

Revised Common Rule Overview of the Key Changes

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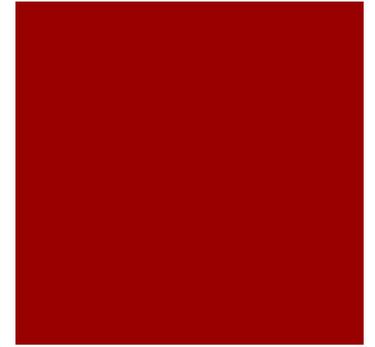
Final Revisions to the Common Rule

The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protections of Human Subjects (the Common Rule). It implements new steps **to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators.**

Implementation Date: January 21, 2019



What's Not Changing?



Minimal change to IRB review of projects that involve:

- More than minimal risk
- Drugs/biologics/medical devices (FDA-regulated)
- Collection of biospecimens
- Children
- Prisoners

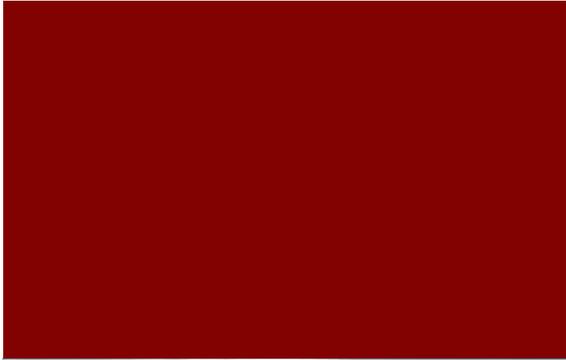
Key Changes

- **Removes certain activities** from the definition of research
- **Eliminates continuing review** for most minimal risk research
- **Expands exemption categories** and changes the review process
- **Reframes informed consent information** and adds required elements
- **Requires single IRB review** of research involving external collaborators



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Remove certain activities from the definition of research

Question 1: Does the activity involve research?

... a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to **generalizable knowledge**

Revised Common Rule

Four types of activities are specifically deemed **not** to be research

- Scholarly and journalistic activities
- Public health surveillance activities
- Information collection for criminal justice purposes
- Operational activities for national security purposes

Scholarly and Journalistic Activities

Collection and use of information focused directly on the specific individuals about whom the information is collected

- Examples include oral history, journalism, biography, literary criticism, legal research, and historical scholarship
- Excludes specific **activities**, not entire academic fields

Public Health Surveillance Activities

Limited to activities conducted, supported, requested, ordered, required or authorized by a “**public health authority**” and:

- Are necessary to allow a public health authority to **identify, monitor, assess, or investigate** potential public health signals, onsets of disease outbreaks, or conditions of public health importance, including **trends, signals, risk factors, patterns of diseases, or increases of injuries** from consumer products
- Provide **timely situational awareness and priority setting** during the course of an event or crisis that threatens public health

Public Health Authority defined as: . . . agency or authority of the United States, a state, territory, political subdivision of a state or territory, Indian tribe, foreign government, or a person/entity acting under the authority of such an agency, including employees or agents of the public agency or its contractors, or granted authority responsible for public health matters by official mandate

Question 2: Does the research involve human subjects?

Human subject: *a living individual about whom an investigator conducting research*

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtain, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

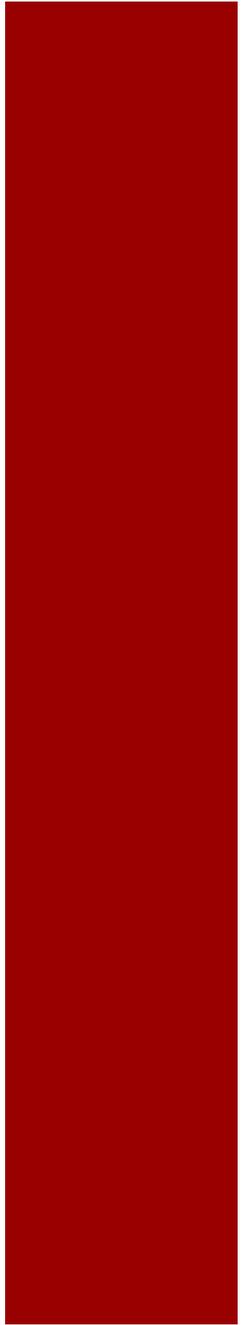
Clarifications

Intervention: includes physical procedures by which information or biospecimens are gathered and manipulations of the subject or subject's environment for research purposes

Interaction: includes communication or interpersonal contact between investigator and subject

Identifiable biospecimens or identifiable private information: biospecimens or private information for which the identity of subject is or may readily be ascertained by the investigators or associated with the information

A project must meet the definition of “research” and “human subject” to be human subject research – requiring IRB review.



