

Death by Committee

and Other Research Admin Hazards

Death by Committee - The slow, painful death of a project prior to completion due to its assignment to a committee. May occur due to squabbling, apathy, or a lack of individual accountability among the members. -- **Urban Dictionary**



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Introduction:

- What is this presentation about
- How many people in this group serve on these committees?
- Spirit animal for committees

Spirit Animal Analysis and Team Naming Exercise

IRB Spirit Animal: Turtle

- Armored, protect human subjects
- Slow, their reviews take forever

IBC Spirit Animal: Peacock

- Showy, have a lot of fancy degreed scientists and staff
- Flighty, good luck getting them to show up for a meeting

IACUC Spirit Animal: Raccoon



**I THINK MY
SPIRIT
ANIMAL
HAS
RABIES**

Outline:

- Overview of Committees and Issues
- Game/Case Study
- Operations Improvement

Committees in Question:

- Institutional Review Board
- HIPAA/Privacy Board/GDPR
- Institutional Animal Care and Use Committee
- Institutional Biosafety Committee
- Institutional Review Entity/DURC/Export Compliance
- Radiation Safety Committee
- Conflict of Interest Committee

Committees in Question: IRB

- Human Subjects Research Ethics Reviews
 - Clinical Trials & Clinical Research (Chart review)
 - Surveys
 - Experimental Psychology
 - Educational Research
- Informed Consent
- Risk Benefit Analysis
- Privacy and Confidentiality
- Key concepts: Respect for Persons, Beneficence, Justice

Committees in Question: HIPAA/Privacy Board/GDPR

- HIPAA – Health Insurance Portability and Accountability Act
 - Applies to a Covered Entity – health care provider, insurance provider
 - PHI and 18 Unique Identifiers
 - Affiliated Covered Entity (ACE)
- Privacy Board
 - Ensures appropriate authorizations are in place
- GDPR – General Data Protection Regulation
 - Residents (citizenship agnostic) of the EEA (EU and Norway, Lichtenstein, Iceland)
 - Data and privacy protections
 - Legal basis for processing data

Committees in Question: IACUC

- Animal subjects research ethics reviews
 - Reduction, replacement, refinement
 - Animal models in research
 - Also reviews safety for research staff and containment
- Tissues purchased from a commercial vendor, tissues normally discarded by researchers, and most invertebrate use generally does not require an IACUC protocol

Committees in Question: IBC

- NIH support means requirement to adhere to NIH Guidelines for Recombinant DNA research
 - Recombinant DNA technology relates to the usage of three main tools: (1) enzymes (restriction enzymes, polymerases, and ligases); (2) vectors; and (3) host organism
- Viral vector/virus based gene delivery vector, genetically modified immune cells (CAR T), DNA vaccines, plasmid, rDNA, Synthetic Nucleic Acids, CRISPR, Gene Silencing Micro RNA
- IBC reviews for PPE, Biosafety Levels, any other safety related questions, and reporting of certain incidents

Committees in Question: IRE/DURC/Export Compliance

- DURC/IRE
 - NIH policy requires this review if you accept any funding
 - 15 DURC Agents and Toxins (Marburg, Ebola, Avian Flu), 7 Experimental effects
 - Biosecurity focus
- Export Compliance
 - Technology controls, sanctions rules
 - Foreign person vs US Person
 - Deemed Export
 - Select agents, other chemical and biological toxins, vaccine research, lab equipment

Committees in Question:

RSC

- Oversee the use of radioactive material and radiation-producing devices and keep radiation doses for employees, students, patients and visitors as low as reasonably achievable for any use including research
- Evaluates new users and uses of radioactive material
 - Training and experience of applicants
- Reviews personnel dosimetry data
- Must review program every 12 months for ALARA, provide recommendations to maintain ALARA

Committees in Question:

COI

- A conflict of interest (COI) arises in situations in which financial or other personal considerations have the potential to compromise or bias professional judgment and objectivity.
- A COI in Research Program administers activities related to
 - reporting, assessing, and managing financial and non-financial interests for the university research enterprise.
- Report: business ownership, stocks, OPA, other salary, gifts, I.P.
- A COI Investigator is an individual, regardless of title, role, or position, who is responsible for the design, conduct, and/or reporting of research – designated by the PI

Game of Committees: Confusion is Coming

- Rules:
 - Three rounds (review, documentation, efficiency) and two case studies
 - First case study is 4 min per round
 - Second case study is 2 min per round (so learn quick)
- Scoring System:
 - Review:
 - +1 for every committee you identify correctly
 - -1 for any incorrectly identify or that you leave off
 - Documentation:
 - Formation of the committee and operations
 - +2 for documenting process for consistency, bonus
 - Efficiency:
 - Turn around time for each committee is 30 days, and goal is to complete the review process within 3 months
 - Each month shaved off your total time to review completion is a bonus of 2 points
- Most efficient and well documented process wins at the end

Case Study 1

A principal investigator just called you to begin the regulatory approval process for a new Phase 2 Oncology Clinical Trial with an unapproved biologic. The trial involves enrolling human subjects who are prospectively assigned to either an experimental treatment group (administration of the investigational biologic) or standard of care treatment group. The investigational biologic production involves recombinant DNA, and the principal investigator owns stock in the biologic company providing the drug for the trial. Subjects will be receiving CT scans for research purposes only and the research is conducted in a university hospital.

Case Study 1 - answers

Case Study 2

An investigator asks to discuss an opportunity they were just contacted about - involvement in an early-stage international vaccine study that will be conducted at numerous sites in both the European Union (EU) and the United States. The research involves a high-risk adenoviral-vectored vaccine to protect against the avian flu, which will eventually be tested in human subjects. The investigator at your institution will be 1 of 3 sites around the world to begin testing with animal models, which includes the collection and use of identifiable human tissue samples. Animal model research and tissue collection will be conducted in a purely academic setting (i.e. not in a hospital). Data will be analyzed and stored in one of the EU sites, but will at some point be transferred to the US. Although the investigator does not get paid on behalf of the study sponsor, they have frequently spoken at the company's events for which their travel expenses are covered.

