Office of Research
Research Development and Support Series

How to Navigate the IRB doing SBER

Thursday, November 8, 2018

Holly Bante, Assistant Vice President for Ethics in Industry Engagement

Tangeman University Center, Room 400A

University of CINCINNATI | OFFICE OF RESEARCH

Our Experts

- **John Holden**, Associate Professor of Psychology
- **Jacinda Dariotis**, Professor and Director of the Evaluation Services Center
- **Janet Moore**, Professor of Law

Moderator: **Claudia Norman**, Education and Outreach Specialist in UC's Human Research and Protection Program

Navigating IRB Compliance

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Presentation Overview

- Getting the Compliance Metaphor Right.
- Categories of Research and Levels of Oversight
- Coordinating Research Compliance with Other Federal/State Regulations.
- Tips for Writing Protocols
- A Few Counterintuitive but Recurring Issues
- Pending ePAS to RAP Transition

A Metaphorical Understanding of Compliance

- Historically, conceptual meaning was attributed to rationality and logic.
  - By the 1980's cognitive linguists assembled a compelling case that shared meaning has a metaphorical basis in embodied experiences.
    - *Argument is war*: "I demolished his argument"; "Your claims are indefensible"
    - *Love is a journey*: "We're spinning our wheels"; "We're at a crossroads"
    - *Knowing is seeing*: "I see what you mean"
- Novel meaning is understood metaphorically, through our everyday experiences as embodied beings.
    - E.g. see George Lakoff, Mark Johnson, Raymond W. Gibbs Jr.

A Metaphorical Understanding of Compliance

- Are these sufficient metaphors for guiding your IRB interactions?
  - The IRB as the DMV of Research?
    - In the DMV metaphor questions like "Is this study subject to FDA regulation? "Is it a medical device study?" Feel like those obscure questions on a driving test: "How many feet before a turn must you signal on a two lane highway?
    - Under this metaphor IRB is an ineffective bureaucracy that questions your ability to do something that you are trained to do, and that you've been doing for many years.
  - The IRB as Automotive Service/Repair?
    - Under the repair metaphor, you tell the IRB "what you do" and they tell you "what you need"
      - Researcher: "I study elementary school children's self-concept in one-on-one interviews"
      - IRB: "Oh you need to submit an expedited protocol, with vulnerable population attachments for parental consent and children's assent."
      - By the repair metaphor, the IRB is a service oriented entity that achieves compliance for you.
- These metaphors tend to come up short…

A Metaphorical Understanding of Compliance

- A better metaphor for guiding your IRB interactions:
  - You're a Building Contractor, the IRB is a Construction Code Inspector.
    - Architects and contractors have intimate knowledge of code requirements
    - As a researcher, you are responsible for building a research program
    - You need intimate knowledge of applicable procedures, guidelines, and rules
- Appropriate oversight strongly depends on your own compliance knowledge. You must anticipate requirements.
- Your knowledge will streamline your compliance efforts
- ***Most important*: Get the best-fit research category**

Four Basic Research Classifications

Not Human Subjects Research (NHSR)

Exempt Research

Expedited Research

Full Board Review

- Next, we'll briefly overview the defining features and the increasing each classification.
- Accurately matching a classification with your research program will compliance effort footprint

1.) Not Human Subjects Research

- Activity is **not** systematic or not designed/expected to yield generalizable knowledge
- Does **not** involve intervention or interaction with living persons, except if person is **not** providing info about self, or any other identifiable person
  - Examples: Quality assurance, program assessments, training activities…
- Determination is needed when planned activities may resemble research
- Oversight burden: One-time determination. Re-apply if changes needed. No consents, personnel, amendments, closures.

2.) Exemption Eligible Research

- Research on established/accepted educational practices, surveys, interviews, existing data, public benefits, taste eval./consumer acceptance.
- Data recorded such that subjects are unidentifiable, and no risk to subject's legal or social standing if data is disclosed.
  - Examples: Studies using published instruments, accepted data collection paradigms.
  - The new 2018 regs. are more explicit in broadening this category to include many common SBER data collection activities and practices if participants are adults and provide prospective consent.
- Oversight burden: One-time determination, no continuing review, or closures required. Personnel amendments possible.

3.) Expedited Research

- Minimal risk research entailing potentially identifying information, or where identities are be retained (e.g., tumor discovered from fMRI).
  - Voice, Photo/Video recording, fMRI
  - Certain clinical studies, noninvasive biosample, stick style blood sampling, any nonexempt studies of cognition, culture, language etc.
- Procedures in place to minimize disclosure risks
- May involve vulnerable population: Children, Prisoners etc.
- Oversight burden: Consent forms, Annual (or 3 year) review, closures, amendments required. (Can apply for information-sheet consenting)

4.) Full Board Review

- Research that poses greater than minimal risk.
- For SBER studies, risks typically related to subject's social or legal standing, coercion/COI, privacy of participation.
- May involve vulnerable population: Children, Prisoners, Employees, Indigenous Persons etc.
- If your protocol goes to full board, you can/should present prior to closed deliberation/vote.
- Oversight burden: Same as medical studies, consent forms, annual review, amendments, closures required.

