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| The purpose of this worksheet is to provide support for IRB members reviewing research. This worksheet must be used. It does not need to be completed or retained. (LAR = “subject’s legally authorized representative”) | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. General Considerations (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | The convened IRB (or Designated Reviewer) has, or has obtained through consultation, adequate expertise. | | | | | | | | | | |
| Yes  No  N/A | | | | | For initial review none of the investigators or research staff are Restricted. **(“N/A” if not initial review)** | | | | | | | | | | |
| Yes  No | | | | | Materials are complete. | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. Criteria for Approval of Research: (All must be “Yes” or “N/A”) (Applies to initial, continuing, modifications, convened, and expedited) | | | | | | | | | | | | | | | |
| Yes  No | | | | | Risks to subjects are minimized by using procedures, which are consistent with sound research design and which do not unnecessarily expose subjects to risk. | | | | | | | | | | |
| Yes  No  N/A | | | | | Risks to subjects are minimized by using procedures already being performed on the subjects for diagnostic or treatment purposes. **(“N/A” if no such procedures)** | | | | | | | | | | |
| Yes  No | | | | | Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.  In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. | | | | | | | | | | |
| Yes  No | | | | | Selection of subjects is equitable. Consider the purpose and setting of the research, involvement of vulnerable subjects, selection criteria, and recruitment, enrollment, and payment procedures. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. | | | | | | | | | | |
| Yes  No  N/A | | | | | The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. **(“N/A” if no more than minimal risk)**  When the IRB determines that data and safety monitoring is appropriate, the IRB will evaluate the adequacy of those plans by considering such issues as reporting mechanisms, the frequency of the monitoring, the entity that will conduct the monitoring, the specific data to be monitored, procedures for analysis and interpretation of the data, actions to be taken upon specific events or end points, and procedures for communication from the data monitor to the IRB and sites. (AAHRPP Tip Sheet #6, section 5) | | | | | | | | | | |
| Yes  No | | | | | There are adequate provisions to protect the privacy of subjects.  The IRB will consider it appropriate to include adequate provisions to protect the privacy of subjects when there is a reasonable expectation that prospective research subjects will want to control how, and with whom, they interact and communicate, particularly on issues that may be “sensitive” or “private.” The IRB will determine whether there are adequate provisions to protect the privacy of subjects by considering subjects’ potential comfort with the procedures being performed, comfort with the research setting, and comfort with the information being sought. (AAHRPP Tip Sheet #5 section 2b-c) | | | | | | | | | | |
| Yes  No | | | | | There are adequate provisions to maintain the confidentiality of data. | | | | | | | | | | |
| Yes  No  N/A | | | | | Additional safeguards have been included in the study to protect the rights and welfare of subjects vulnerable to coercion or undue influence. Vi  **(“N/A” if no vulnerable subjects)**  When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects. | | | | | | | | | | |
| Yes  No | | | | | The informed consent process meets one of these sections or checklists | | | | | | | | | | |
| **Section 5: Consent Process** | | | **Waiver or Alteration of Consent Process** | | | | | | **Permanently closed to enrollment** | |
| Yes  No | | | | | The informed consent documentation meets one of these sections or checklists | | | | | | | | | | |
| **Section 6: Long Form** | | **Waiver of Written Documentation of Consent** | | | | | | | **Permanently closed to enrollment** | |
| **Short Form** | | **Waiver or Alteration of Consent Process** | | | | | | |  | |
| Yes  No  N/A | | | | | The criteria in the corresponding checklist are met when the research involves: **(“N/A” if none involved)** | | | | | | | | | | |
| **Children** | **Neonates** | | | **Pregnant Women** | | | **Cognitively Impaired Adults** | | | **Prisoners** |
|  | | | | | | | | | | | | | | | |
| Yes  No  N/A Additional applicable criteria are met[[1]](#endnote-2)  WORKSHEET – Advertisements; WORKSHEET – Payments; CHECKLIST - Pregnant Women; CHECKLIST - Non-Viable Neonates; CHECKLIST - Neonates of Uncertain Viability; CHECKLIST - Prisoners; CHECKLIST – Children CHECKLIST - Cognitively Impaired Adults; CHECKLIST - Non-Significant Risk Device. | | | | | | | | | | | | | | | |
| 1. Additional Considerations (May be “Yes” or “No”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | Does the research involve no more than minimal risk[[2]](#footnote-2) to subjects?  *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal persons or during the performance of routine physical or psychological examinations or tests in normal persons. | | | | | | | | | | |
| Yes  No | | | | | Does the research require Continuing review? **(Note that for FDA or DOJ overseen research or research subject to Pre-2018 Requirements, there is no option not to require Continuing review.)**  The research does not require Continuing review if one of the following apply:  The research is eligible for expedited review. **(See “CHECKLIST: Expedited Review (HRP-413).”)**  The research has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care. | | | | | | | | | | |
| Yes  No | | | | | Based on risk should review take place more often than annually? [[3]](#footnote-3) If so, specify period.  Consider nature and level of risks; degree of uncertainty regarding the risks; subject vulnerability; investigator experience; IRB’s experience with investigator or sponsor; projected rate of enrollment; and whether study involves novel procedures. | | | | | | | | | | |
| Yes  No  N/A | | | | | Is verification needed from sources other than the investigator that no material changes have occurred since prior IRB review? (Implement when the veracity of the information provided is questioned.) **(“N/A” if initial review)** | | | | | | | | | | |
| Yes  No  N/A | | | | | Is there information that needs to be provided to current or former subjects because it may affect their willingness to continue participation? **(“N/A” if initial review)** | | | | | | | | | | |
| Yes  No  N/A | | | | | Advertisements meet **WORKSHEET: Advertisements** criteria **(“N/A” if no advertisements)** | | | | | | | | | | |
