitled.	☐	☐	☐
26	As statement that significant new findings developed during the course of the research which may relate to the participant willingness to continue participation will be provided to the participant (*look for in long term clinical trials*).	☐	☐	☐
27	A statement describing anticipated circumstances under which the participant may be terminated by the investigator without regard to the participants' consent (*look for when the protocol mentions this as a possibility*).	☐	☐	☐
28	A description of procedures for orderly termination of participation by the participant (*look for when such procedures are part of the protocol*).	☐	☐	☐
29	If a clinical Trial, the consent contains Clinical Trial.gov statement as required by law.	☐	☐	☐
30	All required elements of informed consent have been included in the documentation.	☐	☐	☐

Notes: **Submit notes via eProtocol**

Consent Information (waivers and/or alterations of consent)

When using a Research Information Sheet, a waiver of written documentation of consent is requested.	Yes	No	N/A
Waiver of Consent **and/or** Parental Permission	☐	☐	☐
Waiver for written documentation of consent	☐	☐	☐
Waiver of consent and waiver of written document of consent to screen	☐	☐	☐
Alteration of informed consent (*Removing elements of consenting/or elements from the research information sheet*)	☐	☐	☐
If a waiver or alteration of consent is requested (e.g., secondary data, database, chart review), has the PI provided protocol specific justification and have all the regulatory criteria been met?	☐	☐	☐
If there is an alternative to written consent requested, is the justification stated and appropriate?	☐	☐	☐
PLANNED EMERGENCY RESEARCH: Is there a request for waiver of consent for planned emergency research?	☐	☐	☐
Appropriate justification is provided for the waiver of planned emergency research?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Assent Information (Procedures)

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

	Yes	No	N/A
Are the individuals listed as obtaining assent also included under the Personnel information section as key personnel?	☐	☐	☐
Is the assent process clearly defined?	☐	☐	☐
Is the appropriate type of assent/ information sheet selected and included with the submission?	☐	☐	☐
Assent Waiver:			
Is a waiver of Assent being requested?	☐	☐	☐

Are the justifications provided for Waiver of Assent appropriate? **(please also see Children as Research Participants Addendum)**	☐	☐	☐

IF SUBMISSION INCLUDES AN ASSENT DOCUMENT

PLEASE COMPLETE THE ASSENT DOCUMENT CHECKLIST (at the end of this form) & CHILDREN AS RESARCH PARTICIPANTS CHECKLIST

Notes: **Submit notes via eProtocol**

HIPAA

If not applicable Select N/A and go to next section ☐ **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?	☐	☐	☐
Is a waiver of HIPAA Authorization requested?	☐	☐	☐
If a waiver of HIPAA Authorization is requested, is a waiver of consent also requested (see Protocol Checklist & Consent Information section)?	☐	☐	☐
Does the HIPAA "uses" and "disclosures" match what is indicated for the HIPAA Authorization?	☐	☐	☐
For full board submission has the HIPAA reviewer provided comments?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Protocol Information-Attachments Checklist

	Yes	No	N/A
PI's CV/Resume is attached	☐	☐	
Research Proposal/Protocol/Dissertation is attached	☐	☐	
Data Collection Tools (questionnaires, surveys, etc.) are provided	☐	☐	☐
Recruitment Materials (flyers, advertisements, etc.) are provided	☐	☐	☐
Does the recruitment materials meet the IRB's Criteria for Advertising?	☐	☐	☐

Advertising Criteria:

- Purpose indicates that the activity is research
- 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

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Recruitment materials/advertisements **DO NOT**:

- 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.

FDA Regulated Research: Recruitment materials/advertisements **DO NOT:**

- Make any claim (directly stated or implied) that the drug, biologic or device being studied is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device, or otherwise promote the test article.
- Use the terms "new treatment", "new medication" or "new drug" without explaining that the test article is investigational.
- Make any claim (explicit or implicit) about a drug, biologic, or device being studied that is inconsistent with FDA labeling
- Include any statement (direct or implied) that the research is approved by the FDA

	Yes	No	N/A
Scripts	☐	☐	☐
Letters of Support (Non-Affiliate Sites & Outside of PI's Department)	☐	☐	☐
COVID-19 Participant Documents Attached (not required)	☐	☐	☐
Ancillary Reviews/Approvals are provided	☐	☐	☐

Ancillary Reviews include:

☐ DMC	☐ PRMC-Protocol Review and Monitoring Committee (KCI/Cancer Studies)	☐ VA Clinical Investigation Committee (CIC)
☐ Department of Psychiatry	☐ Radiation Safety Committee (RSC)	☐ Institutional Biosafety Committee (IBC)
☐ Export Control (International Research)	☐ Dean of Students (WSU Campus wide student recruitment)	☐ McLaren Approval & Authorization

Appendix D Cognitively Impaired Mentally Disabled Participants	☐	☐	☐
Appendix F: Use of Drugs, Biological Agents, or Devices **(see checklist at the end of this form)**	☐	☐	☐
Appendix G: Imaging/Diagnostic Radiation Procedure **(see checklist at the end of this form)**	☐	☐	☐
Appendix H: The Use of Biological Specimens **(see checklist at the end of this form)**	☐	☐	☐

Notes: **If revisions are requred for these documents, submit notes via eProtocol**

Protocol/Research Proposal Document Checklist

	Yes	No	N/A
The full descriptive research proposal design is ethical.	☐	☐	
Background, Rationale, and methodology are adequate.	☐	☐	
Literature references are cogent and up-to-date as related to the protocol.	☐	☐	
There are concerns about the proposed research study (if yes, include comments in eProtocol).	☐	☐	

Notes: **Submit notes via eProtocol**

eProtocol Internet Addendum Checklist

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

	Yes	No	N/A
Internet Addendum is completed.	☐	☐	☐
Recruitment conducted via internet. If yes, procedures are described.	☐	☐	☐
Data Collection conducted via internet. If yes, procedures are described.	☐	☐	☐
Are social media platforms being used?	☐	☐	☐
If yes, site administrator(s) approval(s) has been provided from social media platforms that are being used.	☐	☐	☐

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.	☐	☐	☐
Approval from Export control is provided.	☐	☐	☐
Local IRB review/approval provided.	☐	☐	☐
If local IRB review is not available, has the researcher provided documentation of the following: (I) lack of local IRB review and (2) plans for observing local ethical standards? DOD research requires local ethics review.	☐	☐	☐
Letters of Support provided.	☐	☐	☐
Investigator and research staff are qualified for conducting research in respective country.	☐	☐	☐
Informed consent/assent/questionnaires/surveys are written both in English and the in the native language of the proposed research site.	☐	☐	☐
Risks are minimized	☐	☐	☐

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
Children as Research Participants	☐	☐	☐
Coordinating Center Reviewer Checklist	☐	☐	☐
DOD Questionnaire –Department of Defense	☐	☐	☐
NIH Genomic Data Sharing	☐	☐	☐
Pregnant Women, Fetuses & Neonates as Research Participants	☐	☐	☐
Prisoners as Research Participants	☐	☐	☐
VAMC Checklist for John D. Dingell VAMC Site	☐	☐	☐

Criteria for Approval

Criteria for approval must be met for granting approval or SMR

	Yes	No	N/A
Is the research more than minimal risk to participants? **If yes, study is not eligible for expedited review.**	☐	☐	☐
Is a plan for data safety and monitoring necessary?	☐	☐	☐
Is the selection of participants equitable?	☐	☐	☐
Is there any potential for coercion or undue influence of participants? If yes measures are taken to minimize or eliminate coercion or undue influence?	☐ ☐	☐ ☐	☐ ☐
Are there adequate provisions to maintain participant privacy and confidentiality?	☐	☐	☐
Is informed consent being sought?	☐	☐	☐
Is the consent process appropriate?	☐	☐	☐
Is informed consent being documented?	☐	☐	☐
Is a waiver of documentation of consent or waiver of consent requested?	☐	☐	☐
Are the risks reasonable in relation to the benefits and resulting in knowledge?	☐	☐	☐

Notes: **Submit notes via eProtocol**

Reviewer Note:

Please complete all applicable checklists at the end of this document (i.e. Checklist for Appendix H, F, & Assent).

Vulnerable Population Checklists are located on the IRB Reviewer's website (click here)

Risk Category Determinations (Full Board Review)

Reviewer must provide a protocol specific examples to justify the selected risk level. If children are enrolled, examples are required to justify that the conditions are met.

☐ **Level 1** Research not involving greater than minimal risk.

Level 1 Risk Justification:

If a minimal risk study remains as full board submission, please provide justification to remain as a full board study:

☐ **Level 2** Research involving greater than minimal risk but presenting the prospect of direct benefit to the participant.

IF CHILDREN ARE ENROLLED: All 3 of the following conditions must be met ***for children*** in order to qualify for risk Category 2:

- The risk is justified by the anticipated benefit to the subjects;
- The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

Level 2 Risk Justification:

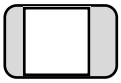
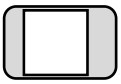
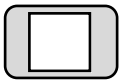
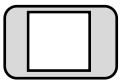
☐ **Level 3** Research involving greater than minimal risk and NO prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's condition or disorder.

IF CHILDREN ARE ENROLLED: All 4 of the following conditions must be met ***for children*** in order to qualify for risk Category 3:

- The risk represents a minor increase over minimal risk;
- The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- The intervention of procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and
- Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408.

Level 3 Risk Justification:

Full Board Review **Reviewer Determination**				
Approved	**Specific Minor Revisions** Submit comments in eProtocol	**Table** Submit comments in eProtocol	**Disapprove**	**Defer**
☐	☐ Response to issues can be reviewed by Chair/designee.	☐ Response to issues will be brought back to the committee for review.	☐ Protocol as written is rejected. PI must address issues and resubmit as a new submission.	☐ Not reviewed due to internal error, not posted/given to reviewers, or appropriate membership not in attendance.
Notes: **Submit notes via eProtocol**				

Full Board Review Approval Period			
12 months 	**Flexible Review Policy** **3 Year Approval Period** 	**Other:** 3 months, 6 Months, etc. 	**Determination Note Made** Submission is Tabled, Disapproved or Deferred 
☐ **Appendices Checklist completed below** ☐ **N/A**		☐ **Vulnerable Population Checklist completed & submitted to IRB Administration (available on the IRB reviewer's website)**	

Full Board Reviewer's Signature:	**Date:**

Expedited Review
Reviewer Determination

Approved	Different expedited category applies than PI selected. State Categories	Specific Minor Revisions Submit comments in eProtocol	Change Review type
☐ Please sign reviewer sheet and submit the IRB Administration Office	☐ New Category _____	☐ Date Revisions Requested: _____ Date Revisions Completed: _____	☐ ☐ Exempt Review ☐ Full Board Review Provide justification in notes below. Inform the Research Compliance Administrator of the review type change

☐ Appendices Checklist completed below ☐ N/A	☐ Vulnerable Population Checklist completed & submitted to IRB Administration (available on the IRB reviewer's website)

Notes:

Submit notes via eProtocol

Expedited Review Approval Period

Status Check-In every 2 years	Flexible Review 3 Year Approval Period
☐	☐

Expedited Risk Category

Level 1 Research not involving greater than minimal risk.

Risk Justification:

Expedited Reviewer's Signature:	Date:

Checklists for Appendices F, G, H, & Assent Document

Protocol Information-Attachments

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

Appendix H: The Use of Biological Specimens

	Yes	No	N/A
Biological specimens or standard of care laboratory results will be used as part of this study.	☐	☐	☐
All specimens procedures are complete and justified	☐	☐	☐
If genetic information will be collected, are there any concerns about safeguards?	☐	☐	☐
If specimens will be stored for the future, are there any concerns about safeguards?	☐	☐	☐

Notes: Submit notes via eProtocol

Appendix F- Drugs

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

	Yes	No	N/A
Will any marketed or experimental investigational drugs or biological products or diagnostic agents be used in this study?	☐	☐	☐
If yes, the PI provided an IND#, Date, and letter from the FDA or sponsor.	☐	☐	☐
If no, notification from the FDA that an IND# is not required has been provided.	☐	☐	☐
A copy of the Investigator's Brochure or Package Insert(s) are provided.	☐	☐	☐
The risks listed for the Investigator's Brochure or Package insert is consistent with the information stated for the consent documents.	☐	☐	☐
There is an adequate drug accountability plan for: Receiving, Storing, Dispensing, final disposition, and accountability of the drugs.	☐	☐	☐

Notes: Submit notes via eProtocol

Protocol Information-Attachments
Appendix F: Devices

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

	Yes	No	N/A
A medical device is being studied to evaluate its effectiveness and/or safety	☐	☐	☐
Significant Risk Device			
The device meets the criteria for a Significant Risk Device.	☐	☐	☐
If yes, has the PI provided protocol specific rationale for its use?	☐	☐	☐
If yes, the PI has provided: IDE number, or a letter from the FDA stating an IDE not required, or an exemption category?	☐	☐	☐
There is an adequate device accountability plan for: Receiving, Storing, Dispensing, final disposition, and accountability of the drugs?	☐	☐	☐
Non-Significant Risk Device			
The device meets the criteria for a Non-Significant Risk Device	☐	☐	☐
If yes, the PI has provided sufficient documentation to justify that the device and/or its proposed use does not pose a significant risk to participants (i.e. complete protocol with scientific justification and device use and description, appropriate labeling, device cost, and detailed accountability plan)	☐	☐	☐
The IDE is provided.	☐	☐	☐
If No, documentation is provided with the submission providing the basis for IDE-exempt or Non-significant risk device categorization. If the FDA has determined that the study is IDE-exempt or NSR, documentation of that determination is provided.	☐	☐	☐

	Yes	No	N/A
The IRB reviewer is determining the following for this Non-Significant Risk Device: ☐ The device is not an implant ☐ The devices is not used to support or sustain human life ☐ The device is not of significant importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human life ☐ The device does not present a potential for serious risk to the health, safety, or welfare of a participant	☐	☐	☐

Notes: Submit notes via eProtocol

Protocol Information-Attachments

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

Appendix G: Imaging/Diagnostic Radiation Procedures

	Yes	No	N/A
Research participants will be exposed to imaging MRI's PET scans, or diagnostic radiation (e.g. x-rays, CT scans, etc).	☐	☐	☐
Is the frequency and amount of radiation for research purposes stated consistently across documents?	☐	☐	☐
Is the language describing the frequency and amount of radiation exposure in lay terms for consent and participant documents?	☐	☐	☐
The radiation Safety Committee Memo or Radioactive Drug Committee Memo is attached.	☐	☐	☐

Notes: Submit notes via eProtocol

Protocol Information-Assent Section
Assent Document Checklist

Required Elements of Assent

		Yes	No	N/A
1	A statement that the study involves research.	☐	☐	☐
2	Statement that participation is voluntary.	☐	☐	☐
3	Consent document begins with a clear and concise presentation of "Key Information".	☐	☐	☐
4	An explanation of the purposes of the research.	☐	☐	☐
5	An explanation of the expected duration of participants' participation.	☐	☐	☐
6	A description of the procedures.	☐	☐	☐
7	Identification of any procedures that are experimental (may be omitted if there are none).	☐	☐	☐
8	Description of any reasonably foreseeable risks or discomforts to the participant.	☐	☐	☐
9	Description of any benefits to the participant or to others which may reasonably be expected from the research.	☐	☐	☐
10	Disclosure of alternative procedures or treatment, if any, that might be advantageous to the participant.	☐	☐	☐
11	Explanation as to whether compensation is available.	☐	☐	☐
12	Statement that parents or guardians are aware of the research.	☐	☐	☐
13	Statement that includes contact information.	☐	☐	☐
14	Is the footer with version# and date added to the bottom of the document?	☐	☐	☐

Notes: Submit notes via eProtocol

Advertising Policy:

Criteria for advertisement review includes the following:

- Advertisements may not imply a certainty of favorable outcome or benefits beyond what is outlined in the informed consent.
- No claims should be made that the drug, biologic or device is safe or effective for the purposes under investigation, or that the test article is known to be equivalent or superior to any other drug, biologic or device.
- The terms "new treatment", "new medication" or "new drug" should not be used without explaining that the test article is investigational.
- Advertisements should not promise "free treatment", when the intent is only to say that participants will not be charged for taking part in the investigation.
- Advertisements may state that the participants will be paid, but should not emphasize the payment or the amount to be paid, by such means as larger or bold type. See the IRB policy on “Compensation for Research Participants” for guidelines on compensation.
- Advertisements should state that it is for a research study.
- Advertisements may not be coercive or imply undue pressure.
- Advertisements may be limited to the information the prospective participants need to determine their eligibility and interest.
- Advertisements may not include exculpatory language.

The following items may be included in advertisements (the inclusion of all of the listed items is not required):

1. The name and address of the clinical investigator and the identity of the research facility.
2. The condition under study and/or the purpose of the research.
3. The criteria, in summary form, that will be used to determine eligibility for the study.
4. A brief list of the benefits or incentives of participation, if any.
5. The time or other commitment required of the participants.
6. The name of the person or office to contact for further information.