SOP-A-001: TC IRB Standard Operating Procedure (SOP) for Establishing, Implementing and Updating IRB Policies and Procedures

Purpose
To establish a standardized process for creating, updating, reviewing, and approving policies and procedures (P&Ps) within the Teachers College Institutional Review Board (TC IRB).

Scope
This SOP applies to all members of the TC IRB, including the Quality Assurance & Education Specialist, IRB Chair, Research Compliance Director, and other relevant stakeholders involved in the review and approval process of IRB P&Ps.

Responsibilities
- **QA & Education Specialist:** Drafts and initiates the review process for new or updated P&Ps.
- **IRB Chair/Research Compliance Director**: Provides input, comments, and final approval for P&Ps.
- **Institutional Official (IO)/Research Integrity Officer (RIO)**: Reviews P&Ps as needed, with varying levels of involvement to assess institutional liability and support.
- **Other Stakeholders (e.g., IT, General Counsel, Global Engagement, Risk Management)**: Review P&Ps for specific expertise when necessary.

Policy
The TC IRB operates under federal regulations governing human subjects research and is supported by institutional policies and written procedures to ensure the rights and welfare of human research subjects. The IRB maintains compliance with 45 CFR Part 46 (Common Rule), and the HIPAA Privacy Rule (45 CFR Parts 160 and 164).

Procedure
1. **Drafting the Policy**
    - The QA & Education Specialist drafts the initial version of the P&P.
    - The draft is based on regulatory requirements, benchmarking with other institutions, and internal feedback on current practices.
2. **Initial Review**
    - The drafted P&P is sent to the IRB Chair and the Research Compliance Director for initial review and comments.
    - If the P&P involves specialized areas (e.g., IT, legal aspects), the relevant departments are consulted for their input.
3. **Revision and Feedback**
    - The QA & Education Specialist incorporates feedback from the initial review.
    - The revised draft is circulated among selected IRB members or specific stakeholders for further comments. To minimize delays, this review may be done via email with a set deadline for responses.
4. **Internal Approval**

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- After incorporating all necessary revisions, the final version of the P&P is reviewed and approved by the IRB Chair or Research Compliance Director.
- The RIO/IO is involved in the final review if their input is deemed necessary.

5. **Board Review**
   - The approved P&P is presented to the full board during a regularly scheduled meeting for final comments and input.
   - Proposed changes are included in the meeting agenda and distributed at least one week prior to the meeting.
6. **Legal Review**
   - If applicable, the final version of the P&P is reviewed by a legal expert to ensure compliance with institutional, local, state, and federal regulations.
7. **Information Technology Review**
   - If the P&P involves or impacts information technology systems or processes, an IT review is conducted to ensure technical feasibility and compliance with IT policies.
   - The IT review is performed after the legal review and before final approval by the IRB Chair/Research Compliance Director.
   - The IT department provides feedback on any necessary technical adjustments or considerations.
8. **Implementation**
   - Once the IRB board and relevant stakeholders provide their input, and any additional revisions are made, the P&P is implemented.
   - The final version is circulated to all IRB members and relevant stakeholders as an official document.
9. **Communication**
   - All updated or new P&Ps are communicated to the IRB members and relevant parties via email and are made available on the TC IRB website and document repository in Mentor IRB, as applicable.
   - A summary of significant changes is provided to ensure clear understanding among the members.
10. **Monitoring and Evaluation**
    - The effectiveness of the P&P is monitored through regular audits and feedback from IRB members.
    - Necessary adjustments are made based on this feedback to ensure continuous improvement.
    - Each approved P&P will be reviewed at least every three years. The review date is determined from the last date of approval. Extensions may be granted by the Research Compliance Director as needed. Additionally, changes may be required on an ad-hoc basis if the particular P&P is affected by new changes or revisions to federal, state, and/or institutional policies

Documentation

- All drafts, feedback, and final versions of P&Ps are documented and archived.
- Records of the review and approval process are maintained for transparency and future reference.

References

- ISO 9001 - Clause 7.5 Documented information
- 45 CFR 46.103

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- 45 CFR Parts 160 and 164 (Privacy Rule)
- OHRP and FDA Guidance on IRB Written Procedures (2018)

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