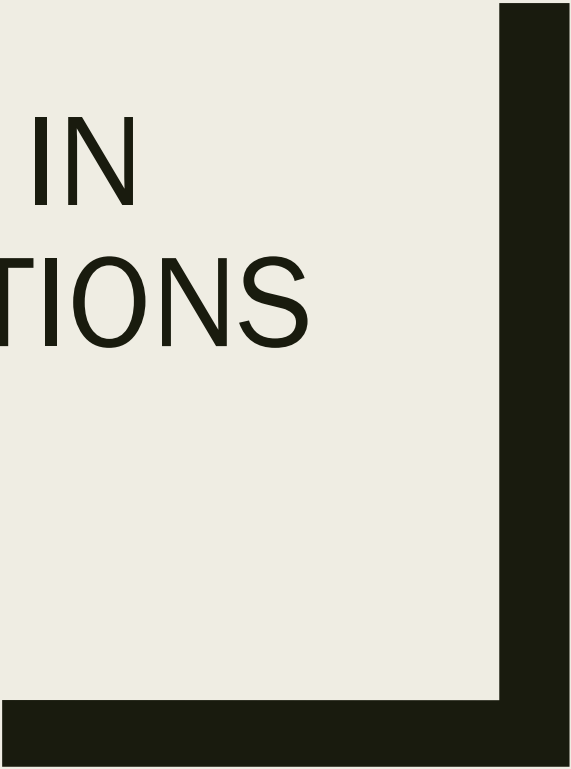




IRB - CHANGES IN FEDERAL REGULATIONS

Effective January 19, 2019



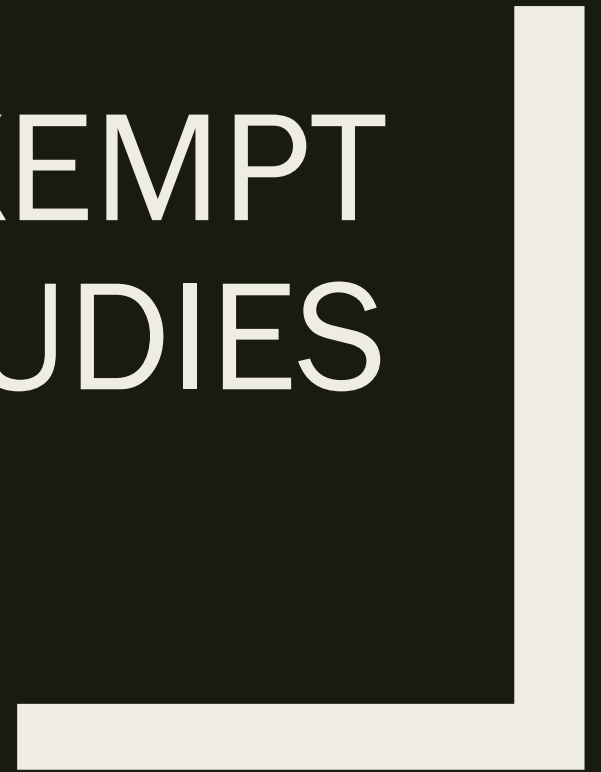
Objectives

- Background information regarding the regulatory changes
- Changes to Exempt applications
- Changes to Expedited applications
- Changes in Consent
- Changes in Data security requirements
- New IRB applications
- Timeline

Background

- Revisions to Common Rule have been discussed since 2011.
- There have been 2 delays to the implementation of the rule
- The changes are scheduled to go into effect January 19, 2019
- Changes apply only to projects approved after January 19, 2019. No changes to existing projects.

CHANGES TO EXEMPT STUDIES



Changes – Exempt studies

- Review and approval of Exempt studies
 - Only requires official determination that it is exempt, which will be done administratively in ORSP. Informed consent and data security measures should still be followed when applicable.

Exempt Categories

- Exempt Category 1 is reworded (new language in red):

Research, conducted in established or commonly accepted educational settings, **that specifically involves ~~involving~~ 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 ~~such as~~** research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt Categories

- Exempt Category 2 (expanded)

Research that only includes interactions involving educational tests, surveys, interviews, and observations of public behavior when (one of the following must be met):

- Information recorded cannot be readily linked back to subjects directly or through identifiers, or
- Any information disclosure would not place subjects at risk of certain harms, or
- Disclosure would place subject at risk and identifiable information recorded. IRB conducts limited IRB review for privacy and confidentiality protection (Limited IRB review)

Exempt Categories

- Exempt Category 3 (new)

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 audio/visual recording.