Types of Protocols

- Single study, single protocol
  - A specific study, with a specific set of procedures/instruments.
  - E.g., a student thesis
  - Not very efficient if you do lots of data collection

- Program of Research Protocol
  - A blanket protocol that covers ongoing, all routine research activities in your lab
  - Good option for relatively coherent research program.

Guidelines for Writing Protocols

- Introduction/background should just sufficient to justify as research, worthy of pursuit, **not** a detailed scholarly review.
- Don't write yourself into a box
    - If you say you will collect data from 20 participants, and you collect data from 21, it's a deviation, or you need to submit an amendment.
    - If you specify a range, or an annual range, and indicate that numbers depend on subject availability, you have more flexibility.
    - If you supply an exact list of instruments/procedures, and later decide to do something a bit different, an amendment may be in order. Instead, discuss survey instruments/procedures as illustrative examples, that may be exchanged for similar instruments--Always keeping risk/benefit ratio equivalent.
    - If you supply an illustrative list of tasks, and indicate that changes not impacting risk may be made to accommodate various circumstances/research questions then no amendment is needed.
- Don't just pawn it off to your students
    - Student-written protocols often contain inconsistencies, missing information, and other problems that tend slow the process to a halt, or into an infinite cycle of doing and redoing.

Guidelines for Writing Protocols

- When possible, use HHS definitions and classifications in your prose
  - Most protocols are written under the repair metaphor, not the contractor metaphor
  - Reviewers are concerned with risk/reward trade-offs, and the protections of participant's mandated rights--Walk the reviewer through these issues succinctly, clearly, and accurately.
- The IRB is primarily interested in discussion of activities/issues that impact or alter the participant's risk/benefit profile
  - For non-medical studies, a precise and choregraphed list of activities is not needed.
  - Summarize activities in terms of issues relating to risk/benefit balance.
- Yes, IRB can require changes in procedures and methodology
  - The process is not much different than the peer review process

Coordination with other Regulations

- Sometimes research protocols have implications for other FED/State regulations.
  - **Title IV** sex-based abuse/discrimination reporting requirements
  - **FERPA** protections of academic records
  - **HIPPA** personal health information protections
  - **State of OHIO** felony reporting requirements
- You are not immune to these regs. just because you are doing research
- If your research intersects with issues covered by these laws, you'll need to consult with a relevant UC office to devise a solution/SOP.
- From the IRB perspective, it is crucial that potential subjects are informed about a researcher's obligations regarding these laws as part of the informed consent process.

Common Issues/Pitfalls

- Students **cannot** serve as sole PI on IRB protocols
  - Students are in training, supervising faculty must be PI or Co-PI
- Your funded/unfunded NIH/NSF proposal is **not** appropriate or sufficient to serve as an IRB protocol.
- All full/expedited protocols must be formally closed when research is complete.
  - Simply allowing a protocol to expire yields a reportable event
  - If data is deidentified, protocol can be closed before data analysis (good for students)
- Approval of a pristine protocol takes a minimum of 1 month.
  - If there are loose ends that need to be addressed (e.g., inconsistencies, missing info). The clock restarts once corrections are finalized.
  - Contact HPA if decision is overdue, or for urgent (e.g. funding related) requirements
- Plan ahead for Continuing Reviews, as they can disrupt data collection.
  - Cycle them for the summer, or when you are unlikely to be collecting data

