

UPCOMING CHANGES TO REGULATIONS ON HUMAN SUBJECTS RESEARCH

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**Human Research Protection Program
University of Kansas Medical Center**



A NEED FOR CHANGE:

**Our current regulations were
published in 1991**



The world in 1991

No internet

No cell phones

No digital cameras

No social media

No apps

No big data

No whole genome sequencing

No concept of IRB reliance

Q.E.D. It's high time we had some changes to the regulations!



Federal Goals for the 2018 Revisions

“The new rule **strengthens protections** for people who volunteer to participate in research, while ensuring that the oversight system does not add **inappropriate administrative burdens**, particularly to low-risk research. It also allows **more flexibility** in keeping with today’s dynamic research environment.”



When do the 2018 rules apply?

- Greater-than-minimal risk studies approved on or after January 21, 2019
- Minimal risk studies:
 - Approved on or after January 21, 2019
 - Federally funded/supported or FDA-regulated



What happens to old studies?

- All of these changes only apply to new studies approved after 1/21/19
- Default: existing studies stay under the old rules
- IRBs can choose to move existing studies to the new rules
- If a study is transitioned, then all the new rules apply
- IRBs will be proceeding with caution
- Later in the year, we may consider transitioning some existing studies where enrollment is complete



Going Forward, There Will Be Three “Buckets” of Research

- Pre-2018 requirements (existing studies)
- 2018 Requirements (after Jan 21, 2019)
- Flexible IRB review
 - Minimal risk
 - No federal funding/support
 - No study activities that trigger FDA regulations



Today's Focus:

**Research that must comply with
the new 2018 requirements**



WHAT *HASN'T* CHANGED

- Eight Federal criteria for approving human subjects research
- IRB approval prior to study initiation
- Requirement to obtain informed consent in most cases
- Reporting adverse events, non-compliance, and other problems



Major Changes on Jan 21st

- More new studies will qualify for exemptions
- Closer alignment with HIPAA rules
- No continuing review for new minimal risk studies
- Certain consent forms must be posted on a public website
- Changes to informed consent documents



For researchers doing minimal risk research

- **New exemption categories**
- **Elimination of the continuing review requirement for new studies initially approved after January 21st**
- **New definition of HHS purview**



Federal Purview

“Human subject” means a living individual about whom an investigator (whether professional or student) conducting research:

(i) Obtains information **or biospecimens** through intervention or interaction with the individual, and uses, studies, or analyzes the information **or biospecimens**; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information **or identifiable biospecimens**.



Exemptions for Studies that are Federally Funded/Supported

<i>Category</i>	<i>Research Activities</i>	<i>2018 Revisions</i>
Exemption #1	Education Research	Restrictions Added
Exemption #2	Surveys, interviews	Expanded
Exemption #3	Benign Behavioral Interventions	New
Exemption #4	Use of Existing Data and Specimens	Expanded and New
Exemption #5	Public officials	Expanded
Exemption #6	Taste testing	Unchanged
Exemption #7	Storage of existing data and specimens	New
Exemption #8	Use of existing data and specimens	New

What does “exempt” mean?

- Does not have to comply with the majority of the federal rules
- Still requires approval from the IRB
- The informed consent process is typically streamlined/simplified
- HIPAA rules still apply



EXEMPT CATEGORY 1

Normal Educational Practices

- Most educational research falls into this category
- Must be in an established educational setting
- Typically involves research on the effectiveness or comparison of various educational methods
- NEW - Can't deny standard educational content to students or negatively impact their learning opportunities
- NEW - Can't negatively impact the employment of instructors being evaluated by the research



EXEMPT CATEGORY 2

Tests, Surveys, Interviews, Observations

- Research involving only interactions with subjects: educational tests, cognitive tests, surveys, interviews and observation of public behavior
- “Interactions” are interpersonal contact – written and verbal responses
- Preference for data that is anonymous or very low risk
- Potentially sensitive information might be allowed under this exemption if there is an additional ‘limited IRB review’ --- *new concept*
- Focus group research will now fit into this category



EXEMPT CATEGORY 3

Benign behavioral interventions

- This is an entirely new category
- More behavioral research will likely fit under this exemption
- Preference to data that's anonymous or very low risk
- Potentially sensitive information might be allowed under this exemption if there is an additional 'limited IRB review' --- *new concept*
- There are some restrictions:
 - Intervention itself must be brief: generally a few hours and within a single day
 - Subjects must be adults who can consent for themselves
 - Data collection must be only through verbal or written responses (not devices sensors, or low risk medical interventions).
 - Audiovisual recordings are allowed
- Federal advisory committee has published examples



