15.03.01.O1.01 IRB Procedural Workflow for Human Subjects Research

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Procedure Statement

This Standard Administrative Procedure (SAP) establishes the procedural workflow for the review and oversight of human subjects research protocols by the Institutional Review Board (IRB). It defines the pathways for Exempt, Expedited, and Full Board review and delineates the specific responsibilities of the Director of Research Compliance, the IRB Research Compliance Coordinator, and the Chair of the IRB. The goal is to ensure consistent, efficient, and ethically rigorous protection of human subjects in accordance with the Belmont Report, the Common Rule (45 CFR 46), FDA regulations (21 CFR 50 & 56) where applicable, and system and institutional policy.

This SAP applies to all research involving human subjects conducted under the auspices of the institution, whether funded or unfunded, by faculty, staff, students, or agents, or using institutional facilities or resources. It covers initial review, continuing review, amendments, and related determinations (including Not Human Subjects Research determinations when routed through the IRB office).

Key Positions and Responsibilities

Director of Research Compliance (DRC)- The Director provides strategic and operational leadership for the Human Research Protection Program (HRPP) and Research Compliance Office.

- Oversees the IRB office infrastructure, staffing, and resource allocation.
- Ensures institutional policies and SOPs remain aligned with federal regulations and System requirements.
- May perform or supervise Not Human Subjects Research (NHSR), Exempt determinations, and other high-level regulatory assessments as delegated.
- Makes section 118 determinations
- Supervises review of Export Control disclosures.
- Serves as primary institutional liaison to OHRP, sponsors, and external IRBs for reliance agreements.
- Receives and escalates reports of serious or continuing non-compliance, unanticipated problems, and suspensions/terminations to the Institutional Official.
- Administers external database access for human research.
- Administers the SMART IRB reliance agreement systems.
- Manages Committee Membership and annual review process
- Conducts or oversees periodic quality assurance and compliance monitoring of the IRB process.

- Reports metrics, risks, and program performance to the Institutional Official (Vice President for Research).

IRB Research Compliance Coordinator (RCC)- The IRB Research Compliance Coordinator manages the day-to-day operations of the IRB office and serves as the primary operational point of contact for investigators and IRB members.

- Serves as a voting member of IRB
- Receives and logs all protocol submissions (new, amendment, continuing review, adverse events, non-compliance and closure).
- Tasked with the determination of exempt protocols.
- Provide guidance on Not Human Subjects Research (NHSR).
- Conducts administrative pre-review for completeness, required training documentation (CITI), conflict-of-interest disclosures, export controls, and other supporting materials.
- Performs initial risk and category assessment and recommends the appropriate review pathway (Exempt, Expedited, or Full Board) to the Chair.
- Performs review of NHSR, Section 118 Determinations, Exempt Protocols and as needed triages individual submission needs to the Director or Chair.
- Assigns Expedited and Full Board protocols to designated reviewers or prepares packets for convened meetings under the Chair's direction.
- Drafts determination and approval correspondence for Chair signature; maintains official protocol files and the IRB tracking system.
- Tracks timelines, issues reminders for continuing review, and manages the IRB meeting calendar, communicates with IRB members to ensure convened meeting attendance and minutes process.
- Organizes IRB convened meetings and records the minutes of the meeting.
- Provides all IRB members, at each monthly convened meeting, a list of protocols approved by expedited review since the previous meeting, with exempt and Not Human Subjects Research determinations included for information; receipt of the list is recorded in minutes.
- Serves as the primary communication channel between the PI, reviewers, and the Chair.

Chair of the IRB- The IRB Chair (or Co/Vice Chair when designated) provides scientific, ethical, and regulatory leadership for all IRB review activities.

- Makes or designates the official determination of the appropriate review category for Expedited or Full Board incoming protocol using the OHRP Human Subject Regulations Decision Charts and institutional guidance.
- Designates experienced IRB members available to conduct Expedited and Full Board Reviews.
- Meets with investigators to provide training or resolve other issues
- As outlined under SOP10 leads inquiries and investigations of non-compliance
- May exercise all authorities of the IRB for Expedited review except the authority to disapprove research (disapproval requires convened Full Board review).
- Chair(s) convenes Full Board meetings, ensures quorum (including at least one community member), and facilitates discussion and majority voting.
- Signs final approval for Expedited and Full Board determination letters.

