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Revised Common Rule

Upcoming Changes to Human Research Protection Regulations:

How Do the Changes Impact Researchers?

2019

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Welcome to the Zoom Session, Revised Common Rule

- Zoom Session Structure
  - 45 minutes for the presentation
    - During the presentation, we ask that attendees please use the mute function to reduce background noise and save any questions for the end of the presentation.
    - If you have a question that you do not want to forget during the presentation portion, please feel free to submit the question through the Zoom chat.
  - 15 minutes for questions and answers
    - Questions received through the chat will be answered during this time.
    - We will follow-up with any questions that we are unable to answer or are not able to get through because of the end of the session.

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Agenda

- Introduction
- Overview of Substantial Changes
- Impact on New and Ongoing Studies
- Resources
- Questions

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Introduction

- The Federal Policy for the Protection of Human Subjects is known as the "Common Rule" because it has been adopted by a number of federal departments and agencies.
- A final rule that revised the Common Rule was published in the *Federal Register* on January 19, 2017, and was amended to delay the effective and compliance dates.
  - The revised Common Rule is also known as the 2018 requirements.
  - The current Common Rule is also known as the pre-2018 requirements.
- Exceptions
  - U.S. Department of Justice has NOT adopted the revised Common Rule.
  - U.S. Food and Drug Administration has NOT incorporated the 2018 requirements into their regulations.

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Substantial Changes

- This webinar will provide an overview of substantial changes that impact researchers.
- These changes include:
  - What is Research Involving Human Subjects
  - Exemptions
    - Limited IRB Review
    - Revised and New Exemption Criteria
  - Non-Exempt
    - Elimination of Annual Renewal for Some Studies
    - New Informed Consent Requirements
    - Posting of Clinical Trial Consent Forms
    - Single IRB

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Definitions of Research Involving Human Subjects

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Revised Definition of Research

- Definition of research revised to add categories of activities deemed NOT to be research.
- Added to provide clarity regarding:
  - Scholarly and journalistic activities
  - Public health surveillance activities
  - Criminal justice activities
  - National security activities

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Revised Definition of Research:
Scholarly and Journalistic Activities

- Revised to add categories of activities deemed NOT to be research.
  - Scholarly and journalistic activities (***e.g.,*** oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that ***focus directly on the specific individuals about whom the information is collected***.
- Studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand their beliefs, customs, and practices, and the findings apply to the studied community or group, and not just the individuals from whom the information was obtained, fall within the scope of the definition of research of the final rule.

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Revised Definition of Research:
Public Health Surveillance Activities

- Revised to add categories of activities deemed NOT to be research.
  - ***Public health surveillance activities***, including the collection and testing of information or biospecimens, ***conducted, supported, requested, ordered, required, or authorized by a public health authority***. Such activities are limited to those 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 in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- For more information, see the U.S. Office for Human Research Protections draft guidance document, https://www.hhs.gov/ohrp/draft-guidance-public-health-surveillance-activities.html

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Revised Definition of Research:
Criminal Justice or Criminal Investigative Purposes

- Revised to add categories of activities deemed NOT to be research.
  - Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Clarifies that, consistent with current practice and interpretation of the pre-2018 rule, data collection and analysis that enables the conduct of certain activities carried out as part of the criminal justice system are not research.

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Revised Definition of Research:
National Security

- Revised to add categories of activities deemed NOT to be research.
  - Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- Clarifies current federal practice and the interpretation of the pre-2018 rule that the definition of research does not include authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

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Biospecimens

- The revised Common Rule DOES NOT include the change that proposed expanding the definition of research to include biospecimens, regardless of whether the biospecimen is identifiable.

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New Definition of Identifiable Biospecimen

- New definition of identifiable biospecimen.
  - *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
- A biospecimen is deemed to include private information.
- Once a biospecimen becomes identifiable (e.g., by being tagged with the name or other information that indicates the person from whom the biospecimen was obtained), then an investigator using that biospecimen is already using something to which definition of human subject would apply (i.e. obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens).