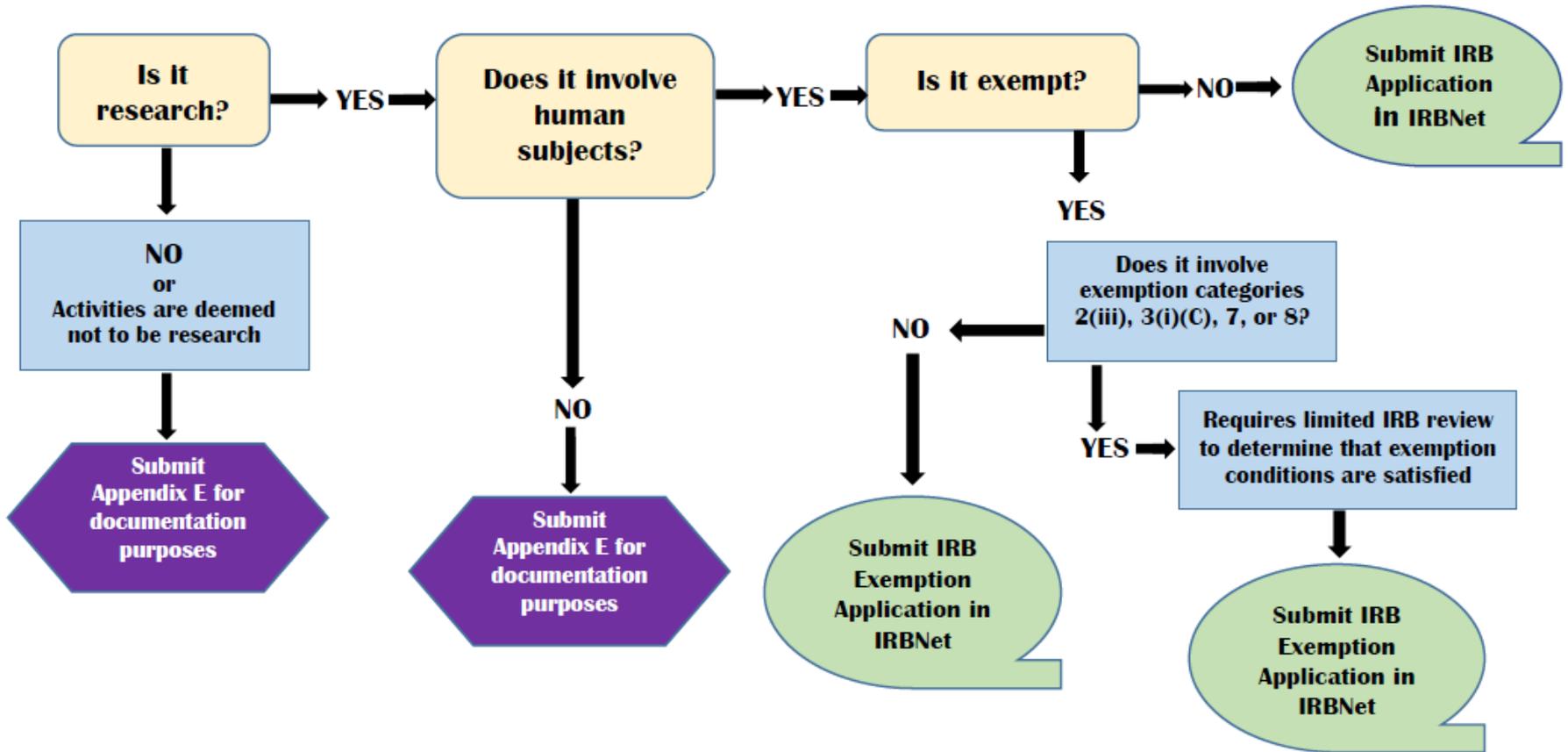
Test Your Knowledge

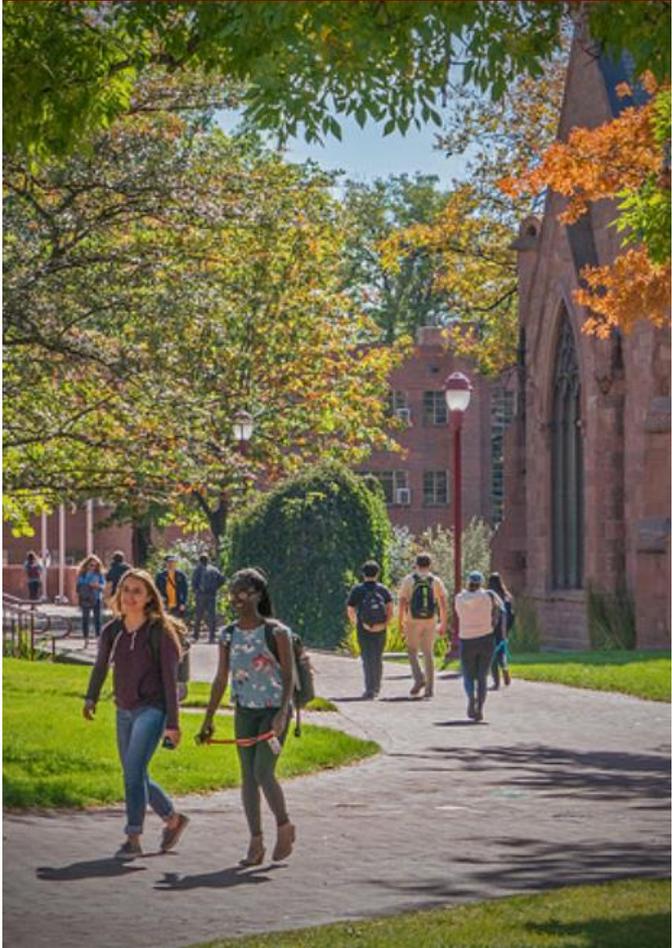
An investigator plans to analyze the GPA of students in intramural sports teams at a small college. The records will contain only the students' GPA, date of birth, gender, and race.

Are these records identifiable information under the Common Rule?

- A. Likely yes
- B. Likely not
- C. Undecided

When to Apply the Revised Common Rule?

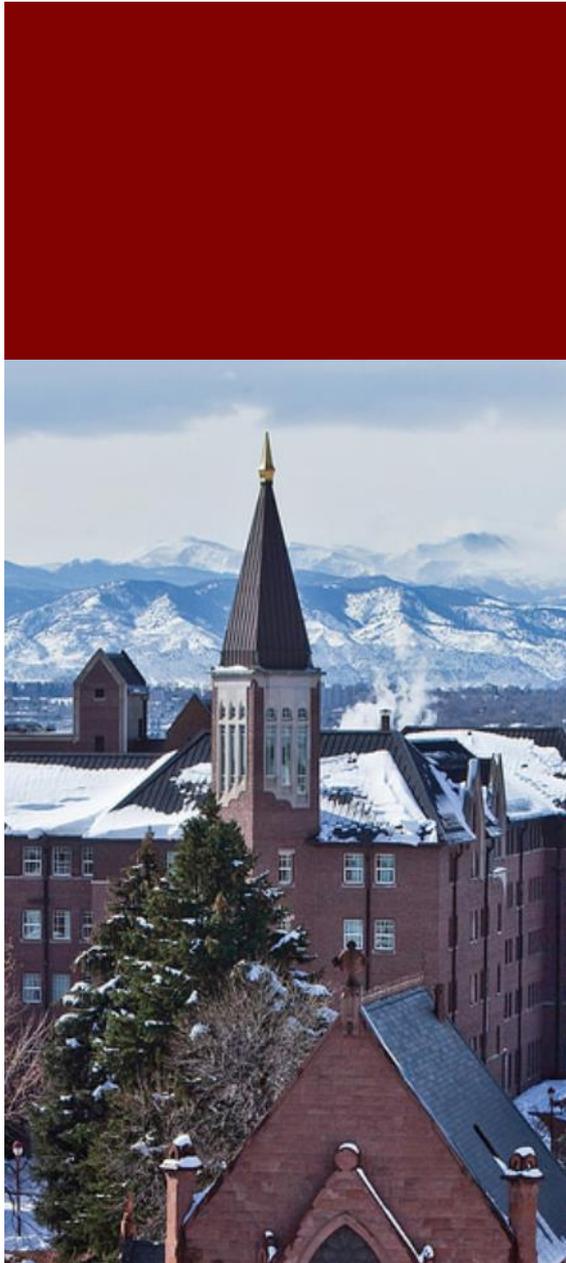




Eliminates continuing review for most minimal risk research

Changes to Continuing Review

- Continuing review is eliminated for studies reviewed via expedited review
 - The IRB can require continuing review for a study if there is cause
- Also eliminated for full board projects once subject interaction is complete
- Amendments and Adverse Event/Reportable Events are still required
- Investigators will receive reminders about submitting continuing review reports for full board review only
- Implementation of Post Approval Monitoring Program