Transition from ePAS to RAP

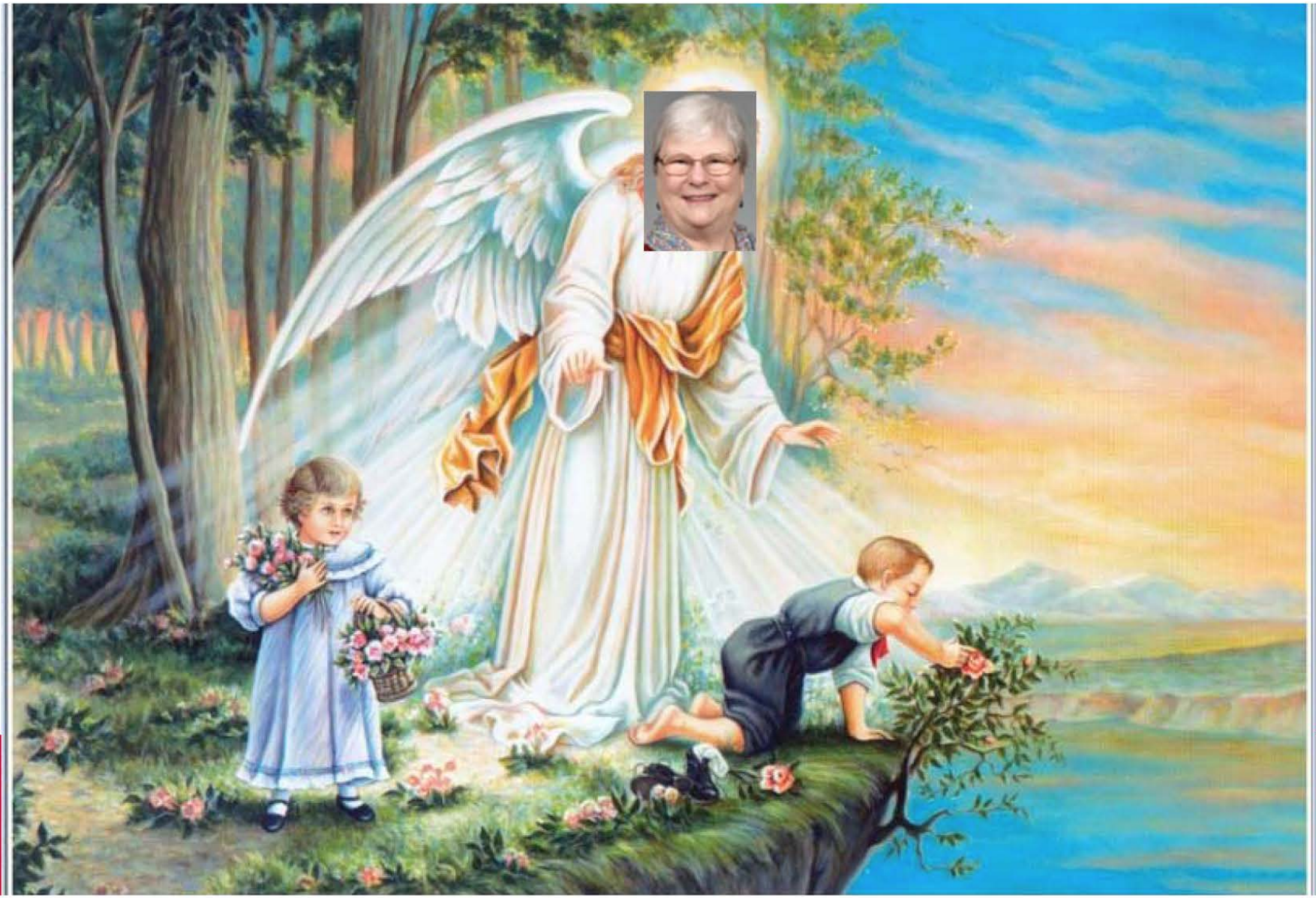
- ePAS is controlled by CCHMC, UC purchased a related electronic protocol to better target our needs and improve the experience.
- The goal is a simper, more intuitive system.
- Go-Live Target date is **Jan 14th**
- **Nov 30th** is deadline for any new submissions/Amendments/CRs to be submitted via ePAS be submitted via ePAS and migrated.
- Only items in an APPROVED state will be migrated.
- Then everything IRB at UC will be done in RAP.

Some Useful Links

- HHS.gov Decision Flow Charts
- Text of HHS 45 CFR 46 Regulations
- UC's Research Office Webpage

IRB PTSD:
Causes, Consequences, & Cures

Janet Moore, Professor of Law
janet.moore@uc.edu



Respect
Beneficence
Justice

IRB PTSD:

Causes

- Student projects
- CBPR
- Action research

Student Project: JAG Attorney Views on the Death Penalty

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

February 16, 2016

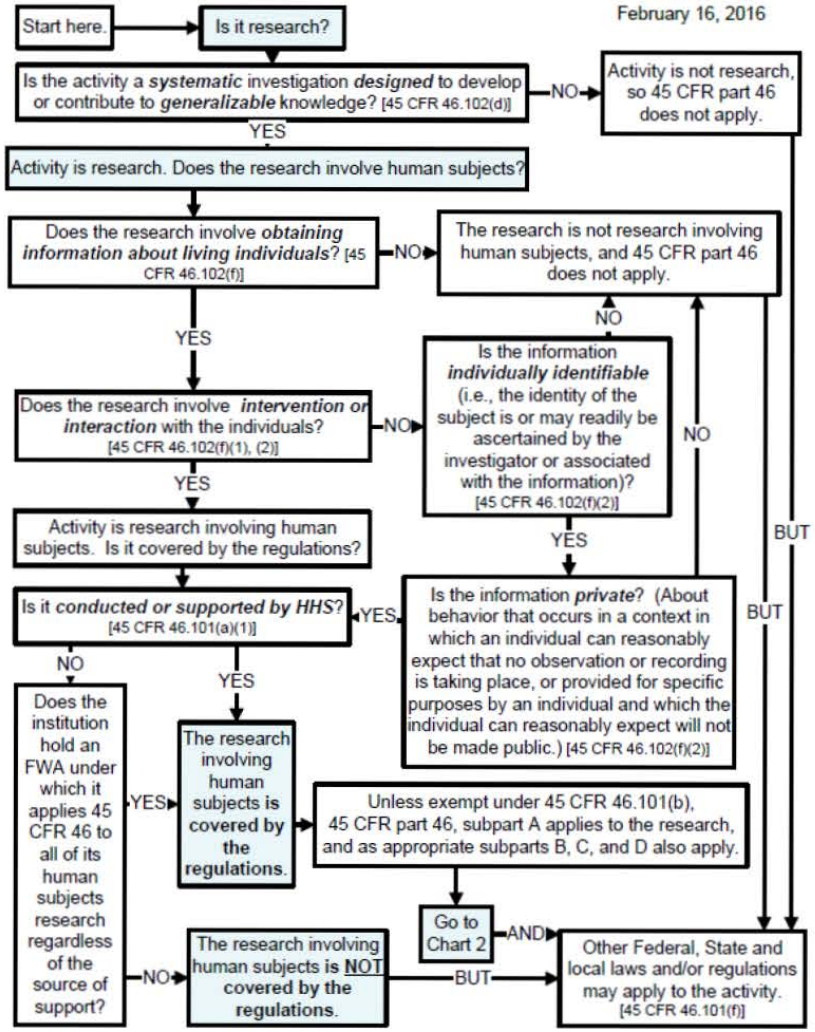


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

February 16, 2016

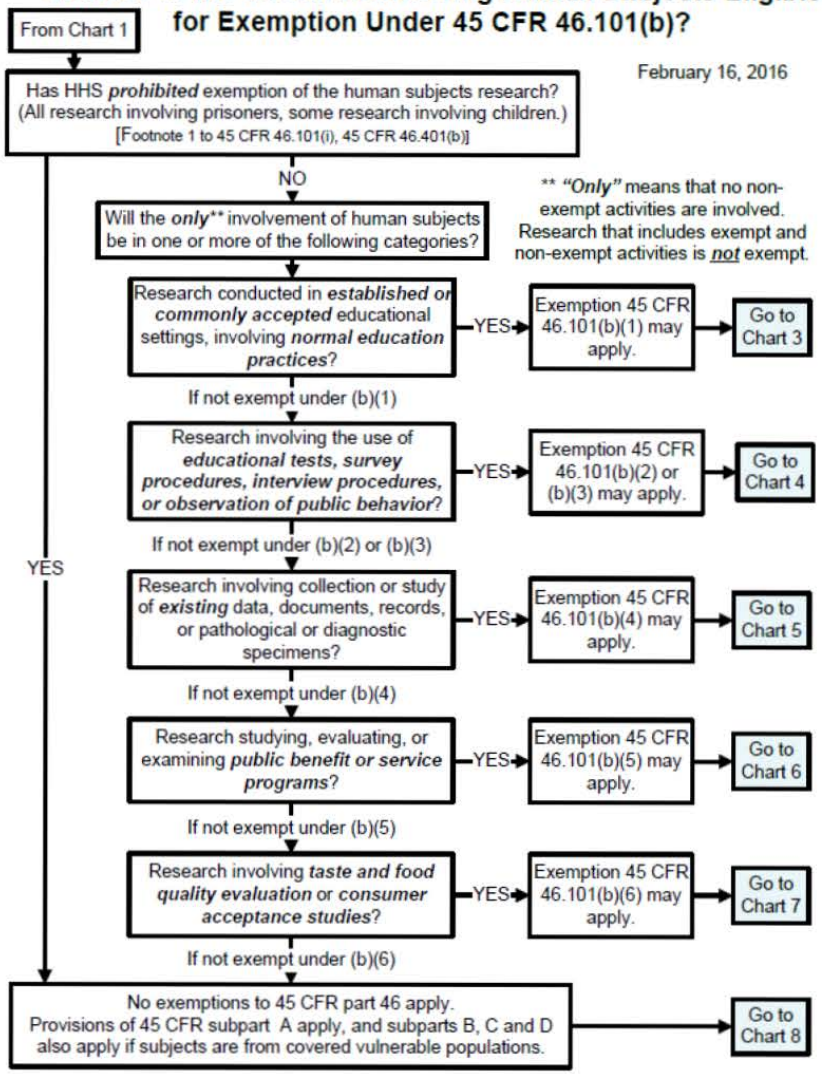
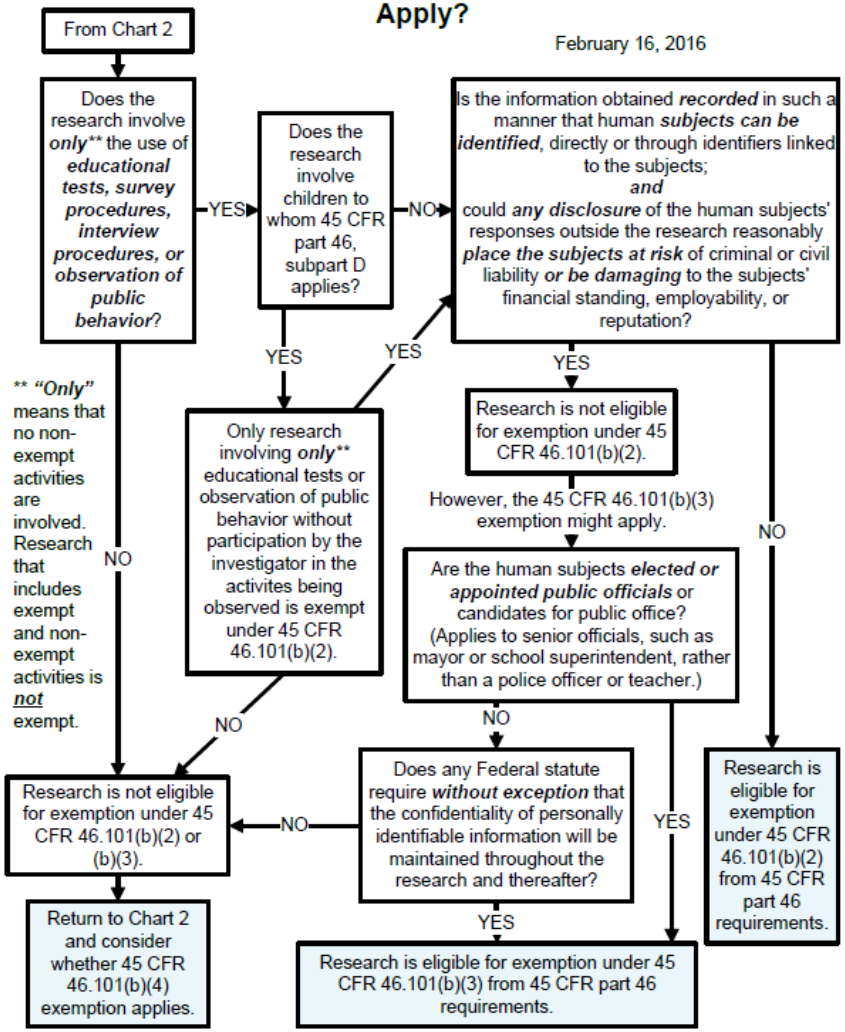


Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?



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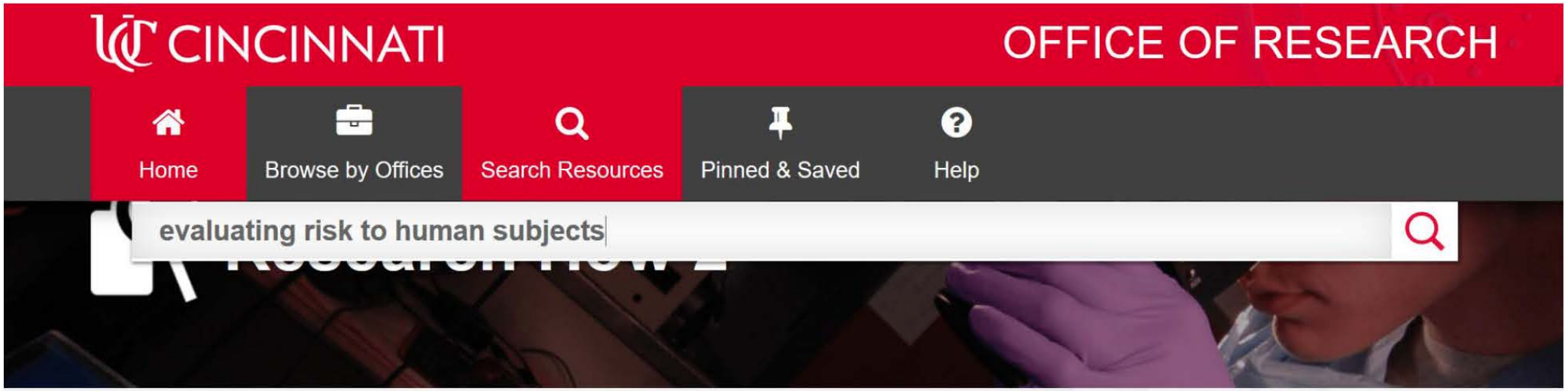

About

Welcome to Office of Research's integrated and functional portal designed to support University of Cincinnati's faculty, staff and students. We believe connecting "how to's" to the "why's" is important, and key to establishing connections that build and extend knowledge with simple intuitive actions. With this in mind, we have introduced three key features in our newly upgraded website.

"Smart search" makes it easy to look for a specific document related to Office of Research's work stream. Plug in search key words and the search engine queries all of our research resources to give you fast and relevance based results that support UC's research excellence.

