



Observations and Follow-up after Association for the Accreditation of Human Research Protection Programs (AAHRPP) Reaccreditation Site Visit

CCRHB Meeting

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Michael Gottesman, M.D.

Deputy Director for Intramural Research and Institutional Official



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AAHRPP Accreditation Process

- AAHRPP is the major not-for-profit national accrediting body for human subjects protection programs
- The process involves an extensive application one year in advance and subsequent site visit
- NIH was previously fully accredited for an initial 3 years beginning in 2014. The reaccreditation site visit was December 12-16, 2016.
- There were 4 AAHRPP site visitors who conducted 114 interviews, including IRB chairs, IRB members and staff, clinical researchers and staff, IC and HRPP leadership.
- The site visit lasted 5 full days included entrance and exit briefings of NIH leadership.

AAHRPP Overview (1 of 2)

Excerpts from AAHRPP Report, March 20, 2017

- *Organization-wide, all Institutes have expansive concept development and significant scientific review processes at both protocol initiation and also during the conduct of the study that significantly contributes to the scientific integrity of the protocols and the protection of human participants.*
- *The Clinical Center's Patient Representative and Office of Patient Safety and Clinical Quality serve as a model for improving participant protections.*

AAHRPP Overview (2 of 2)

- *NIH's Office of Human Subjects Research Protection was highly valued by researchers, research staff, Institutes Directors, Institute IRBs and administrative staff for their guidance, expert knowledge, and leadership in support of the HRPP.*
- *The Clinical Center's Department of Bioethics and National Institute of Mental Health's Human Subjects Protection Unit provided educational opportunities and consultation in consent methods...*
- *The highly-trained clinical research nursing staff were sensitive to the needs of research participants and supported the needs of clinical research.*
- *There was strong dedication at all levels of NIH to prioritizing exceptional patient care in the context of human participant research.*

AAHRPP Recommendation

Full Reaccreditation
March 20, 2017

Key Observations (1 of 2)

- ***The [NIH] HRPP was not allocated the resources necessary to carry out policies and procedures across all federated institutes. Researchers and administrative personnel across the organization described a lack of resources to support protocol development, IRB oversight and administration, the OHSRP office, and IT infrastructure to harmonize application systems, establish connections to isolated data such as monitoring data, and to efficiently conduct functions such as internal training and assessment.***

Key Observations (2 of 2)

- ***Researchers described review of research by the convened IRB as not timely. Contributing to this area of concern are the use of three separate IRB computer systems, inconsistency in the review processes across multiple IRBs, lack of standardization of application forms, consent templates, and protocols, duplication of review between scientific reviews and IRB review, and inefficiencies in the conduct and operation of the individual IRBs.***

Actions (1)

1. Implement one NIH-wide system (Integrated Research Information System [**iRIS**]) to manage all protocols.
2. Use standardized protocol templates for scientific and IRB reviews. The proposal clarifies that scientific review and review of COI are not the primary responsibility of IRBs.
3. Create a centralized IRB Operations Office to assign protocols and track progress for reviews by six NIH IRB panels with 7-13 members that will meet weekly.

Actions (2)

4. IRB panels will be generic medicine/pediatrics or thematic with possible special panels as needed (e.g., epidemiology, oncology).
5. Expedited reviews are evaluated and approved by IRB Operations staff, IRB Chairs/Vice-chairs, and or designees of the Chair, although panel review remains an option.
6. Access to protocol navigators for all NIH clinical investigators and IRBs is provided through a centralized Office of Research Support within the Clinical Center.

Questions?



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