**Changes in the IRB Laws: What You Need to Know and Do**

Amanda Udis-Kessler, Director of Assessment and Program Review, Fall Conference 2018, August 23, 9:45-10:45, WES Room; updated January 22, 2019

Introduction

Following several years of solicitation of suggestions for improving the IRB regulations, the Office of Human Research Protections revised the Common Rule, the set of regulations that guides the Colorado College IRB and all such bodies. The revisions went into effect in January 19, 2019.

Not all of the changes are required; the Colorado College IRB will not implement optional changes if they would complicate matters, or if they would not be relevant to more than one or two researchers. For example, for those who have already reviewed the rules about broad consent, the CC IRB is likely to continue with prior definitions rather than switching to the broad consent model.

Matters relating to biomedical research, biospecimens and broad consent are not covered in this document. It only covers the changes that will be most important for the largest number of CC professors, students, and staff. The same page on which this document can be found includes a full copy of the new regulations with changed areas marked for easier location.

Note that where the federal language uses the term “human subjects” the CC IRB (and others) uses the term “participants.”

Not Research

There are several new categories of research that are not defined as research by the federal government, and therefore do not fall under the purview of the IRB. The types most relevant to CC are “scholarly and journalistic activities such as oral history, journalism, biography, etc. that focus on specific individuals for legal or historical purposes.”

In plain English: research that focuses on individuals not as examples of larger social patterns but strictly as individuals no longer comes under the IRB bailiwick.

Implications:

* Actual journalism projects (defined by a professor or advisor as journalism) will not require IRB review. Informational materials explaining criteria by which a project would count as “journalistic” will be developed
* Most history projects, and all oral history projects, will not require IRB review
* Venture Grant projects that fall into the “journalistic” category (interviews of individual people with no intent to draw broader conclusions or contribute to understandings of larger social patterns) will not require IRB review.
* HOWEVER, “investigative journalism”-style Venture Grant projects that are studying individuals to better understand *larger* social or historical patterns (understanding pilgrimage as a social or historical phenomenon, for instance) will still require IRB interaction, though a project involving interviews of adults will still be exempt under exemption 2 below

Who is impacted:

* History faculty and students
* Journalism faculty and students
* Students carrying out certain kinds of venture grants

Please see the relevant form on the IRB homepage.

Exemptions

Exempt categories:

1. Educational research (modification of earlier category)

2. Interactions: educational tests, surveys, interviews, and observations of public behavior (modification of earlier category)

3. Benign behavioral interventions (new category)

4. Secondary research for which consent is not required (modification of earlier category)

5. Not relevant to CC

6. Not relevant to CC

7, New broad consent category not likely to be adopted at CC

8. New broad consent category not likely to be adopted at CC

This document covers exemptions 1 through 4.

Exemption 1: Text (italics indicate new material)

Research conducted in established or commonly accepted educational settings, *that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.* This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management techniques.

What has changed, in plain English:

* It is now specified that the research may not interfere either with student learning or with the evaluation of teaching.

Implications:

* Educational research will no longer be exempt if it involves experimental design since using a control group in the study of a teaching method arguably deprives students in the control group of a potentially useful learning experience

Who is impacted:

* MAT students
* Education majors
* Education professors

See the new educational research exemption determination form on the IRB homepage.

Exemption 2: Text (italics indicate new material)

Research *that only includes interactions involving* educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior *(including visual or auditory recording) if at least one of the following criteria is met:*

* *The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects or*
* Any disclosure of the human subjects’ responses outside of the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation); *or*
* The information is recorded *by the investigator* in such a manner that the identity of human subjects *can be readily ascertained*, directly or through identifiers linked to the subjects; *and an IRB conducts a limited [expedited] IRB review to make the determination required*:

The language for the third bullet point above reads: “When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.” Safety in this case refers to confidentiality and privacy.