- Has authority to escalate any protocol to Full Board review if concerns arise, even if it appears to qualify for a lower pathway.
- Collaborates with the DRC and RCC on policy interpretation, training, and continuous improvement of the HRPP.

Official Procedure(s)

1. Overall Intake and Triage Workflow- All human subjects research protocols follow a common intake path before branching into the specific review pathway.

    a. Submission: Principal Investigator (PI) submits a complete protocol application (protocol narrative, consent documents, recruitment materials, instruments, training certificates, COI disclosures) through the institutional electronic system (Cayuse).
    b. Receipt and Logging: IRB Research Compliance Coordinator logs the submission, assigns a protocol number, and opens the official file.
    c. Administration Pre-Review (typically within 3-5 business days): IRB Research Compliance Coordinator reviews for completeness, required training, signatures, and supporting documents. Incomplete submissions are returned to the PI with a clear list of deficiencies.
    d. Initial Category Recommendation: IRB Research Compliance Coordinator performs a preliminary assessment against the Human Subject Regulations Decision Charts and recommends the review pathway (Exempt / Expedited / Full Board) to the Chair.
    e. Official Determination of Review Type: IRB Chair (or designee) makes the final determination of the review pathway. The Chair may request additional information or reclassify the protocol at any time.
    f. Assignment: IRB Research Compliance Coordinator routes the protocol according to the Chair's determination (to designated reviewer(s) or to the Full Board agenda).

2. Not Human Subjects Research (NSHR)

    a. NHSR projects do not require review by the IRB. In general, the secondary analysis of existing data from publicly available sources does not require IRB review when it does not fall within the definition of human subjects research per 45 CFR 46.102. Public-use data with non-identifiable datasets (data with no direct or indirect identifiers) from open-access or restricted open-access sources do not require IRB review. The study team must also not have access to the key to re-identify any coded data for the duration of the study. Principal Investigator (PI) NHSR self-determination is allowed for the secondary analysis of existing data. Researchers with access to identifiable private information prior to data de-identification are subject to IRB review. Research that meets the definition of human subjects research, involves prisoners, or is FDA regulated research does not qualify for PI self-determination.

3. Exempt Review Pathway

a. Applicable when the research fits one or more of the exempt categories under 45 CFR 46.104 (and any limited IRB review conditions required by the 2018 Common Rule). Self-determination is not allowed.

b. Key Characteristics

   i. Generally, no more than minimal risk and falls within a defined exempt category.
   ii. Determination made by the experienced reviewer (not by the investigator).
   iii. Full 45 CFR 46.111 criteria are not applied; the specific exemption conditions are verified.
   iv. Continuing review is generally not required under the 2018 Common Rule (unless the IRB specifically requires it or limited IRB review conditions apply).There are four exemption provisions under the 2018 Common Rule where the exemption itself requires limited IRB review:
      1. 45 CFR 46.104(d)(2)(iii): certain identifiable/riskier survey, interview, or public-behavior research
      2. 45 CFR 46.104(d)(3)(i)(C): certain benign behavioral intervention research involving adults
      3. 45 CFR 46.104(d)(7): certain storage/maintenance of identifiable information or biospecimens when broad consent is involved
      4. 45 CFR 46.104(d)(8): certain secondary research using identifiable information/biospecimens with broad consent

c. For those categories, an IRB member must conduct the specified limited review. The review is narrower than a normal IRB review; for example, it may focus on privacy/confidentiality protections or whether the research falls within the scope of broad consent.