| Yes  No  N/A | | | | | Payments to subjects meet **WORKSHEET: Payments** criteria **(“N/A” if no payments)** | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. Primary Reviewer Criteria for Initial review (All must be “Yes” or “N/A”; These items may be determined by a primary reviewer) | | | | | | | | | | | | | | | |
| Yes  No  N/A | | | | | The research has the resources necessary to protect subjects. (Time to conduct and complete, staff, facilities, subject population, and medical/psychosocial resources for subjects.) **( “N/A” if not initial review)** | | | | | | | | | | |
| Yes  No  N/A | | | | | The plan for communication of information among sites is adequate to protect subjects. **(“N/A” if not a multicenter trial, the investigator is not the lead, or not initial review)** | | | | | | | | | | |
| **Complete remaining items when applicable** | | | | | | | | | | | | | | | |
| 1. Consent Process (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | The investigator will obtain the legally effective informed consent of the subject or LAR. | | | | | | | | | | | | |
| Yes  No | | | Consent will be obtained only under circumstances that provide the prospective subject or LAR sufficient opportunity to consider whether or not to participate. | | | | | | | | | | | | |
| Yes  No | | | Consent will be obtained only under circumstances that minimize the possibility of coercion or undue influence. | | | | | | | | | | | | |
| Yes  No | | | Information to be given to the subject or LAR will be in language understandable to the subject or LAR. | | | | | | | | | | | | |
|  | | | The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. | | | | | | | | | | | | |
|  | | | Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. | | | | | | | | | | | | |
|  | | | Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR’s understanding of the reasons why one might or might not want to participate. | | | | | | | | | | | | |
| Yes  No | | | There is no exculpatory language through which the subject or LAR is made to waive or appear to waive the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability from negligence. | | | | | | | | | | | | |
| Yes  No | | | Consent will disclose the elements in **Section 8:** Elements of Consent Disclosure | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. Long Form of Consent Documentation (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | The written consent document is accurate, complete, and consistent with the protocol. | | | | | | | | | | | |
| Yes  No | | | | The written consent document embodies the elements in **Section 8:** Elements of Consent Disclosure | | | | | | | | | | | |
| Yes  No | | | | The investigator will give either the subject or LAR adequate opportunity to read the consent document before it is signed. | | | | | | | | | | | |
| Yes  No | | | | The subject or LAR will sign and date the consent document. | | | | | | | | | | | |
| Yes  No | | | | The person obtaining consent will sign and date the consent document. | | | | | | | | | | | |
| Yes  No | | | | A copy of the signed and dated consent document will be given to the person signing the document. | | | | | | | | | | | |
| Yes  No  N/A | | | | | If there is an LAR or parent signature line, the IRB has approved inclusion of adults unable to consent or children. **(“N/A” if no signature line)** | | | | | | | | | | |
| Yes  No  N/A | | | | | When a subject or LAR is unable to read: an impartial witness will be present during the entire consent discussion and the consent document notes that the witness attests that the information in the consent document and any other information provided was accurately explained to, and apparently understood by, the subject or the subject's LAR, and that consent was freely given. **(“N/A” if all subjects are able to read)** | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| 1. Additional Considerations for Electronic Consent (Check if “Yes” or “N/A”. All must be checked) | | | | | | | | | | | | | | | |
|  | Electronic consent document includes all elements in **Section 8: Elements of Consent Disclosure** | | | | | | | | | | | | | | |
|  | The date of the electronic signature will be captured  **(N/A if waiver of documentation of consent is requested and justified )** | | | | | | | | | | | | | | |
|  | Questions or methods to gauge subject comprehension of key study elements are clearly defined in the informed consent procedures. | | | | | | | | | | | | | | |
|  | Electronic consent process includes age appropriate materials to facilitate comprehension. | | | | | | | | | | | | | | |
|  | Electronic consent process is suitable to the study population or procedures are outlined to accommodate subject’s needs. | | | | | | | | | | | | | | |
|  | Electronic consent document/process allows subjects to proceed forward or backward or pause for review later. | | | | | | | | | | | | | | |
|  | Measures are present to ensure that subjects have access to all of the consent related materials, including hyperlinks or other external documents. | | | | | | | | | | | | | | |
|  | Plans are adequate to maintain external hyperlinks or documents and subject access to these documents throughout the lifespan of the study until completion are detailed in the informed consent procedures. | | | | | | | | | | | | | | |
|  | The informed consent process outlines in detail how any included documents will be utilized. | | | | | | | | | | | | | | |
|  | Measures are present to ensure that the identity of the signer and the integrity of the data can be verified when consent is not witnessed by the study team. | | | | | | | | | | | | | | |
|  | For FDA-Regulated Clinical Trials including children as research subjects, if the parent or guardian initially documents the child’s assent, procedures are in place to verify the child’s identity and assent when the child initially presents to the investigator.  (N/A if the research is not an FDA-Regulated Clinical Trial ) | | | | | | | | | | | | | | |
| 1. **Elements of Consent Disclosure** (All required and all appropriate additional elements must be disclosed and documented) | | | | | | | | | | | | | | | |