Expands exemption categories and changes the review process

Exemption Category Changes

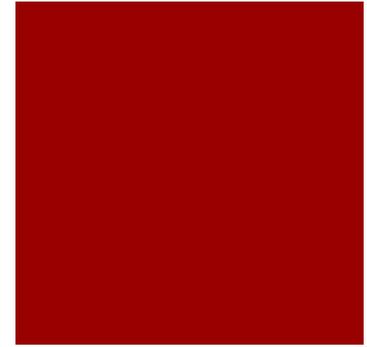
Revisions to Exemptions

- New restrictions have been added to the old exemptions – only category 6, the taste and food quality study exemption remains the same
- New uses and restrictions on exemptions for research involving children
- New exemption categories 2, 3, 7, & 8 require a “limited IRB review”

New Exemptions

- Research involving benign behavioral interventions in conjunction with the collection of information from adults
- Secondary research uses of identifiable private information or identifiable biospecimens
- Storage or maintenance for secondary research use of private information or identifiable biospecimens
- Research involving the use of private information or identifiable biospecimens that have been stored or maintained for research use





IRB Exemption Changes

Exemption with “limited IRB review” – new regulatory category

- For projects collecting sensitive, identifiable data, the IRB must review **privacy/confidentiality protections** (review by an IRB member)
- “Limited IRB review” will be conducted through an expedited review process to ensure adequate provisions are in place to **protect the privacy of subjects and to maintain the confidentiality of data.**
- An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under 45 CFR 46.104 for which **limited IRB review** is a condition of exemption (**exemption categories 2, 3, 7 & 8**)



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Exemption 1: Restrictions Added

Normal educational practices in established or commonly accepted education settings

What's new?

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

Test Your Knowledge

An investigator wants to study whether middle school students improve their math scores by adding more math lessons during the school week. One group of students will take 20 hours of math and 10 hours of English lessons in a week, and the other group will take the regular curriculum of 15/15 hours of math and English.

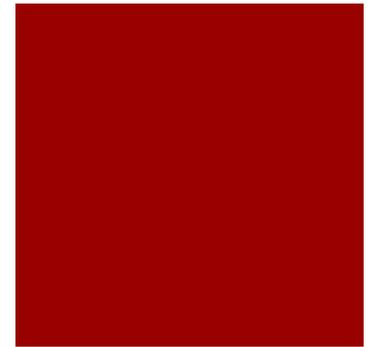
Would this research meet the criteria for exemption 1 in the revised common rule?

- A. Yes
- B. No
- C. It depends

Exemption 2: Expanded

Research that only includes interactions involving educational tests, surveys, interviews, and observations of public behavior, if:

- i. Information recorded cannot be readily linked back to subjects, **or**
- ii. Any information disclosure would not place subjects at risk of harm, **or**
- iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection

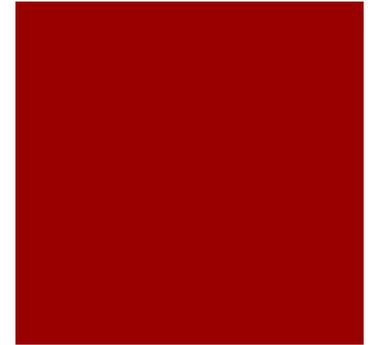


Exemption 3: New Exemption category

Research involving **benign behavioral interventions** with adults who prospectively agree, when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, and:

- i. Information recorded cannot be readily linked back to subjects, **or**
- ii. Any information disclosure would not place subjects at risk of harm, **or**
- iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection

“Benign behavioral interventions – these are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and investigator has no reason to think the subjects will find the interventions offensive or embarrassing



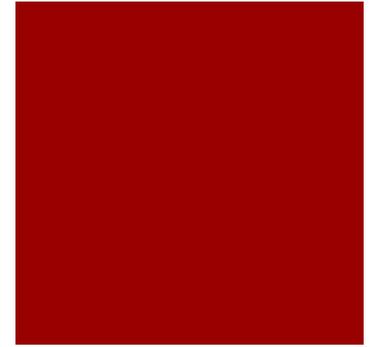
Test Your Knowledge

An investigator wants to study whether calming music improves cognitive performance in adults. One group of subjects will take a cognitive test in a quiet room, and the other group will take it in a room with calming background music. The investigator will collect the tests without any individually identifiable information.

Would this research meet the criteria for exemption 3?

- A. Likely yes
- B. Likely no
- C. It depends
- D. Undecided

Exemption 4: Expanded Secondary Research Uses of Identifiable Information or Biospecimens

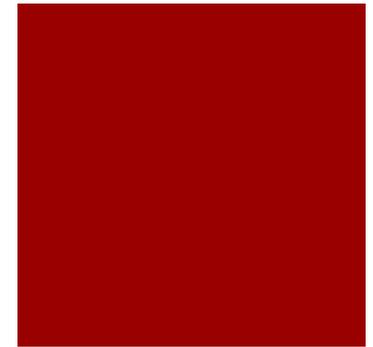


What is **Secondary Research**?

Research use of information or biospecimens collected for:

- Research studies other than the one proposed, or
- Non-research purposes (e.g., clinical care, public health, education)

Exemption 4: Secondary Research Uses of Identifiable Information or Biospecimens



Materials no longer need to be “existing”

Exempt if:

- i. Identifiable materials are publicly available, **OR**
- ii. Information, which may include information about biospecimens, is **RECORDED** by the investigator in such a manner that the identity of the human subjects cannot be readily ascertained directly or through identifiers linked to the subjects, and the investigator does not contact the subjects or re-identify subjects, **OR**
- iii. Investigator's use is regulated under HIPAA as “health care operations,” “research,” or “public health,” (NOTE: HIPAA does not apply to biospecimens) **OR**
- iv. Research is conducted by, or on behalf of, a Federal agency using data collected or generated by the government for nonresearch purposes, and the information is protected by federal privacy standards

Test Your Knowledge

Last year, an investigator collected videotaped interviews of Amazonian indigenous tribes to study anthropology. Now the same investigator wants to analyze this data again for a study in linguistics.

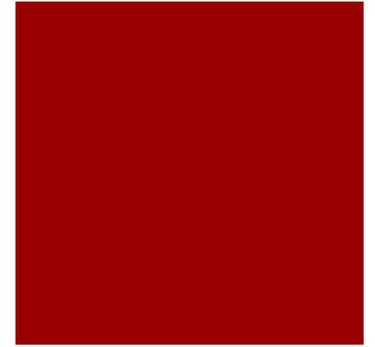
Is the new data analysis secondary research?

- A. Yes
- B. No, because it is the same investigator
- C. Undecided

Exemption 5: Expanded

Public benefit and service programs research and demonstration projects:

- Expanded to apply to federally-supported research; no longer limited to federally-conducted research
- Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research



New Exemptions Applicable to Secondary Research: Exemptions 7 and 8

Exemption 7: Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research

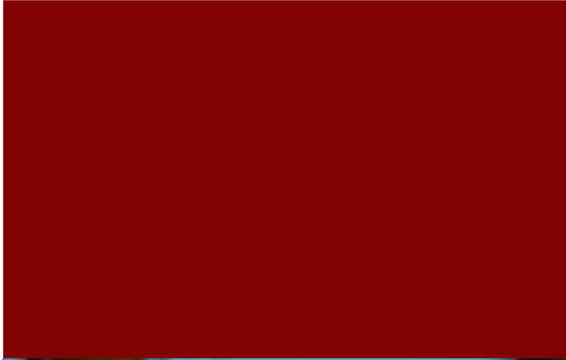
Exemption 8: Secondary research using identifiable private information or identifiable biospecimens

Investigator does not include returning individual research results to subjects as part of the study plan except when required by law

Both require:

Broad consent for storage, maintenance, and future secondary use of identifiable information or identifiable biospecimens

Limited IRB review for privacy and confidentiality protection, and some aspects of broad consent



