

# Transition Action Form

The Final Revisions to the Common Rule will become effective on **January 19, 2018**. Studies that need to transition to the new requirements should use the Transition Action Form to determine what changes need to be made to the protocol to comply. **The Transition Action Form is a tool for investigators; It does NOT need to be submitted to the IRB with the modification.**

## Modification Steps:

- Determine need to transition
  - IRB requested transition
  - Investigator anticipates transition, verified with IRB
- Open modification in OSIRIS
- Specify reason in the modification coversheet: transition to New Rule
- Make changes as necessary

## What changes need to be made?

### Key Information

**Regulation** → 46.116(a)(5)(i): 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, and provide sufficient information that a “reasonable person” would want to have. 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

### Investigator Action:

- No action:** study procedures are conducted under a waiver of informed consent
- No action:** enrollment completed
- Modify** consent form to include summary (Guidance on Informed Consent Summary)

## Future Use

**Regulation → 46.116(b)(9):** Notice of future use of identifiable private information or identifiable biospecimens must include one of the following statements:

- Identifiers might be removed and the de-identified information or biospecimens could be used for future research without additional informed consent, or
- The information or biospecimens will not be used or distributed for future research even if identifiers are removed

### Investigator Action:

- No action:** The study does not involve identifiable private information or identifiable biospecimens
- No action:** The consent form already contains the necessary language
- Modify** consent form to state that de-identified information or biospecimens could be used for future research without additional informed consent, ensure consistency with OSIRIS 5.8
- Modify** consent form to state that the information or biospecimens will not be used or distributed for future research even if identifiers are removed, ensure consistency with OSIRIS 5.8 (if this option is chosen, no data or specimens from the study can be shared, even if de-identified)

## Commercialization

**Regulation → 46.116 (c)(7):** If applicable, include a statement that identified or de-identified biospecimens may be used for commercial profit and whether the subject will share in the profit or not

### Investigator Action:

- No action:** The study does not involve identifiable or de-identified biospecimens
- No action:** The consent form already contains the necessary language
- Modify** consent form to state whether or not a subject will share in commercial profit

## Clinically Relevant Research Results

**Regulation → 46.116(c)(8):** if applicable, include a statement whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions

### Investigator Action:

- No action:** The study does not involve clinical procedures
- No action:** The consent form already contains the necessary language
- Modify** consent form to state whether or not the results will be disclosed and under what circumstances

## Whole Genome Sequencing

**Regulation** → **46.116(c)(9)**: if applicable, for research involving biospecimens, include a statement that the research will or might include whole genome sequencing

### Investigator Action:

- No action**: The study does not involve identifiable or de-identified biospecimens
- No action**: The consent form already contains the necessary language
- Modify** consent form to state that whole genome sequencing may occur (Consider that sequencing may take place in the future if specimens are to be shared).

## Screening/Eligibility Review Without Waiver of Informed Consent

**Regulation** → **46.116(g)**: An IRB may 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 informed consent under certain circumstances

**Pre-2018 Regulation** → Required an IRB approved waiver of informed consent for screening, recruiting, or determining eligibility of prospective subjects by means of interaction or use of existing records or biospecimens

### Investigator Action:

- No action**: The study does not involve a waiver of consent for screening/recruiting purposes
- No action**: Access relying on the waiver is complete
- Modify** OSIRIS 4.7 to remove “Medical record review for ONLY the identification of potential subjects”. Ensure that OSIRIS 4.2 includes a statement regarding the privacy and confidentiality safeguards for the information obtained.

## Waiver or Alteration of Informed Consent

**Regulation** → **46.116(f)(2)(iii)**: Additional criterion: If the research involves using identifiable private information or biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format

### Investigator Action:

- No action**: The study does not involve a waiver or alteration of informed consent
- No action**: Access relying on the waiver is complete
- Modify** OSIRIS 4.7 to explain how the study meets the additional criterion