| **Required:** *(\*Starred elements can be omitted if there are none*.)  A statement that the study involves research.  An explanation of the purposes of the research.  An explanation of 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 to 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.*\**  An explanation of how to contact the research team for questions, concerns, or complaints about the research.  An explanation of how to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects’ rights; to obtain information; or to offer input.  An explanation of whom to contact in the event of a research-related injury to the subject.  A statement that participation is voluntary.  A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.  A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.  One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:  A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; or  A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.  A statement that the subject’s biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. (**N/A if research is subject to Pre-2018 Requirements)**  A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. (**N/A if research is subject to Pre-2018 Requirements)**  For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). (**N/A if research is subject to Pre-2018 Requirements)**  Any additional information which should be given to subjects when in the IRB’s judgement the information would meaningfully add to the protection of the rights and welfare of subjects. [[4]](#endnote-3)  **Required for Research Involving More than Minimal Risk**  An explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.  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. | | | | | | | | | | **Required for Clinical Trials**  The approval of the IRB.  The probability for random assignment to each treatment.  The subject's responsibilities  When applicable, the reasonably foreseeable risks or inconveniences to an embryo, fetus, or nursing infant.  The important potential benefits and risks of the alternative procedures or courses of treatment that may be available to the subject.  When there is no intended clinical benefit to the subject, a statement to this effect.  A statement that monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.  If the results of the trial are published, the subject’s identity will remain confidential.  **Required for FDA-Regulated Research**  A statement that notes the possibility that the Food and Drug Administration may inspect the records.  The data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.  The investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.  For FDA-regulated non-Phase I controlled trials: “A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”  **Additional:** (Include when appropriate.)  A statement that the particular treatment or procedure may involve risks to the subject, which are currently unforeseeable.  A statement that if the subject is or becomes pregnant, the particular treatment or procedure may 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 the subject that may result from participation in the research.  The consequences of a subject’s decision to withdraw from the research.  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.  The approximate number of subjects involved in the study.  The amount and schedule of all payments.  For DoD funded research:  In addition to the basic and required consent disclosures, consent documents must include:  A statement that the DoD or a DoD organization is funding the study.  A statement that representatives of the DoD are authorized to review research records. | | | | | |
|  | | | | | | | | | | | | | | | |
| The purpose of this worksheet is to provide support for IRB members reviewing research regulated by specific federal agencies. This worksheet must be used. It does not need to be completed or retained. | | | | | | | | | | | | | | | |
| 1. Additional Criteria for Veterans Administration (VA) Research (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | The research is not an intervention involving neonates. | | | | | | | | | | |
|  | | | | | The research does not involve the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289g(b)). | | | | | | | | | | |
| Yes  No | | | | | The research is not classified. | | | | | | | | | | |
| Yes  No | | | | | The research is not planned emergency research that involves a waiver of the consent process | | | | | | | | | | |
| Yes  No | | | | | The protocol and consent document are consistent with the HIPAA authorization. | | | | | | | | | | |
| Yes  No | | | | | If the research involves pregnant women as subjects, the VA medical facility Director must certify that the medical facility has sufficient expertise in women’s health to conduct the research if the research includes interventional studies or invasive monitoring of pregnant women as subjects. | | | | | | | | | | |
| Yes  No | | | | | The research does not involve clinical interventions with the potential of greater than minimal risk for children who are pregnant. | | | | | | | | | | |
| Yes  No | | | | | If the research involves biological specimens and data obtained from children, it is considered research involving children even if de-identified. | | | | | | | | | | |
| Yes  No | | | | | If the research involves neonates, the VA medical facility Director must certify that the medical facility has sufficient expertise in neonatal health to conduct the proposed research | | | | | | | | | | |
| Yes  No | | | | | If the research involves fetal tissue, it meets the requirements of the NIH Reminder of Legal Requirements Regarding the Acquisition and Use of Human Fetal Tissue for Research Purposes and NIH Policy on Informed Consent for Human Fetal Tissue Research. | | | | | | | | | | |
| Yes  No | | | | | If the research involves stems cells, it meets the requirements of the NIH Guidelines for Stem Cell Research. | | | | | | | | | | |
| Yes  No | | | | | If the research involves prisoners as subjects, a waiver has been granted by the Chief Research and Development Officer. | | | | | | | | | | |
| Yes  No | | | | | If the research involves children as subjects, the VA medical facility Director must approve participation in the research. | | | | | | | | | | |
| Yes  No | | | | | If the research is international research, approval has been granted from the VA medical facility Director and an approval document signed by the VA medical facility Director is provided. | | | | | | | | | | |
| Yes  No | | | | | If the research is an international Cooperative Studies Program activity, it has been approved by the Chief Research and Development Officer. | | | | | | | | | | |
| Yes  No | | | | | If the research includes taking a photograph, video and/or audio recording, the informed consent cannot be waived by the IRB. | | | | | | | | | | |
| Yes  No | | | | | If the research is exempt and involves interaction with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions, the following information must be given to the prospective human subject as applicable in writing or orally:   * Permission to participate can be withdrawn; * Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and * Contact information for the VA Investigator. | | | | | | | | | | |