What has changed, in plain English:

* The term “interactions” is used; interpretations of this term are that “interventions” are not acceptable; the interpretation in the preamble to the new rule is that “interventions” (such as experimental conditions) are not acceptable (for many IRBs, this was always the assumption)
* Audio and visual recording is now mentioned explicitly as acceptable, clarifying assumptions that many of us have held for a long time about audio recording and adding a clarification about video recording (previously disputed among IRB professionals)
* It has been clarified that investigators may know the identity of their participants without raising privacy/confidentiality concerns as long as they *record* the information in such a way as to maintain privacy/confidentiality as appropriate (this was assumed before but the clarity is useful)
* There are now three standalone criteria for what would permit a project to count as exempt under this category, all involving identification in relation to the risk of harm

Implications (beyond “what has changed” above):

* Projects that might not previously have been exempt due to the use of video recording now will be exempt if they meet all of the other criteria
* There is a new expedited IRB review situation (if a project otherwise meets the exemption criteria here but participant identities can be easily determined and there is some possible risk of harm; the review is to make sure that the researcher has added adequate safety provisions)

Who is impacted:

* Students, faculty and staff carrying out research involving educational tests as described in the exemption (education faculty, MAT students, education majors)
* Students, faculty and staff carrying out survey research, interview research, or observation of public behavior (so virtually any department, plus Venture Grants that are not otherwise exempt)

Exemption 2 and children:

* Exemption 2 does not hold for survey [and presumably interview] research if children are involved. [I have not been able to find language about children and interviews.]
* Exemption 2 holds for educational test research involving children only if EITHER:
* Participant identity cannot be ascertained based on researcher recording of information OR
* Participant identity can be ascertained but the project is harmless as defined above
* Exemption 2 holds for research based on observation of public behavior involving children only if:
* The investigator(s) does not/do not themselves participate in the activities being observed AND EITHER
* Participant identity cannot be ascertained based on researcher recording of information, OR
* Participant identity can be ascertained but the project is harmless as defined above

See the revised interaction research exemption determination form on the IRB homepage.

Exemption 3: completely new; replaces old exemption 3, which was not relevant to CC:

*Research involving benign behavioral interventions in conjunction with the collection of information from an* ***adult*** *subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:*

* *The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects;*
* *Any disclosure of the human subjects’ responses outside of the research would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation); or*
* *The information is recorded by the investigator in such a manner that the identity of human subjects can be readily ascertained, directly or through identifiers linked to the subjects; and an IRB conducts a limited [expedited] IRB review to make the determination required: “When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects”* [this section is the same as in exemption 2]

*For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subject play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.*

*If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.*

New rule, in plain English:

* Permits research involving, not just interactions (exemption 2), but “interventions” or activities that change someone’s situation or status in some way temporarily
* Information can be collected in any one of a number of ways (verbal responses, written responses, audio recording, visual recording, audiovisual recording) or any combination of these
* Adults only. Research on children that otherwise meets these criteria is not eligible for the exemption
* The participant must agree to participate ahead of time, so a good informed consent process is absolutely crucial
* There are three standalone criteria for what would permit a project to count as exempt under this category, all involving identification in relation to the risk of harm; they are identical to those in revised exemption 2
* There are a series of sub-criteria that must be met for this exemption to be granted:
	+ The research must not take very long for the participant to complete
	+ Participating in the research must be harmless for all participants; the CC IRB will treat harmlessness here as including all traditional IRB meanings of “harm”
	+ Participating in the research must not cause participants any physical pain
	+ The research cannot involve actions that a reasonable participant would find physically invasive in any way
	+ Any effect that the research would have on the participant must be brief and particularly cannot cause harm of any sort to the participant for more than a brief period [this seems to contradict the “no harm” language that falls earlier; the CC IRB will err on the side of complete harmlessness pending federal clarification]
	+ The research would not be found “offensive or embarrassing” to participate in for a reasonable participant (here, I really cannot improve on the original language). If you have any question about whether your research involves “offensive or embarrassing” activities or experiences, consider whether your friends, sweetheart, professors (if relevant) and/or relatives would find it so. If any of them would find it so, it is probably not a candidate for this exemption.
	+ Deception is only permissible if the participant is forewarned during the consent process that they will be deceived or misled and agrees that this is acceptable. Claiming “demand characteristics” (of particular relevance to psychology) is still permissible for an expedited review but not for this exemption. Both passive (lack of information) and active (misleading) deception fall into this category. The IRB has developed a special consent form for this exemption; that form must be used with this exemption.

