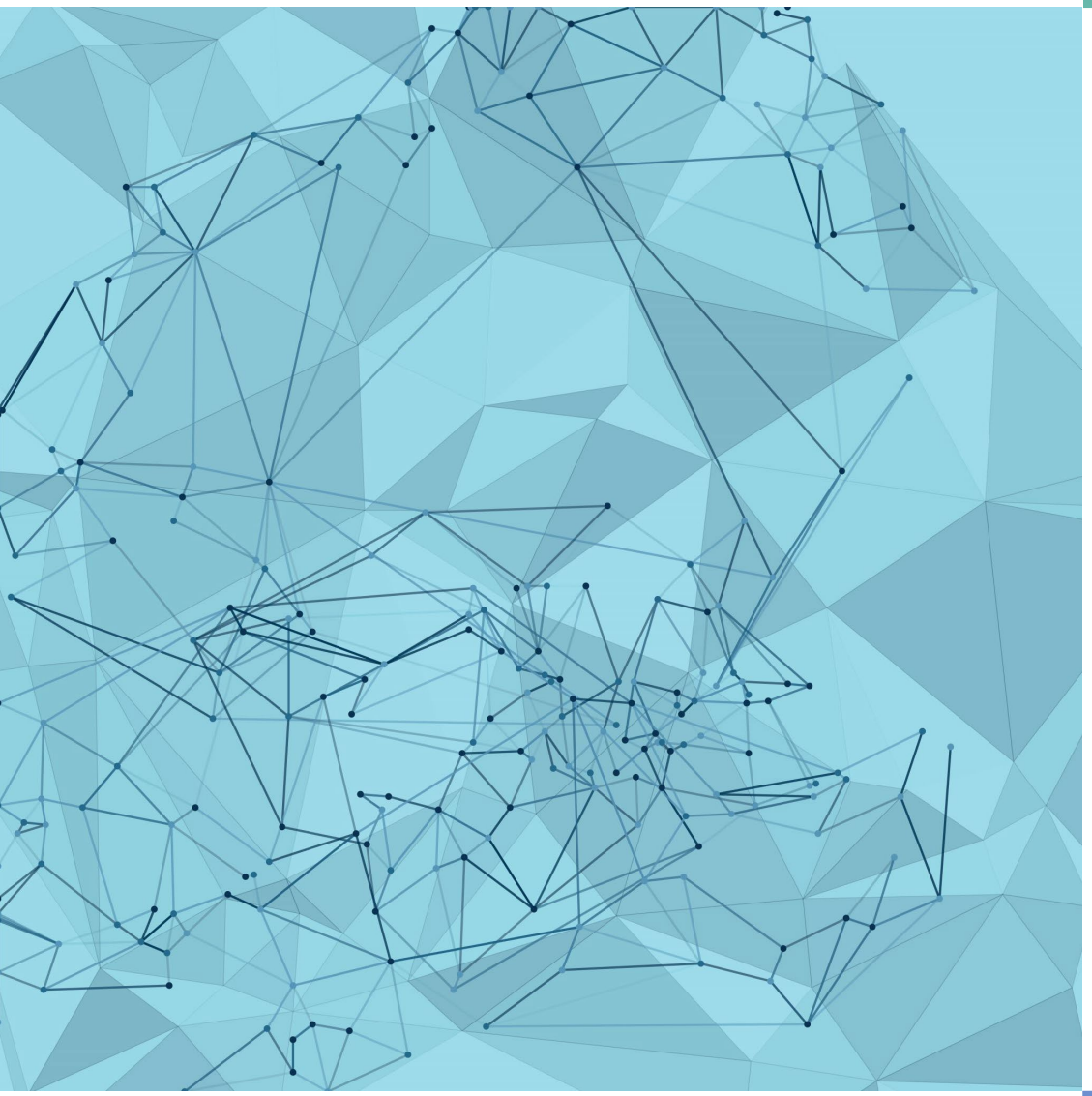

Institutional Risk Assessment Process for Principal Investigator-Initiated, Externally-Funded Clinical Studies

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Two quick explanations

+ Indemnification in a contract:
  - Shifts the allocation of risk and responsibility for injuries, damages, and losses that may occur as a result of the performance of a research project or the use of the results generated by a research project to another party. (Company protects the University from damages).
+ Subject Injury reimbursement:
  - The University does not expect research subjects to pay for any injuries incurred during their participation in a research study. The University expects the Sponsor to pay for any such expenses.

What is the University practice?

- For Industry sponsored clinical trials, the standard contract must contain:
  - The Sponsor's indemnification of the University.
  - Reimbursement from the Sponsor for subject injuries.
- Source: January 29, 2008 memo from then Provost Kuncl.

  "University policy further requires that research study sponsors reimburse the University for reasonable and necessary expenses incurred in providing medical care for any injuries directly caused by the drugs or devices that are being studied, or by required study procedures."

What is the University risk assessment process?

- If a contract from a commercial/industry sponsor does not contain these provisions (indemnification for the University, reimbursement of subject injuries) the University may make an exception to its standard policy.
- Contracts associated with Industry sponsored ***Investigator Initiated*** trials routinely do not provide these provisions.
- In order to determine if an exception should be made, the University requires a risk assessment.

What is exempt from this process?

- This process does not apply to:
  - Protocols previously reviewed via a peer review process (e.g., federally funded, or studies supported by most voluntary health or large foundations.) Most grants fit in here.
  - Studies that are not categorized as greater than minimal risk by the Research Subjects Review Board (RSRB), e.g., minimal risk studies like observational studies, registry studies, etc.

Who is on the Risk Assessment Committee?

- Committee meets on an ad-hoc basis to provide a recommendation to the Senior Associate Dean for Clinical Research (SADCR)
- Membership includes:
  - ORPA
  - RSRB/OHSP
  - Office of Counsel
  - Non-study team faculty member with relevant expertise (most often the RSRB Board Chair)
  - Representative for SADCR
  - Others as needed

What is required from the PI and Study team?

- Protocol and consent must be submitted to the RSRB.
- The checklist found on the ORPA website will be completed and submitted to the ORPA RA negotiating the contract. They will provide it to the ORPA RA facilitating the committee meetings (along with the contract under negotiation).
- In addition to the checklist please provide:
  - Copy of the current consent form.
  - Copy of the current protocol.
  - List of study personnel.
  - Any other relevant documentation or information.

What does the committee review?

- **Includes but not limited to:**
- The information from the PI.
- Relevant research in the field.
- Contract terms.
- The incremental risks to the patients.
- Whether alternatives exist.
- Human subject protections.
- Perceived risk/benefit.
- Who holds the IND/IDE (who is the FDA named Sponsor)

What is the timeline?

- From the time of submission of all materials to ORPA RA:
- Anticipate 2-4 weeks to set up committee meeting.
- Most meetings result in a request for follow up with study team or Sponsor.
- RSRB approval is not required for SADCR approval (but must be underway).
- Once SADCR approves, there still may be other budget, compliance, or contract negotiations to finalize.

Resources

+ Subject injury memo
+ Risk assessment process
+ Risk assessment checklist