| Yes  No | | | | | If consent is obtained electronically, the following must be met:  Authentication controls on electronic consent provide reasonable assurance that such consent is rendered by the proper individual; and  The subject dates the consent as is typical or that the software provides the current date when signed.  The consent process and document will disclose:  A statement that VA will provide treatment for research related injury in accordance with 38 CFR 17.85.  When applicable:  A statement that VA research subjects and/or their insurance will not be charged any costs related to the research except that some veterans are required to pay co-payments for medical care and services provided by VA and that these co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.  Information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio recordings will be used for the research, and whether the photographs, video, and/or audio recordings will be disclosed outside VA. | | | | | | | | If the research includes broad consent: (UMB is not currently utilizing broad consent)  Broad consent can only be obtained for the use of information or biospecimens that are collected initially for research purposes.  Documentation of informed consent for broad consent cannot be waived by the IRB.  The broad consent process and document will disclose:  A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations.  When applicable:  A statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research | | |
| Yes  No  Yes  No | | | | | For VA Research:  The consent document must be signed and dated by the subject or legally authorized representative, and by the person obtaining consent.  The IRB may waive the requirement for the signature of the person obtaining consent when there is no physical contact with the subject (e.g., where the only contact with the subject is through telephone or mail). | | | | | | | |  | | |
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| 1. Additional Criteria for Veterans Administration (VA) Research for Multi-Site Research When the Investigator is the Multi-Site Study PI for All Participating Facilities and the VA Central IRB is Not Being Used (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | Each participating site has an active FWA. | | | | | | | | | | |
| Yes  No | | | | | Each participating site has provided documentation of all relevant approvals, including approval of its IRB of record. | | | | | | | | | | |
| Yes  No | | | | | The IRB has approved the study-wide protocol and sample informed consent document to be provided to each participating site. | | | | | | | | | | |
| Yes  No | | | | | The study-wide protocol contains a mechanism for ensuring that any differences in the protocol or informed consent at engaged local participating sites are justified by the local site investigators, and that they are approved by the principal investigator before being implemented. | | | | | | | | | | |
| Yes  No | | | | | There are clear adverse event reporting requirements, a data monitoring committee if applicable (or other reliable monitoring mechanism) with clear procedures and requirements, and a clearly defined feedback loop to the investigator’s or study sponsor’s IRB. | | | | | | | | | | |
| Yes  No | | | | | The PI’s plan for communicating appropriate critical information (e.g., reports of data and safety monitoring) to engaged participating sites is adequate. | | | | | | | | | | |
| Yes  No | | | | | The principal investigator and all local site investigators will obtain written approvals from the relevant local VA facilities’ IRBs of record and all other local committees, subcommittees, and other approvals according to the respective applicable local, VA and other federal requirements. | | | | | | | | | | |
| Yes  No | | | | | Research will not be initiated at any given site until the local investigator has obtained written notification that the research can be initiated from the local associate chief of staff for research and development. | | | | | | | | | | |
| Yes  No  N/A | | | | | Confidentiality and information security requirements are met for information storage at and transmission to statistical or coordinating centers. **(“N/A” if there is no transmission of data.)** | | | | | | | | | | |
| Yes  No  N/A | | | | | Data monitoring committees will provide reports to the IRB **(“N/A” if there is not data monitoring committee.)** | | | | | | | | | | |
|  | | | | | **Additional Criteria when Service as the sIRB reviewing Veterans Administration (VA) Collaborative Research** | | | | | | | | | | |
| Yes  No | | | | | For reliance agreements, records of an IRB are addressed in the MOU for the VA Facility’s use of another entity’s IRB. The MOU ensures that all applicable federal and VA regulations are met | | | | | | | | | | |
| Yes  No | | | | | The protocol or other documentation submitted to the VA IRB of record must clearly delineate which research activities will be conducted as the VA portion of the overall Collaborative Research study ( e.g. by VA researchers on VA time or VA property). | | | | | | | | | | |
| Yes  No | | | | | The VA informed consent document must clearly state when procedures conducted at other non-VA institutions are part of the VA portion of the study. | | | | | | | | | | |
| Yes  No | | | | | Each institution engaged in the collaborative research must use the informed consent document required by its respective institutional policies for participants recruited from that institution or procedures requiring participation of the participants at that institution. The informed consent document may contain information on the project as a whole as long as the document clearly describes which procedures will be performed under VA auspices and which will be performed under a non-VA institution’s auspices. | | | | | | | | | | |
| Yes  No | | | | | The protocol addendum and/or IRB of record application must describe the data to be disclosed to collaborators, the entities to which the data are to be disclosed, how the data are to be transmitted, and how the transmitted data will be stored, retained, destroyed and/or further disclosed and to whom., This includes data from individual participants as well as other data developed during the research such as the analytic data and the aggregate data. | | | | | | | | | | |
| Yes  No | | | | | Refer to HRP-833-WORKSHEET-Considerations for Serving as the sIRB for considerations when serving as the sIRB for VA Research | | | | | | | | | | |
| Yes  No  Yes  No | | | | | **FOR ALL VA Research (whether multi-site or not)**  When VA research involves a certificate of confidentiality:  For studies which will include information about the subject’s participation in the subject’s VHA medical record, information must be given to the prospective subjects as part of the informed consent process.  For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality. | | | | | | | | | | |