Secondary Research Use & Broad Consents

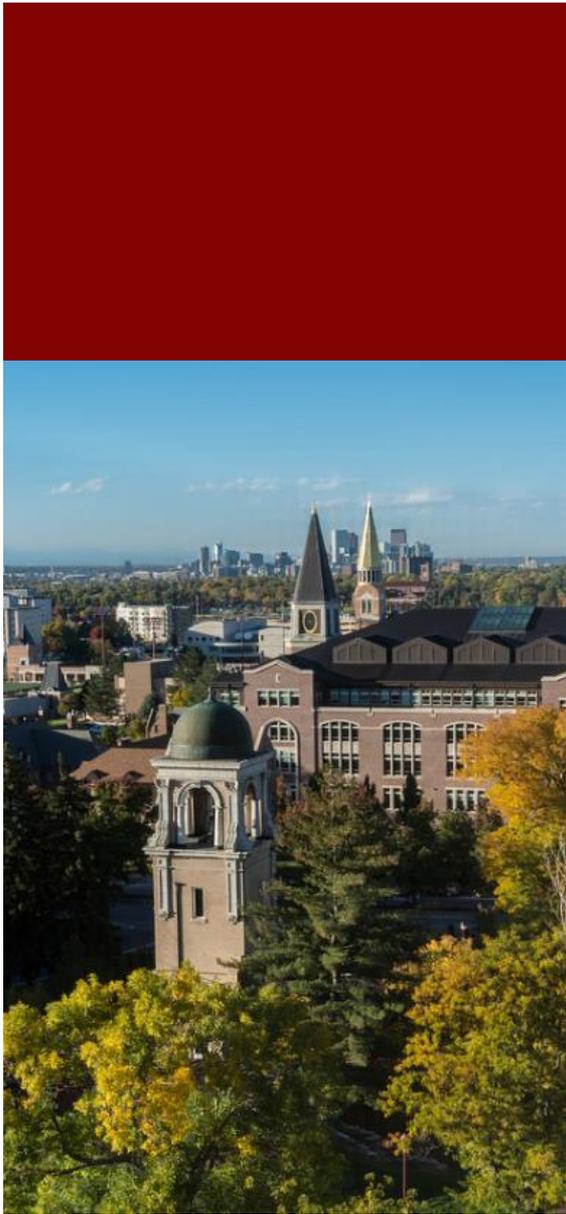
Broad Consent Template

- Allows the individual the right to make a choice whether to allow for the use of their identifiable information or biospecimens for future research use.
- Not required for storage and secondary research use of de-identified data or specimens or for uses consistent with the original informed consent
- This consent must be accessible for verification/tracking if the information will be used and must be managed in order to remove if the individual changes their mind about sharing their information or biospecimens.



- *New Exemption 7 covers the storage and maintenance of data/specimens collected with broad consent*
- *New Exemption 8 covers the secondary use data/specimens collected with broad consent*





Reframes informed consent information and adds required elements

Informed Consent Changes

- Provide a “concise and focused presentation of key information” up front
 - **Key information:**
 - Voluntary participation
 - Summary of research procedures
 - Risks
 - Benefits
 - **New consent elements (if applicable)**
 - Biospecimens may be used for commercial profit (and whether the subject will share in that profit)
 - Clinically relevant results will be returned (or not)
 - De-identified data or biospecimens may be shared for future research (or not)
- New templates will be available on the IRB website and in the Forms & Templates Library in IRBNet by January 21, 2019.

