Initial Review of Research
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Instructions: Complete this checklist prior to the meeting. Use the checklist to organize your review and presentation to the Board members. Turn in this checklist at the end of the meeting, it will be used to create the meeting minutes and letters to the PI.

- The questions are worded so that a "**Yes**" indicates the item is acceptable; any item answered with "No" indicate a possible controverted issue that should be discussed in your presentation to the convened Board)
- You may write comments on the checklist or the IRB application forms. If you write comments on the forms, turn those in with this checklist at the end of the meeting.
- To improve communication, this checklist also provides comments/concerns/questions from the Human Research Protection Program Office (HRPPO).
  - If you disagree with the HRPPO comment/concern, either **draw a line through it or modify it**.
  - If you agree with the HRPPO, **place a check mark next** to it – it will be included in the stipulations to the investigator.
- If you have a conflict of interest, contact the HRPPO or Chair immediately

[Insert Agenda Item Information]

Stipulations Summary:

HRPP:

CITI Training:
Researcher Refresher (Human Subject Protection) training is required for:

-

GCP Refresher (Good Clinical Practice) training is required for:

-

Conflict of Interest training is required for:

-

A 2018 Conflict of Interest (COI) Statement of Financial Interest is required for:

-

REVIEWER:

PI Acceptability & Study Personnel

Acceptability of the PI	YES	NO	N/A
Given the complexity of the study, does the PI have the appropriate training and experience (competence) to oversee the study?			
If the PI is not UTSW faculty or approved affiliate-non-faculty, has an appropriate Faculty Sponsor been listed?			

HRPPO comments/concerns related to PI acceptability

REVIEWER comments related to PI acceptability

Study Personnel – Item 3.0	YES	NO	N/A
Do the individuals engaged in research have the required IRB training for investigators?			
Are the duties and responsibilities of the individuals engaged in research commensurate with their training and experience?			

HRPPO recommended corrections to Study Personnel

HRPPO comments/concerns related to Study Personnel

REVIEWER comments related to Study Personnel

Initial Review of Research
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Research Description
Smart Form/Protocol

Item	Minimizing Risk	YES	NO	N/A
Item 6.2	Is there appropriate justification for this research protocol?			
	Are there adequate preliminary data to justify research?			
Item 22.1	Is the study design sound and likely to answer the research questions?			
	Would an alternative design reduce the likelihood/magnitude of harm while still addressing the purpose of the study?			
Item 8.6	Is the rationale for proposed population(s) reasonable?			
	Would an alternative population reduce the likelihood/magnitude of harm while still addressing the purpose of the study?			
	Is subject recruitment equitable? (dealing fairly and equally with all concerned)			
-Item 6.2 -Item 22.2	Are the rationale and details of research procedures adequately described and acceptable?			
Item 22.1	Is there a clear differentiation between research procedures & standard of care and evaluation?			
	Would alternative procedures reduce the likelihood/magnitude of harm while still addressing the purpose of the study?			
	Would fewer procedures reduce the likelihood/magnitude of harm while still addressing the purpose of the study?			
	Could the PI better utilize procedures already being performed on the participants for diagnostic or treatment purposes?			
	Would fewer participants answer the scientific question?			
	Are the plans for data analysis defined and justified?			
	Should this research be reviewed by a consultant to supplement the IRB expertise?			
Item	**Equitable Selection of Subjects**	**YES**	**NO**	**N/A**
Items 9.1 & 9.2	Are the criteria for enrollment and withdrawal appropriate?			
	Do the scientific objectives – not vulnerabilities or privileges of the subjects – guide inclusion criteria and targeted populations?			
	For subjects vulnerable to coercion or undue influence (lack mental capacity or voluntariness), are appropriate safeguards included to protect the rights and welfare of these subjects?			
Item 53.1.2	If provided, are recruitment materials acceptable?			
Item	**Subject Privacy & Confidentiality**	**YES**	**NO**	**N/A**
Item 53.2	Does the recruitment strategy protect privacy?			
Item 63.0	Is the study designed to protect privacy and confidentiality during and after the study?			

Research Description
Smart Form/Protocol, Continued

Item	Informed Consent	YES	NO	N/A
Item 53.2 & 54.0	Is the consent process well defined?			
	Does the consent process minimize the possibility of coercion or undue influence?			
	Does the consent process provide sufficient time, privacy, & adequate setting for subjects to consider?			
Item 9.3.1	If **excluding** non-English speaking subjects, is the rationale acceptable?			
Item 59.0	If **including** non-English speaking subjects, is the process acceptable?			

