



# Research Ethics Consultation

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# Disclaimer

The views expressed in this talk are my own.  
They do not represent the position or policy  
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# Examples of Challenging Research Ethics Questions

- Research relationships:
  - How should an institution that is participating in an expanded access program for a drug for a rare disease allocate limited amounts of the drug?
- Genetics:
  - Do the researchers studying an autosomal dominant genetic disease have an ethical obligation to disclose the risk of this mutation to the descendants of a deceased research participant?
- Pediatric research:
  - When must researchers report sexual abuse that was disclosed during a study of adolescent parenting skills?

# Why Might Research Ethics Consultation Be Useful?

- While institutional review committees are the foundation for ethical review of research, a consultation service can play a very valuable role for investigators, research regulators, and research participants in addressing ethical questions that arise in the research process

# Research Is Increasingly Complex

- Growth in the number and size of multisite trials
- Comparative effectiveness research
- Advances in genomic research
- New modes of recruitment

# Definition of Research Ethics Consultation

- An *advisory* activity between *researchers or other stakeholders* in the research enterprise and one or more individuals knowledgeable about the ethical considerations in research
- To address ethical question or concerns related to *any aspect* of planning, conducting, interpreting, or disseminating results of research related to human health and well-being.
- The purpose of the interaction is to provide information; identify, analyze, and/or deliberate about ethical issues; and recommend a course of action.

(Beskow, Grady, Iltis, et al 2009)

# History

- First mentioned in the literature in 1990
- An ethics consultation service existed at the National Institutes of Health Clinical Center beginning in the 1990s
- More widespread practice of research ethics consultation developed in the mid-2000s when the National Institutes of Health initiated the Clinical Translational Science Award (CTSA) Program
- the CTSA Clinical Research Ethics Key Function Committee transitioned to become the National Clinical Research Ethics Collaborative  
<https://www.iths.org/crecc/>

# Current Status

- REC services exist in approximately 45 institutions in the US
- Clinical Research Ethics Consultation Collaborative serves as a nationwide group
  - Monthly video conferencing
  - Presentation of consultation cases
  - Publication of cases in the American Journal of Bioethics



# Rationale

- To provide a means of connecting ethical theory to practice
- To provide a venue for addressing new ethical challenges posed by cutting edge research