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Exemptions

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Limited IRB Review

- Limited IRB review is a NEW requirement for *some* of the new exemption categories.
- Some of the new exemption criteria require that the IRB conduct a limited IRB review to meet the criteria of the exemption.
- The limited IRB review can be done through the expedited procedure.
- This means that for exemptions that require limited IRB review, modifications ARE REQUIRED when that modification impacts the limited IRB review criteria (e.g. privacy of subjects, confidentiality of data).
- Annual renewal of limited IRB review exemptions is NOT required.

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Limited IRB Review:
MSU Process

- At MSU, IRB administrators conduct exempt review.
- With exemption criteria that require limited IRB review, an IRB member will also need to review the submission to make the limited IRB determination.
- If an exemption criteria involves limited IRB review, this will be communicated to the PI as part of the exempt review process and included within the exempt determination letter.

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Exemption Criteria:

Research, Conducted in Established or Commonly Accepted Educational Settings (Exemption 1)

- "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 methods." 45 CFR 46.104(d)(1)(2018 requirements)

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Exemption Criteria Changes:

Research, Conducted in Established or Commonly Accepted Educational Settings (Exemption 1)

- Revised to include the criteria that the research is not likely to adversely impact students' opportunity to learn the required educational content or the assessment of educators who provide instruction.

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Exemption Criteria:

Educational Tests, Surveys, Interviews, or Observation of Public Behavior (Exemption 2)

"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:

- (i) 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;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, *educational advancement*, or reputation; or
- *(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).*" 45 CFR 104(d)(2)(2018 requirements)

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Exemption Criteria Changes:

Educational Tests, Surveys, Interviews, or Observation of Public Behavior (Exemption 2)

- Revised to clarify that the research cannot include interventions in addition to the educational tests, survey or interview procedures, or observation of public behavior.
- The third criteria (iii):
  - NEW exemption criteria that requires LIMITED IRB REVIEW to determine there are adequate provisions to protect privacy of subjects and to maintain confidentiality of data.
  - CANNOT involve children.
  - Permits recording identifiable data where disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

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Exemption Criteria:

Benign Behavioral Intervention in Conjunction with Collection of Information (Exemption 3)

"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:

- (A) 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;
- (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).

- (ii) 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 subjects 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.
- (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the 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." 45 CFR 46.104(d)(3)(2018 requirements)

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Exemption Criteria Changes:

Benign Behavioral Intervention in Conjunction with Collection of Information (Exemption 3)

- NEW exemption criteria.
- Similar version used previously at MSU for research that met certain criteria (e.g. unfunded)
- One of the criteria requires a LIMITED IRB REVIEW to determine there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- This exemption CANNOT involve children.

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Exemption Criteria:

Secondary Research Use: Publicly Available (Exemption 4)

"Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;" 45 CFR 46.104(d)(2018 requirements)

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Exemption Criteria Changes:

Secondary Research Use: Publicly Available (Exemption 4)

- Similar to pre-2018 exemption, but expands the scope to permit retention of IDENTIFIABLE private information or IDENTIFIABLE biospecimens.
- Allows the exemption to include research with information and biospecimens that do not yet exist when the research study is proposed for exemption.

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Exemption Criteria:

Secondary Research Use: Identity Cannot Readily be Ascertained (Exemption 4)

"Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(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 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 subjects;" 45 CFR 46.104(d)(2018 requirements)

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Exemption Criteria Changes:

Secondary Research Use: Identity Cannot Readily be Ascertained (Exemption 4)

- Prior exemption extended to now also cover research with information for which identifiers have been removed when the original collection of information or biospecimens occurs in the future.
- Adds the criteria that investigator does not contact the subjects and investigator will not re-identify subjects.

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Exemption Criteria:
Secondary Research Use: HIPAA (Exemption 4)

"Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b);" 45 CFR 46.104(d)(2018 requirements)

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Exemption Criteria Changes:
Secondary Research Use: HIPAA (Exemption 4)

- New criteria that permits exemption when the investigator's use of the identifiable health information is regulated under the Health Insurance Portability and Accountability Act (HIPAA).
- Under HIPAA, protections include, where appropriate, requirements to obtain the individual's authorization for future, secondary research uses of protected health information, or waiver of that authorization by an IRB or HIPAA Privacy Board.
- If the exemption criteria are met, the study would not require a separate research consent (would still need HIPAA authorization, waiver of authorization, etc.).

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Exemption Criteria:

Secondary Research Use: Federal Government Privacy Requirements (Exemption 4)

"Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*" 45 CFR 46.104(d)(2018 requirements)

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Exemption Criteria:

Secondary Research Use: Federal Government Privacy Requirements (Exemption 4)

- New exemption criteria that applies federal statutory privacy safeguards identified in the exemption provision to both the original collection of the information, and to the secondary research use of the information to which the exemption applies.

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Exemption Criteria:
Secondary Research, Broad Consent (Exemption 7, 8)

"(7) Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by § 46.111(a)(8).

"(8) Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

- (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with § 46.116(a)(1) through (4), (a)(6), and (d);
- (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with § 46.117;
- (iii) An IRB conducts a limited IRB review and makes the determination required by § 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results." 45 CFR 46.104(d)(2018 requirements)

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Exemption Criteria:
Secondary Research, Broad Consent (Exemption 7, 8)

- Exemption 7 and 8 are new exemption criteria.
- Requires broad consent.
- Requires limited IRB review.
- MSU is still evaluating these exemption criteria.

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Exemptions and Research Involving Prisoners

- New criteria that permits exempting research involving prisoners when the research is aimed at involving a broader subject population that only incidentally includes prisoners.

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Non-Exempt

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Elimination of Annual Renewal for Certain Kinds of Studies

- Unless required by the IRB, annual renewal is eliminated for:
  - Expedited research
  - Research that has 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.
- ONLY eliminates annual renewal; STILL REQUIRES submission of modifications, reporting of potential unanticipated problems involving risk to subjects or others, study closure, etc.
- Will still have some kind of check in to determine if the study is ongoing or whether it could be closed.

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General Informed Consent Requirements

- New requirement that the prospective subject or the legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.

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General Informed Consent Requirements

- Informed consent must begin with:
  - Concise and focused presentation of 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.

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General Informed Consent Requirements

- Informed consent as a whole must:
  - Present information in sufficient detail relating to the research.
  - 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.

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General Informed Consent Requirements: Guidance

- In general, the beginning of an informed consent would include a concise and brief explanation of the following:
  - The fact that consent is being sought for research and that participation is voluntary;
  - The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
  - Any reasonably foreseeable risks or discomforts to the prospective subject;
  - Any benefits to the prospective subject or to others that may reasonably be expected from the research; and
  - Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

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General Informed Consent Requirements: Guidance

- A brief description of these five factors would encompass the key information most likely to assist a reasonable person (or legally authorized representative) in understanding the reasons why one might or might not want to participate in research.
- The determination by the IRB when reviewing the summary is necessarily project and fact specific; the IRBs may require that somewhat different (or additional) information be presented at the beginning of an informed consent to satisfy the requirement for a concise and focused presentation of key information.

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General Informed Consent Requirements: Guidance

- Initial presentation of the key pieces of information must be relatively short.
- This section of the consent could, in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form.
- If information is included at the beginning of the informed consent, the information included at the beginning typically need not be repeated later in the body of the informed consent.

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New Required Element of Consent

- For research that involves the collection of identifiable private information or identifiable biospecimens, the informed consent document must include one of the following:
  - A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
  - A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.
- Carefully consider which option to include, as it can limit the use of the data in the future.

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New Required Element of Consent

- For research involving biospecimens, the informed consent document must include:
  - A statement that the subject's 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.
  - Whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

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New Required Element of Consent

- For research that may involve clinically relevant research results, the informed consent document must include:
  - A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.

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New Requirements for Waiver or Alteration of Consent

- If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.
- If the research involves using identifiable private information or identifiable biospecimens, to waive or alter consent, the IRB must now also find and document that the:
  - Research could not practicably be carried out without using such information or biospecimens in an identifiable format.

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Informed Consent Exception for Screening, Recruiting, or Determining Eligibility

- New exception that allows an IRB to approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:
  - The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
  - The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.
- Does not require the IRB to waive informed consent if the above criteria are met.

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New Exception for Screening, Recruiting, or Determining Eligibility: FDA

- Keep in mind this criteria is NOT in the FDA regulations; there is FDA guidance, Screening Tests Prior to Study Enrollment - Information Sheet, that provides more information about FDA requirements: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126430.htm

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Posting Clinical Trial Consent Forms

- New requirement to post clinical trial consent forms for each clinical trial conducted or supported by a Federal department or agency.
- *Clinical trial* means 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.
- This definition is very similar to the NIH definition of a clinical trial.

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Posting Clinical Trial Consent Forms

- Requires that:
  - One IRB-approved informed consent form
  - Used to enroll subjects
  - Must be posted
  - By the awardee or the Federal department or agency component conducting the trial
  - On a publicly available Federal Web site that will be established as a repository for such informed consent forms.

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Posting Clinical Trial Consent Forms

- If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal Web site (*e.g.* confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

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Posting Clinical Trial Consent Forms

- The informed consent form must be posted on the Federal Web site:
  - After the clinical trial is closed to recruitment, and
  - No later than 60 days after the last study visit by any subject, as required by the protocol.
- MSU plans to only require this posting for studies subject to the revised Common Rule (2018 requirements) and funded or supported by a Common Rule department or agency.
- Currently, the public website would be clinicaltrials.gov or a docket folder on www.regulations.gov

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New Requirement for Single IRB *(Does Not Implement until 2020)*

- New requirement that any institution located in the United States that is engaged in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States.
- The following research is not subject to this provision:
  - Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe); or
  - Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

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New Requirement for Single IRB *(Does Not Implement until 2020)*

- The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

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Impact of Changes on New and Ongoing Projects

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External IRB Studies

- For studies where MSU is relying upon another institution's IRB as IRB of record, that institution's policies and procedures would apply.

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MSU Studies Subject to the Revised Common Rule (2018 Requirements)

- The revised Common Rule (2018 Requirements) will apply to research, with limited exceptions:
  - Initially approved by the MSU IRB on or after January 21, 2019.
  - Determined exempt by the MSU HRPP on or after January 21, 2019.
  - Studies pending on January 21, 2019 will be subject to the 2018 requirements with limited exceptions.
- Exceptions include:
  - Studies subject to U.S. Department of Justice requirements only. These studies are required to comply with the pre-2018 requirements.
  - Studies regulated by the U.S. Food and Drug Administration must also comply with 21 CFR 50, 56. The stricter requirement applies.

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MSU Studies Subject to Pre-2018 Requirements

- The pre-2018 Requirements apply to research:
  - Initially approved by the MSU IRB before January 21, 2019.
  - Determined exempt by the MSU HRPP before January 21, 2019.
  - Studies where U.S. Department of Justice requirements apply.
- Research initially approved by the MSU IRB or determined exempt by the MSU HRPP before January 21, 2019 is not required to comply with the Revised Common Rule (2018 requirements).
- However, a study may be transitioned to the revised Common Rule (2018 requirements) by the IRB.

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Transition of MSU Studies Subject to Pre-2018 Requirements

- A study may be transitioned by the IRB from the pre-2018 requirements to the revised Common Rule (2018 requirements).
- Must be determined and documented by the MSU IRB.
- Must comply with the **entirety** of the revised Common Rule (2018 requirements).

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Transition of MSU Studies Subject to Pre-2018 Requirements

- MSU plans to consider whether to transition studies on a study by study basis at the time of continuing review.
- When determining whether to transition an ongoing study, the IRB will consider factors such as:
  - Enrollment status
  - Consent process and/or form(s)
  - Reliance agreement(s)
  - Review level
  - Funding
  - Regulatory oversight

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Single IRB Requirement

- The compliance date for the Single IRB requirement in the 2018 Requirements is January 20, 2020.

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Resources

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MSU HRPP Revised Common Rule Website

- https://hrpp.msu.edu/help/revisedrule/index.html
- Also accessible from the main HRPP webpage.
- Includes detailed information about the significant changes.
- Guidance and revised template documents are being posted as they become available.

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Questions?