Item	Are the Risks Reasonable in Relationship to the Benefits?	YES	NO	N/A
Components that offer the prospect of **direct benefit** **Item 49.1**	Are all the risks that can be reasonably expected for each study intervention being tested or evaluated under this protocol?			
	Have the risks for each intervention been **minimized** to the extent possible within the limitations of this study?			
	Do you agree that there is a benefit related to each intervention?			
	Is the prospect of a benefit applicable to all subjects exposed to each intervention?			
	Are the **risks** related to each intervention **reasonable in relation to the associated benefit?**			
Item 48.3.1	For all research procedures with a prospect of direct benefit, is the balance of risks and benefits for the procedures equivalent to that associated with accepted practice? (Research Equipoise = genuine uncertainty whether the study procedure or accepted practice is preferred)			
Components that **do not** offer the prospect of direct benefit Item 48.2	Are all the risks that can be reasonably expected for each component listed in the protocol?			
	Have the risks for each component been **minimized** to the extent possible within the limitations of this study?			
	Are the **risks** related to each component directly **related** to a study **objective**?			
	For all research procedures without a prospect of direct benefit, are the risks related to these procedures reasonable in relation to the importance of the knowledge that may reasonably be expected to result from the study?			
Safety Precautions Item 48.5	Are the safeguards appropriate to the risks of the study and adequate for protecting subjects?			

Research Description
Smartform/Protocol, Continued

Item	Subject Privacy & Confidentiality	YES	NO	N/A
Confidentiality Items 62.0 and 63.0	Are there adequate provisions to protect the confidentiality of private identifiable information during & after research?			
Item 63.1	Are there adequate provisions for storage, coding and use of identifiers?			

Item	Equitable Selection of Subjects - Compensation	YES	NO	N/A
Payment Items 53.5 and 53.6	Is the compensation to subjects reasonable; no undue influence from the offer of payment?			
	Is the child/adolescent compensated directly? - Please comment if they should or should not be.			
	If subject does not complete the study, will compensation be pro-rated?			
Costs: Item 42.0	Are the costs associated with the research acceptable?			

HRPPO recommended corrections to Smartform/Protocol

HRPPO comments/concerns related to Smartform/Protocol

REVIEWER comments related to Smartform/Protocol

Consent Form(s)

Review of the Required Elements of Consent	YES	NO	N/A
Will the informed consent of the subject be documented using a written consent document that embodies the elements of informed consent required by §46.116 *(listed below)*?			
Are the following "basic" elements of consent found in each consent form?			
A statement that the study involves research			
An explanation of the purposes of the research			
The expected duration of the subject's participation			
A description of the procedures to be followed			
Identification of any procedures which are experimental			
A description of any reasonably foreseeable risks or discomforts to the subject			
A description of any benefits to the subject or others which may reasonably be expected from the research			
A disclosure of appropriate alternative procedures or courses of treatment, **if any**, that might be advantageous to the subject			
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained			
For research **involving more than minimal risk**, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained			
An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject			
A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled			

AND

Are any of the following additional/optional elements of consent needed? For those determined to be appropriate for this study, also determine whether the consent contains the element. (Check all that apply)

Additional elements of consent	Needed	Contained in Consent
A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable and / or if the participant is or becomes pregnant, the particular treatment or procedure might involve risks to the embryo or fetus, which are currently unforeseeable		
Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent		
Any additional costs to subject that may result from participation		
The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject		
A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject		
Approximate number of subjects to be involved		

Consent Form(s) (Continued)

Other Elements of Consent	YES	NO	N/A
Are the basic and additional elements of informed consent sufficient to inform the subject – (no additional information is needed)?			

Informed Consent	YES	NO	N/A
Does the consent form adequately document the basis for consent?			
Is the consent form free of exculpatory language?			
Is the information given to the subject in language understandable to the subject?			
If there is a declared COI and the management plan requires discloser to participants, is the language wording appropriate in the consent?			
For NIH funded research - does the Informed consent(s) agree with the NIH model consent?			
Does the investigator plan to use a short form written consent form stating that the elements of informed consent have been presented **orally**?			
If yes, is there a plan: • for a witness to the oral presentation, • for the subject/LAR and witness to oral presentation to sign the short form • to provide a copy of the written summary and short form to the subject/LAR **and** is the written summary of the oral presentation acceptable (can be the long English ICD)?			

HRPPO recommended corrections to Consent Form(s)

HRPPO comments/concerns related to Consent Form(s)

Does the research-related injury information agree with the sponsor's provisions?