| Yes  No | | | | | Creating or updating a VHA health record and creating a progress note for all research subjects (Veterans or non-Veterans) who receive research procedures or interventions as inpatients or outpatients at VA medical facilities that are either used in or may impact the medical care of the research subject at a VA medical facility or at facilities contracted by VA to provide services to Veterans (e.g., Community-Based Outpatient Clinics or community living centers). | | | | | | | | | | |
| Yes  No  Yes  No | | | | | Research involving the provision of in vitro fertilization services can be conducted by VA investigators while on official duty, or at VA facilities, or at VA-approved off-site facilities.  Research in which the focus is either a fetus, human fetal tissue, in-utero, or ex-utero, cannot be conducted by VA investigators while on official duty, or at VA facilities, or at VA-approved off-site facilities. | | | | | | | | | | |
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| 1. Additional Criteria for the Department of Defense (DOD) Research (All must be “Yes” or “N/A”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | The investigator and research staff are aware of the specific DOD requirements and have been educated about these requirements. | | | | | | | | | | |
| Yes  No | | | | | Confirm the following when serving as the reviewing IRB for DoD institutions:  Yes  No Each institution engaged in non-exempt human subject research must have a current federal assurance of  compliance.  Yes  No The involvement of DoD personnel in the conduct of the research is secondary to that of the non-DoD institution  Yes  No The DoD institution, non-DoD institution, and the non-DoD institution’s IRB have a written agreement defining the responsibilities and authorities of each organization in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02.  Yes  No If the research constitutes classified human subject research, the Component Office for Human Research Protections (COHRP), on behalf of the Component’s Senior Designated Official, must approve the agreement to rely on the non-DoD institution’s IRB. | | | | | | | | | | |
| Yes  No | | | | | For research that involves DOD-affiliated personnel as subjects , the key investigator must receive approval from the DOD component Human Research Protections Program to conduct the research. | | | | | | | | | | |
| Yes  No | | | | | For research that takes place in a DOD facility, the key investigator must receive approval from the command or DOD component HRPP or its delegate responsible for the facility. | | | | | | | | | | |
| Yes  No  N/A | | | | | For classified research, waivers of consent are prohibited | | | | | | | | | | |
| Yes  No | | | | | Civilian investigators attempting to access military volunteers should seek collaboration with a military investigator familiar with service specific requirements. | | | | | | | | | | |
| Yes  No | | | | | The review has considered ( and will document) the scientific merit of the research with feasibility of study completion considered. The IRB may rely on outside experts to provide an evaluation of the scientific merit. | | | | | | | | | | |
| Yes  No | | | | | The research does **NOT** involve prisoners of war or detainees as subjects.  This includes any person captured, detained, held, or otherwise under the control of DOD personnel (military, civilian, or contractor employee). Such persons include: Enemy Combatant, Lawful Enemy Combatant, Unlawful Enemy Combatant, Enemy Prisoner of War, Retained Person., and Civilian Internee. Such persons do not include personnel of the DOD being held for law enforcement purposes. It does not include persons being held primarily for law enforcement purposes, except where the United States is the occupying power. This prohibition does not apply to activities covered by investigational new drug or investigational device provisions the purpose of diagnosis or treatment of a medical condition in a patient. 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 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. | | | | | | | | | | |
| Yes  No | | | | | The research does not involve the testing of chemical or biological agents which is prohibited pursuant to Section 1520a of Title 50 U.S.C. unless exceptions for research for prophylactic, protective or other peaceful purposes apply.  Explicit written approval from DOHRP was obtained prior to the initiation of excepted testing of chemical or biological agents involving HSR. | | | | | | | | | | |
| Yes  No | | | | | Military personnel will not paid for research conducted while on duty.  Although federal personnel participating as human subjects in DOD-conducted research while on duty may be compensated up to $50 for each blood draw for scientific and research purposes in connection with the care of any person entitled to treatment at government expense, this IRB allows no such compensation when compensation is otherwise prohibited. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw. Non-Federal persons may be compensated for research participating other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. | | | | | | | | | | |
| Yes  No | | | | | Military personnel will not be paid from federal funds for research conducted while off duty. | | | | | | | | | | |
| Yes  No | | | | | Military and civilian supervisors, officers, and others in the chain of command will not influence the decisions of their subordinates regarding participation in research. | | | | | | | | | | |
| Yes  No | | | | | Military and civilian supervisors, officers, and others in the chain of command will not be present at the time of recruitment and consent process for any DoD affiliated personnel. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session. | | | | | | | | | | |
| Yes  No | | | | | When a subject is a Service Member, all Research Component, and or national Guard members in a federal duty status are considered to be adults. If a Service Member, Research Component, or Guard member in federal duty status , student at a service academy, or trainee is under 18 years of age, the recruitment process and the necessity of including such members as human subjects are considered during IRB review. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves a survey performed on DOD personnel, approval will be obtained from the DOD before the research commences. **(“N/A” if no survey with DOD personnel)** | | | | | | | | | | |