- brief in duration, harmless, participant will not find intervention embarrassing or offensive
- strictly behavioral, not physical (no blood draw, FitBit, etc.)
- does not include research with children

Exempt Categories

- Exempt Category 3 (new)
 - Does allow for the use of deception, if the participants agrees during the consent process.
 - Must meet same criteria as Category 2:
 - anonymous or deidentified, or
 - does not involve sensitive information, or
 - identifiable sensitive information, but requires Limited IRB review.

Exempt Categories

- Exempt Category 4 (expanded and added)
- Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required, if at least one of the following conditions is met:
 - The data/specimens are publicly available;
 - The information is recorded so that it is not possible to link the data to the subjects' identities, the researcher has no contact with the subjects, and will not re-identify the data;
 - The research involves only information regulated by HIPAA; or
 - The research is conducted by or on behalf of a federal department or agency, and other specific conditions are met.

Exempt Categories

- Exempt Category 5 (expanded)

This category has been altered/clarified, but it applies primarily to research conducted by departments in the federal government. The changes are not likely to affect UWG researchers.

Research and demonstration projects that are conducted or supported by a Federal department or agency and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.

Exempt Categories

- Exempt Category 6 (unchanged)
- This category, for food evaluation and acceptability studies, is unchanged.

Exempt Categories

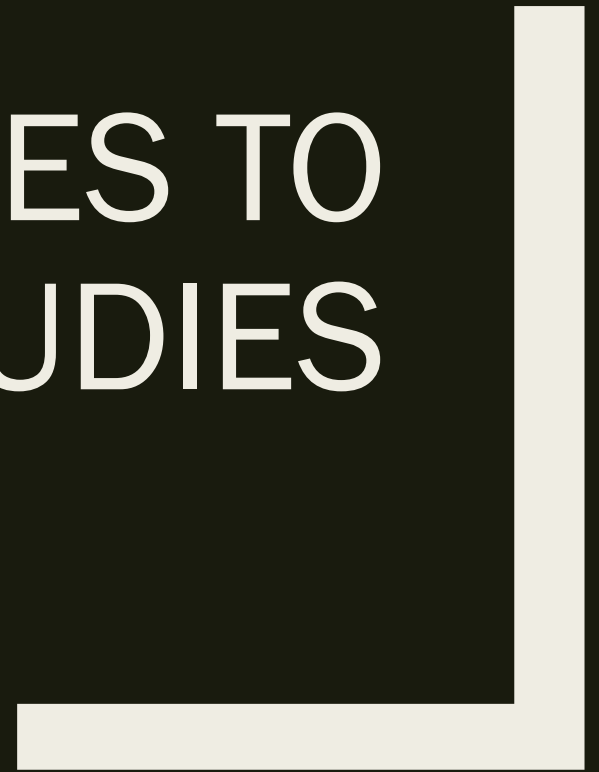
- Exempt Categories 7 & 8 (new)
- Data and specimen banking with broad consent
 - These two new categories are used when broad consent is obtained for future, unspecified research. The two categories are related: Category 7 governs the setup of a data/biospecimen bank, while research using the banked data/biospecimens would fall under Category 8.

UWG will not implement categories 7 & 8 at this time.

Exempt Categories

- Modifications to approved protocols must still be submitted for IRB review
- Research Completion form must still be submitted at the project end

CHANGES TO EXPEDITED STUDIES



Expedited

- Continuing Review

Expedited Protocols: Annual renewals will no longer be required for protocols that were approved under the Expedited Review process (with the exception of FDA regulated studies).

Investigators will now be required to renew their Expedited protocols every 3 years

Expedited

■ Continuing Review

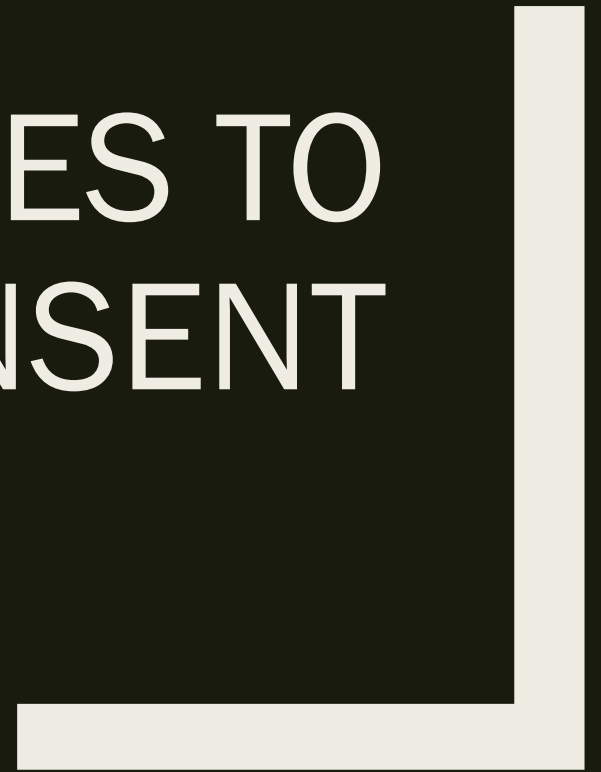
Expedited and Full Board Protocols: Continuing review will no longer be required for protocols that have progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:

- Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
- Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Expedited

- Modifications to approved protocols must still be submitted for IRB review
- Research Completion form must still be submitted at the project end

CHANGES TO INFORMED CONSENT



Consent

- The revised Common Rule explicitly establishes a new standard: to provide the information that a **reasonable person** would want to have in order **to make an informed decision about whether to participate**

Consent

■ Emphasis-

- “Long” consent documents must begin with concise and focused presentation of the key information
- Subjects must be provided with the information that a “reasonable person” would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information.
- 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 facilitate the prospective subject’s understanding of the reasons why one might or might not want to participate.

Consent

- Basic elements remain the same
 - Study involves research
 - Description of risks or discomforts
 - Description of benefits
 - Disclosure of alternative treatment, if any
 - Extent to which confidentiality will be maintained
 - If more than minimal risk, compensation and treatment in event of injury
 - Who to contact for answers about the research and subjects' rights
 - Participation is voluntary and subject may discontinue at anytime

Consent

New element

- If research involves collecting identifiable private information or identifiable biospecimens, the consent document must explain that either:
 - The data/specimens could be de-identified and stored for use in future studies, either by the PI or other researchers; OR
 - The data/specimens will not be used for any other research, not even if they are de-identified.

Consent

Additional elements if needed:

- A statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- a statement about whether the research project will or might include whole genome sequencing.

Consent

Emphasis

- For anonymous internet-based surveys, include “I agree” or “I do not agree” buttons on the website for participants to click to indicate their active choice of whether or not they consent to participate. For paper surveys, inform participants that submitting the completed survey implies their consent.
- A copy of the consent information **MUST** be given to the participant, either with a print option or by including a second copy for participants to retain.

Consent - Waivers

- Waivers or alteration of consent (eliminating some or all of the required elements of informed consent):
 - Requires the IRB to find and document that all of the following apply:
 - The research involves no more than minimal risk to subjects;
 - The research could not practicably be carried out without the requested waiver or alteration;
 - the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
 - Whenever appropriate, the subjects of legally authorized representatives will be provided with additional pertinent information after participation;
 - (NEW) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

DATA SECURITY



Data Security

■ Limited IRB review

- The extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified;
- The use of the information;
- The extent to which the information will be shared or transferred to a third party or otherwise disclosed or released;
- The likely retention period or life of the information;
- The security controls that are in place to protect the confidentiality and integrity of the information; and
- The potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption.

Data Security

- Qualtrics

- It is highly recommended that UWG researchers use the UWG licensed version of Qualtrics when possible to conduct survey research. It is not required but since already UWG has already vetted the security controls for this software, additional information is not required. If you choose to another survey tool, be prepared to contact the vendor for detailed information on their security controls to complete the form.

Data Security

- If you choose not to use Qualtrics considering the following when addressing data security:
 - Does the site you are using stipulate who owns the data?
 - How will the data available in the event of a disaster?
 - What security controls are in place to prevent the inadvertent or malicious disclosure of the data?
 - What happens if a subpoena is issued?
 - Does the vendor/site have Information Security/Cyber Liability insurance?
 - What encryption standards are used in the storing and transmission of the data?

NEW IRB FORMS



New IRB Forms

- We are in the process of creating new forms to incorporate the changes.
- New forms and guidance will be posted on the UWG IRB web page
- New tool for determining if a project is research – matrix will be posted on the web page
- This presentation will be posted

TIMELINE



Timeline

- New rules – January 19, 2019 (Saturday)
- Changes apply to IRB applications reviewed and approved after January 19, 2019
- Changes do not apply to existing IRB or projects approved prior to January 19, 2019
 - *There will be communication regarding when the old forms will be taken down.*



QUESTIONS?

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