☐ **Check if consent form is attached with your corrections noted**

REVIEWER comments related to Consent Form

Alteration or Waiver of Consent
Waiver of Documentation of Consent

Section	Informed Consent	YES	NO	N/A
Item 55.2	Do you agree with the investigator's explanation of how the risk in this research is minimal?			
Waiver or Alteration of Consent; Item 55.3	Do you agree with the investigator's explanation of how the rights and welfare of the participants will not be adversely affected?			
Item 55.4	Do you agree with the investigator's explanation that consent cannot be practicably obtained?			
Item 55.5	Is it appropriate to provide subjects with additional information after the study?			
Waiver Consent Documentation Items 56.1 – 56.3	Do you agree with the investigator's rationale for waiver of a consent document?			
Item 56.4	In the absence of a consent document, do you consider it appropriate to provide subjects with a written statement regarding the research before participation?			
Item 56.5	If yes, is the information provided by the investigator acceptable?			

HRPPO recommended corrections to Waiver/Alteration of Consent/Waiver of Documentation

HRPPO comments/concerns related to Waiver/Alteration of Consent/Waiver of Documentation

REVIEWER comments related to Waiver/Alteration of Consent/Waiver of Documentation

HIPAA
Partial Waiver/Alteration/Waiver of Authorization

Item	Informed Consent	YES	NO	N/A
Item 65.4	Do you agree with the investigator's explanation of why it is not practicable to obtain written authorization to obtain PHI?			
Item 65.5	Do you agree with the investigator's explanation of why it is not practicable to conduct the research without access to and use of PHI?			
Item 65.2	Given the nature of the health information being obtained, do you agree that the intended use and/or disclosure of PHI involves no more than a minimal risk to the privacy of individuals?			
Item 65.6	Is the plan to protect the identifiable health information sufficient?			
	Do you agree that only the minimum information necessary to complete the waived activities will be obtained?			

HRPPO recommended corrections to HIPAA Waiver/Alternation

HRPPO comments/concerns related to HIPAA Waiver/Alternation

REVIEWER comments related to HIPAA Waiver/Alteration

Off-Site/Collaborative Research

Item		YES	NO	N/A
Item 5.7.4	Have the collaborating **assured** institutions that are engaged in research provided IRB approval?			
Item 5.7.9	Have the collaborating **assured** institutions that are engaged in research requested to Rely on UTSW IRB with appropriate local context present?			
Item 5.1.1	Do collaborating **non-assured** institutions that are engaged in research have an adequate plan to obtain an Assurance?			
Items 5.7.3 – 5.7.8	Is the Lead PI's plan for the management of information with collaborating sites acceptable?			
Item 5.2	**International Research -** Has the PI provided information relevant to the local context and/or IRB/Ethics committee approval?			

HRPPO recommended corrections to Off-Site Research

HRPPO comments/concerns related to Off-Site Research

REVIEWER comments related to Off-Site Research

Use of a Drug in Research

Item	FDA Regulated Research	YES	NO	N/A
Item 28.1	Are all the drugs listed in this section approved by the FDA for the intended use in this study?			
Item 27.1	Do all unapproved drugs have the required IND?			
Item 27.1 (sub-form)	Is there supporting documentation that the IND information is accurate?			

Use of an Approved Drug in an Unapproved Manner

Item	IND Information for Off Label Use	YES	NO	N/A
Protocol, IB, (if sponsored) and/or Item 29.3.2b	If IND application was submitted, is there supporting documentation that the IND information is accurate?			
Item	**Off Label Use**		**YES**	**NO**
Item 29.3.3a	Do you agree that the use is **not** intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling of the drug?			
Item 29.3.3b	Do you agree that the use is **not** intended to support a significant change in advertising of the product?			
Item 29.3.3c	Do you agree that the use does **not** involve: • a route of administration or dosage level, • use in a subject population, or • other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug?			
	Do you agree that the use **will** be conducted in compliance with the requirements for IRB review and informed consent? (e.g., There is an informed consent present)			
	Do you agree that the use **will** be conducted in compliance with the requirements concerning the promotion and sale of drugs?			
	Do you agree that the use **will not** invoke 21 CFR 50.24? (Exception from Informed Consent Requirements for Emergency Research)			

Choose one	Summary of Off Label Use
☐	All six statements above are checked YES, the drug(s) listed will not require an IND submission to the FDA
☐	Not all six statements above are checked YES, the drug(s) listed will require an IND submission to the FDA

Use of a Placebo in Place of Standard Therapy

Item	Placebo Use	YES	NO
Item 48.4	Do you agree with the justification for using placebo in place of standard therapy?		

