Consolidating/Centralizing IRBs at the NIH

CCRHB Meeting

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IRB Challenges/Problems at NIH

- There are 12 IRB panels; three are administratively consolidated (neuroscience panels).
- There are three different document repository systems for protocols (iRIS x2 and PTMS).
- Number of protocols per IRB varies (50-470).
- Time for processing and approving protocols is variable and in some cases lengthy.
- IRB processes are diverse and vary among ICs--too often involve variable deliberations and minor stipulations.
- Inconsistent practices cause concerns about lack of efficiency and variable follow-up to some compliance issues, despite operating as fully accredited by AAHRPP.

Recommendations for Centralization

- Arose most recently from the NIH Leadership Forum (November 2016), the Advisory Committee to the DDIR (June 2016), and our AAHRPP site visit (January 2017).
- Advice on process was sought from outside the NIH, including HRPP Directors from JHU, U. Michigan, Partners (Boston), and Washington U. St. Louis.
- Advice was also sought from inside the NIH, including IC Directors, SDs, CDs, IRB Chairs, IPAC members, OHSRP at various meetings.
- Goal: Reorganize the NIH IRB system by consolidation and centralization within the coming year

Source of the Proposal

- A committee of IC Directors and delegates was assembled and met 3 times between January and April 2017
- An executive committee of IC Directors together with two IRB professionals and the Office of Human Subjects Research Protections Director prepared the draft proposal after 6 meetings.
- Proposal has been reviewed and approved by committee as a whole, Scientific Directors, Clinical Directors, NIH Director

Proposal Elements and Target Dates (1)

1. Procure a unified NIH-wide protocol management system utilizing iRIS. A Joint Technical Team of PTMS and iRIS experts is overseeing migration of data from legacy systems to new iRIS system. To be completed Spring 2018.
2. Will require use of standard protocol templates for both scientific and IRB review.
3. Long-term: Integrate protocol authoring tool, data management, protocol resource requirements into a relational database using BTRIS resources.
4. Clarify that scientific review and review of COI are not primary responsibilities of the IRBs.

Proposal Elements and Target Dates (2)

5. Create a centralized IRB Operations Office in the CC to assign protocols to panels, track performance metrics, etc. Recruitment of new Director of IRB operations about to begin. All IRBs come under central management by June 30, 2018.
6. Create approximately 6 IRB panels with 7-13 members each with supporting alternates. These will start as consolidations *in situ* and then be centralized. Panels will all meet weekly.
7. The 6 panels will be generic and thematic with possible special panels as needed. Pilot panel has been created to review all protocols from NHLBI, NCI and NIAID IC, Scientific, and Clinical Directors, and NHGRI and NHLBI staff (Begin operating November 14, 2017).

Proposal Elements and Target Dates (3)

8. The following 6 panels are envisioned (most current protocols are from the IC shown in parentheses but eventually protocols will be assigned from all ICs):

- Oncology (NCI)
- Epidemiology (NIEHS, Epidemiology, NCI Special Studies)
- General Medicine #1 [pilot] (NHLBI, NHGRI, NIAID & NCI leadership)
- General Medicine #2 (NIAID)

(continued)

Proposal Elements and Target Dates (4)

8. (continued)

- **General Medicine #3** [likely to be the next panel to be activated after General Medicine #1] (NIDDK, NIAMS, NICHD). Initially, this will include many pediatric protocols, but eventually pediatric protocols will be assigned to general medicine IRBs with appropriate expertise.
- **General Medicine #4 (**currently the consolidated neuroscience IRB with NINDS, NIMH, NEI, NIDCD, NIDCR, NIAAA, NIA, CC etc.). General Medicine #4 will also incorporate NIDA-NIAAA substance abuse IRB.

  [NOTE: The possibility of a dedicated sIRB panel for multisite studies is under consideration.]

Proposal Elements and Target Dates (5)

9. A new Chair and Vice-chair, and new members will be chosen for each panel in the initial consolidation process as the new procedures are being put into place.
10. Chair and Vice-chair will be paid; members not affiliated with NIH receive per diem and honorarium; other member participation will be supported through their ICs. The Chairs and VC and panels will undergo annual evaluations as to the quality, meaningfulness, and efficiency of the IRB reviews.
11. The Chair, VC, and member time-limited appointments are renewed on a regular schedule, and reappointment will be based on performance evaluations and the needs of the IRB.

Proposal Elements and Target Dates (6)

12. A new protocol is assigned to next available and theme/expertise appropriate panel by the IRB Operations Office.
13. Protocols remain with panel until final approval of initial review. Amendments may or may not be sent to the original panel; determination made based upon extensiveness, risk, and complexity of changes.
14. Meeting packets circulated electronically via iRIS
15. Medical writers take minutes at all meetings, edit protocols, and draft stipulations, with the benefit of electronic tools to the extent possible.

Proposal Elements and Target Dates (7)

16. Submissions for expedited review are evaluated and approved by IRB Operations staff, Chairs/Vice-chairs, and or designees of Chair; panel review is an option.
17. Problem reports are assigned to the panel that reviewed the original protocol.
18. Chairs and Vice-chairs meet monthly with officials; annual retreat is a feature.

NOTE: Ongoing evaluation and continuous education to be applied.

Questions?

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