WSU IRB eProtocol

Full Board Amendment Reviewer Checklist

Please complete all sections of this checklist

Submit Comments via eProtocol

PI's Name:	IRB#:
Study Title:	
Study Sponsor:	**Current Risk Level:**
Assigned IRB:	☐ Adult ☐ Pediatric
Date of Meeting:	Notes to Reviewer:
Primary Reviewer:	Secondary Reviewer:

KEY PERSONNEL MODIFICATIONS	If No Changes, Select N/A and go to next section. ☐ N/A		
	Yes	**No**	**N/A**
Is this a Change in PI? (if yes go to change in PI checklist below)	☐	☐	☐
Is there addition of key personnel? Note: New personnel will have a "New" call icon by their name.	☐	☐	☐
Is there deletion of key personnel?	☐	☐	☐
	Yes	**No**	**N/A**
COI SECTION: Have any of the new personnel indicated a conflict of interest?	☐	☐	☐
COI SECTION: If yes, is the management plan attached? **See Protocol Information-Attachments section**	☐	☐	☐
COI Management Plan: 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.	☐	☐	☐
Change in PI checklist			
The reason for Change in PI is provided	☐	☐	☐
The proposed PI's professional and education experience is appropriate to become principal of the study.	☐	☐	☐
The new PI's bio sketch or CV is provided for the Protocol Information-Attachment's section	☐	☐	☐
Documents have been provided revising the contact information to include the new PI's information (consent, assent, recruitment materials)	☐	☐	☐

PROTOCOL FORM MODIFICATIONS

Select all that apply

If No changes, Select N/A and go to next section. ☐ N/A

Participant checklist (see checklist below) ☐	Study Location ☐	VAMC Checklist VA not accepted via eProtocol. Must submit as new study via paper process	Protocol Checklist ☐
Funding ☐	DOD Questionnaire ☐		

Protocol Form-Protocol Information Sections

Summary & Purpose (see checklist below) ☐	Background, Rationale, Data Analysis, Procedures ☐	Participant Population (see checklist below) ☐	Recruitment Process, Participant Compensation and Costs (see checklist below) ☐
Risks ☐	Data Safety & Monitory ☐	Benefits ☐	Procedures to Maintain Confidentiality ☐
Consent Information ☐	Assent Information ☐	HIPAA ☐	Drugs and Devices ☐
Attachments (see checklist below) ☐			

If there are revisions requests or inquiries regarding the amendment submit comments via eProtocol

Participant Checklist

If no changes, select N/A & go to next section. ☐ N/A

	Yes	No	
Are vulnerable participants being added? (if yes use appendix checklist)	☐	☐	
If yes, justification has been provided for the **Participant Population** section.	☐	☐	

Summary & Purpose

In no changes select N/A & go to next section. ☐ N/A

	Yes	No	
Study Title Change	☐	☐	
Summary	☐	☐	
Purpose	☐	☐	

Participant Population

In no changes select N/A & go to next section. ☐ N/A

	Yes	No	
Accrual changes	☐	☐	
Addition of a **Vulnerable Population** is appropriate & justification has been provided.	☐	☐	
Addition of Non-English speaking participants	☐	☐	
Changes to screening procedures	☐	☐	

Recruitment, Participant Compensation, and Costs

If No changes select N/A & go to next section. ☐ N/A

	Yes	No
Recruitment Procedures revised-changes are appropriate	☐	☐
Participant Compensation-revised -changes are appropriate	☐	☐
Participant Costs revised-Changes are appropriate	☐	☐

Attachments	If No changes, select N/A & go to next section. ☐ N/A		
	Yes	No	N/A
Revised Recruitment Materials	☐	☐	☐
New or Revised Data Collection Tools	☐	☐	☐
Participant Materials	☐	☐	☐
Study Letters	☐	☐	☐
New/Revised Appendices (Appendix G, H, F etc)	☐	☐	☐

HIPAA	If No changes, select N/A & go to next section. ☐ N/A		
	Yes	No	N/A
Are the indicated HIPAA changes appropriate?	☐	☐	☐
If applicable, has the HIPAA Authorization been updated to reflect changes?	☐	☐	☐

If No, include comments in eProtocol.