HRPPO recommended corrections to Use of Drugs/Placebo

HRPPO comments/concerns related to Use of Drugs/Placebo

REVIEWER comments related to Use of Drugs/Placebo

Use of Investigational Device Form

Item	Significant Risk vs. Non-significant Risk Device	YES	NO
Item 30.0 (N-S Risk) Item 31.0 (S Risk)	Do you agree with the reason the device does not need an IDE?		
	Do you agree with the reason the device use is **not** intended as an implant **and** presents no potential for serious risk to the health, safety, or welfare of a subject?		
	Do you agree that the device is **not** for use in supporting or sustaining human life **and** represents no potential for serious risk to the health, safety, or welfare of a subject?		
	Do you agree that the device use is **not** for a use of substantial importance in diagnosing, curing, mitigating, or treating disease **or** otherwise preventing impairment of human health **and** presents no potential for serious risk to the health, safety, or welfare of a subject?		
	Do you agree that this is **not** a device that otherwise represents a potential for serious risk to a subject?		

Choose one	Summary of Device Use
☐	All four statements above are checked YES, the device listed is considered non-significant risk (NSR) and the study will not require an IDE submission to the FDA
☐	Not all four statements above are checked YES, the device listed is considered significant risk (SR) and the study will require an IDE submission to the FDA

HRPPO recommended corrections to Use of Device

HRPPO comments/concerns related to Use of Device

REVIEWER comments related to Use of Device

Monitoring Participant Safety and Data Integrity

Item	PLAN for MONITORING DATA for SAFETY	YES	NO	N/A
Safety data / events Item 66.2	Will the safety data/events being collected provide a complete representation of safety issues relevant to this study?			
Responsibilities Item 66.1	Are the individuals responsible for safety monitoring appropriate?			
Frequency of Analysis Item 66.3	Is the frequency of safety data analysis appropriate?			
Procedure of Analysis Item 66.1.1	Is the plan for evaluating the safety data acceptable? (Does it include evaluation criteria resulting in prompt reporting to the IRB of UPIRSO)			
Reporting Items 66.0 and 67.0	Is the plan for reporting safety analysis acceptable?			
Actions Item 67.0	Is the plan for local action to be taken as a result of safety data analysis (consider that a local PI may need to take substantive action in response to safety issues) acceptable?			
Item 67.0	Is the description of the safety monitoring entity acceptable?			
Data Integrity Item 66.0	Is the plan for monitoring the integrity of the data acceptable?			

HRPPO recommended corrections to Data & Safety Monitoring

HRPPO comments/concerns related to Data & Safety Monitoring

REVIEWER comments related to Data & Safety Monitoring

Inclusion of Incompetent Adults or Adults with Impaired Decision-Making Capacity

Item	Justification	YES	NO	N/A
Item 12.0	Has the investigator provided a compelling justification for the inclusion of incompetent adult subjects that mitigate any additional risk of their inclusion?			
Item 61.1	Is the plan for determining an individuals' competency to consent including the criteria to be used in determining competency acceptable?			
Item 61.4	Do you agree with the investigator's presumption (and plan if appropriate) whether to expect that during the course of the research, subjects with capacity to consent may lose the capacity to consent, or that subjects without the capacity to consent may vary in their ability to assent or their ability to withdraw?			
Item 61.3.2	Is the plan for identifying who is authorized to provide consent acceptable?			
Item 61.2	Are the criteria for determining when to obtain assent acceptable?			
Item 61.4.1	Are the methods for determining dissent acceptable?			
	Local Investigator will enroll subjects Outside the state of Texas	**YES**	**NO**	**N/A**
	Are there adequate provisions to account for any differences in other applicable state laws?			

HRPPO recommended corrections to Include Decisionally Impaired

HRPPO comments/concerns related to Include Decisionally Impaired

REVIEWER comments related to Include Decisionally Impaired

Research Involving Pregnant Women, Fetuses, &/or Neonates

Item	Section 1 - Pregnant Women	YES	NO	N/A
Item 13.0	Has the PI confirmed his/her understanding of the limitations on research involving pregnant women or fetuses?			
	Does the information contained in the rest of the IRB application agree with the prohibition of inducements to terminate a pregnancy or investigators engaged in the research participating in any decisions as to the timing, method, or procedures used to terminate a pregnancy; or determining the viability of a neonate?			
Item 13.2	Is the scientific justification for including pregnant women/fetuses acceptable or is the rationale why this information is not needed acceptable)?			
Item 13.4	Do you agree with the investigator that the **risks to the fetus** are either: • not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means? **OR** • greater than minimal risk **and** are caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus?			
Item 13.3	Is the rationale for the anticipated risks to the fetus acceptable?			
Item 13.4.2	Is the explanation why any risk is the least possible for achieving the objectives of the research acceptable?			
Item 13.4	Is the choice for who is required to sign the consent document acceptable?			
Consent Form Item 54.1.1a	Does the consent form fully inform regarding the reasonably foreseeable impact of the research on the fetus or neonate?			
	If some or all the pregnant women are also children are the provisions for obtaining assent and parental permission in accord with the provisions of Subpart D (Form W) presented in the IRB application?			
Item	**Section 2 – Neonate of Uncertain Viability or Nonviable Neonates**	**YES**	**NO**	**N/A**
Item 13.0	Has the PI confirmed the limitations on research involving neonates?			
	Does the information contained in the rest of the IRB application agree with the prohibition of investigators engaged in the research participating in any determination of viability of a neonate in this study?			
	Is the explanation in Section 4 of Form C of how consent of both parents of the neonate will be obtained acceptable?			
	Is the scientific justification for including neonates acceptable or is the rationale why this information is not needed acceptable)? Where scientifically appropriate, have preclinical and clinical studies been conducted and provided data for assessing potential risks to neonates.			