d. Procedural Steps

   i. After the IRB Research Compliance Coordinator confirms the protocol is a candidate for exemption, the IRB Research Compliance Coordinator or DRC reviews the protocol.
   ii. The Research Compliance Coordinator evaluates the protocol against the applicable exempt categories and any limited IRB review requirements (privacy and confidentiality protections).
   iii. If the Research Compliance Coordinator or DRC determines the research does not qualify for exemption, the protocol is returned to the Chair for reclassification (typically to Expedited or Full Board). During the exempt protocol review process, the RCC or DRC may counsel PIs on best practices to be followed before a final determination can be provided.
   iv. Upon confirmation of exemption, the IRB Research Compliance Coordinator prepares the Memorandum / Determination of Exemption letter. The IRB Research Compliance Coordinator issues the letter to the PI and files all documentation. The PIs are fully responsible for implementing the study as submitted to IRB for determination. Modifications to the study must be submitted promptly prior to implementation, and unanticipated events must be promptly reported to the IRB.

v. Typical target timeline: 1–3 weeks from complete submission, depending on volume and complexity.

4. Expedited Review Pathway

    a. Applicable when research involves no more than minimal risk and falls within one or more of the categories published by the Secretary of HHS (and FDA, when applicable) under 45 CFR 46.110 / 21 CFR 56.110.

    b. Key Characteristics

        i. "Expedited" refers to the method of review (Chair or designated experienced reviewer(s)), not necessarily the speed.
        ii. Full approval criteria of 45 CFR 46.111 apply.
        iii. Some expedited reviews may be requested by funding agencies.
        iv. Reviewers may exercise all IRB authorities except disapproval; disapproval requires convened Full Board review.
        v. Continuing review requirements depend on the category and institutional policy

    c. Procedural Steps

        i. Chair confirms the protocol meets expedited criteria (minimal risk + category fit) and designates one or more experienced reviewers (often a Primary and Secondary reviewer model). If the protocol does not meet the expedited criteria, the protocol will be returned to the RCC for exempt determination. However, if the risks are higher and require an elevated level of review, the protocol will be assigned for full committee review.
        ii. The Research Compliance Coordinator assigns the protocol submission to the assigned reviewer(s) in the Cayuse portal
        iii. Reviewer(s) evaluate the protocol against the 45 CFR 46.111 criteria, consent process, risk/benefit balance, subject selection, privacy/confidentiality, and any vulnerable population protections.
        iv. Possible outcomes: Approved; Approved with conditions/stipulations; Deferred pending additional information; or Referred to Full Board.
        v. If stipulations are issued, the IRB Research Compliance Coordinator or DRC communicates them to the PI. The PI responds; the same reviewer (or Chair) verifies resolution.
        vi. Upon final approval, the IRB Research Compliance Coordinator prepares the approval letter (including approval period and any required continuing review interval). The Chair signs; the letter is issued, and the file is updated.
        vii. Typical target timeline: 2–5 weeks from complete submission.

5. Full Board (Convened) Review Pathway

    a. Required for research that is greater than minimal risk, does not fit an exempt or expedited category, involves certain vulnerable populations in ways that preclude lower review, or is referred by the Chair or designated reviewer.

    b. Key Characteristics

i. Review occurs at a convened meeting with a quorum of IRB members present, including at least one member whose primary concerns are in nonscientific areas.
ii. Approval requires the affirmative vote of a majority of those members present at the meeting.
iii. Full 45 CFR 46.111 criteria are applied and discussed.
iv. Continuing review is typically required at intervals determined by the IRB (commonly annually, or more frequently if risk warrants).

c. Procedural Steps

i. Chair (or designee) confirms the protocol requires Full Board review. IRB Research Compliance Coordinator places it on the agenda for the next convened meeting that allows adequate lead time (materials distributed to members typically ≥7 business days in advance).
ii. Primary and Secondary reviewers (or a similar assignment model) are designated by the Chair to lead the discussion.
iii. At the convened meeting, the Chair ensures quorum, discloses any conflicts of interest (members with conflicts recuse), and facilitates review.
iv. Possible actions: Approve; Approve with conditions; Defer (table) pending substantial revisions or additional information; Disapprove.
v. The IRB Research Compliance Coordinator records the discussion and vote in the official minutes. Minutes are reviewed and approved at a subsequent meeting.
vi. If conditions are imposed, the Chair or designated reviewer communicates them to the PI. Responses are reviewed by the Chair or designated reviewer (or returned to the Full Board if the conditions were substantial).
vii. Final approval letter is prepared by the IRB Research Compliance Coordinator, signed by the Chair, and issued. The approval period and continuing review interval are stated.
viii. Typical target timeline: 4–8+ weeks, driven primarily by the meeting calendar and any required revisions.