| Yes  No  N/A  Yes  No  N/A | | | | | If the research involves an interventions or interactions with subjects (“experimental subjects”), consent will be obtained unless waived by the Secretary of Defense. **(“N/A” if no interactions or interventions with subjects)**  Research involving a human being as an experimental subject is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition does not include exempt research involving human subjects)  (The requirement for consent may be waived by the ASD(R&E) if the following three conditions are met: (1) The research is necessary to advance the development of a medical product for the Military Services. (2) The research may directly benefit the individual experimental subject. (3) The research is conducted in compliance with all other applicable laws and regulations. The ASD(R&E) may delegate the waiver authority.)  If the research subject does not meet the definition of “experimental subject,” the IRB is allowed to waive the consent process. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research Involves cognitively impaired adults, there is anticipated direct benefit to the subject. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves Prisoners, the convened IRB reviewed the research. (Review by the expedited procedure is not allowed.) | | | | | | | | | | |
| Yes  No  N/A | | | | | Research involving fetal tissue must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.  See: <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g> (This is the enabling statute for 45 CFR 46.205. Compliance with Subpart B complies with this statute.) See also: <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-1>, and <http://codes.lp.findlaw.com/uscode/42/6A/III/H/289g-2>v | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves emergency medicine research, the Secretary of Defense must approve a waiver of the advance informed consent in accordance with provision 10 USC 980. | | | | | | | | | | |
| Yes  No  N/A | | | | | DoD-affiliated personnel, military and civilian supervisors, officers, and others in the chain of command:   * Are prohibited from influencing their subordinates to participate in research involving human subjects. * Must not be present at any human subject recruitment sessions or during the consent process for DoD-affiliated personnel * May participate in separate human subject research recruitment sessions. | | | | | | | | | | |
| Yes  No  N/A | | | | | If a subject becomes a prisoner, if the investigator asserts to the IRB that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-subject may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB’s approval to change the research protocol.  Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.  The convened IRB, upon receipt of notification that a previously enrolled human subject has become a prisoner, shall promptly (no longer than 30 days) re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy.  The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject’s confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-subject to continue to participate in the research.  This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves DOD-affiliated personnel as subjects, when applicable, the following is required.  If the research includes risks to their fitness for duty (e.g. health, availability to perform job, data breach), then informed consent form must inform DOD-affiliated personnel about these risks and that they should seek command or HRPP guidance before participating  For **greater than minimal risk research** involving DoD-personnel, when recruitment and consent occurs in a group setting, the IRB must appoint an ombudsperson.  The ombudsperson:  Must not have a conflict of interest with the research or be a part of the research team.  Must be present during the recruitment, monitoring that the recruitment and informed consent explain that  participation is voluntary and that the information provided about the research is consistent with the IRB-approved  script and materials, including digitally provided materials.  Should be available to address DoD-affiliated personnel’s concerns about participation.  If the study involves large-scale gnomic data (LSGD) collected from DoD-affiliated personnel (including the secondary uses or sharing of de-identified data or specimens) then the following is required:  The research is subject to DoD component security review and DOHRP approval  The research will apply an HHS Certificate of Confidentiality  Administrative, technical, and physical safeguards are considered, as the disclosure of the data may pose a risk to national security. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research is subject to Section 980 of Title 10, USC., consent will be obtained unless waived by the DOHRP . The IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e. the consent indicates that participation in the research is voluntary and the participant/representative is informed of research risks). | | | | | | | | | | |
| Yes  No  N/A | | | | | The key investigator must receive approval from the DoD-affiliated personnel’s command or DoD Component Human Research Protection Program (HRPP) for research that requires a waiver of informed consent oursuant to paragraph (b) of Section 980 of title 10 US.C. | | | | | | | | | | |
| Yes  No  N/A | | | | | When conducting multi-site research, a formal agreement is required to specify the roles and responsibilities of each party including a Statement of Work (SOW) and specific assignment of responsibilities. | | | | | | | | | | |
| Yes  No  N/A | | | | | The disclosure regarding provisions for research-related injury follows the requirements of the DOD component. **(“N/A” if no requirements of the DOD component.)** | | | | | | | | | | |
| Yes  No  N/A | | | | | If recruitment is in a group setting: **(Check if “Yes”. Either must be checked.)**  Research involves greater than minimal risk: The IRB has appointed an ombudsman who is unassociated to the research and will be present during the recruitment to monitor that voluntary participation is clearly and adequately stressed and that information provided about the research is clear, adequate, and accurate. The ombudsman may also be the research monitor.  Research involves minimal risk: The IRB has discussed and determined whether to appoint an ombudsman based in part on the subject population, the consent process, and the recruitment strategy. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves Human Subjects who are not U.S. citizens or personnel of the DOD, and is conducted outside the United States, and its territories and possessions: **(“N/A” if no category applies)**  Applicable national laws and requirements of the foreign country will be followed.  When a DoD-affiliated person who is also a citizen of the host nation is a research subject where differences in applicable standards exist between the United States and the host nation, the standard that is most protective of human subjects will be applied.  Take into consideration the cultural sensitivities in the setting where the research will take place. | | | | | | | | | | |
| Yes  No  N/A | | | | | When broad consent is used, DOHRP notification is required. | | | | | | | | | | |