Research Involving Pregnant Women, Fetuses, &/or Neonates, Continued

Item	Section 2 – Neonate of Uncertain Viability or Nonviable Neonates, Continued	YES	NO	N/A
Neonates of Uncertain Viability	Do you agree with the investigator that the research either: • holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, AND any risk is the least possible for achieving that objective? **OR** • The research has the main purpose of the development of important biomedical knowledge, which cannot be obtained by other means AND there will be no added risk to the neonate resulting from the research?			
Neonates of Uncertain Viability or Nonviable Neonates	Has the PI confirmed the limitations on research involving neonates of uncertain viability and nonviable neonates? (e.g., Individuals engaged in the research having no part in determining the viability of a neonate)			
Nonviable Neonates	Has the PI confirmed the additional limitations on research involving nonviable neonates? All of the following additional conditions are met: (1) Vital functions of the neonate will not be artificially maintained; (2) The research will not terminate the heartbeat or respiration of the neonate; (3) There will be no added risk to the neonate resulting from the research; (4) The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means; and (5) The legally effective informed consent of both parents of the neonate is obtained (waiver or alteration of consent is not allowed). However, there are some exceptions.			
Item	**Section 3 – After Delivery, Placenta, Dead Fetus, or Fetal Material**	**YES**	**NO**	**N/A**
Item 13.0	Is the rationale for recording identifiable information and plan for consent acceptable?			

HRPPO recommended corrections to Pregnant Women, Fetuses, &/or Neonates

HRPPO comments/concerns related to Pregnant Women, Fetuses, &/or Neonates

REVIEWER comments related to Pregnant Women, Fetuses, &/or Neonates

Prisoners

Item	Section 1 - Prisoners	YES	NO	N/A
Item 14.1	Has the PI confirmed his/her understanding the definitions concerning research involving prisoners?			
Item 14.1.1	Do you agree the research falls into one of the following categories of allowable prisoner research? (if YES, select which category):			
	• Category 1: Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, that the study presents no more than minimal risk and no more than inconvenience to the subjects where minimal risk is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons;			
	• Category 2: Study of prisons as institutional structures or of prisoners as incarcerated persons, and the study presents no more than minimal risk and no more than inconvenience to the subjects where minimal risk is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons;			
	• Category 3: Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his intent to approve such research; or			
	• Category 4: Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of the intent to approve such research.			
	• Category 5: The study has as its sole purpose either: (i) to describe the prevalence or incidence of a disease by identifying all cases; or (ii) to study potential risk factor associations for a disease. (This category is not included in Subpart C, but is permitted under the HHS Secretarial waiver for certain epidemiological research if the research presents no more than minimal risk and no more than inconvenience to the prisoner-participants, and prisoners are not a particular focus of the research (As published in the Federal Register / Vol. 68, No. 119 / Friday, June 20, 2003 / Rules and Regulations, page 36929.)			

Prisoners, Continued

Item	Section 1 – Prisoners, Continued	YES	NO	N/A
	If prisoner subjects will be randomized, do you agree that the control group participants will potentially benefit?			
Item 14.2	Do you agree that any possible advantages accruing to the prisoner through participation in the research **are not** of such a magnitude that would impair his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison?			
	Do you agree that the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers?			
	Do you agree that the plan for the selection of subjects within the prison is fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners (including random selection when including control subjects)?			
	Do you agree that the information is presented in language which is understandable to the subject population?			
	Do you agree that there are adequate assurances that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner will be clearly informed in advance that participation in the research will have no effect on his or her parole?			
Item 14.3	If there is a need for follow-up examination or care of participants after the end of their participation, do you agree that there is adequate provision for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and there is adequate provision for informing participants of this?			