Search Results

Back

15 search results for **evaluating risk**

Policy III.01 IRB Review Human Subjects (PDF)

Download

Pin

The University of Cincinnati (UC) Institutional Review Board (IRB) is authorized by UC's Institutional Official (IO) to review human subjects' research projects and clinical investigations. All UC faculty, students, staff, or other representatives of the University must submit for UC IRB review any human subjects research project, regardless of funding source (or lack thereof) and/or location at which the research will be conducted. UC IRB approval or acknowledgement is required before a project may begin.

Contact Office: HRPP
Modified: 08/02/2018

researchhow2.uc.edu/docs/default-source/hrpp/policy-iii-01-irb-review-human-subjects.pdf?sfvrsn=98296cc1_0

Research Protections

Human Research Protections
- About HRP and the IRB
- Researchers
- IRB Members
- Participants
- Single IRB (sIRB) / Reliances
- Other UCI Committees

Animal Care & Use

Human Stem Cell Research

Institutional Biosafety

Comments & Suggestions

Assessing Risks and Benefits

Regulations:

OHRP: 45 CFR 46.111

FDA: 21 CFR 56.111

Background

Per DHHS and FDA regulations (45 CFR 46.111 and 21 CFR 56.111) two of the required criteria for granting IRB approval of the research are:

1. Risks to subjects are *minimized* by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB Committee will consider only those risks

Definitions

- **Benefit** A valued or desired outcome; an advantage.
- **Risk** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."
- **Minimal Risk** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests.

- **Social and Economic Harms** Some invasions of privacy and breaches of confidentiality may result in embarrassment within one's business or social group, loss of employment, or criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Some social and behavioral research may yield information about individuals that could "label" or "stigmatize" the subjects. (e.g., as actual or potential delinquents or schizophrenics). Confidentiality safeguards must be strong in these instances. Participation in research may result in additional actual costs to individuals. Any anticipated costs to research participants should be described to prospective subjects during the consent process.

Please select the section below that is applicable to your research project. Note that the options selected below will determine which forms will need to be completed in the rest of the application.

*

	Research Classification	Description
●	STANDARD RESEARCH PROJECT	Studies that involve either or both of the following: **interaction or intervention** with human subjects. Analysis of **individually identifiable** specimens or data that will be **collected in the future**
○	USE OF EXISTING RECORDS AND/OR SPECIMENS	The proposed research involves the use of specimens and/or data that are existing at the time of this submission and were all originally collected and retained for non-research (clinical) purposes, and/or the research involves the use of specimens and/or data that were previously collected.
○	NOT HUMAN SUBJECTS DETERMINATIONS	Requesting a determination that this project does not meet the regulatory definition of Research Involving Human Participants.
○	RELIANCE ON IRB THAT IS NOT CCHMC OR UC	Request to rely on an authorized Central IRB per an existing Memorandum Of Understanding (MOU) or similar contractual relationship. At this time the authorized Central IRBs are: CCHMC investigators – NCI PedCIRB only UC investigators – Western IRB, Schulman IRB, NCI AdultCIRB
○	HUMANITARIAN USE DEVICES	This submission is a request for IRB approval for the clinical use of a Humanitarian Use Device under and FDA approved Humanitarian Use Device Exemption.
○	NOTIFICATION OF EMERGENCY USE - Drug/Biologic	This submission is the formal notification to the IRB of the Emergency Use of an unapproved drug/biologic
○	NOTIFICATION OF EMERGENCY USE - Device	This submission is the formal notification to the IRB of the Emergency Use of an unapproved device