“Limited IRB Review”

- Required when potentially sensitive data is needed for Category 2 and Category 3
- Confirms the rationale for the sensitive data and privacy/security protections
 - Access
 - Security controls
 - Sharing process
- One-time only, unless the protocol changes

EXEMPT CATEGORY 4

Secondary Research

- “Secondary use” means the data or specimens must be from non-research sources or from studies other than what is now being proposed.
- Significant changes have been made to this category.
 - Anonymous or coded data *and specimens* are allowed.
 - This exemption can be used for *both* retrospective and prospective collection.
 - Identifiable health information shared outside KUMC with collaborators who are not covered by HIPAA will have additional requirements.



EXEMPT CATEGORIES 5 AND 6

- #5 - Demonstration projects that are conducted or supported by a federal agency. These projects will be published on a federal website.
- #6 - Evaluations of taste and food quality (no changes to this category)



EXEMPTIONS 7 and 8

- Storage and maintenance of identifiable data and specimens collected under the new 'broad consent' provisions
- Broad consent must be tracked and denials must be honored for other research at the institution
- No IRBs are implementing this yet
- KUMC may evaluate the value and feasibility of this option in the future



Changes to Continuing Review

- **New minimal risk studies, approved after Jan 21, 2019, will not need continuing review (Note: Ongoing studies still need continuing review)**
- **Full-board studies, approved after Jan 21, 2019, can forgo continuing review if they are:**
 - **Not FDA-regulated**
 - **Progressed to the point of data analysis or only collecting follow-up data from standard clinical care**
- **If continuing review is required for a minimal risk project, the IRB will have to justify its rationale. (The feds are serious!)**
- ***Caveat:* Even if continuing review is not required, investigators must still obtain prior approval for protocol changes or new study personnel and update the IRB about problems, COI, etc.**



Consent form changes for studies under the new rules



New Regs - Entire Consent

“Informed consent **as a whole** must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or legally authorized representative’s understanding of the reasons why one might or might not want to participate.”



New Elements of Informed Consent

- **New Required Notification for all studies:** A statement that the data might later be de-identified and used for other purposes; alternatively, a statement that future research will **not (never)** happen even if identifiers are removed
- New additional elements, **as applicable:**
 - A statement that biospecimens could be used for commercial profit and whether the profit would be shared with subjects
 - A statement about whether clinically-relevant research results will be disclosed to the participant
 - A statement on whether biospecimens would be used for whole genome sequencing



New Regs – Key Information

“Informed consent must begin with a **concise and focused presentation of the key information** that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons **why one might or might not want to participate** in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”



A Unique Circumstance

- IRBs must implement this key information requirement without official federal guidance
- Current knowledge will get us pretty close
- We're moving forward based on the preamble to the regs, presentations by the feds at national IRB meetings, conversations with other IRBs around the country, and input from patient groups



Fed Goals for Key Information

- Simplify information from very complex consent forms
- Bring meaning to the facts
- Help people decide
- Focus on what a reasonable person would want to know
- Address therapeutic misconception



“Therapeutic Misconception”

Evidence from Research on Informed Consent

- Subjects are often confused about the nature of research
- Misunderstanding about randomization is common
- Misestimation of potential harms
- Unrealistic optimism



How is key information different?

- Locally developed
- Limited to certain information
- Simply written, short paragraphs
- Often just one page, maybe two
- Much lower reading level
- Opportunity for graphics
- Reflects the study team's knowledge



**At KUMC, we will institute
this requirement for consent
forms longer than 8 pages**



Major themes to highlight

- Reason for the research
- Nature of the intervention
- Brief summary of procedures
- Reasons someone might join
- Several very common risks
- Any rare but potentially serious risk
- Drawbacks/things to consider
- Alternatives to participation



Templates Posted So Far

- A starting point
- Short sentences, short paragraphs
- Much lower reading level
- Others under development



An Opportunity for Creativity

The feds encourage a creative approach in the developing this section of your consent form.

Investigators are encouraged to use graphics, charts and diagrams to promote comprehension of the study.



For Studies In Process

- Changes will be required if the project is approved after **January 18th**
- We will work with you to suggest themes for your key information section
- We will all learn as we go



What's next?

- **January 21, 2019 is the drop-dead date**
- **Application forms and consent templates are being revised**
- **New webpage will have resources**
- **We'll use input from patient groups and IRBs**
- **Institutions are proceeding with their best judgment until guidance is published**
- **Mid-course adjustments are highly likely 😊**



Questions and Discussion

