COMMON RULE CHANGES

GOOD TIMES

DEFINITELY NOT RESEARCH

1. ORAL HISTORIES,
2. PUBLIC HEALTH SURVEILLANCE,
3. HOMELAND SECURITY ACTIVITIES.

NOT RESEARCH, DOESN'T NEED TO BE SUBMITTED TO IRB

CHANGES TO EXEMPT CATEGORY 1

- Classroom research
- Still exempt, but new qualification that "the research must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction."

CHANGES TO EXEMPT CATEGORY 2

- Educational Tests, Surveys, Interviews, Observations of Public Behavior
- Prior to the 2018 revisions, Exemption 2 used to apply if (1) the information collected was recorded in a non-identifiable manner, or (2) disclosure of the subjects' responses outside the research would not reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. The revised Common Rule has retained these two applicability criteria, with an addition to the second criterion requiring that the disclosure of the subjects' responses outside the research would not reasonably be damaging to the subjects' "educational advancement."
- Exemption 2, prior to the 2018 revisions, used to apply where the information collected was recorded in a non-identifiable manner, or where disclosure of the subjects' responses outside the research would not reasonably place them at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. The revised Common Rule includes **another** opportunity for studies to qualify for Exemption 2: where identifiable information (even if sensitive) is recorded, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study. (See subsequent slide on what this "limited review" entails).

NEW TYPES OF EXEMPT STUDIES

- CATEGORY THREE: Benign behavioral interventions in conjunction with the collection of information from adult subjects.
    - Information obtained is not identifiable.
    - Disclosure outside of the research would not put subjects at risk of harm.
    - Information obtained can be identifiable but an IRB has done a limited IRB review in keeping with 46.11(a)(7) of the Final Rule which relates to there being adequate provisions for protecting privacy and maintaining confidentiality.
    - ONLY adults, not children, and ONLY behavioral, not biomedical of any sort

BENIGN BEHAVIORAL INTERVENTIONS

The regulations also add that benign behavioral interventions are:

Brief in duration

Painless

Harmless

Not physically invasive

Not likely to have a significant adverse lasting effect on the subjects

The investigator has no reason to think the subjects will find the interventions offensive or embarrassing

The preamble gives the following examples of benign behavioral interventions: having the subjects play an online game; solve puzzles under various noise conditions; comparing test performance of test takers in quiet or noisy surroundings; or decide how to allocate a nominal amount of received cash between themselves and someone else.

EXEMPT CATEGORY 4

- Exemption 4 applies to the secondary research use of identifiable private information or identifiable biospecimens.
- One change in the revised Common Rule is that the private information and biospecimens no longer have to be in existence prior to the start of the research.
- Another change is that if an investigator records information about individuals in a nonidentifiable manner, the investigator must not attempt to re-identify or contact the research subjects.

EXEMPT CATEGORY 4

- In the pre-2018 Common Rule, there are two provisions for when Exemption 4 can be used: (1) when the identifiable materials are publicly available, or (2) when the information is recorded by the investigator in a nonidentifiable manner. The revised Common Rule retains these two provisions, and it also adds two new ones:
  - When the investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health." Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).
  - When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for nonresearch purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

EXEMPT CATEGORY 5

- Exemption 5 has been expanded to cover more research than it does under the pre-2018 Common Rule. In the pre-2018 Common Rule, Exemption 5 applies to research that is designed to study, evaluate, improve, or otherwise examine public benefit or public service programs, if the research is conducted by a federal department or agency. This has been expanded to include research that is also supported by a federal department or agency (for example, through a grant of funding). There is also a new requirement for the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.

EXEMPT CATEGORY 6

- **Has Exemption 6 for research involving taste and food quality evaluation, and consumer acceptance studies changed with the revised Common Rule?**
- No. The revised Common Rule made no changes to Exemption 6.

EXEMPT CATEGORY 7

- Exemption 7 is a new exemption in the revised Common Rule that covers the storage or maintenance of identifiable private information or identifiable biospecimens for secondary research. Secondary research refers to research with materials originally obtained for nonresearch purposes or for research other than the current research proposal. The exemption can only be used when there is broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

EXEMPT CATEGORY 8

- Exemption 8 is a new exemption in the revised Common Rule that covers the secondary research use of identifiable private information or identifiable biospecimens originally obtained for nonresearch purposes or for research other than the current proposal. There are four requirements that must be satisfied to use exemption 8: broad consent must be obtained from the subjects for the secondary research use of their identifiable materials, documentation or waiver of documentation of informed consent must be obtained, an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent, and investigators cannot include the return of individual research results to subjects in the study plan. Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.

CLINICAL TRIAL DEFINITION

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Note: This may mean that many studies previously considered behavioral (e.g., assigning two groups of participants to a positive psychology exercise to evaluate effects on well-being) may now be considered a clinical trial.

Clinical trials are subject to all sorts of reporting and regulations.

MUST POST INFORMED CONSENT FORM

Federal funding only?

"LIMITED IRB REVIEW"

Essentially, just check privacy and confidentiality.

Used for sensitive versions of edu testings/surveys, sensitive benign behavioral research, or secondary review.

Can use broad consent.

Limited IRB review may be done via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair (although it can also be conducted by the full IRB). Continuing review is not required.

REQUIRED LIMITED IRB REVIEW

- There are four exemptions that may require limited IRB review: Exemptions 2, 3, 7, and 8.
- Exemption 2 is for research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior if at least one of the three provisions included in this exemption is met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. For this provision of Exemption 2, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
- Exemption 3 is for research involving benign behavioral interventions in conjunction with specified data collection methods if the criteria listed in one of three possible provisions are met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. For this provision of Exemption 3, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.
- Exemption 7 is for the storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use, for which broad consent is required. This exemption requires limited IRB review to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained.
- Exemption 8 is for secondary research involving identifiable private information or identifiable biospecimens, for which broad consent is required. This exemption requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

CHANGES TO CONSENT: START WITH KEY INFORMATION

- The fact that consent is being sought for research and that participation is voluntary;
- The purposes of the research, expected duration of the prospective subject's participation, and procedures to be followed in the research;
- The reasonably foreseeable risks or discomforts to the prospective subject;
- The benefits to the prospective subject or others that may reasonably be expected from the research;
- Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

CHANGES TO CONSENT

Consent forms will need to say either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not happen.

There are three new additional elements of informed consent at section. They may not be relevant to all studies, in which case, they wouldn't need to be included.

One is a notice about possible commercial profit,	the second is a notice about whether clinically relevant research results will be returned to the subjects,	and the third is a notice about whether research activities will or might include whole genome sequencing.

CHANGES TO CONSENT

- **What are the new flexibilities to the requirement for informed consent for screening, recruiting, or determining eligibility under the revised Common Rule?**
- Under the revised Common Rule, an IRB may approve a proposal for the investigator to obtain information or biospecimens to screen, recruit, or determine eligibility of prospective subjects for a research study without informed consent. In other words, the revised Common Rule removes the pre-2018 Common Rule requirement for an IRB to approve a waiver of informed consent for these types of activities. This is applicable if (1) the information is obtained through oral or written communication with the subject or the subject's legally authorized representative, or (2) identifiable private information or identifiable biospecimens are obtained by accessing records or stored identifiable biospecimens. This change harmonizes with FDA.

CHANGES TO CONTINUING REVIEW

No longer necessary for expedited applications

No longer necessary for full applications if you have reached the data analysis stage or are just conducting follow-up assessments.

Not necessary for limited IRB review applications