Informed Consent under the Revised Common Rule
Session Objectives

- Review 2018 Common Rule changes related to informed consent
- Discuss the revised Ohio State consent template
- Discuss recent electronic signature developments
- Describe the transition plan
Overview of Consent Changes

- Process requirements
- New basic and additional consent elements
- Electronic consent
- Consent waiver and alteration criteria
- Broad consent (not applicable @ Ohio State)
- Posting consent forms
Consent Process
New Process Requirements

Informed Consent

Key Information

Reasonable Person
Reasonable Person

Subjects must be provided with the information that a “reasonable person” (undefined) would want to have to decide whether or not to participate in the study.

Responsibility remains with the investigator to:
• Provide more information when requested
• Make sufficient time and opportunity to discuss the research
• Answer questions to improve a subject’s understanding
Key Information

- Located at beginning of consent process/document
- Concise and focused presentation
- Likely to assist a prospective subject/LAR in understanding the reasons why one might want to participate in the research
Key Information (cont.)

- Must be organized and presented in a way that facilitates comprehension and promotes discussion
- Revised consent templates
- Required for most consent documents
- Initial submissions
Key Information Components

- Consent is being sought and participation is voluntary
- Purpose of the research, expected duration of participation, and research procedures
- Most important risks or discomforts
- Reasonably expected benefits
- Appropriate alternative procedures or course of treatment
- Other information
New Basic & Additional Elements of Consent
New Basic Required Element of Consent

De-identified information/bio-specimen use/sharing
• Studies collecting identifiable information and/or bio-specimens
• Identifiers might be removed
• May be used for future research studies
• No additional consent will be obtained
Will my de-identified information (and biospecimens) be used or shared for future research?

- Yes, it/they may be used or shared with other researchers without your additional informed consent.

  OR

- No.
New Additional Elements of Consent

Commercialization of bio-specimens
• Use of bio-specimens for commercial profit
• Whether subjects will or will not share in commercial profit
Currently approved language:
If you agree to participate, your samples will be considered a gift to The Ohio State University. The university may sell or share your samples and personal information with others, such as private companies, government agencies, or other universities. The university will be paid if your samples and personal information are sold.

• Your samples and personal information may be used to make new products or technologies. You will not be paid if these new products or technologies are sold or make money.

• You cannot choose how your samples and personal information will be used. If you do not want to let others decide how your samples and personal information will be used, then you should not donate your samples.
New Additional Elements of Consent

Return of clinically relevant research results
• Types of results returned
• Circumstances of release
• Notification process
Address whether clinically relevant research results, including individual research results, will or will not be returned to participants (Section: Will my study-related information be kept confidential?)

If we find information that significantly impacts your health, we will/will not share it with you. [Insert a description of the types of research results which may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.]
New Additional Elements of Consent

Whole genome sequencing
• Applies to research using bio-specimens
• May identify participant
For research involving bio-specimens and whole genome sequencing (Section: What risks, side effects or discomforts can I expect from being in the study?)

Research using your specimens may include mapping your DNA (whole genome sequencing). This information could identify you. Ask the study team if you have questions.
Documentation of Informed Consent
Electronic Signatures

- Electronic signatures are permitted
- A written copy must be given to person signing the consent form
Electronic Signature Approval

- Website/OCIO
- System administrator
- IRB submission
- Resources
Electronic Signature for Informed Consent

https://u.osu.edu/esigforinformedconsent/
Electronic Signature Approval Process

Platform/System

- Approved
- New system

Proposed Method

- System administrator
- OCIO

IRB Submission

- No documentation
- Written approval
Short Form Requirements

• Key information requirement applies
• Template will be revised to comply
Additional Waiver of Documentation

When subjects are members of a cultural group or community in which signing forms is not the norm

• Minimal risk
• Alternate method for documenting that consent occurred
Waiver or Alteration of Consent
Waiver or Alteration of Informed Consent

- Minimal risk
- Could not practicably be carried out without the waiver or alteration
- If the research involves using identifiable private information or identifiable bio-specimens, the research could not practicably be carried out without using such information or bio-specimens in an identifiable format
- Will not adversely affect the rights and welfare of the subjects
- Provided with additional pertinent information after participation
Posting Clinical Trial Consent Forms
Posting Clinical Trial Consent Forms

Clinical trials conducted or supported by a federal department or agency:

- Must post copy of IRB-approved consent on publicly available federal website (e.g., ClinicalTrials.gov)
- Awardee or federal department/agency is responsible for posting
- Can post after recruitment is closed, no later than 60 days after last study visit
Posting Clinical Trial Consent Forms (cont.)

- Redaction of proprietary or institutionally sensitive information is allowed
- Only one unsigned version must be posted
- Only one posting for each multi-institution study
- Does not require versions for each study population
Broad Consent

Ohio State will not implement the Broad Consent provision as there is no system in place to accurately track Broad Consent throughout the institution.
Timeline for Adherence to the Final Rule

• Studies approved on or after January 21, 2019 must follow all applicable consent revisions
• Revised consent templates posted soon
• Additional criterion for waiver or alteration of consent added to Buck-IRB
Summary Overview

- Major revisions to make consent process more meaningful
- New elements
- Electronic consent allowed
- New requirement to post
- Revised templates coming soon

Contact Ellen Patricia (patricia.1@osu.edu) with questions