



Navigating the Study Approval Process

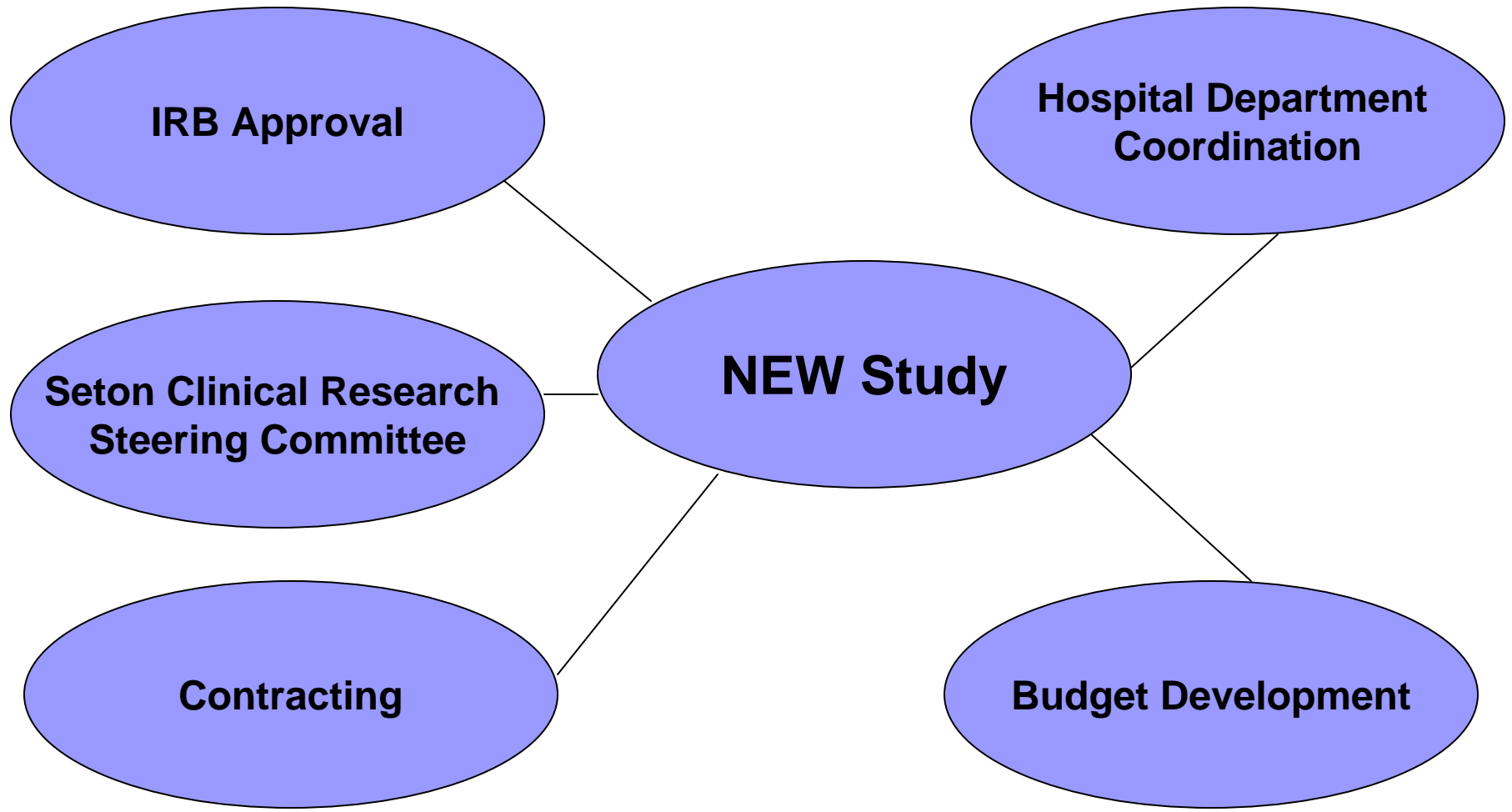
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Objective

- To “de-mystify” the study approval process through:
 - Brackenridge Hospital IRB &
 - Steering Committee

The Big Picture





Roles of IRB vs. Seton CRSC

- IRB

- Safety and ethical review

- Seton CRSC

- Feasibility
- Legal implications
- Financial implications
- Departmental “weigh in”
- Can over-ride IRB approvals as an institutional prerogative (*cannot over-ride IRB denials*)



All studies conducted at Seton
require:

1. IRB approval
2. Seton CRSC approval
3. Contract (when necessary)



Steering Committee Study Approval Process

- Completion of Steering Committee submission form
- Revenue Cycle form
 - To identify non-standard of care procedures and the guarantor for any given visit
- Budget form
- Completion of Human Subjects training for ALL study team members



