WSU IRB eProtocol Initial Submission (Full Board & Expedited)

Reviewer Checklist

Please complete all sections of the checklist

Submit Comments via eProtocol

PI's Name:	IRB#:
Study Title:	
Date of Meeting:	
Primary Reviewer:	Secondary Reviewer:

Personnel Information (Dean/Chair Authorization)	**Yes**	**No**	**N/A**
OBLIGATIONS SECTION: The appropriate Department Chair/Dean completed the obligations section indicating that the submission procedures are consistent with sound research design, appropriate support will be provided for the research project including adequate facilities, and ethical oversight has and will be provided?			
	Yes	**No**	**N/A**
COI SECTION: Has any 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? If yes, include with your eProtocol comments. **(ii)** Does the management plan include information that sould be added to the consent/assent? If yes, has that information been added?			

Participant Checklist	**Yes**	**No**	**N/A**
Based on review of the protocol/research proposal, consent/assents etc. all applicable populations have been selected.			

Study Location	**Yes**	**No**	**N/A**
Correct Study Location is indicated.			
Are there any non-WSU sites?			
Are sites included outside of the PI's Department.			
Letters of support are attached for Non-WSU Site or site outside of PI's department.			
If DMC, Karmanos, McLaren or Psychiatry the appropriate approval letters are attached for the Protocol Information-Attachments section.			
If WSU is the Coordinating Center for this study, the Coordinating Center Form attached.			
If International Site, see International Addendum & see International Research checklist.			

Funding	Yes	No	N/A
The study is funded.			
The study supported by the U.S. Department of Defense 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) the PI provided the DOE Checklist for IRBs to Use in Verifying that Human Subject Research Protocols are in Compliance with Department of Energy (DOE) Requirements? **Check the Protocol Information-Attachments Tab**			

Protocol Information: Study Details	Yes	No	N/A
The study title is consistent throughout the submission and on attachment documents where applicable (protocol, consent, assent, information sheet, etc.).			

Expedited Submissions **(IF FULL BOARD GO TO NEXT SECTION)**	Yes	No	N/A
Does this study meet the definition of human subject research?			
The research meets regulatory requirements for an expedited submission: ☐ No more than minimal risk ☐ Involves one or more of the expedited categories			
The appropriate Expedited Category or Categories are selected?			
Will knowledge of the research methods and/or results only be available to individuals who have U.S. government security clearances? If yes, refer to the Full Board.			

Summary & Purpose	Yes	No	N/A
The information is concise, in lay terms and is consistent with the protocol and consent documents.			

Background, Rationale, Data Analysis, and Procedures	Yes	No	N/A
Based on the summary and purpose information and the protocol document the background and rationale is concise, in lay terms clearly stating the rationale for conducting the study, population included, inclusion/exclusion criteria, alternatives, etc.			
ProcedureS			
Research procedures are described as well indicating who will conduct the research activities.			
Frequency of study visits and total duration of study participation (total time commitment) is provided.			
Data Collection			
If there are data collection instruments, all instruments, surveys and/or educational materials are included in the attachments section and are in easy to understand language.			
AUDIO VIDEO RECORDING If audio recording this information is listed in consent with a statement regarding when recordings will be destroyed.			

USE OF DECEPTION When there is a potential for deception or experimental manipulation, is protocol-specific scientific justification provided and the reviewer agrees. If yes, the study must meet the criteria for an alteration to informed consent.			
There is an acceptable plan to debrief participants.			

Participant Population	**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.			

Recruitment Process, Participant Compensation & Costs	**Yes**	**No**	**N/A**
Recruitment procedures are clearly defined.			
If use of recruitment materials are indicated those materials (i.e. flyers, notices, advertisements, verbatim scripts, etc. are included for the eProtocol Information-Attachments tab.			
Participant Compensation meets IRB policy guidelines.			
If participants will incur additional costs, is the information clearly stated?			

Risks	**Yes**	**No**	**N/A**
The nature and degree of potential risks to participants (physical, psychological, legal, economics, and social) is stated.			
Risks are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.			

Risks are minimized when appropriate by using procedures already being performed on the participants for diagnostic procedures, treatment or educational purposes.			
Is the risk benefit ratio acceptable? (also see benefits section of eProtocol)			
Are the risks to participants more than minimal?			
Are the risks described accurately and included in the consent/assent forms?			
Are all activities that could potentially result in identification of child abuse, reportable diseases, criminal activities addressed?			
If yes are there reasonable and appropriate measures to minimize risks to privacy and confidentiality?			

Benefits	**Yes**	**No**	**N/A**
Are the benefits described accurately?			
Are the benefits described also included in the informed consent/assent documents?			

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

Consent Information (Procedures)	**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?			
WAIVER OR ALTERATION OF CONSENT (Select the appropriate waiver or alteration)			
	Yes	**No**	**N/A**
Waiver of Consent **and/or** Parental Permission			
Waiver of consent and waiver of written document of consent to screen for study eligibility			
Waiver for written documentation of consent (**use of an information sheet-no signed consent document**)			
Alteration of informed consent			
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?			