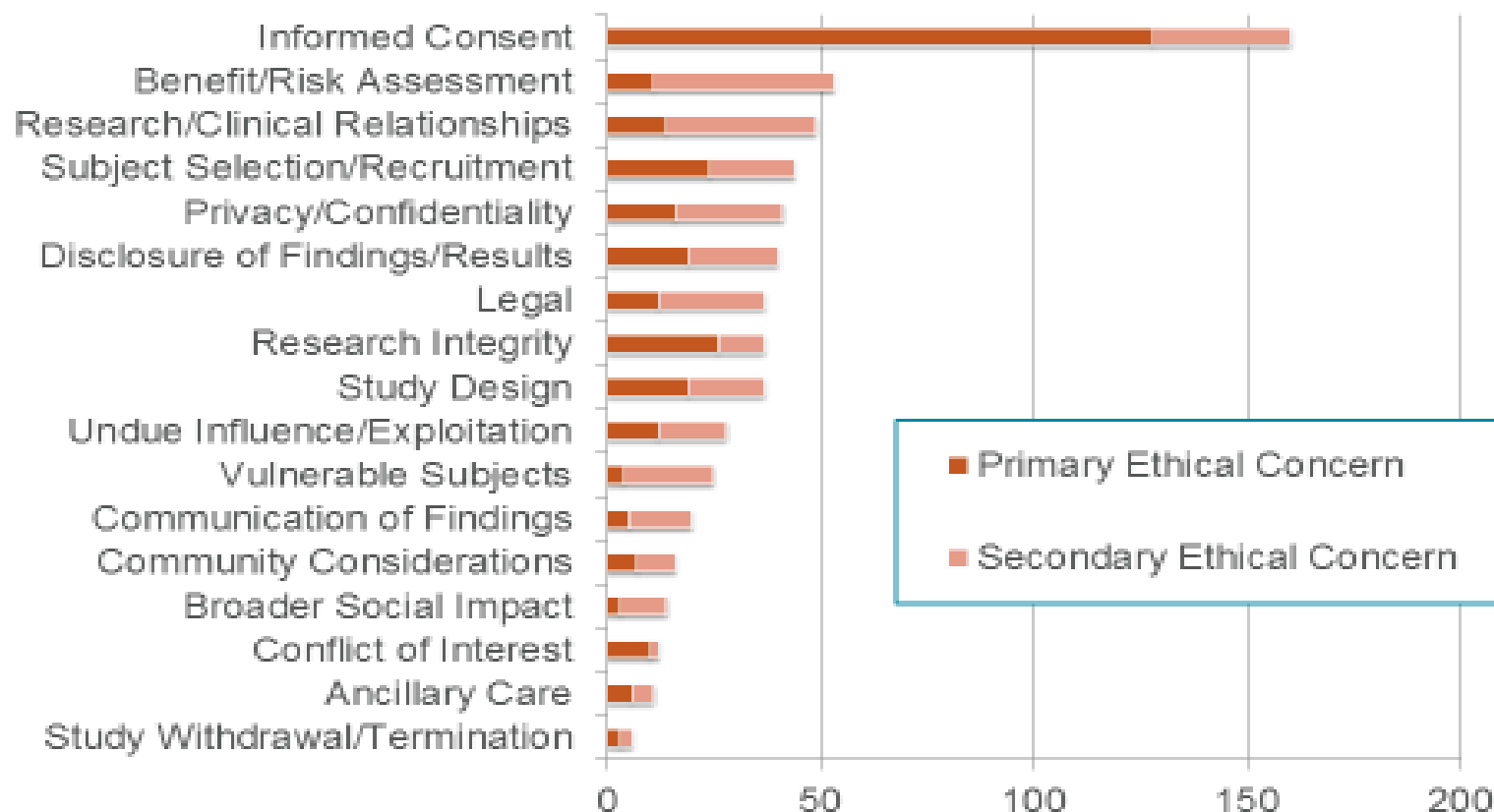
# The Goals of Research Ethics Consultation

- To enhance the substantive deliberations and determinations of IRBs.” (MacKay, 2001)
- To help scientists to address ethical and societal issues that may not have been considered yet or lie outside the scope of the existing regulatory framework (Harvard, Cho, Magnus. 2012)
- To generate a body of new scholarship arising from deliberation about questions during the course of the consultation service, there is the opportunity the communication of ideas, insights, and experiences from which others can learn or to which they can respond critically. (Wilfond 2012)
- To help maintain trust in the research enterprise

# Who provides REC?

- Individuals who have subject matter expertise in research ethics as well as practical training in serving as an ethics consultant
- Often these individuals have served on an IRB or a clinical ethics consultation service
- Core competencies
  - general facts related to the research oversight system
  - ethics historical facts
  - ethical reasoning
  - application of ethics analysis skills

## Ethical Concerns (N=359)



# Source Materials

- International research guidelines
- Federal regulations
- Professional codes of conduct
- State laws
- Case law
- Institutional policy
- National commission documents
- Academic literature
- Precedence of past consultations

# Consultation Methods

- REC should be structured in a systematic way to provide thorough and consistent advice
- Ascertain precisely what the question or concern is that needs to be addressed
  - Simple policy questions can be quickly answered
  - Complicated questions require formal meetings
  - Invite relevant stakeholders to join in the meeting
  - Seek out relevant literature on the issue in preparation for the meeting

# Consultation Methods

- Structure meeting to includes these elements:
  - Introduction of participants
  - Review of the ethical concern that needs to be addressed,
  - Presentation of the background information
  - Invitation of any additional, factual questions that need to be answered about the issue
  - Facilitation of a discussion of the ethical ramifications of the situation
  - Consideration of the various ethically acceptable solutions to the ethical concern.