Implications:

* The examples provided in the new exemption itself are particularly relevant for psychologists and economists but could be relevant for researchers in other disciplines as well.
* Very important: see above regarding deception
* Possible new ways to collect information and still receive an exemption, similar to exemption 2 above
* More criteria than in the past about the nature and effects of experiences/activities the research will involve; certain previously expedited projects will be exempt only if these criteria are met

Who is impacted:

* Psychology professors
* Psychology students
* Economics and Business professors
* Economics and Business students
* Possibly other professors/students; will depend on the nature of the project

See the benign behavioral intervention research interaction determination form and the new benign behavioral intervention research consent form on the IRB homepage.

Exemption 4; new text in italics

*Secondary research for which consent is not required: secondary research uses of identifiable private information…if at least one of the following is met:*

* The identifiable private information [is] publically available
* Information…is recorded by the investigator in such a manner that the identity of the human subjects *cannot readily be ascertained* directly or through identifiers linked to the subjects; the investigator does not contact the subjects, *and the investigator will not re-identify the subjects*
* [3 and 4 are essentially not relevant at CC]

What has changed, in plain English:

* Now specifies that the exemption is about secondary research (based on information previously collected for other purposes, either research-related or not research-related) rather than simply using the vague term “existing”
* Now specifies that this exemption is about research for which consent is not (currently) required, which makes sense if it is secondary research
* As with exemption 2, new clarity that the issue is how the information is recorded (in terms of ascertaining identity), not whether the researcher has access to identities
* Adds to the language about identity not being readily ascertained a criterion that the researcher will neither contact nor re-identify participants from the original research
* The bullet point immediately above is only relevant if the information is not already publicly available

Implications:

* This exemption focuses on reusing identifiable information that had been collected for some other primary or initial activity that might or might not have been research as defined by the federal government and that the current researcher would find in existing records
* This exemption does not include primary/currently new research but other exemptions do
* While the language suggests information collected from previous activity (research or not), IRB experts are interpreting this exemption to include prospective data as well; that is, information that will be collected in the near future is fair use for researchers down the line

Who is impacted:

* Any type of researcher who may use already existing data/information (this suggests database research but could involve other kinds, such as an interview study in which interviews are being mined for a different set of insights)

Additional information about exemptions: changes in who can be exempt:

* Pregnant women can now be exempt
* Prisoners can (newly) be exempt if and only if they are part of research aimed at involving a broader subject population that only incidentally includes prisoners

See the secondary research exemption determination form on the IRB homepage.

Expedited Review

The old expedited review categories hold and now any research that falls into those categories and does not involve more than minimal risk can be reviewed on an expedited basis.

In plain English: No change. CC IRB has always interpreted expedited research in this manner.

Implications: No change. CC IRB has always interpreted expedited research in this manner.

Continuing Review

Continuing review is no longer required for research that is/was:

* Eligible for expedited review
* Approved by limited/expedited review
* At the stage of data analysis

This is not functionally different from the previous CC IRB interpretation of continuing review.

Vulnerable Populations

New definition/language:

“research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons”

Notice that pregnant women are no longer listed above.

Otherwise, there is functionally no change here other than a slight clarity to the language.

Informed Consent

This section is covered differently, primarily through the summarization of changes rather than direct quotes. The language here comes from the organization PRIM&R, the IRB ethics and education society; it has been modified slightly from the denser legal text. Please see the new regulations, section 116 and 117, for further information.

Change 1: a new section containing a “concise and focused presentation of key information” is now required at the beginning of the consent form, no matter how short the consent form is and no matter its format. This presentation must be designed to “assist in understanding the reasons why one might or might not want to participate in the research” and must be “organized and presented in a way that facilitates comprehension”.

This new section is not eligible for waiver or alteration.

Change 2: Changes in the basic and additional elements

New basic required element of consent process: Research collecting identifiable private information must:

* State that collected data may be de-identified and used for future research or be given to another investigator for future research without additional informed consent process OR
* State that collected data will not be used for future research, even if de-identified

The CC IRB has generated a completely new set of consent and assent forms to meet these requirements. All forms are available on the IRB homepage.