HRPPO recommended corrections to Prisoners

HRPPO comments/concerns related to Prisoners

REVIEWER comments related to Prisoners

Initial Review of Research
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Children

Item	Section 1 - Children	YES	NO	N/A
- 404 Item 10.1.1	Do you agree that the risk of the research is only minimal? (must be Yes to approve under 404)			
- 405 Item 10.1.1	Do you agree that the risk of the research is greater than minimal?			
Item 49.1	Do you agree with the investigator's list of benefits to the subjects?			
Item 48.5	Do you agree with the investigator's explanation that the risks are reasonable in relation to the benefits?			
Item 50.0	Do you agree with the investigator's explanation that the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches? (must be Yes to approve under 405)			
- 406 Item 10.1.1	Do you agree that the risk of the research is greater than minimal risk and there is no prospect of direct benefit to individual subjects?			
Item 52.1	Do you agree with the investigator's explanation that the risks are a minor increase over minimal risk?			
Item 52.2	Do you agree with the investigator's explanation that the research presents experiences that are reasonably commensurate with those inherent in their actual situations? (e.g., actual or expected medical, dental, psychological, social, or educational situations)			
Item 52.3	Do you agree with the investigator's explanation of the importance of the knowledge to be gained? (e.g., of vital importance for the understanding or amelioration of the subjects' disorder or condition and)			
- 407 Item 10.1.1	Do you agree that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children?			
	Has the responsible federal agency (e.g., Secretary of HHS), after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, determined either: • That the research fell into categories 1 through 3; or • The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and the research will be conducted in accordance with sound ethical principles.			

Children, Continued

Item	Section 2 – Additional Information Children	YES	NO	N/A
	Is the justification for including children acceptable?			
Item 60.0	Is the justification for waiving assent acceptable (If not applicable Assent is required) because: ○ the capability of some or all of the children is so limited that they cannot reasonably be consulted or ○ the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research the subjects are capable of assenting, however the assent requirement is waived under circumstances in which consent may be waived in accord with §46.116 of Subpart A (minimal risk, does not adversely affect rights and welfare, and the research could not practicably be carried out without the waiver?			
Item 54.1.1	Is the plan for soliciting assent and assessing dissent acceptable?			
Item 54.1.1	Is the plan for obtaining parental consent (permission) acceptable? (At least one of the parents for 404 and 405 and both parents for 406)			
	Is the request for a waiver of parental consent acceptable?			
	Is the plan for parental involvement acceptable?			
	Does the research team have appropriate knowledge and experience of children and their families?			

HRPPO recommended corrections to Children

HRPPO comments/concerns related to Children

REVIEWER comments related to Children

DoD Funded Research

Item	Informed Consent	YES	NO	N/A
Item 54.2	**If the research meets the DoD definition of "Research Involving a Human Being as an Experimental Subject," the PI is not requesting to waive the consent process** *(this prohibition does not apply to screening of records to identify possible subjects).* *Research involving an Experimental subject: An activity, for research purposes, where there is an intervention or interaction with a human subject for the primary purpose of obtaining the effect of the intervention of interaction (32 CFR 219.102(f)).*			
Protocol	**Does the study require the Secretary of Defense to waive** the prohibition of consent waiver with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws? (this is not common)			
Item 54.2 Item 58.0	**Exception from Informed Consent (EFIC) – Planned Emergency Research** DoD regulations prohibit an exception from informed consent in planned emergency medicine research unless the PI obtains a waiver from the Secretary of Defense.			
Item	**Inclusion of US Military Personnel**	**YES**	**NO**	**N/A**
Protocol	Will service members follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty?			
Protocol	Are all the following **required** additional protections in place to minimize undue influence (as applicable): a. Officers are not permitted to influence the decision of their subordinates. b. Officers and senior non-commissioned officers may not be present at the time of recruitment. c. Officers and senior non-commissioned officers have a separate opportunity to participate. d. When recruitment involves a percentage of a unit, an independent ombudsman is present.			
Item 53.5.1	Are the following limitations on dual compensation satisfied (as applicable): a. Prohibit an individual from receiving pay of compensation for research during duty hours. b. US military personnel may be compensated for research if the participant is involved in the research when not on duty c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw. d. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.			
Item	**Inclusion of Pregnant Women and Fetuses**	**YES**	**NO**	**N/A**
Item 8.6 Item 13.0	**Does the study involve Pregnant Women and/or Fetuses?** *Please note, the following apply:* *a. DoD research involving pregnant women is subject to the DHHS Subpart B.* *b. For purposes of applying Subpart B to DoD research, the phrase "biomedical knowledge" shall be interpreted as "generalizable knowledge."* *c. The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus; or involves fetuses or neonates as participants.* d. *Fetal DoD research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.*			