# Consultation Methods

- Following the meeting, the consultant should prepare a consultation report summarizing:
  - The question
  - Background information
  - Details about the process of the consultation
  - Analysis and recommendations
- Subsequently the consultant should seek feedback about the report from the requestor before it is finalized.



# Practical Considerations

- Promote awareness of the consultation service
  - Offer to provide educational sessions to research groups on ethical concerns that researcher commonly encounter
  - Present consultation cases
  - Lectures on research ethics to trainees
  - regularly attend meetings held by research teams
  - Post notices on the institutional website about the consultation service
  - Include brochures about the consultation service in introductory materials given to new research participants
- Make the service easily accessible and rapidly responsive

# Practical Considerations

- It is not feasible for all research institutions to dedicate the necessary resources to establish a REC
- Strategies for outsourcing or sharing this function
  - Formation of a network may be useful solutions when this is the case.
  - Participation in the Clinical Research Ethics Consultation Collaborative (CRECC)  
<https://www.iths.org/crecc/consultations/request-a-consult/>).

# Evaluation

- Evaluation methods have been well developed for clinical ethics consultation services and can serve as a model for evaluation of REC (ASBH 2011)

# Controversies

- *Should the ethics consultant act as an expert or a facilitator?*
  - Subject matter expert vs. expert in the process of deliberation or mediation among others
- *How specific should ethical advice be?*
  - Giving a single answer or a range of morally acceptable options in response to a requestor's quest for advice

# Controversies

- *How broad should the consultant's advice be?*
  - Keeping the advice focused vs. broadening the analysis and recommendations beyond the requestor's question

# Controversies

- *How should research ethics consultation relate to research oversight committees and other institutional entities?*
  - Serving as one entity, separate entities, or overlapping entities
  - The answer may depend upon institutional resources and structure

# Controversies

- *How much confidentiality should RECs offer to requestors?*
  - If a consult is sought on a protocol that has already been reviewed and approved by the IRB, a note summarizing the consult will be forwarded to the director, ORS to be included in the protocol file.
  - If information is provided to RECS staff that constitutes a grave moral and/or regulatory violation, and the investigator is unwilling to disclose it him/herself to the IRB and/or institutional officials, RECS staff reserve the right to do so.

Taylor and Kass *American Journal of Bioethics* 8 (2008):33–35.

# Controversies

- *How should consultants handle consultation requests when laws and regulations diverge from ethically sound advice?*
  - Ethics consultants are not legal experts, unless they are specifically trained in law, and should not give legal advice.
  - If an ethics consultant believes that a law or regulation and ethically advisable action conflict, they should bring this discrepancy to the requestor's attention. How the requestor should then proceed is a matter of debate.



# Controversies

- *How should RECs handle situations when RECS and IRBS disagree?*
  - IRBs have regulatory authority while RECS are advisory.
  - The requesting researcher may find it useful to bring the consultation report that the REC has prepared to the IRB for their consideration.

# Controversies

- *Should there be triggers that lead to consideration of REC?*
  - Some recurring issues arise during the conduct of research that warrant consultation even if the issue is familiar.
  - Examples are situations when research involves a very risky intervention or a research subject is considered vulnerable and routine monitoring of consent would be advisable

# Conclusion

- Evidence indicates that research ethics consultation has played an advisory role in the conduct of clinical research.
- It has facilitated the translation of ethical theory into practice.
- Research ethics consultants tend to be called upon
  - When the conduct of research poses questions that are not fully addressed by existing regulations
  - When questions have not been anticipated by existing ethics scholarship
  - When regulations and scholarship seem to yield contradictory direction