Clear

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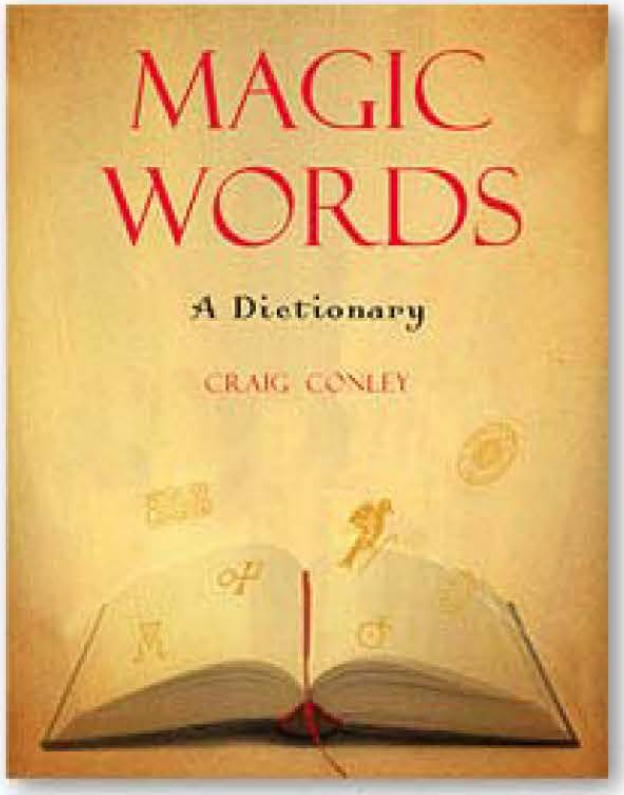
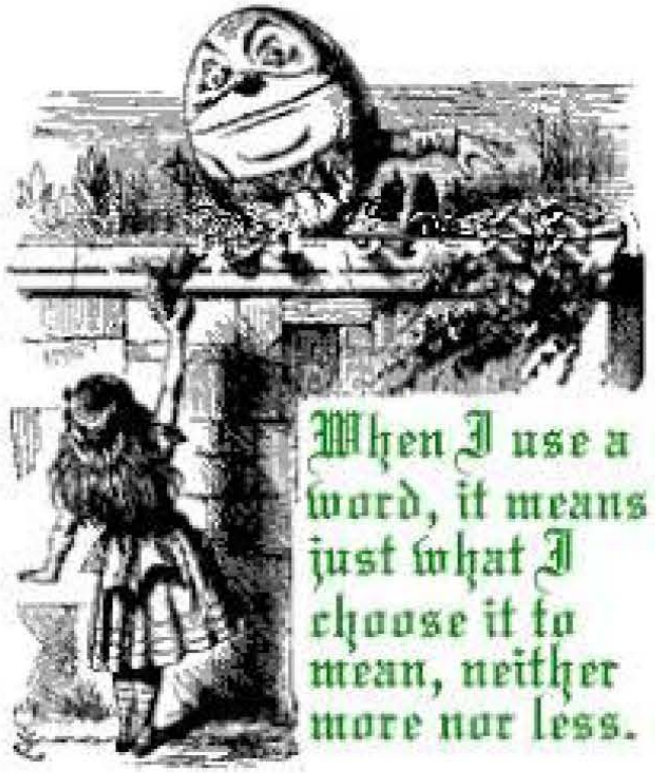

MAGIC
WORDS
A Dictionary
CRAIG CONLEY


When I use a word, it means just what I choose it to mean, neither more nor less.

IRB PTSD: Consequences

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CBPR and Action Research

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- Bioethics
- Biosafety and Biosecurity (BSS)
- Clinical Research Coordinator (CRC)

Human Subjects Research (HSR)

HSR provides foundational training in human subjects research and includes the historical development of human subject protections, ethical issues, and current regulatory and guidance information.

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to communicate
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Compliance: REs, CRs, & Audits

IRB PTSD: Consequences

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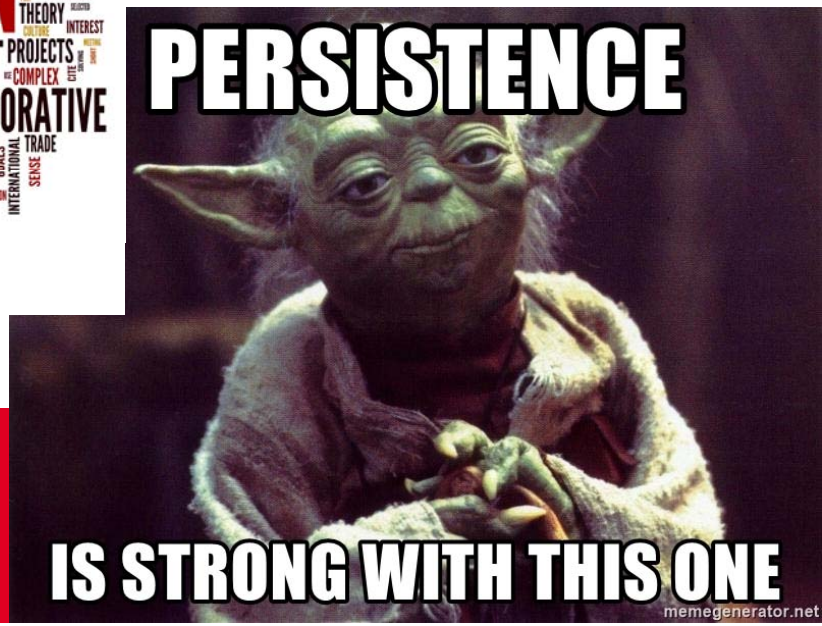
IRB PTSD: Cures