| Yes  No  N/A | | | | | If providing data or information to a DoD Component under a pledge of confidentiality, ensure the data or information provided must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent. • All studies involving large scale genomic data collected on/from DoD-affiliated personnel will apply an DHHS Certificate of Confidentiality. | | | | | | | | | | |
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| 1. Additional Criteria for the Department of the Navy (DOD) Research (All must be “Yes” or “N/A”) | | | | | | | | | | | | | | | |
| Yes  No  N/A | | | | | For research involving more than minimal risk to subjects, the protocol includes an arrangement for emergency treatment and necessary follow-up of any research-related injury. **(“N/A” if no more than minimal risk)** | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves any of the following, the Secretary of the Navy has approved the research: **(“N/A” if no category applies)**  Waiver or alteration of the consent process.  Exceptions to the requirement for the consent process under 21 CFR 50.24.  Request for waiver of requirements of the Department of the Navy policy regarding human research protections.  Research involving severe or unusual intrusions, either physical or psychological, on Human Subjects (such as consciousness-altering drugs or mind control techniques).  Prisoners.  Potentially or inherently controversial topics (such as those likely to attract significant media coverage or that might invite challenge by interest groups). | | | | | | | | | | |
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| 1. Additional Criteria For Department of Justice (DOJ) Research Funded by the National Institute of Justice (NIJ) (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | The investigator and research staff are aware of and have been educated about the specific requirements of DOJ research funded by NIJ. | | | | | | | | | | |
| Yes  No | | | | | Projects have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer. | | | | | | | | | | |
| Yes  No | | | | | All investigators and research staff have signed employee confidentiality statements which are maintained by the investigator. | | | | | | | | | | |
| Yes  No | | | | | Identification of the funding agency (ies). | | | | | | | | | | |
| Yes  No | | | | | A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by the NIJ the subject should be informed that private, identifiable information will be kept confidential and will only be used for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the participants need to be explicitly notified. If the researcher intends to disclose any information, the participant needs to be explicitly informed what information would be disclosed under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research. | | | | | | | | | | |
| Yes  No | | | | | Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting | | | | | | | | | | |
| Yes  No | | | | | A copy of all data will be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.  At least once a year, the researcher shall provide the Chief, Office of research and Evaluation, with a report on the  progress of the research.  At least 12 working days before any report of findings is to be released, the researcher will distribute one copy of the  report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the  warden of each institution that provided data or assistance. The researcher shall not include an abstract in the  report of findings.  In any publication of results, the research shall acknowledge the Bureau’s participation in the research project.  The research shall expressly disclaim approval or endorsement of the published material as an expression of the  policies or views of the Bureau.  Prior to submitting for publication the results of a research project conducted under this subject, the research shall  provide two copies of the ,material | | | | | | | | | | |
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| 1. Additional Criteria For Department of Justice (DOJ) Research Conducted within the Federal Bureau of Prison (BOP) Research (All must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | The investigator and research team are aware of and have been educated about the specific requirements of BOJ research within the BOP | | | | | | | | | | |
| Yes  No | | | | | The project will not involve medical experimentation, cosmetic research, or pharmaceutical testing. | | | | | | | | | | |
| Yes  No | | | | | The research design is compatible with both the operation of prison facilities and protection of human participants. | | | | | | | | | | |
| Yes  No | | | | | The investigator will observe the rules of the institution or office in which the research is conducted. | | | | | | | | | | |
| Yes  No | | | | | Investigators who are not BOP employees have signed a statement agreeing to adhere to the requirements of 28 CFR 512. | | | | | | | | | | |
| Yes  No | | | | | All research proposals will be reviewed by the Bureau of Prisons Research Institutional Review Board. | | | | | | | | | | |
| Yes  No | | | | | The project has an adequate research design and will contribute to the advancement of knowledge about corrections. | | | | | | | | | | |
| Yes  No | | | | | The selection of participants within any one organization is equitable. | | | | | | | | | | |
| Yes  No | | | | | Incentives will not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. | | | | | | | | | | |
| Yes  No | | | | | Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:   * No longer in Bureau of Prisons custody. * Participating in authorized research being conducted by Bureau employees or contractors. | | | | | | | | | | |
| Yes  No | | | | | If a non-employee of the BOP will receive records in a form not individually identifiable, advance adequate written assurance that the record will be used solely as a statistical research or reporting record has provided to the agency. | | | | | | | | | | |
| Yes  No | | | | | Except as noted in the consent statement to the participant, the investigator will not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain. | | | | | | | | | | |
| Yes  No | | | | | Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system. | | | | | | | | | | |
| Yes  No | | | | | The consent will disclose: | | | | | | | | | | |
| Identification of the investigators  Anticipated uses of the results of the research.  A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable). | | | | | | A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an investigator may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.  A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility. | | | | |
| Yes  No | | | | | The investigator has academic preparation or experience in the area of study of the proposed research | | | | | | | | | | |