6. Summary Comparison of Review Pathways

Dimension	Exempt	Expedited	Full Board
Risk Level	Minimal / fits exempt category	No more than minimal risk + category	Greater than minimal risk or does not fit lower pathways
Who Reviews	Chair or IRB Research Compliance Coordinator	Chair and 1+ designated experienced reviewers (can be IRB Research Compliance Coordinator)	Convened IRB with quorum (majority vote)
Approval Criteria	Specific exemption category conditions (+ limited review if required)	Full 45 CFR 46.111 criteria	Full 45 CFR 46.111 criteria discussed & voted
Continuing Review	Generally, not required	Often required (depends on category/policy)	Typically required (interval set by IRB)
Key Roles	IRB Research Compliance Coordinator (pre-review) → Chair/ IRB Research Compliance Coordinator (determination)	IRB Research Compliance Coordinator (pre-review & assignment) → Chair/designated reviewers	IRB Research Compliance Coordinator (packet & minutes) → Chair (meeting) → Full Board
Typical Timeline	1–3 weeks	2–5 weeks	4–8+ weeks (meeting-dependent)

7. Post-Approval Responsibilities

    a. Amendments / Modifications: All changes must be submitted to the IRB before implementation (except those necessary to eliminate apparent immediate hazards). The IRB Research Compliance Coordinator and Chair determine whether the change is minor and the Research Compliance Coordinator will review(eligible for expedited review) or major and requires Chair review.
    b. Continuing Review / Administrative Check-In: Managed by the IRB Research Compliance Coordinator according to the approval letter. The Chair or designated reviewers re-evaluate the protocol under the applicable pathway.
    c. Unanticipated Problems / Non-Compliance: Reported promptly by the PI to the IRB office. The IRB Research Compliance Coordinator logs and escalates to the Chair and Director. Serious or continuing non-compliance and unanticipated problems involving risks to subjects or others are reported to the Institutional Official and, when required, to OHRP/FDA/sponsors.
    d. Study Closure: PI submits a closure report. IRB Research Compliance Coordinator processes and files; Chair or designee acknowledges as appropriate.
    e. From time to time IRB Office will conduct post-approval monitoring on select protocols as required by SOP 9

Documentation & Record Retention

The IRB Research Compliance Coordinator maintains the official protocol file (electronic and/or paper as required by institutional policy), including the complete submission, all correspondence, reviewer checklists, determination/approval letters, meeting minutes (for Full Board), and continuing review materials. Records are retained for a minimum of three years after the completion of the research (or longer if required by the funding agency, FDA, or institutional policy).

Escalation & Authority

Any member of the IRB office, the IRB Board, and participants of the study may raise concerns about a protocol's classification or conduct. The Chair has final authority to reclassify a protocol to a higher level of review. The Director of Research Compliance has the authority to intervene on systemic compliance issues, resource needs, or external reporting obligations. Ultimate institutional authority for the HRPP rests with the Institutional Official Vice President for Research).

Related Statutes, Policies, or Requirements

- 45 CFR Part 46 (Common Rule) – Protection of Human Subjects
- 21 CFR Part 50 - Protection of Human Subjects in FDA-regulated Clinical Investigations
- 21 CFR PART 56 – IRB General Standards in FDA-regulated Clinical Investigations
- The Belmont Report (Respect for Persons, Beneficence, Justice)
- Institutional Federalwide Assurance (FWA) with OHRP
- OHRP & FDA Joint Guidance on IRB Written Procedures

Contact Office

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