DoD Funded Research, Continued

Item	Inclusion of Prisoners	YES	NO	N/A
Item 8.6 Item 14.0	**Does the study involve Prisoners?** *Please note, the following apply:* *1. In addition to allowable categories of research on prisoners in Subpart C, the following two additional categories are allowable:* *a. epidemiological research is also allowable when:* *i. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.* *ii. The research presents no more than minimal risk.* *iii. The research presents no more than an inconvenience to the participant.* *iv. Prisoners are not the focus of the research* b. *Research involving human subjects that would meet the criteria described in 32 CFR 219.101(b) can be conducted, but must be approved by a convened IRB and meet the requirements of subpart C, DODI 3216.02, and other applicable requirements.*			
	Adult subjects unable to provide informed consent	**YES**	**NO**	**N/A**
Item 8.6 Item 12.0 Item 61.0	**If the study involves cognitively impaired subjects, are all of the following true?** • Adult subjects will be enrolled after a legally authorized representative provides consent • If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participants, and the IRB must agree that the research is intended to benefit subjects.			
	Prisoners of War	**YES**	**NO**	**N/A**
Item 25.1	If the study involves prisoners of war, are the following conditions met?: Research involving prisoners of war is prohibited unless: a. The activities are covered by investigational new drug or investigational device provisions for the purpose of diagnosis or treatment of a medical condition in a patient, and b. Such treatment (e.g., an investigational new drug) may be offered to detainees with the detainees' informed consent when the medical products are subject to FDA regulations investigational new drugs or investigational medical devices, and c. Only when the same product would be offered to members of the U.S. Military Services in the same location for the same medical condition and only when consistent with established medical practice involving investigational drugs and devices.			

DoD Funded Research, Continued

	Research Monitor	YES	NO	N/A
Item 66.1.1 Item 67.2.3	Does the research require a Research Monitor? • The appointment of a research monitor is required for research involving greater than minimal risk, although the IRB or organizational official can require this for a portion of the research or studies involving no more than minimal risk if appropriate			
Protocol Item 66.1.1	Is the research monitor appointed by name and operating independently of the team conducting the research?			
Protocol	There may be more than one research monitor (e.g. if different skills or experience are needed. **Does this research require more than one monitor?**			
Item 67.2.1	The monitor may be an ombudsman or a member of the data safety monitoring board. **Do you agree with the written summary of the monitors' duties, authorities, and responsibilities?** *For reviewer Information:* *The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:* • *Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis)* • *Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study* • *Report observations and findings to the IRB or a designated official.* *The research monitor has the authority to:* • *Stop a research study in progress.* • *Remove individuals from study.* • *Take any steps to protect the safety and well-being of participants until the IRB can assess.*			

HRPPO recommended corrections to DoD Research

HRPPO comments/concerns related to DoD Research

REVIEWER comments related to DoD Research

Initial Review of Research
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Conflict of Interest

Item	COI	YES	NO	N/A
COIC Management Plan	Do you agree with the Conflict of Interest Committee's recommended Management Plan?			
HRPPO staff notes (below)	If no Management Plan is present, is there a Conflict of Interest that requires management?			

If you do not agree with the COIC Management plan, or if a Conflict requires management (without a COIC management plan) what do you suggest?

Add	Remove	Modify	Element of IRB Directed COIC Management Plan
☐	☐	☐	Disclosure of the interest in consent form
☐	☐	☐	Public disclosure of the interest in future publications or presentations
☐	☐	☐	Prohibit individual with the conflict from any involvement with recruitment or consenting potential subjects
☐	☐	☐	Allow individual with the conflict to be involved with recruitment or consenting potential subjects only with another research team member present
☐	☐	☐	Monitoring of research by independent reviewer
☐	☐	☐	Disclosure of the conflict to sub-investigators, research study staff, research residents or students
☐	☐	☐	Divestiture of significant financial interest
☐	☐	☐	Severance of relationships that create actual or potential conflict
☐	☐	☐	Modification of the research plan as follows:
☐	☐	☐	Other Management Plan elements:

HRPPO recommended corrections to Conflict of Interest Management

HRPPO comments/concerns related to Conflict of Interest Management

REVIEWER comments related to Conflict of Interest Management

Initial Review of Research
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Conclusions of the Reviewer – Summary Page

Summarize your detailed review below. This section can be used to present your review to the Board at the convened meeting.