IF SUBMISSION INCLUDES A CONSENT DOCUMENT
SEE THE CONSENT DOCUMENT CHECKLIST

Consent Document Checklist

Required Elements of Consent

If No Consent, select N/A & go to next section
N/A

		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.			

Assent Information (Procedures)	**If No Assent, select N/A and go to next section**		
			N/A
select "Assent Information" Title to complete the following:	**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 consent/ 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 SEE THE ASSENT DOCUMENT CHECKLIST & CHILDREN AS RESARCH PARTICIPANTS CHECKLIST			

Assent Document Checklist **Required Elements of Assent**		**If no Assent, select N/A and go to next section**		
				N/A
		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?			

HIPAA Information	If No HIPAA, select N/A and go to next section N/A		
	Yes	No	N/A
If medical records will be accessed, or if a database or specimen bank will be created, are there any HIPAA concerns?			
USES described for the HIPAA Summary Form are also listed for the HIPAA Authorization.			
DISCLOSURES described for the HIPAA Summary Form are also listed for the HIPAA Authorization			
Is a waiver of HIPAA Authorization requested?			
If a waiver of HIPAA Authorization is requested a waiver of consent is also requested (see Consent Information section)?			

Protocol Information-Attachments Checklist			
	Yes	No	N/A
PI's CV/Resume			
Research Proposal/Protocol/Dissertation			
Data Collection Tools (questionnaires, surveys, etc)			
Recruitment Materials (flyers, advertisements)			
Scripts			
Appendix D Cognitively Impaired Mentally Disabled Participants			
Appendix F: Use of Drugs, Biological Agents, or Devices			
Appendix G: Imaging/Diagnostic Radiation Procedure			
Appendix H: The Use of Biological Specimens			
Coordinating Center Application (included under Study Location Section)			

Drugs and Devices **Appendix F- DRUGS**	**If No Drugs, 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.			
There is an adequate drug accountability plan for: Receiving, Storing, Dispensing, final disposition, and accountability of the drugs.			

Drugs and Devices **Appendix F:DEVICES**	**If No Device, 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 device?			
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			

Protocol Information-Attachments **Protocol/Research Proposal Document Checklist**			
	Yes	**No**	**N/A**
The full descriptive research proposal design is ethical.			
Background, Rationale, and methodology is 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).			
The study meets the criteria necessary to require more than annual review. If yes, included reasons when recommending for approval via eProtocol.			
If this is a multi-center study where the local PI is the **Coordinating Center**, has the PI 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: unanticipated problems and adverse events, protocol modifications and interim study results*)			

Protocol Information-Attachments **Appendix G: Imaging/Diagnostic Radiation Procedures**	**If no Appendix G select N/A and go to next section** **N/A**		
	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).			
The frequency and amount of radiation for research purposes and the lay terms equivalent of this amount is stated consistently across all documents.			
The radiation Safety Committee Memo or Radioactive Drug Committee Memo is attached.			

Protocol Information-Attachments Appendix H: Imaging/Diagnostic Radiation Procedures	If no Appendix H, select N/A and go to next section N/A		
	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?			

ePROTOCOL ADDENDUMS

Additional Checklist provided if the Submission includes the following:	If No go to next section select N/A and go to next section	
	Yes	No
DOD Questionnaire		
Children as Research Participants		
Pregnant Women, Fetuses & Neonates as Research Participants		
Prisoners as Research Participants		

ePROTOCOL Addendum: Internet Use in Research Checklist	If No, 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.			
All appropriate permissions are provided for social media platforms, if applicable.			

ePROTOCOL Addendum: International Research Checklist	If No, select N/A and go to next section N/A		
	Yes	No	N/A
International Addendum is completed.			
Letters of Support provided and or local ethics review/approval provided.			
Risks are minimized.			

Risk Category Determinations	
Level 1 Place check mark HERE if category 1	Research not involving greater than minimal risk. **Level 1 Risk Justification:**
Level 2 Place check mark HERE if category 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 Place check mark HERE if category 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:**

Criteria for Approval

Criteria for approval must be met in order to provide Approval or Specific Minor Revisions

	Yes	No	N/A
Is a plan for data safety and monitoring necessary?			
Selection of participants is equitable.			
Is there any potential for coercion or undue influence of participants? If so what measures are taken?			
Informed consent be sought?			
Informed consent be documented, or a waiver of documentation w/info sheet granted?			
Confidentiality measures are sufficient.			
Risks to participants are minimized.			
The risks are reasonable in relation to the benefits and resulting knowledge?			

Review Motions:

		Full Board Review ONLY-Not Available for Studies reviewed via the expedited/exempt procedures		
Approve ☐	**Specific Minor Revisions** ☐ Response to issues can be reviewed by Chair/designee.	**Table** ☐ Response to issues will be brought back to the committee for review.	**Disapproved** ☐ Protocol as written is rejected. PI must address issues and resubmit as a new submission.	**Defer** ☐ Not reviewed due to internal error, not posted/given to reviewers, or appropriate membership not in attendance.

Notes:

Approval Period:

12 months	Status Check-In within 2 years	Flexible Review Policy	Other:
☐	☐	☐	☐

Reviewer Signature:	Date:

<u>Advertising Policy:</u> 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.