|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| The purpose of this checklist is to provide support for IRB staff conducting Pre-review. This checklist is to be completed by the HRPP Office staff in ETHOS.[[1]](#footnote-1) | | | | | | | | | | | | | | | | | |
| **IRB Number:** | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| **Protocol Name:** | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
| **Investigator:** | | | | Click or tap here to enter text. | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| **Regulatory Oversight** *(Check all that apply)* | | | | | | | | | | | | | | | | |
|  | [HHS (Department of Health and Human Services)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html)[[2]](#footnote-2) | |  | | [DOD (Dept. of Defense)](https://www.ncbi.nlm.nih.gov/books/NBK236819/) [[3]](#footnote-3) | | |  | [DOJ (Dept of Justice)](https://www.nij.gov/Pages/welcome.aspx)[[4]](#footnote-4) |  | | [EPA (Environmental Protection Agency)](https://www.govinfo.gov/content/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml)[[5]](#footnote-5) | | |  | Other Federal Agency |
|  | [FDA (Food and Drug Administration)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)[[6]](#footnote-6) | |  | | [DOE (Dept of Energy)](https://www.law.cornell.edu/cfr/text/10/745.101)[[7]](#footnote-7) | | |  | [ED (Dept. of Education)](https://www2.ed.gov/about/offices/list/ocfo/humansub.html)[[8]](#footnote-8) |  | |  | | |  | [ICH-GCP (International Center for Harmonization of Good Clinical Practices)](https://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html)[[9]](#footnote-9) |
|  | [OCR (Office of Civil Rights)](https://www.hhs.gov/ocr/about-us/index.html)[[10]](#footnote-10) | |  | | [NSF (National Science Foundation)](https://www.nsf.gov/bfa/dias/policy/human.jsp)[[11]](#footnote-11) | | |  | Tribal Law |  | |  | | |  | None |
|  | | | | | | | | | | | | | | | | |
| **Clarifications Requested** | | | | | | | | | | | | | | | | |
| Submission Type = New Study, Change in Protocol, Continuing Review, or Report Form  Instructions:   1. Enter your requested clarifications in the **Pre-Review Template Email** below. Enter also the submission type and date received in the brackets. Then, copy and paste your message into a new email sent from RSPP. Use the email subject line below for that email. 2. When the PI responds, evaluate whether all requested clarifications requested have been adequately addressed.    1. If so, update the Pre-Review in ETHOS noting “Resolved.”    2. If not, use the same template for a second email with only the remaining requested clarifications included.   **Pre-Review Template Email**  Pre-review of your submission is complete. The items with an asterisk listed below must be completed before the IRB can continue review of your submission. You may resubmit after these items are complete. If you have any questions about these items, please click "Add Comment" and notify the IRB Coordinator.  The following ancillary review committees have been assigned and documentation of approval from these entities must be provided:  \*Cancer Protocol Review Committee  \*Fairview Research  \*Gillette Research  \*HRPP Scientific Review  \*Regulatory review  The following documents or required information were noted as missing:  \*<required>  \*<required>  The items below were also noted during pre-review. These items do not need to be complete for the IRB to review your submission but they must be completed before the IRB will grant final approval.  Documentation of approval from:  Academic Health Center – Information Exchange (AHC-IE)  All University Radiation Protection Committee (AURPC)  Biorepository and Laboratory Services (BLS) Formerly BioNET  Clinicaltrials.gov registration review  Health information and Privacy Compliance Office (HIPCO)  Center for Magnetic Resonance Safety Committee (CMRR)  Institutional Biosafety Committee (IBC) including: rDNA Advisory Committee  Office of Institutional Compliance – Conflict of Interest  Stem Cell Research Oversight (SCRO)  Documentation of completion of required training for the following study team members:  <names>  Other items to address prior to final approval:  <items>    Information about ancillary reviews may be found on the Ancillary Review Matrix (https://drive.google.com/file/d/0B7644h9N2vLcMTl0ZE9yQkhLd3c/view)  For any revised documents, use track changes when making your edits. Leave track changes on; however, be sure to confirm your formatting is correct by viewing your document with “No Markup” before re-submitting. Please see the job aid, “Updating Documents,” for guidance.  Please note that resources such as Job Aids and Templates can be found by clicking on the "Help Center" tab in ETHOS. Or by visiting the IRB's website at: https://research.umn.edu/units/irb/how-submit/ OR https://research.umn.edu/units/irb/toolkit-library/templates  Please note that pre-review has three primary purposes:  1. It is a high level evaluation to ensure that a submission is complete and “review-ready”, whether that review is conducted by a committee or designated reviewer. This high level evaluation should identify missing items or very obvious inconsistencies between the protocol and other submitted materials.  2. Identification/assignment of ancillary review requirements and training requirements  3. Determination of risk level  Pre-review is NOT a full review of the study and is NOT a guarantee against additional modification required or deferral. | | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | |
| **Special Determ**in**ations (**Check all that apply) | | | | | | | | | | | | | | | | |
|  | Children | | | | |  | Non-Significant Risk Device (FDA) | | | |  | | Waiver/alteration of the consent process | | | |
|  | Wards | | | | |  | Non-viable neonates | | | |  | | Waiver of HIPAA authorization | | | |
|  | Pregnant women | | | | |  | Neonates of uncertain viability | | | |  | | Waiver of consent documentation | | | |
|  | Prisoners | | | | |  | Cognitively impaired adults | | | |  | | Waiver of consent for emergency research | | | |
|  | Students/Employees | | | | |  | Broad Consent | | | |  | |  | | | |
|  | | | | | | | | | | | | | | | | |
| **Protocol Tracking (**Check all that apply) | | | | | | | | | | | | | | | | |
|  | | Social/Behavioral/Education | | | |  | Biomedical/Clinical | | | |  | | | Clinical Trial | | |
|  | | Certificate of Confidentiality | | | |  | Deception | | | |  | | |  | | |
|  | | | | | | | | | | | | | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Notes** | | | | |
| Click or tap here to enter text. | | | | |
|  | | | | |
| **STUDY CLOSURE** | | | | |
|  | Research can be closed. | | | |
|  | | | | |
| IRB Analyst Name | | Click or tap here to enter text. | Date | Click or tap here to enter text. |

1. This document satisfies AAHRPP elements I.1.A, I.1.E, I.6.A, I.6.B, I.7.A, I.7.C. I-9, II.3.G, II.4.B, III.2.C [↑](#footnote-ref-1)
2. HHS agencies and departments that have signed on to the Common Rule. For all participating departments and agencies the Common Rule outlines the basic provisions for IRBs, informed consent, and Assurances of Compliance.  [↑](#footnote-ref-2)
3. Human research that is supported or conducted by the Department of Defense (DoD), or that involves of DoD personnel must comply with the Common Rule, Subparts B, C, and D ([32 CFR 219](http://www.ecfr.gov/cgi-bin/text-idx?SID=6ab4dd793ad42ddcd750e4c69ad54079&node=pt32.2.219&rgn=div5)); the [*DoD Instruction*, Number 3216.02, November 8, 2011](https://www.ncbi.nlm.nih.gov/books/NBK236819/); [*Dual Compensation Act*](https://www.govtrack.us/congress/bills/88/hr7381/text); [DoD Directive 3216.2](https://www.ncbi.nlm.nih.gov/books/NBK236819/), [SECNAVINST 3900.39D](https://fas.org/irp/doddir/navy/secnavinst/index.html); [OPNAVINST 5300.8C](https://www.med.navy.mil/bumed/humanresearch/Pages/default.aspx); [10 U.S.C. 980: *Limitation on use of humans as experimental subjects*](http://www.gpo.gov/fdsys/granule/USCODE-2011-title10/USCODE-2011-title10-subtitleA-partII-chap49-sec980/content-detail.html); and other regulations as applicable, including those specific to the separate DoD components: Army, Navy, Air Force and Marine Corps. [↑](#footnote-ref-3)
4. DOJ applies to National Institute of Justice (NIJ) and recipients of its funds are required to comply with Department of Justice regulations. [↑](#footnote-ref-4)
5. EPA has adopted the Common Rule at 40 CFR 26 and has published additional requirements for research it supports or conducts and for research intended for submission to the EPA as described in EPA Order 1000.17. Research that is conducted or supported by EPA must follow these additional requirements. [↑](#footnote-ref-5)
6. FDA applies to all clinical investigations regulated by the FDA involving human subjects. [↑](#footnote-ref-6)
7. DOE applies to all research funded by DOE, conducted at DOE institutions, or performed by DOE employees or their contractors. [↑](#footnote-ref-7)
8. ED applies to research funded through the Department of Education. The Family Educational Rights and Privacy Act (FERPA) (20 USC 1232g; 34 CFR 99) governs the disclosure of personally identifiable information from “education records” and access to education records by parents and eligible students. FERPA applies to all public elementary and secondary schools as well as post-secondary institutions that receive federal funding through the U.S. Department of Education. [↑](#footnote-ref-8)
9. ICH GCP describes the responsibilities and expectations of all participants in the conduct of clinical trials, including investigators, monitors, sponsors and IRBs. GCP covers aspects of monitoring, reporting and archiving of clinical trials and incorporating addenda on the Essential Documents and on the Investigator's Brochure. [↑](#footnote-ref-9)
10. OCR enforces civil rights laws, conscience and religious freedom laws, the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security, and Breach Notification Rules, and the Patient Safety Act and Rule [↑](#footnote-ref-10)
11. NSF is a common rule signatory. [↑](#footnote-ref-11)