HRP-401 | 3/29/2024

CHECKLIST: Pre-Review

The purpose of this checklist is to provide support for IRB Staff conducting Pre-review. This checklist is to be completed by the IRB staff, signed, dated, and retained.[[1]](#endnote-2)

Submission Information

|  |  |
| --- | --- |
| **Basic Information** | **Submission Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Investigator: | Click or tap here to enter text.  |
| Person Completing Checklist (Name): | Click or tap here to enter text. |
| Date Checklist Completed: | Click or tap here to enter text. |

Regulatory Oversight *(Check all that apply)*

[ ]  **Common Rule Requirements prior to January 21, 2019**

[ ]  **Common Rule Requirements as of January 21, 2019**

[ ]  DHHS[[2]](#endnote-3)

[ ]  FDA[[3]](#endnote-4)

[ ]  OCR/ OCR[[4]](#endnote-5)

[ ]  DOD / DOD[[5]](#endnote-6)

[ ]  DOE / DOE[[6]](#endnote-7)

[ ]  NSF / NSF[[7]](#endnote-8)

[ ]  DOJ / DOJ[[8]](#endnote-9)

[ ]  ED / ED[[9]](#endnote-10)

[ ]  Tribal Law / Tribal Law

[ ]  EPA / EPA[[10]](#endnote-11)

[ ]  EU GDPR / EU GDPR

[ ]  Other Federal Agency

[ ]  ICH-GCP / ICH-GCP[[11]](#endnote-12)

[ ]  None

Restrictions (Check if applicable)

☐ Principal Investigator is Restricted

Missing Materials

Click or tap here to enter text.

Special Determinations (Check all that apply)

[ ]  Children

[ ]  Wards

[ ]  Pregnant women

[ ]  Prisoners

[ ]  Students/Employees

[ ]  Not significant risk device (FDA)

[ ]  Non-viable neonates

[ ]  Neonates of uncertain viability

[ ]  Individuals with impaired decision-making capacity

[ ]  Waiver/alteration of the consent process

[ ]  Waiver of HIPAA authorization

[ ]  Waiver of consent documentation

[ ]  Waiver of consent for emergency research

Additional Study Features (Check all that apply)

[ ]  Social/Behavioral/Education

[ ]  Single-Site Study[[12]](#endnote-13)

[ ]  Deception

[ ]  Certificate of Confidentiality

[ ]  Biomedical/Clinical

[ ]  Collaborative Study (Lead Site)

[ ]  Collaborative Study (Participating Site)

[ ]  Clinical Trial

[ ]  Multi-Site Study (Lead Site)

[ ]  Multi-Site Study (Participating Site)

[ ]  Other

Notes

Click or tap here to enter text.

STUDY CLOSURE

[ ]  Research can be closed.

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 [↑](#endnote-ref-2)
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.  [↑](#endnote-ref-3)
3. The FDA includes a definition of clinical investigation that helps determine what FDA regulations (some or all) may apply, such as IND regulations. IND regulations apply to any clinical investigation of a drug. Clinical investigation means any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of 21 CFR 312, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice [21 CFR 312.3(b)]. Even if a drug is being used according to its label, if it is being used in a clinical investigation, the applicability of IND regulations will be assessed. FDA has long held that a clinical investigation is different from the practice of medicine where the primary intent is to treat an individual patient. [↑](#endnote-ref-4)
4. 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 [↑](#endnote-ref-5)
5. 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. [↑](#endnote-ref-6)
6. DOE applies to all research funded by DOE, conducted at DOE institutions, or performed by DOE employees or their contractors. [↑](#endnote-ref-7)
7. NSF is a common rule signatory. [↑](#endnote-ref-8)
8. DOJ applies to National Institute of Justice (NIJ) and recipients of its funds are required to comply with Department of Justice regulations. [↑](#endnote-ref-9)
9. 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. [↑](#endnote-ref-10)
10. 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. [↑](#endnote-ref-11)
11. 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. [↑](#endnote-ref-12)
12. “Single Site” status is recorded in Basic Study Information page of the ETHOS smartform rather than the “Additional Study Features” section of the pre-review. [↑](#endnote-ref-13)