Case Study 2 - answers

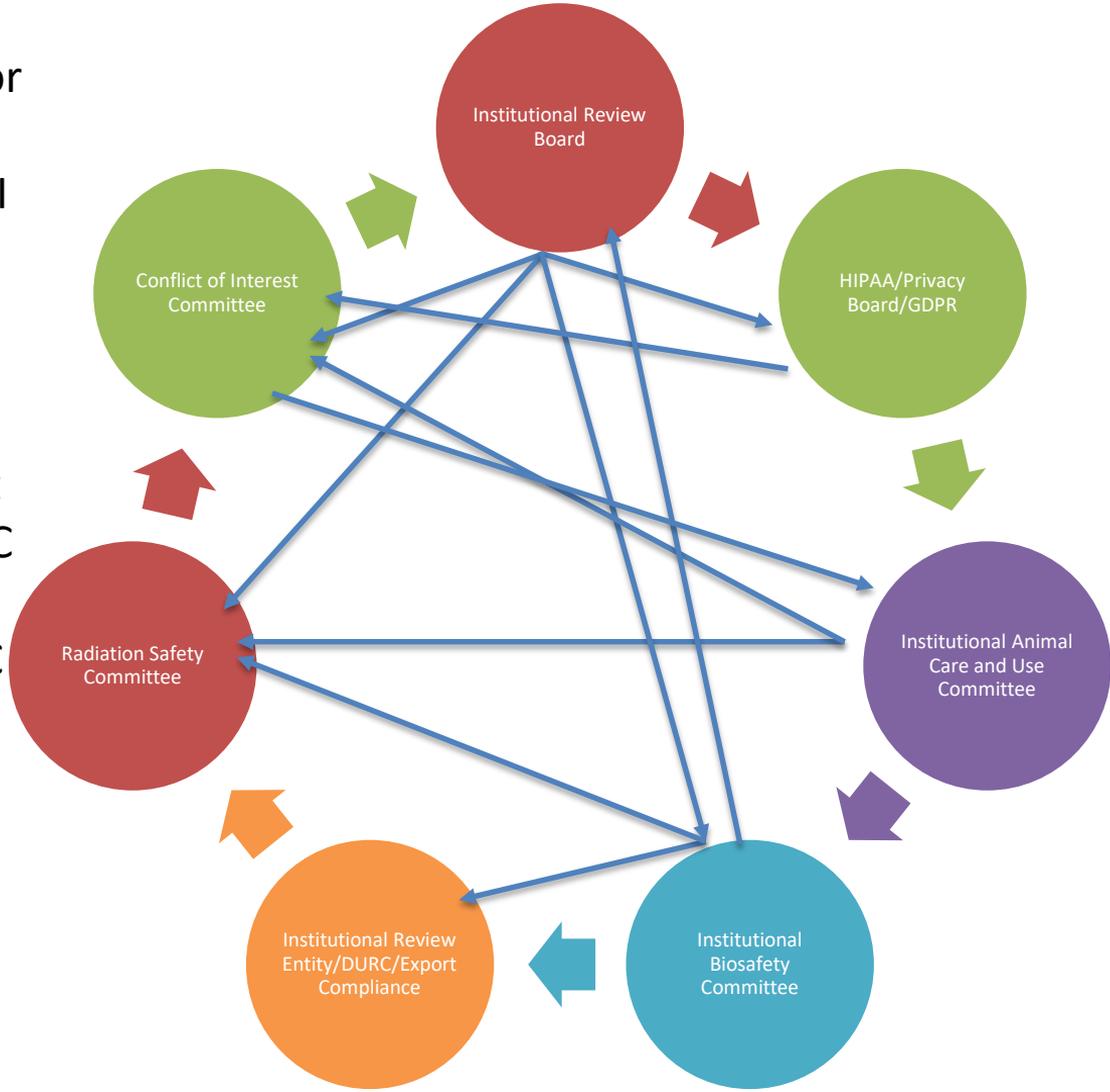
Committee Improvement ideas

- Committee cross pollination
 - Share membership across complimentary committees
 - IACUC chair serves on IBC
 - Biosafety Officer serves on IACUC
 - IRB analyst serves on IBC
 - COI analyst serves on IRB
 - Etc...

Committee Improvement ideas

- Committee Communication
 - IRB and IBC
 - IRB and RSC
 - IRB and COI
 - IACUC and IBC
 - Export and IBC
- Created a written SOP between committees
 - Established documentation standards
 - Established timelines for responses
 - Addressed issues navigating full reviews vs initial determinations
 - Inform between the groups the information that needs to be shared

- IBC reviews IRB for biosafety
- COI reviews IRB PI conflicts
- Privacy Board reviews IRB data
- RSC reviews IRB informed consent
- IBC reviews IACUC for biosafety
- DURC reviews IBC protocol for security
- Etc...



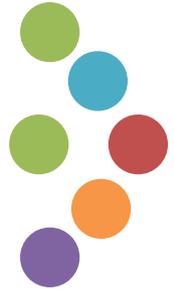
1 -- IACUC/IBC/IRE/RSC



2 -- IRB/COI



3 -- GDPR other Reviews



Efficiency Examples

- Combining certain complimentary committees
 - IRB, Privacy Board
 - IBC, IRE
- Approval times for IRB and IBC
 - 30 day turn around vs 5 day
 - Number of protocols that only needed the 5 day review

Questions?

