

The Ethics Committee and The Role of the Institution

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The Ethics Committee and the Role of the Institution

- The relationship between the EC and the Institution
 - The role of each with respect to the other
 - Key functions
- Pitfalls for both
- Strategies for successful co-operation in fulfilling respective missions

The Role of the Institution

- What kinds of institutions?
 - Hospitals, biomedical research centers, universities and colleges, and combinations of all of these
 - Healthcare providers
 - Researchers and scholars
 - Teachers and trainers
 - Policy-makers, health ministries

The Role of the Institution, cont.

- To maintain/expand its reputation by successfully fulfilling its multiple missions
- To maintain the PUBLIC TRUST
 - Funding
 - Personnel: Students, Faculty, Study Participants

The Role of the Ethics Committee

- To serve as a built-in conscience of the institution
- To review and approve studies prospectively and ongoing
- To enforce applicable rules
 - Using sanctions on approval and/or funding
- To foster a culture of awareness of subjects' welfare and rights
 - Education/training
 - Enforcement

The Role of the Institution, cont.

- In view of the existence of the EC:
- ...to support its EC adequately to enable it to fulfill its mission
- ...to refrain from interfering with the EC's efforts to fulfill its mission
 - Allow its EC to conduct its own independent review and exercise power that may exceed the leader's of the institution on certain issues:
 - If IRB disapproves a study, it cannot be conducted, even by directive of institutional leader

The Role of the Ethics Committee

- Serves as a form of self-governance by researchers of the institution
 - Usually, majority of EC members are affiliated with institution (exceptions in India)
- Serves as a quasi-independent body (independent of institution)
 - Enforces applicable rules
 - Must include members who are not employed by institution and are not scientists
 - Must have balanced, mixed membership'
 - Gender, background, professions

The Role of the Ethics Committee

- Education of its own members, of researchers
- Quality assurance of its own operations
- Capacity building with partner IRBs

Pitfalls

- Institutional leaders/administration may underfund the EC operations
- Institutional leaders/administration may not reward or compensate service of members on EC
- Researchers may show hostility toward EC; institutional leadership may do nothing to address this tension

Pitfalls

- IRB may adopt too antagonistic a tone toward researchers, overlook the importance of a collegial or customer-service ethic
- IRB may not ask for sufficient support from its institution, give in to inertia, and be too slow to do quality improvements
- IRB may fail to communicate to researchers the flexibility existing in US rules
 - E.g., for waivers of elements of consent

Pitfalls

- IRBs may not communicate the key importance of the Federal Wide Assurance and its terms (promises the institution makes to the US Government)
- IRBs may otherwise not explain the reasons for rules
- IRBs may take hard-line approach and avoid reasoned, principled compromises

Pitfalls

- IRBs may not identify and manage conflicts of interest well
 - Of IRB members, with respect to studies under review
 - Of institutional leaders, with respect to studies under review
 - Of researchers on studies under review, with respect to study sponsors

Pitfalls

- Institutions may not have robust COI disclosure and management systems
- ...and may not share COI information on a timely basis with EC
- ...and may not include ECs in management of COIs affecting studies under review

Strategies for Successful Cooperation

- Institutions must give adequate support to EC: space, personnel, budget, respect
- Institutional leaders must *demonstrate* respect for the EC and its independence of review
- Institutional leaders, lawyers, and researchers must refrain from interfering with EC's obligations
 - Including enforcing rules such as reporting noncompliance to federal agencies and sponsors and alerting financial administrators to shut off funds

Strategies for Successful Cooperation

- Institutions should include EC representatives in their COI management committees, ensure that COI disclosure systems are robust, and make data available to ECs timely
- Institutions should appoint a well respected senior person to chair the EC

Strategies for Successful Cooperation

- EC leaders must demonstrate respect for researchers and practice collegiality and a customer-service ethic
 - Be willing to listen to complaints/concerns and respond constructively
- EC leaders must cultivate/protect the independence of its review and actions
 - Support EC member and staff morale
 - Seek ways to reward/compensate members for service

Strategies for Successful Cooperation

- EC must communicate clearly to institutional leaders its needs for support
- EC leaders must be brave and fair!
- EC leaders should seek to cultivate consensus whenever possible, especially for difficult cases and policy questions, to ensure grounding within the institution

Strategies for Successful Cooperation

- EC should develop ties with other ECs and professional ethics organizations, to avoid isolation within the institution
- EC should strive to maintain a balance between supporting the research goals of the institution and enforcing external standards of ethical behavior
- ECs should remember to communicate the importance of maintaining the PUBLIC TRUST to the longevity of both institution and EC

Strategies for Successful Cooperation

- ECs must educate institutional leaders and researchers about the Federal Wide Assurance
 - What the institution has promised
 - Why it matters to keep the FWA valid
 - How the FWA works as the mechanism for OHRP to use to sanction noncompliant institutions

Asante

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