IRB's in Austin

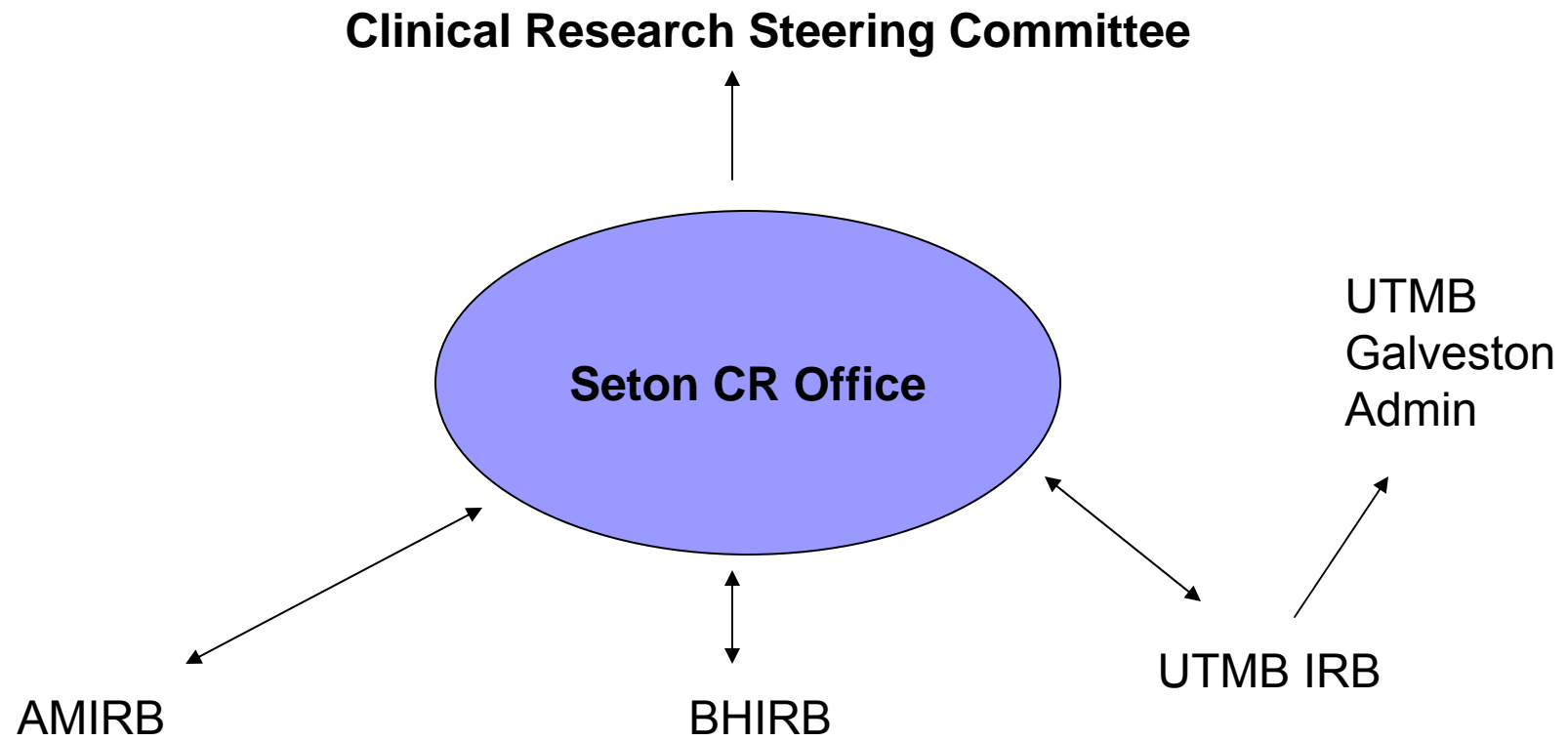
1. Brackenridge Hospital IRB (BHIRB)
2. Austin Multi-Institutional IRB (AMIRB)
3. UTMB-Austin IRB



Which IRB do I use?

- **AMIRB** – Industry-sponsored studies
- **BHIRB** – NCI studies, “unfunded” studies
 - BHIRB has a Federal Wide Assurance (FWA)
- **UTMB IRB** – Any study team member with UTMB primary affiliation

How does the 'system' fit together?





Where can you find forms?

- Website

- http://www.seton.net/medical_services_and_programs/clinical_research/forms/



What are the investigator responsibilities?