The three optional elements, which are not covered in this document, involve biospecimens or clinically relevant research results.

Changes in waiver or alteration of consent:

* Original language: An IRB can grant a waiver of consent or approve a consent procedure that omits some or alters some/all of the basic and additional elements of informed consent if the IRB finds and documents that all of the following conditions are met:
* Research involves no more than minimal risks to subjects,
* Research could not practicably be carried out without the requested waiver or alteration,
* Waiver or alteration will not adversely affect the rights and welfare of the subjects, AND
* Whenever appropriate, subjects or legally authorized representatives will be provided with additional pertinent information after participating

New, additional language:

“If the research involves using identifiable private information [and] could not practicably be carried out without using such information…in an identifiable format

In other words, a researcher can receive a waiver or alteration even if the information is both private and identifiable if it is crucial to the research that the information remain identifiable. In most CC situations, this will not be crucial.

New clarifications regarding legally authorized representatives (LARs) relevant to consent:

* A “legally authorized representative” (LAR) is “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research”
* If there is no applicable law (e.g., statute) addressing the issue, the LAR is an individual recognized by institutional policy as appropriate to provide consent in a non-research context
	+ Example: if parents/guardians were not already legal LARs for their children, the CC IRB would treat them as such for the purpose of research involving children

Documentation of informed consent:

* Must include basic elements (and appropriate additional elements, generally not relevant at CC)
* It is now possible to obtain an electronically signed copy of the consent form (if the signature is waived this is not necessary)
* Some states require signature of a witness; it is the researcher’s responsibility to determine whether this is the case for their research
* An approved consent form can be read to the participant or their LAR if the situation requires it for the purpose of comprehension (e.g., the participant is illiterate)
* The participant or their LAR receives a written copy of the form, even if the form has been read to them
* An optional short form with verbal explanation can be used where the potential participants are non-English speaking and there is no native language version of the consent form, or in the case of the native language not having a written form, or if the potential participant has diminished mental capacity
	+ The short form includes an IRB-approved written summary that includes all the basic elements and any appropriate additional elements; this summary is presented orally, with key information presented first, to the potential participant or their LAR
	+ The short form is signed by the participant or their LAR, who receives a copy of the short form and the summary
	+ A witness observes the presentation of consent information and signs both the short form and the summary
	+ The person obtaining consent (the researcher) signs the summary

Note that the CC IRB has not developed a short form template, as this approach would not be relevant to most CC research.

Wavier of informed consent form signature:

* The informed consent form signature can be waived if it is the only record linking the participant to the research and there is a potential risk of breach of confidentiality, OR
* The research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research setting, OR
* It is not the cultural norm for participants to sign such documents (as long as the research is no more than minimal risk and an alternative documentation mechanism is used) [this criterion is new]

“Preparatory to Research”: A situation in which informed consent is not required

An IRB may approve an activity of screening, recruiting, and/or determining eligibility of one or more participants in a research project without the use of informed consent if EITHER

* The investigator obtains the relevant information by communicating directly (oral or written) with a participant or their LAR, OR
* The investigator is obtaining identifiable private information by accessing records
* In these cases, the IRB still reviews and approves the entire/overall research proposal.
* This situation is appropriate in estimating the number of potential participants who meet the study criteria.
* It is documented as a notice to the IRB and does not require an application or approval.
* It allows for the collection of identifiable information for purposes of screening, recruiting, or determining eligibility of prospective participants but may not be used in any other way, and it serves as an exception to a rule rather than a waiver of it, strictly speaking.
* It presumes that investigator will protect private identifiable information obtained during screening, regardless of whether individual is recruited to take part in research or not.

Miscellaneous

The new language acknowledges tribal sovereignty over US laws where relevant. It is the responsibility of the researcher to determine where this change may apply.

In Closing

Thank you! Please contact Amanda Udis-Kessler at audiskessler@coloradocollege.edu or 719-227-8177 with questions or concerns regarding the changes.