

# The Human Subjects Institutional Review Board Workshop



Part 1: An Introduction to Human Subjects  
Research Ethics and the IRB Process

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[Office of Research](#)  
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# IRB Who?

## Meet the team

- ❖ IRB coordinator
  - Screens and assigns proposals
- ❖ 10-15 committee members
  - Mostly faculty volunteers
  - Number and composition must reflect capacity for ethics review in different disciplines
- ❖ AVP of Office of Research
  - Institutional officer – final approval

# IRB Why?

The pieces of the policy puzzle and balancing the ethics scale

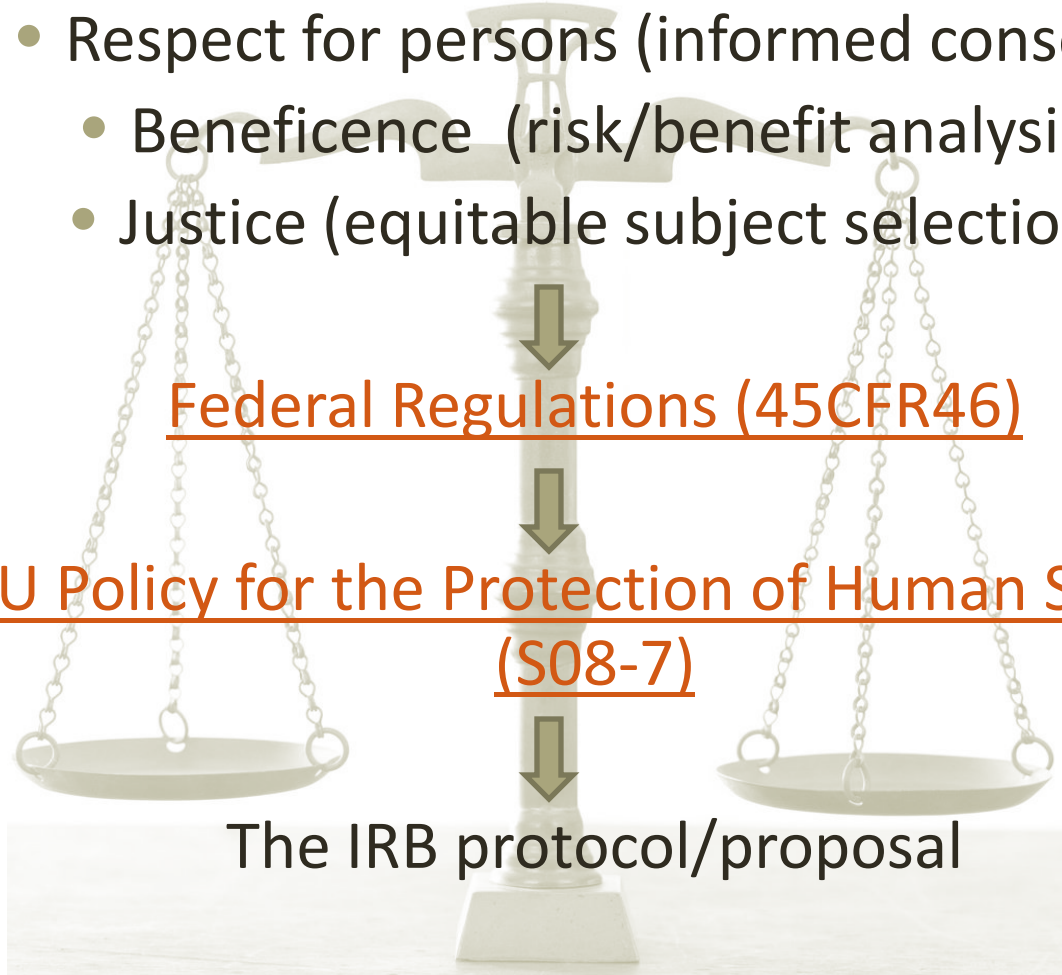
## Belmont Report

- Respect for persons (informed consent)
  - Beneficence (risk/benefit analysis)
  - Justice (equitable subject selection)

## Federal Regulations (45CFR46)

## SJSU Policy for the Protection of Human Subjects (S08-7)

The IRB protocol/proposal



# IRB What & When?

## A different process for different work

**Before** commencement of work!!

- Exclusion (2-5 business days)
- Exemption (7-10 business days)
- Expedited Review (one month)
- Full Review (one month or more - no summer and winter schedule)
- Registration (2-5 business days)

# Exclusion (Notification time: 2-5 business days)

## The (only) two criteria for review

- ❖ Is your work research?
  - A **systematic investigation** designed to contribute to **generalizable knowledge**
  - Usually includes a publication/dissemination component
- ❖ Does your work involve human subjects?
  - Direct interaction / intervention with individuals
  - Analysis of or access to private records

# Exemption (Notification time: 7-10 business days)

## Oversight without a formal IRB review

- Research that's no greater than minimal risk
- No protected groups – children, pregnant women, prisoners...
- Must fit into at least one of the prescribed categories

(see [exemption screening form](#))

- Office of Research screens for eligibility and registers the research
- Complete protocol required

# Formal (non-exempt) IRB Review Categories

(Notification of approval time: 1 month)

“Expedited” is defined by how well prepared your protocol is

## Expedited Review

- **Default** review process if research is not eligible for exemption
- One reviewer evaluates and approves the protocol

## Full Review

- IRB member optional recommendation
- A majority of committee members must decide
- Problematic protocols/ethical concerns

# IRB Registration (Notification time: 2-5 business days)

## One form for (almost) everything else

Express your intent to conduct human subjects research if you are:

- An SJSU investigator with a pending grant
- An SJSU investigator with IRB approval from an outside institution
- An outside investigator with IRB approval from home institution

No review takes place!

Creates a paper trail for documenting compliance

# Addendums and Extensions

(Notification of approval time: 7-10 business days)

## Investigator responsibilities after IRB approval

- Communicate any significant changes to IRB coordinator via email - always include your tracking number
- Approval is granted for one year
- Investigators must apply for an extension to continue with data collection beyond the one year approval period
- Use [Extension Request Form](#)
- Report any problems or injuries immediately to the Office of Research

# IRB How?

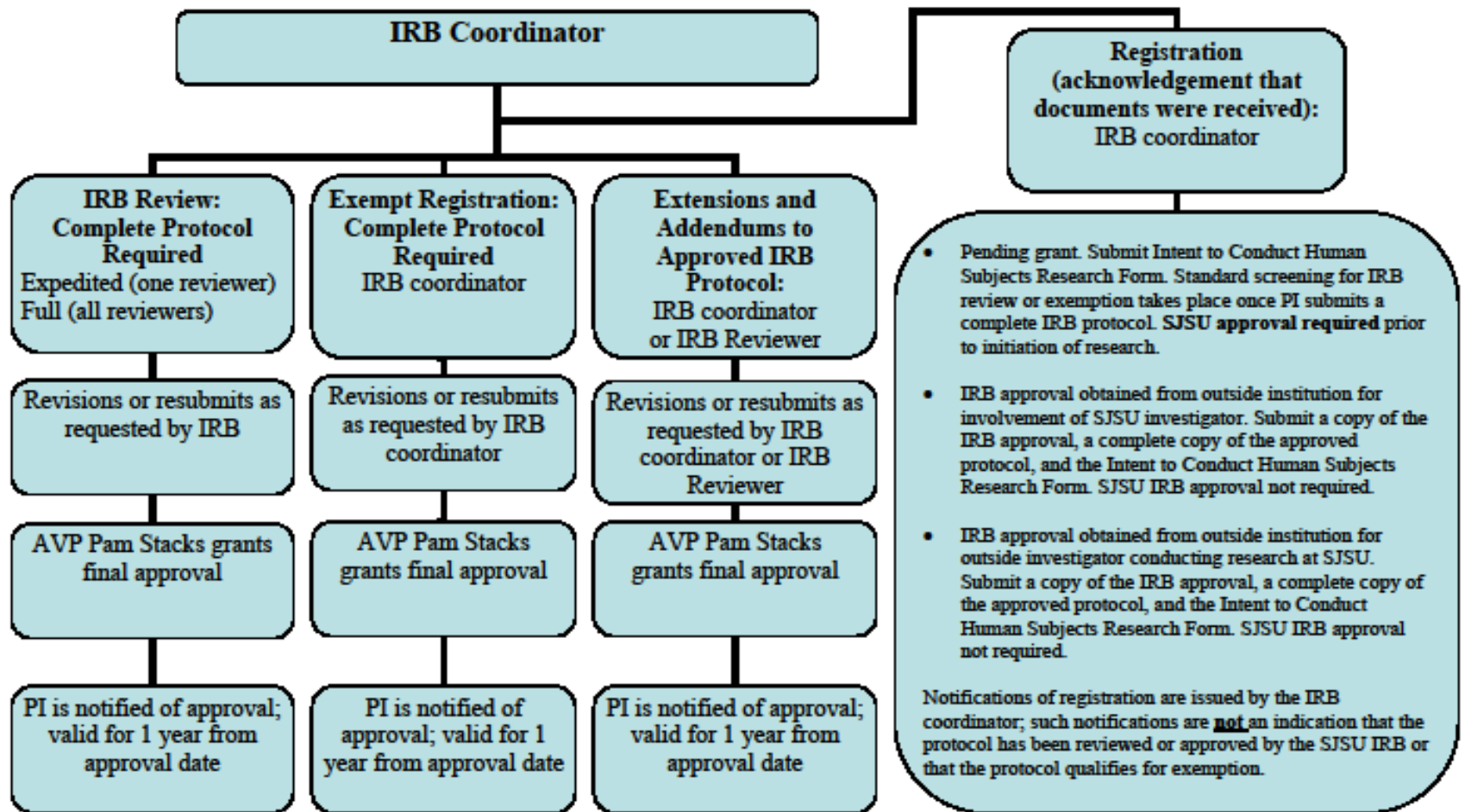
As in, “How long is this going to take? I needed approval yesterday!”



Possible reasons for delay:

- Not enough info from investigator/missing documents/conflicting info within protocol
- Protected groups
- Adversarial relationship between investigator and IRB
- Human error

**IRB Process Flow Chart (can only occur prior to initiation of research)**



# IRB How?

As in, “How do I get the ball rolling?”

Utilize the many resources available:

- [IRB website: http://www.sjsu.edu/research/irb](http://www.sjsu.edu/research/irb)
- [IRB checklist](#)
- [IRB FAQs](#)
- [IRB workshop](#) (student and discipline centered)
- [CITI training](#)
- Contact the IRB coordinator...

# IRB Questions?

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Don't forget to view Part 2 of this IRB Workshop...

## Preparing Your IRB Protocol