- Assure that forms are timely, accurate and complete
- That all team members are adhering to research policies
- Assuring that all necessary departments are aware of and approve of studies impacting their resources or personnel
- Study team is adequately trained and monitored
- Patient and physician billing is conducted accurately
 - (MUST identify research patients at EACH visit with Admissions and patient billing no later than the day of Visit)
- Proper study procedures are followed by all team members
- Proper study documentation
- Communication with IRB
- Communication with Sponsor



Where do you submit forms?

- Clinical Research office (LL Brack):
 - Contact: Rene Sewell

**Clinical Research Office
Brackenridge Hospital
601 East 15th Street
Austin TX 78701
Fax : 512-324-7792**



BHIRB

Study Approval Process



Institutional Review Board (IRB)

Purpose:

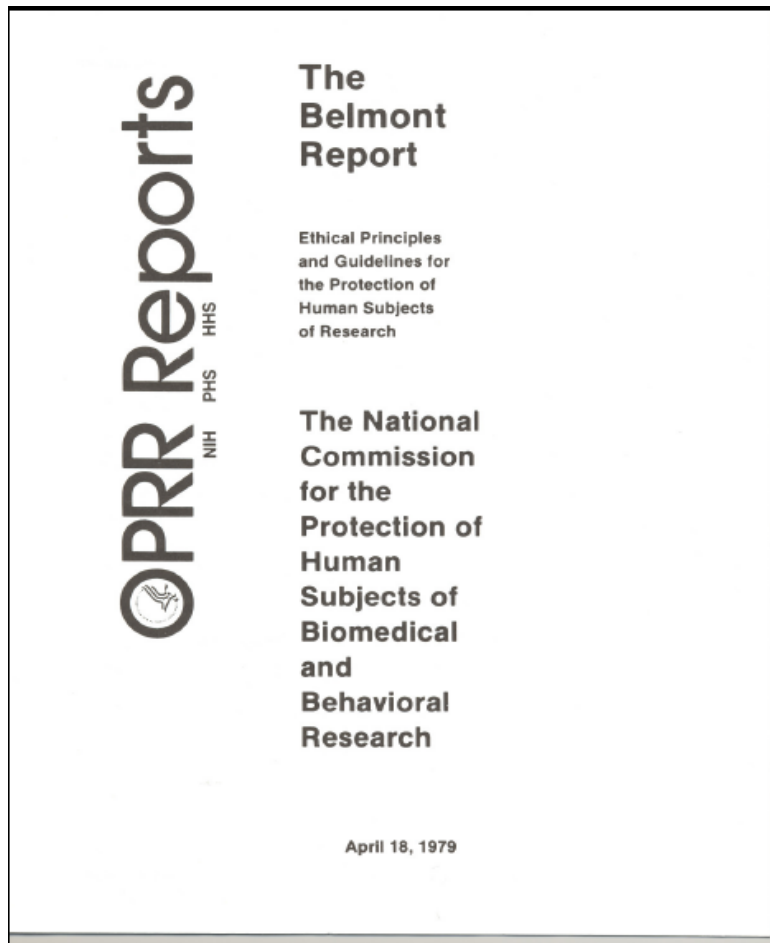
- To assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research.
 - Initial Protocol, Consent/Assent Review
 - Continuing Protocol, Consent/Assent Review



Federal Guidelines

- *Title 45, Code of Federal Regulations, Part 46*
- Defines IRB authority, responsibility, & guidelines for determining:
 - Human Subject Involvement
 - Level of Risk
 - Protections Against Risk

The Belmont Report, 1979



- Ethical Principles & Guidelines for the Protection of Human Subjects of Research
- In developing proposals, researchers must attend to these principles.




Basic Ethical Principles

- **Respect for Persons**
 - Informed Consent
 - Voluntary Participation
- **Beneficence**
 - Implement procedures to reduce/minimize risks
 - Risk:Benefit considerations
- **Justice**
 - Who benefits from the research?
 - Who bears the burden of research?
 - Equitable enrollment in studies
 - Randomization to treatment arms



IRB Review Process

- All materials related to the study are reviewed:
 - Protocols (research proposal)
 - Consents/Assents
 - Recruitment materials (e.g. flyers, cover letters, websites, email notices/invitations)
 - Questionnaires, survey, diagnostic procedures
 - Adverse events