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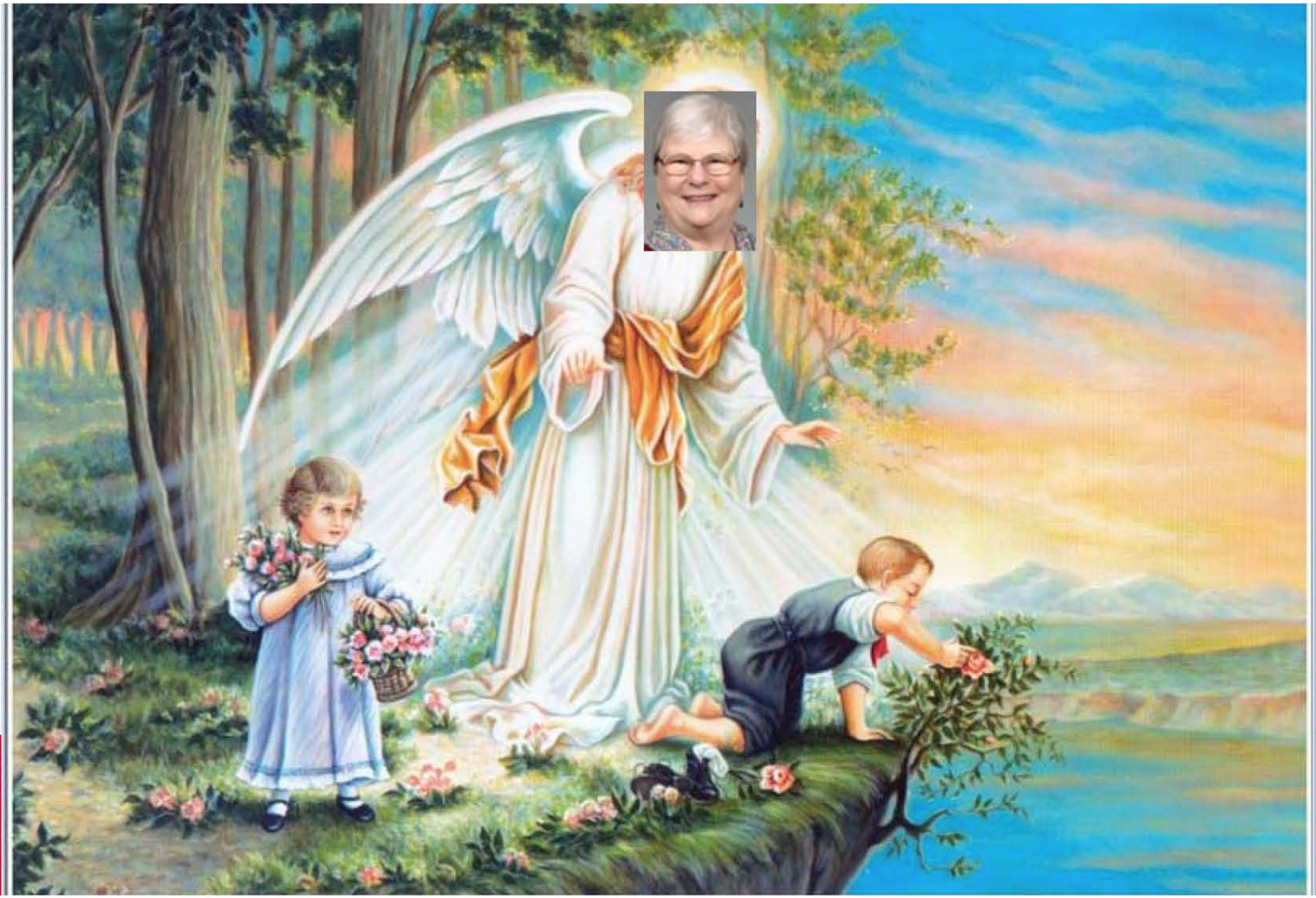
Research Ethics

Volunteer!



Office of Research Resources

Office of Research Web Site (research.uc.edu)

Office of Research How2 (researchhow2.uc.edu)

Research Directory (researchdirectory.uc.edu) – Ohio Department of Higher Education – Ohio Innovation Exchange (OIEx)

SPIN (research.uc.edu/funding/spin)

Limited Submissions (via web portal (rsrch-webserver.uc.edu/)) Two types – faculty research nominations and research proposals; Selection process dependent on type.

Office of Research Initiatives

Internal Funding Opportunities

- Collaborative Research Advancement Grants Program
  - Track 1: Pilot Teams
  - Track 2: Strategic Teams
- Faculty Bridge Program
- Science Engineering + Art Design (SE+AD) Advancement Grant
- Core Capability Development Grant Program
- Core Equipment Grant Program
- University Research Council
  - Creative & Performing Arts Cost Support Program
  - Humanities and Social Sciences Cost Support Program
  - Faculty Research Cost Support Awards Program
  - Graduate Student Stipend and Research Cost Awards for Faculty-Student Collaboration
  - Undergraduate Student Stipend and Research Cost Awards for Faculty-Student Collaboration

Research Development and Support Series

Title	Date/Time/Location
How to Navigate the IRB doing SBER	Thursday, November 8, TUC 400A, 10:30 AM to 12:00 PM
Working with Industry/Foundations	Wednesday, November 14, UHall 454, 1:00 PM to 2:30 PM
How to Work with Local and State Governments	Friday, November 30, TUC 425, 10:30 AM to 12:00 Pm
Arts & Humanities in the Age of Impact	Monday, December 10, DAAP 8220, 11:30 AM to 1:00 PM

Help us improve!

https://www.surveymonkey.com/r/HTNIRBFall2018