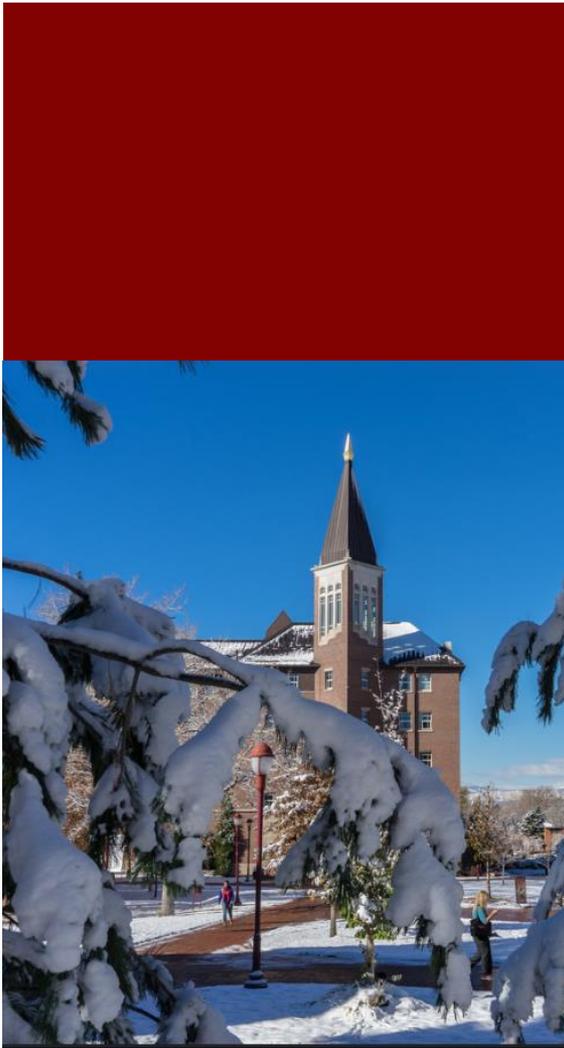


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Single IRB (sIRB) Review Requirement

- Requires that all federally-sponsored research with multi-institutional collaborators be reviewed by one designated IRB of Record
- Requires an IRB Authorization Agreement signed by a DU authorized signatory official and other institution
- Not required until January 2020



Other Changes Occurring in the DU IRB Office

- Updating IRB submission forms to reflect new revised Common Rule changes
- Implementing new review processes
- Revising IRB determination/approval letter templates and notifications
- Updating Human Research Protection Program (HRPP)/Institutional Review Board (IRB) policies
- Creating new section on IRB website with revised Common Rule information



Changes to IRBNet Submissions

- Modify **Exemption Application Form** to include new exemption categories
- Revise IRB Determination Form – Appendix E to reflect **new definitions of “human subject” and “research”** – a form to evaluate whether a project requires IRB review
- Change Informed Consent templates to include **new elements** and require **version control of consent forms**
- Add **Broad Consent template** to allow for the use of identifiable information or biospecimens for future research use



Timeline for Transition

January						
S	M	T	W	T	F	S
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

- The new rule is effective **January 21, 2019**
 - Projects approved on or after January 21 must be compliant with new rules
 - Projects approved before January 21 will be approved under current rule
- Updates regarding the transition will be provided to the research community through individual investigator letters, IRB update newsletters, IRB website postings, etc.

How are current **EXEMPT** projects affected by the revised Common Rule?

- All exempt projects will be assigned a **two-year review period**. This review period will appear in IRBNet in the “Next Report Due” field.

Project Status as of: 01/14/2019 ▼

Reviewing Board: University of Denver (DU) IRB, Denver, ...

Project Status: Exempt	Project Expiration Date:
Initial Approval Date: 03/28/2018	Next Report Due: 03/27/2020
Project Risk Level: Minimal Risk	

- **No expiration dates** will be affixed to exempt consent documents (Exempt Information Letter). Version dates of consent documents will be required.
- **Post approval monitoring** will occur within 24 months after the study has been granted exempt status.

How are current **EXPEDITED** projects affected by the revised Common Rule?

- All expedited projects will be assigned a **two-year review period**. This review period will appear in IRBNet in the “Next Report Due” field. Project expiration dates will be removed in IRBNet administratively by the IRB Office.

Project Status as of: 01/14/2019 ▼

Reviewing Board: University of Denver (DU) IRB, Denver, ...

Project Status: Active
Initial Approval Date: 02/05/2016
Project Risk Level: Minimal Risk

Project Expiration Date: 01/17/2019
Next Report Due:

- **Expiration dates** will be removed from consent documents. Version dates of consent documents will be required.
- ***Continuing review will no longer be required.**
- **Post approval monitoring** will occur within 24 months after the study has been approved.

* The IRB may require a continuing review for some studies if there is cause.



Federal Common Rule Resources

Federal Policy for the Protection of Human Subjects, Text of New Rule

<https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01058.pdf>

Secretary's Advisory Committee on Human Research Protections, August 2, 2017, Letter to the HHS Secretary and Attachments, including:

Attachment B, Recommendations on Benign Behavioral Intervention

Attachment C, Recommendations for Broad Consent Guidance

<https://www.hhs.gov/ohrp/sachrp-committee/recommendations/sachrp-recommendations/index.html>



QUESTIONS



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IRB Website
www.du.edu/orsp/research-compliance/human-subjects

THANK YOU!

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