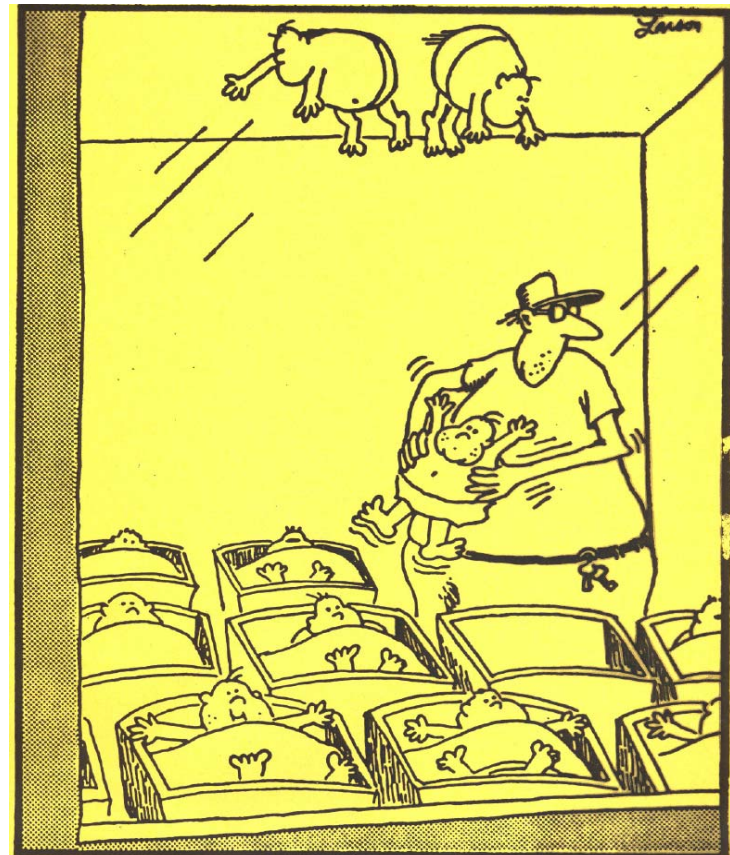


IRB '101'

- IRB approval is good for a MAXIMUM of 1-year from the date of original approval (*NOT study initiation*)
- ALL studies require ANNUAL RENEWAL or a notice of TERMINATION on or before the date of original approval.

Primary Goal: To Minimize Risks to Human Subjects

- Minimize risk;
- Fully informed consent;
- Voluntary (non-coercive);
- Equitable selection, equitable treatment



Late at night, and without permission, Reuben would often enter the nursery and conduct experiments in static electricity.



Clinical Research Office

- Internet access:
- http://www.seton.net/medical_services_and_programs/clinical_research/
- At the website, choose the “**Forms**” link



BHIRB Forms

- Under “Initial Submissions” download:
 - New Protocol Submission Form
 - Informed Consent Template
 - If needed, Research Proposal Template
- Under “Other” download:
 - IRB Action Request Form



New Protocol Submission

- Investigator must justify the inclusion of vulnerable populations.
- Ex:
 - Pregnant women are the focus of the study (e.g. nutrition, pregnancy risks); OR
 - Pregnant women can be in the sample, but they are not the focus (e.g. survey research).



New Protocol Submission

- For studies with minors, the level of risk is identified.
- Level of IRB Review:
 - Expedited
 - Exempt
 - Full Board
 - Based on Title 45, Code of Federal Regulations, Part 46



Expedited IRB Review

- Expedited ≠ stat or a.s.a.p.
- Studies that are eligible for expedited review must meet standards pertaining to:
 - The level of risk, &
 - The type of data collected.
 - The categories are fully detailed in the New Protocol Submission Form.



Exempt Status

- IRB review is conducted to determine whether or not a study is exempt from IRB review.
- Those research activities that are exempt from IRB review are detailed in the New Protocol Submission Form.
- Investigators are seeking concurrence or verification that their study does indeed meet the Exempt categories.



Full Board Review

- For all studies that involve more than minimal risk, Full Board review is required.
- Minimal risk is determined by judging the risk entailed in the protocol *in comparison to risks of everyday life experienced by healthy individuals.*



Protocol Documents

- Investigators submit copies of:
 - Action Request Form,
 - New Protocol Submission Form,
 - Proposal,
 - Consent/Assent form,
 - Questionnaires, surveys, interview guides.
 - Diagnostic protocols when the procedure is “experimental” or novel.
 - Recruitment materials.



BHIRB Review

- BHIRB Policies and Procedures Manual is on the Clinical Research website under the “IRB” link.
- New & Continuing protocols are reviewed to ensure:
 - Risks to subjects are minimized:
 - Use procedures that do not unnecessarily expose subjects to risks; and
 - Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
 - Risks are reasonable in relation to the anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.



BHIRB Review

- Subject selection is equitable.
- Extra vigilance is applied to research involving vulnerable populations:
 - Children,
 - Prisoners,
 - Pregnant women,
 - Mentally disabled persons, or
 - Economically or educationally disabled persons.
- Informed consent of each subject will be appropriately documented.
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of subjects.
- There are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of data.