|  | | | | | The IRB application includes a statement regarding assurances and certification required by federal regulations, if applicable. | | | | | | | | | | |
| Yes  No | | | | | The investigator will assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the investigator. | | | | | | | | | | |
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| 1. Additional Criterion for Environmental Protection Agency (EPA) Research and Research Intended to be Submitted to the Environmental Protection Agency (Must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No | | | | | The research does not involve the intentional exposure of pregnant women, nursing women, or children to any substance. | | | | | | | | | | |
| Yes  No  N/A | | | | | If the results of research involving an intentional exposure of human subjects are intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA) the IRB’s determinations and approval will be submitted to the EPA Human Subjects Research Review official for final review and approval before the research can begin. **(“N/A” if the results of research involving an intentional exposure of human subjects are NOT intended to be submitted to or held for inspection by the Environmental Protection Agency (EPA))** | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves children, the research must either be:  observational research not involving greater than Minimal Risk or  observational research involving great than Minimal Risk but presenting prospect of direct benefit  **(“N/A” if the research does not involve children)** | | | | | | | | | | |
| Yes  No  N/A | | | | | If the research involves the intentional exposure of participants to a pesticide, the subjects of the research must be informed of the identity of the pesticide and the nature of its pesticidal function. | | | | | | | | | | |
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| 1. Additional Criterion for Department of Energy (DOE) Research (Must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No  Yes  No | | | | | Proper protections are in place for DOE/National Nuclear Security Administration (NNSA) who may be subject to coercion or undue influence. DOE and DOE site employees are considered vulnerable employees when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g. by ensuring they do not report to members of the research team) and that data collected about them is kept confidential.  The “Checklist for IRBs to Use in Verifying That HS Research Protocols Are in Compliance with DOE Requirements” submitted by the investigator verifies compliance with the Department of Energy requirements for the protection of Personally Identifiable Information  The protocol addresses the following DOE requirements:   * Keeping PII confidential. * Releasing PII only under a procedure approved by the responsible IRB and DOE. * Using PII only for purposes of the IRB-approved project. * Handling and marking documents containing PII as “containing PII or containing Protected Health Information (PHI). * Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII. * Making no further use or disclosure of the PII except when approved by the responsible IRB(s) and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project; (d) when required by law; or (e) with the consent of the participant/guardian. * Protecting PII data stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified. * Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1. * Minimum of twelve (12) non-blank characters * Must contain a lowercase letter * Must contain an uppercase letter * Must contain a number or special character * Must contain a nonnumeric in the first and last position * Must not contain the use ID * Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped. * Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products. * Accessing data via a secure, encrypted internet connection or through an Electronic Data Interface using TLS 1.1 or newer * Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, separate letter. * Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII * Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: <http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf>. * Reporting the loss or suspected loss of PII immediately upon discovery to (1) the DOE funding office program manager, or, if funded by a DOE laboratory, the DOE laboratory Program manager and the (2) the DOE HSP Program Manager and the NNSA HSP program manager. If these individuals are unreachable, immediately notify the DOE-CIRC by phone at 1-866-941-2472, by fax at 702-932-0189 or by email at [circ@jc3.doe.gov](mailto:circ@jc3.doe.gov). For additional information, see <http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident> reporting. | | | | | | | | | | |
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| 1. Additional Criterion for Department of Education (ED) Research (Must be “Yes”) | | | | | | | | | | | | | | | |
| Yes  No  N/A | | | | | If prior consent[[5]](#footnote-4) or written documentation of consent or parental permission is waived, the research does NOT involving gathering information about any of the following: (1) political affiliations or beliefs of the student or the student’s parent; (2) mental or psychological problems of the student or the student’s family; (3) sex behavior or attitudes; (4) illegal, anti-social, self-incriminating, or demeaning behavior; (5) critical appraisals of other individuals with whom respondents have close family relationships; (6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; (7) religious practices, affiliations, or beliefs of the student or student’s parent; or (8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program), **(“N/A” if neither consent nor written documentation of consent were waived)** | | | | | | | | | | |

1. HRP-312 - WORKSHEET - Advertisements; HRP-313 - WORKSHEET - Payments; HRP-418 - CHECKLIST - Pregnant Women; HRP-419 - CHECKLIST - Non-Viable Neonates; HRP-420 - CHECKLIST - Neonates of Uncertain Viability; HRP-417 - CHECKLIST - Prisoners; HRP-421 - CHECKLIST - Children; HRP-422 - CHECKLIST - Cognitively Impaired Adults; HRP-423 - CHECKLIST - Non-Significant Risk Device. [↑](#endnote-ref-2)
2. [↑](#footnote-ref-2)
3. [↑](#footnote-ref-3)
4. 21 CFR 56.109 (b): (b) An IRB shall require that information given to subjects as part of informed consent is in accordance with 50.25. The IRB may require that information, in addition to that specifically mentioned in 50.25, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects. [↑](#endnote-ref-3)
5. Prior consent means prior consent of the student, if the student is an adult or emancipated minor; or prior written consent of the parent or guardian, if the student is an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any Department of Education-funded survey, analysis, or evaluation. [↑](#footnote-ref-4)