IRB SUBMISSION AND REVIEW PROCESS

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REALLY? WHY ME? I JUST WANT TO SURVEY SOME PEOPLE OR ANALYZE SOME DATA.
AND . . . WHY ME?

Slade Research Agenda: Social Construction of Science and the Science of Science Policies


Why Us? Because We ....

- Are a research university with a health sciences research focus.
- Have a Federal Assurance to meet laws and regulations concerning human participation in research (45 CFR 46).
- Have higher expectations to meet standards of the Association of the Accreditation for Human Research Protection Programs (AAHRPP).
WHY US?

We have seen some scary human participant in research proposals!
OUR RESPONSIBILITIES FOR REVIEW

▪ Is it research, meaning … is “the activity a systematic investigation designed to develop or contribute to generalizable knowledge”?

▪ Are there “any living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information”? 
SO WHAT IS RESEARCH?

A **systematic investigation** designed to develop or contribute to *generalizable knowledge*. 
IS MY PROJECT CONSIDERED RESEARCH?

‘Systematic’ means:

A project or study that involves a prospective plan that incorporates:

- data collection (either quantitative or qualitative)
- data analysis to answer a compelling question of general interest.
IS MY PROJECT CONSIDERED RESEARCH?

‘Generalizable knowledge’ means:

The intent of the project is to contribute to knowledge in a specific field or discipline.

- The analysis of data is intended to lead to generalizable claims.
- There is an intent to publish or present the project as research to a very broad audience to change science or practice.
Student and classroom studies

“Student work involving human subjects at AU generally falls into one of two categories: course research practica and individual student research projects.” Not research with some exceptions (deception and vulnerable populations).

Quality improvement research

OHRP guidance … “The intent to publish is an insufficient criterion for determining whether a quality improvement activity involves research.” Quality improvement is typically not research.
DOES MY PROJECT INVOLVE HUMAN PARTICIPANTS?

A human participant is a living individual about whom an investigator who is conducting research obtains data through intervention or interaction with the individual with or without identifiable private information.
HUMAN PARTICIPATION IN RESEARCH

*Intervention* means data gathered and manipulations of the participant are for research purposes.
**HUMAN PARTICIPATION IN RESEARCH**

*Interaction* means interpersonal contact or communication (even on-line) between investigator(s) and participant(s).
HUMAN PARTICIPATION IN RESEARCH

Includes human derived materials including chart and record review collected for non-research purposes.
HUMAN PARTICIPATION IN RESEARCH

Who determines if your project is Human Participation in Research?

*The Institutional Review Board (IRB)*

- Your faculty colleagues
- Scientists and nonscientists
- Community members
- Representatives for prisoners, military, and vulnerable populations (children and pregnant women)
WHAT IS AN INSTITUTIONAL REVIEW BOARD (IRB)?

Any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of research involving human participants.
IRB RESPONSIBILITIES

Protects the welfare, rights and safety of human participants and human derived material. Our criteria for review:

- risks are minimized and reasonable in relation to anticipated benefits,
- the selection of subjects is equitable,
- informed consent is obtained and documented unless a waiver is granted,
- measures to protect the privacy and confidentiality of data are adequate,
- adequate provisions for monitoring data to ensure safety are made,
- appropriate safeguards for vulnerable populations are in place.
Level of potential risk determines level of review for social behavioral educational research.
THE IRB PROCESS

1. PI Submission
2. IRB Administrative Analysis
3. IRB Review
4. QA Compliance Approval and Release
IRB ADMINISTRATIVE ANALYSIS

2-3 Business Days of Submission

Initial Analysis of Submission

PI should respond within 2-3 business days of receipt

Package Unlocked if there are revisions required

Once all revisions complete, package forwarded to IRB for review
HELPFUL HINTS

Review submission prior to hitting the submit button:

- All required documents uploaded.
- Current CITI and CVs linked for all research team members.
- Packages signed by PI, chair, and if applicable faculty advisor.
HELPFUL HINTS

- Less is more. Focus on review criteria.
- Proofread *please*, really, and check consistency between forms.
- Faculty advisors who sign own the project.
HELPFUL HINTS

- Use guidance documents in IRBnet when you start a project.
- Check policies and procedures on IRB website.
- Walk-in Wednesdays and Wednesday Clinics Summerville Reese Library.
- IRB rosters posted online.
THE IRB REVIEW

Package assigned to IRB Reviewer

3-5 Business days of Receipt

IRB review Completed
- IRB Stipulations sent via Modifications Required Letter

IRB Administrator Begins Final Approval and Release Process
- Once all IRB stipulations have been addressed and approved by IRB Reviewer
WHAT HAPPENS NEXT?

1 Business Day of notification

Quality Assurance Review

Same Day as QA Completed

Results Sent to IRB Administrator
- Major errors require correction before approval released

Package Approval Released
WHY QA?

- Ensures organization, regulatory, accreditation compliance.
- Identifies administrative and board errors.
- Prevents follow-up requests and new packages.
- Identifies areas for improving submission and approval processes and training.
WHAT SHOULD YOU EXPECT FROM QA?

Approval or ... email sent to study team and reviewer that:

- Package is unlocked.
- Stipulations letter for new package.
TIMELINES

• Package submitted and no correspondence 3 business days? Contact IRB Administrator.
• Unsure of Package Status? Contact IRB Administrator.
• Address IRB required revisions, stipulations, etc. quickly ... since if no response in 30 days, IRB may administratively withdraw it meaning ....

INFO OVERLOAD

STAWP
And just when we thought we had it figured out .... new regulations are coming. Hopefully for the better for Sber.

We're just going to relax and take it easy. We all make changes.

Dick Kitts
QUESTIONS, ISSUES, PROBLEMS, CONCERNS?