General Form Overview for Reviewer	Yes	No	N/A
All changes to the eProtocol Form are appropriately summarized and applicable sections revised. ***If No, include comments in eProtocol.***	☐	☐	☐

Protocol Document/Study Design Changes

If No Changes, Select N/A and go to next section. ☐ N/A

	Yes	No	N/A
Are the changes to the previously approved protocol described and is there sufficient information to make a determination?	☐	☐	☐
Is the range of inclusion criteria being broadened?	☐	☐	☐
Is the range of exclusion criteria broadened?	☐	☐	☐
Is the dosage or route of administration for a drug being administered being altered?	☐	☐	☐
Has the sample size changed?	☐	☐	☐
Have the enrollment criteria changed?	☐	☐	☐
Do the changes affect the risk/benefit ratio?	☐	☐	☐
Do the changes result in significant changes in design focus or purposed ratio?	☐	☐	☐
Is there a change in treatment? If yes, does it affect the risk/benefit ratio?	☐	☐	☐
Do the proposed changes affect the confidentiality and privacy of the participants?	☐	☐	☐
Are there sections of the eProtocol form that require updates due to the revised protocol?	☐	☐	☐
A revised Protocol document is attached (see Protocol Information –Attachments Tab)	☐	☐	☐

Consent/Assent/Scripts/Information Sheet

If No Changes, Select N/A and go to next section. ☐ N/A

	Yes	No	N/A
Consent Form changes-Modifications are appropriate	☐	☐	☐
Assent Form Changes-Modifications are appropriate	☐	☐	☐
Information Sheet or Script Changes-Modifications are appropriate	☐	☐	☐
Have the revised documents been included in the appropriate Protocol Information – Consent Information or Assent Information sections?	☐	☐	☐
If participants will not be notified of changes is this appropriate?	☐	☐	☐
Does the amendment include a new consent, assent, information sheet? **If yes, see the consent and or assent checklist at the end of this form**	☐	☐	☐

Consent Waiver or Alteration of Consent

If No Changes, Select N/A and go to next section. ☐ N/A

	Yes	No	N/A
Is this a request for Waiver of Consent?	☐	☐	☐
Do you agree with the specific justification for waiver of consent? Consent and parental permission cannot be waived or altered for FDA-regulated research	☐	☐	☐
The Waiver has been completed for the Protocol Information –Consent Information section.	☐	☐	☐
Have all regulatory criteria been met? PI has responded appropriately to the elements for waiver.	☐	☐	☐
Do you agree that the waiver of consent should be granted?	☐	☐	☐
Is this a request for alteration of consent? A consent procedure which does not include or alters some or all required elements of informed Consent (example: Information Sheet with no written consent)	☐	☐	☐

If No Investigator Brochure/Package Insert changes, select N/A and go to next section. ☐ N/A

Investigator's Brochure/Package Insert	Yes	No
Is the revised Investigator Brochure/Package Insert included for the Protocol Information-Attachments Tab?	☐	☐
Has the risk benefit ratio changed? **(note a change in Brochure may or may not require a protocol revision)**	☐	☐

If No Other changes, select N/A and go to next section. ☐ N/A

Other	Yes	No	N/A
Study on Hold Notification	☐	☐	☐
Study Off Hold Notification	☐	☐	☐
Study Closed to Accrual	☐	☐	☐
Other	☐	☐	☐
Do you concur with the notification indicated above?	☐	☐	☐

General Overview for reviewer

	Yes	No	N/A
Are there any significant new findings that arose from the amendment that might relate to participants' willingness to continue participation?	☐	☐	☐
If yes, does this affect the risk/benefit ratio?	☐	☐	☐

Notes:

Should the change or new findings information be provided to participants in a revised consent, assent, information sheet, or other method for:	Yes	No	N/A
New Participants	☐	☐	☐
Current Participants (re-consent or inform them)	☐	☐	☐
If Yes, are the revised documents attached?	☐	☐	☐
Do you agree with the justification provided for the information submitted?	☐	☐	☐

Consent Document Checklist

Required Elements of Consent

If Not, modifying or adding a new 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 obtained.		☐	☐	☐
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 participation 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 Document Checklist Required Elements of Assent		If not, modifying or adding a new 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	Assent 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?	☐	☐	☐

Criteria for Approval

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

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

Appendices/Addendums Checklist Reviewed	Yes	No	N/A
Children as Research Participants (*completed in eProtocol*)	☐	☐	☐
Pregnant Women, Fetuses, & Neonates (*completed in eProtocol*)	☐	☐	☐
Prisoners as Research Participants (*completed in eProtocol*)	☐	☐	☐
NIH Genomic Data Sharing (*completed in eProtocol*)	☐	☐	☐
The above Reviewer checklists are available on the WSU IRBs IRB Reviewer Form & Tools webpage https://research.wayne.edu/irb/forms-tools			

Risk Review	Yes	No	N/A
Following your review of the submitted materials, is the risk to participants in your opinion, greater than what was originally approved?	☐	☐	☐
If Yes, please complete the risk section on the next page.	☐	☐	☐

Review Motions:

Approve	Specific Minor Revisions	Table	Disapproved	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:

Reviewer Signature:	Date:
X	

Risk Category Determinations Please complete if risk category is being changed	
Level 1 ☐	Research not involving greater than minimal risk. **Level 1 Risk Justification:**
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:**

<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.