**Expedited and Full IRB Review Guidance**

This document is intended for use as guidance during the IRB review of an expedited or full board study. It provides issues for consideration to help ensure the criteria for approval are met.

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| **Criterion (45 CFR 46.111 and 21 CFR 56.111)** | **Points for Consideration** |
| 1(i) - Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk. | * Risks can include physical, social, legal, and economic risks, etc. * Are the risks fully identified in the research plan? * What are the probability and magnitude of harm from the risks? * Does the research involve greater than minimal risk to subjects? * Can the specific aims be achieved by the proposed research design? * Can the research questions be answered with less risky or fewer procedures or fewer subjects? * What procedures or resources are available to mitigate risk?   + Investigators qualified?   + Adequate research staffing to conduct study?   + Adequate training of staff and ongoing contact with PI?   + Adequate facilities and resources to conduct the research?   + Do the inclusion and exclusion criteria minimize risk?   + Is there a data safety monitoring board or plan if > minimal risk or NIH sponsored or clinical trial?   + Are resources available for participants should they experience an adverse effect?   + What systems are in place to protect data confidentiality |
| 1(ii) - Risks to subjects are minimized whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. | * Does the study appropriately propose to obtain data from procedures that are already being performed on the subjects for diagnostic or treatment purposes? |
| 2 - 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. | * The IRB should only evaluate risk in terms of procedures being done for research and not include risks related to procedures that are being done for non-research purposes * Is there potential for direct benefit to subjects? * What knowledge is expected to result and what is the importance of that knowledge? * Are risks to subjects reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result? |
| 3 – Selection of subjects is equitable. | * Who is the target population? * Is this group appropriate for the study and to answer the research question(s)?   + Convenience vs. most appropriate * Are populations being unnecessarily excluded? * Are persons vulnerable to coercion or undue influence?   + Consider recruitment and payment methods * If any vulnerable populations are targeted, are proposed protections adequate? |
| 6 – When appropriate, the research pan makes adequate provision for monitoring the data collected to ensure the safety of subjects. | * If the research involves minimal risk, no DSMP/DSMB is required, but may be beneficial. Greater than minimal risk research requires a DSMP/DSMB per VCU WPP. NIH funded research and clinical trials also require a DSMP/DSMB. * If a DSMP/DSMB is needed:   + What data need to be monitored?   + Who needs to monitor the data?   + How often does data need to be monitored?   + What actions might be taken if monitoring identifies an issue?   + What will trigger those actions? |
| 7(i) – When appropriate, there are adequate provisions to protect the privacy of subjects. | * Privacy relates to the person (not the data about the person) * Is there an expectation of privacy? * What is being done to protect subject privacy?   + In recruitment and consenting processes   + During study conduct   + In follow-up contact * Are these provisions adequate to protect the privacy of subjects? |
| 7(ii) – When appropriate, there are adequate provisions to maintain the confidentiality of data. | * Confidentiality refers to data about a person * Is there risk of harm should there be a breach of confidentiality? * What protections are in place to adequately safeguard data during collection and storage?   + Coded data   + Restricted access   + Encrypted data / equipment * Is a Certificate of Confidentiality needed? |
| Additional protections for vulnerable populations – When some or all of the subjects, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence additional safeguards have been included in the study to protect the rights and welfare of these subjects. | * Are special or different consent procedures needed to reduce the possibility of undue coercion? * Is research subject payment appropriate? * Is consent from a legally authorized representative (LAR) needed in situations where subjects are unable to provide independent informed consent? |
| **Informed Consent Criteria** |  |
| 4 – Informed consent will be sought from each prospective subject or the subject's legally authorized representative. | * Will consent or any elements of consent be waived or altered? If yes, are the criteria met? * Will consent be:   + Legally effective   + Provide sufficient opportunity for consideration   + Minimize the possibility of coercion or undue influence   + In understandable language   + Exclude exculpatory language   + Include required and additional elements * Is the process for conducting consent discussions adequate? * Will there be adequate opportunity to read the document before it is signed? * Will there be an opportunity for subjects to ask questions? * Does the consent process minimize the possibility of coercion? |
| 5 – Informed consent will be appropriately documented, in accordance with, and to the extent required by the regulations. | * Has waiver of documentation been requested? If yes, are the waiver criteria met? * Will the subject or LAR sign and date the document? * Will a copy be given to the person signing the document? * Will informed consent be appropriately documented (include all required signature lines)? |
| **Other Pertinent Considerations** |  |
| The PI is appropriately qualified to conduct the study. | * Does the PI have the expertise and experience needed to conduct the study? * If a clinical study and the PI is not a MD, is a medical monitor identified? |
| All real or perceived conflicts of interest have been adequately managed. | * Has a COI been identified? * Is a management plan in place? * Are any additional protections/disclosures needed? |
| If the study is federally funded and congruence needs to be assured, the grant and the research plan are congruent. | * Are all of the following elements of the study congruent with the grant?   + Specific aims/study objectives   + Target subject population   + Study procedures * Instruments, if applicable |
| Have all special regulatory requirements been taken into consideration? | * Children’s category and parent signatures * Prisoner criteria * Pregnant women criteria * Neonate criteria * Funded by Dept of Defense, utilizes resources from a DoD component, or targets active military personnel * Funded by Dept of Justice * Funded by Dept of Education |
| HIPAA privacy protections are appropriate, if applicable. | * Does the study involve PHI? * Will all data be de-identified when recorded making HIPAA not applicable? * Is a partial waiver of authorization needed for identifying and recruiting subjects? * Is a partial waiver of authorization needed to waive any element of authorization (e.g., signature)? * Will a limited data set be used, requiring a data use agreement? * Will signed authorization be obtained? If yes, in a separate form or included in consent form?   + Is a waiver of authorization requested and appropriate? |
| **Full Board Motions** |  |
| Approve (Motion 1)  [Address all applicable points in the motion] | * All criteria for approval are met. If not, study cannot receive outright approval. * The PI is qualified. * Note the risk level of the study (greater than or no greater than minimal risk. If no greater than, can the study be downgraded to expedited for future reviews?) * Note any consent waivers being approved, if applicable. * Note the approval period (one year or more frequent) * Note all approved HIPAA pathways, if applicable? * Review and confirm special regulatory requirements, if applicable:   + Vulnerable populations (children, pregnant women, prisoners)   + Special funding agency requirements (DoD, Dept of Ed, Dept of Justice) * No COI issues remain outstanding. |
| Conditional Approval (Motion 2) | * Are all the criteria met? The convened board must be able to find that all criteria for approval are met in order to give conditional approval. * What minor corrections or confirmations would make this study approvable? * Who should be designated to review the response on behalf of the IRB? * Address all of the points in Approve / Motion 1 above. |
| Tabled (Motion 3) | * Identify which IRB approval criteria have not been met. * Note what would make the study approvable. (This item may reference the reviewer notes in RAMS-IRB or what has already been discussed). |