



University of Colorado
Colorado Springs

February 10, 2016

To: Monique French, Faculty Assembly President
Michele Companion, Past Faculty Assembly President
Barbara Prinari, Faculty Assembly Vice President

From: Kelli Klebe, AVC Research and Faculty Development

RE: IRB "Mission Creep"

In response to a specific complaint about IRB "mission creep", I conducted an investigation to examine this claim. Because Faculty Assembly has raised these concerns before, I am providing you the following summary of what I did and the information faculty provided.

- The full IRB discussed a procedure for investigating "IRB overreach". It was decided to have open forums or individual meetings and members of the full board would participate along with me, but the four main reviewers of protocols would not.
- All faculty and staff with an active IRB (n = 181) were sent an email inviting them to share their concerns about the IRB by attending open meetings with me and one other IRB member or by setting up an individual appointment with me.
 - There were five open meetings scheduled (one got canceled due to snow). Seven people attended the forums.
 - I had eight additional meetings, emails or phone calls with individuals about the IRB.
- I reviewed 40 protocols to look for overreach and inappropriate reviews. I used the protocol from persons who made complaints about IRB over-reach (14 protocols) and randomly selected others such that I had a variety of reviewers and both student and faculty/staff protocols.

For the protocol review, there were 146 different comments made to the 40 protocols. I would judge nearly all of comments to be reasonable questions to understand the protocol and to determine risk or as reasonable requests to bring the protocol in line with expectations outlined by the CU Auditors during the audit our the UCCS IRB records. There were just three comments made that I would consider being potentially outside the goal of understanding the risk to the participants. I would consider questions about methodology and variables as reasonable questions to ask about protocols in most situations as a standard for reviewing a protocol is for there to be sufficient detail so that the reviewer can understand everything the participant will experience and can then assess potential risk to participants. In the protocols reviewed, there were no comments that were negative towards specific methodology. Knowing which variables are in de-identified data sets and the level of analysis detail (e.g., if analysis will be completed on subgroups so that identification may be possible) are also appropriate questions.

The following pages provide my notes taken in the meetings with faculty and staff who responded to the request to participate. These are not exact words but are mostly the "raw"

Associate Vice Chancellor for Research and Faculty Development

MH 312B • 1420 Austin Bluffs Pkwy • Colorado Springs, CO 80918

719-255-3779 • kklebe@uccs.edu

comments without interpretation of why our procedures are the way they are. I have provided the groupings.

There was not a large participation rate (less than 10% of people invited). I do not know if this should be interpreted that people do not have major concerns with the IRB process (2 people stopped by my office and told me this) or if people do not want to speak about the issues.

I am willing to chat with you and faculty representative assembly. This document may be distributed to your group.

Suggestions from Conversations with Faculty Members about IRB Processes

Positive Comments

- Appreciate timeliness of reviews; rolling system for reviews (not waiting for a monthly meeting to happen) (multiple people made this comment)
- Thought reviewers were helpful (multiple people made this comment)
- Office needs to advertise that we are here and willing to help; to let people know we are accessible and willing to do preliminary application review/conversation
- Renewal is easy (so don't change); like that we send reminders

Comments about reviewers

- Train reviewers for purpose of review and what to look for and on how to write comments/questions to focus on risk issues. In general the reviews should be relevant to safety of participants ("safe science") and not on other issues such as sample size, question phrasing, numbering of questions, confounding variables, etc. These types of questions when not relevant to participant risk add burden to the PI for responding (as well as to reviewer for writing/re-reviewing)
- Reviewers sometimes do not understand different disciplinary backgrounds from their own; they sometimes say things can't be done; while this usually gets worked out in review it might be helpful to have discipline specific reviewers. Train reviewers to understand discipline procedures/methodology
- Reviewers are inconsistent (similar projects/protocols get different types of comments and scrutiny). Is there a way to identify for reviewers when similar projects have already been reviewed and approved?
- Training for PIs and for Reviewers around qualitative research and issues related to identifying people
- Training for reviewers and PIs on exempt vs. expedited. PIs think research should be exempt but it comes back as expedited.
- Reviewers don't always seem to pay attention to other sections of protocol so ask a question in one place when the answer is in another place.
- PIs think that questions about type of data analysis or a specific design (e.g., qualitative research) are examples of mission creep in that these questions are not about risk to participants or the PI does not understand how it is related to risk.
- When a PI is getting data from another office, why would a reviewer call the office about the data? This seems like overstepping authority and also sets up a climate of mistrust.
- There should be a climate of trust which assumes that researchers will be ethical. Our processes and review seems to imply that people are going to do wrong.

Comments about process

- Provide training materials for completing form
- Provide models of good forms
- PIs sometimes state "there is minimal risk" and reviewers will want people to outline specific risks which seems false to PIs. Projects which are minimal risk should not need to outline what those minimal risks are. This sometimes seems trivial.

- When we stamp forms as approved, we should remove highlighting (e.g., on consent form) so that people can use that document for project. Highlighted area makes things stand out when not wanting it to.
- Clarify when new protocol is needed vs. report of change (for example, when a long term study has new populations added or when funder changes for same basic protocol)
- CITI is not appropriate for UCCS process; is there way at end of CITI training to let people know where the correct information is for UCCS protocol application and procedures?
- The amount of detail needed seems burdensome. Can a general program of research be described with samples submitted and then approved? Would not then need to submit a ROC for every different study and change. People who came from other institutions were able to do this at those institutions.
- Question raised on whether IRB record needs to match exactly what is done in lab or is there room for flexibility (or perhaps identify areas where may be more there room for flexibility). Question relates to what is “material change” so what needs to be reported as change and what can be more flexible.
- Need clarification and flexibility about dual roles with participants. For example, when interviewing own students the PI was allowed to look at data (qualitative so know lots of information) but not do actual interviews. Added extra layer of work. What can faculty do with students
- Can guidance be provided on appropriate incentives?

Comments about form

- Revise form so it allows spell check, highlighting, doesn't underline input text which makes it difficult to review own work. Make into interactive, fillable PDF; or make a WORD document. Numbering is not flexible; locked boxes. (Multiple people made comments around this form)
- Form is long; there seem to be redundancies that can be eliminated (no specifics given). Do online branching of questions so only when you answer “yes” do you get more; this would make it seem shorter.
- Can there be different forms/processes for exempt, expedited and full (recognize that full is somewhat different in process but not form)