

# Single IRB (sIRB) Review

Research Compliance Office

Stanford University

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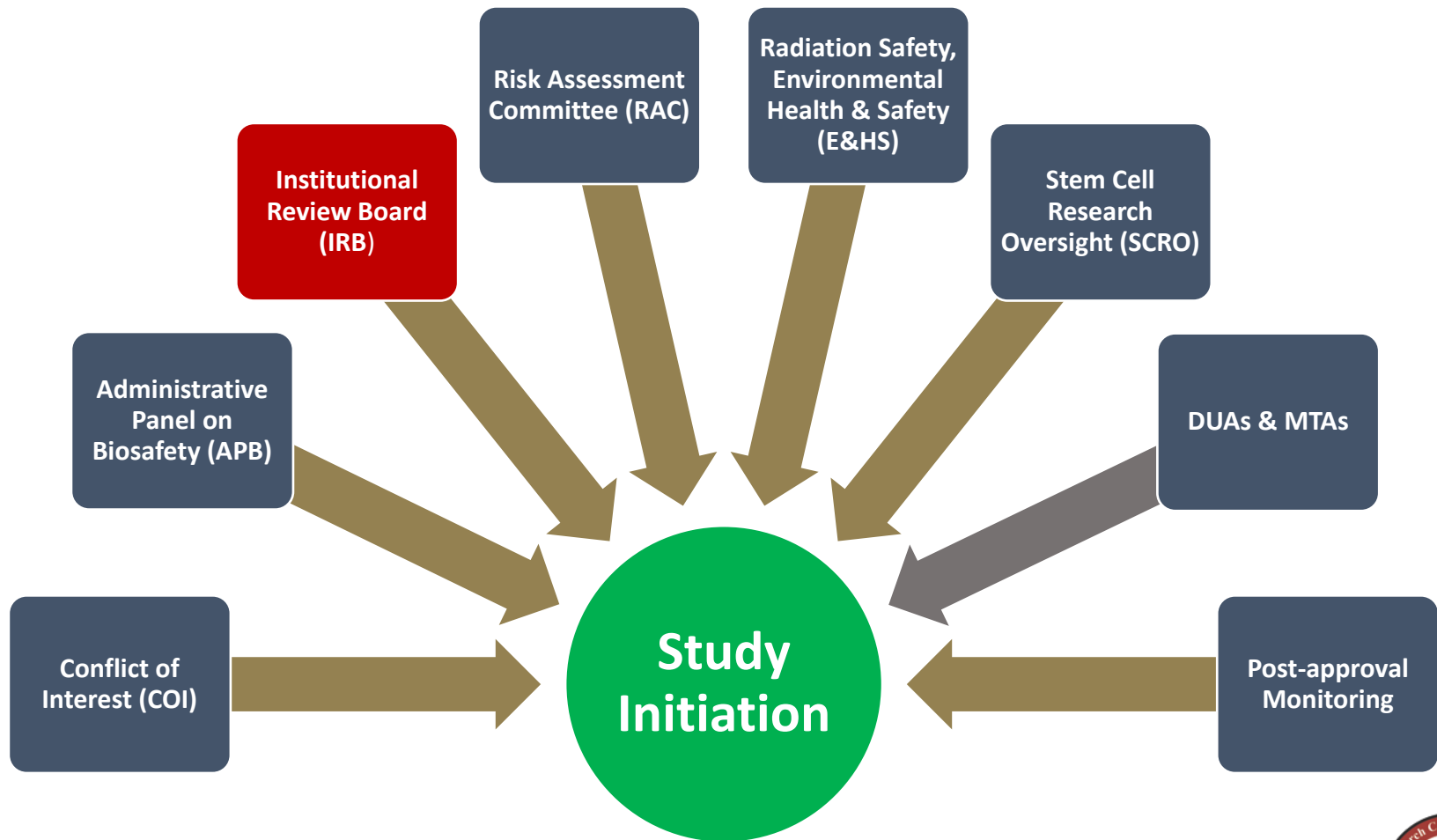


# Single IRB (sIRB) Review

- One IRB of record (Reviewing IRB) provides regulatory & ethical review for all sites participating in a specific study.
- Also referred to as Reliance Agreement
- 2018 Common Rule requires sIRB for federally funded research that involves 2 or more sites
- Does not apply to exempt review categories



# Reliance only covers IRB Review



# Determining When Stanford Relies

- Factors to be considered:
  - Funding source
  - Risk Level
  - Novelty of research
  - Stanford Investigator role
- Stanford relies on commercial IRBs, research network or consortium IRBs & other academic IRBs
- eProtocol sIRB application:
  - Ancillary reviews
  - Local laws and policies
  - Report/Modification submissions



# Stanford Acting as Reviewing IRB - SU sIRB

- Small Business Innovation Research (SBIR) Grants
- Designated with “SU sIRB” in the eProtocol title
- When an “SU sIRB” submission is assigned to a meeting, the sIRB staff has already conducted a pre-review to ensure a reliance is appropriate



# Submissions to Stanford When Acting as Reviewing IRB

- All activities, for relying site(s) must be submitted to the Stanford IRB:
  - Modifications
  - Continuing Reviews
  - Adverse Events/Unanticipated Problems
  - Other reportable events
- Stanford responsibilities for Reportable Events include:
  - Notifying the site(s) of the determination
  - Reporting to Federal agency (as needed)



**QUESTIONS?**