Step 1 - Risk Assessment

☐	Minimal risk	☐	Future reviews may be expedited	☐	More than minimal risk	☐	Minor increase over minimal *(Children 46.406 only)*

Step 2 - Required Determinations to Approve Research	**YES**	**NO**	**N/A**
Are the risks to subjects minimized?			
Are the risks reasonable in relation to the anticipated benefits?			
Is the selection of subjects equitable?			
Will Informed consent be sought from each prospective subject or legally authorized representative **and/or** is the waiver of consent acceptable?			
Will informed consent be appropriately documented **or** is the waiver of documentation acceptable?			
Is plan to monitor data collected to ensure the safety of subjects acceptable?			
Are the provisions to protect privacy and maintain confidentiality adequate?			

Step 3 - Are all the required determinations listed in Step 2 checked "YES"?

☐ **Yes. If yes**, are there any minor modifications needed to the IRB application? *[The clarifications/ modifications are not directly relevant to the "Determinations required for approval" listed above]*

- ☐ **Yes** - your motion should be to **Approve with Conditions** (stipulations) **Continue to Step 4**

  The stipulations should be reviewed by:
  - ☐ IRB Staff (administrative changes) or
  - ☐ Expedited Reviewer (minor changes)

- ☐ **No** - your motion should be to **Approve As Written** **Skip to Step 5**

☐ **No. [Notify the IRB Chair or HRPP Director before the meeting if this is your motion]**
If No, is there a reasonable possibility that the major issues can be resolved?

- ☐ **Yes** - your motion should be to **Defer** (defer to another convened meeting) **Skip to Deferred Section**
- ☐ **No** - your motion should be to **Disapprove** **Skip to Disapproved Section** *(this is not common)*

Step 4 - Additional Determinations for motions to **Approve** or **Approve with Conditions**	**Acceptable**	Requires **minor** corrections noted in the appropriate sections of this checklist:	**N/A**
The request for **HIPAA waiver** is	☐	☐	☐
The investigational use of a **drug** is	☐	☐	☐
The **off-label** use of a **drug** is	☐	☐	☐
The use of a **placebo in place of standard care** is	☐	☐	☐
The investigational use of a **device** is	☐	☐	☐
The use of **radiation** is	☐	☐	☐
The plan for **Off-Site Research (Items 5.1.1, 5.2, or 5.7)** is	☐	☐	☐
The inclusion of **incompetent adults** or adults with impaired decision making is	☐	☐	☐
The inclusion of pregnant women, fetuses &/or non-viable or uncertain viability neonates is	☐	☐	☐
The inclusion of prisoners is	☐	☐	☐
The inclusion of children is	☐	☐	☐

Initial Review of Research
IRB Reviewer Checklist
[Insert 1st line of Agenda Item]

Step 4 - Additional Determinations for motions to **Approve** or **Approve with Conditions**	**Acceptable**	Requires **minor** corrections noted in the appropriate sections of this checklist:	**N/A**
The **DoD** requirements for this study are	☐	☐	☐
The **COI** management plan is	☐	☐	☐

Step 5 - Approval Period				
☐	One Year	☐	Less than one year*	Specify approval period and reason for shortened approval here:

Deferred (defer approval at this meeting) due to **major** issues. *[Major = the clarifications/modifications listed here <u>are</u> directly relevant to the "Determinations required for approval" listed in section 1 above and in the bulleted list below]*

<u>In this section, describe **major** (substantive) issues resulting in deferring protocol. **Include one or more of the following required determinations that could not be met due to the issues.**</u>

- Risks to subjects minimized
- Risks reasonable in relation to the anticipated benefits
- Selection of subjects equitable
- Informed consent be sought from each prospective subject or legally authorized representative and/or the waiver of consent acceptable
- Informed consent be appropriately documented or the waiver of documentation acceptable
- The plan to monitor data collected to ensure the safety of subjects acceptable
- Provisions to protect privacy and maintain confidentiality is adequate\

Insert Deferral Rationale here:

List of other changes/clarifications	**Acceptable**	**Unacceptable because…**
The request for **HIPAA waiver** is	☐	
The investigational use of a **drug** is	☐	
The **off-label** use of a **drug** is	☐	
The use of a **placebo in place of standard care** is	☐	
The investigational use of a **device** is	☐	
The use of **radiation** is	☐	
The plan for **Off Site Research** is	☐	
The inclusion of **incompetent adults** or adults with impaired decision making is	☐	
The inclusion of **pregnant** women, **fetuses** &/or **non-viable or uncertain viability neonates** is	☐	
The inclusion of **prisoners** is	☐	
The inclusion of **children** is	☐	
The **DoD** requirements for this study are	☐	
The **COI** management plan is	☐	

Disapprove (deny the request for approval – study will be withdrawn from further IRB review due to **major** irresolvable issues.

Provide the reason for disapproval: