

## Arizona State University The New Common Rule - What does this mean for ASU Researchers?

This briefing is intended to aid researchers with understanding the New Common Rule and how it will be implemented by the Arizona State University Institutional Review Boards (IRBs). This is not a complete list of all changes in the regulation but it covers areas of common interests and it highlights important areas.

A few of the changes implemented should result in a reduction of burden for investigators and others present additional work for investigators and the IRB.

### **Implementation Date:**

The new common rule applies to federally funded or supported projects approved after the implementation date of January 22, 2019.

All new IRB approved after the implementation date will be approved under the new rules. These projects will be pre-reviewed by the ORIA Staff and expedited reviewers prepared for IRB approval under the new regulations on the implementation date.

### **Projects approved prior to the implementation date are grandfathered under the old rule**

All projects reviewed and approved under expedited criteria prior to the implementation date remain under the old rule until their next regularly scheduled continuing review. At the time of continuing review each study will be reviewed for transition to the new regulations. Grandfathered projects will be provided information on transitioning to the new rules at the time of continuing review (if applicable).

### **Definition of Research**

The new rule revises the definition of research and removes four categories of activities from oversight.

- Scholarly or journalistic activities, including oral history, journalism, biography, literary criticism, legal research, and historical scholarship
- National security missions
- Public health surveillance
- Criminal justice activities

Most of these changes are clarification for ASU research as the IRB has long recognized that these activities that these activities were outside of the IRB scope. This will have little impact to ASU researchers.

### **Clinical Trial Definition**

The old rule did not define clinical trial. Under the New rule a clinical trial is defined as:

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.

## Definition of – Benign Behavioral Intervention

The old rule provided no definition of benign behavioral interventions. Under the revised regulations a benign behavioral intervention is defined as:

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.

Examples 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.

Since 2008 the ASU IRB has been flexible in reviewing benign behavioral interventions based on the circumstance of little to no risk to participants.

## Exemptions, including limited IRB review

There is no change to exempt determinations. The exemption must be made by the IRB or a designated member of the IRB.

### Exempt categories

The exempt categories have been revised as noted below. Those shown in italics represent the change for revised categories.

**REVISED** Exempt category 1 – research in educational settings is revised to include documentation that the research does not adversely affect students' opportunity to learn required educational content or the assessment of educators who provide instruction.

**REVISED** Exempt category 2 – research involving educational tests, survey procedures, interview procedures, or observations of public behavior has been revised to included limited IRB review for privacy and security of data. The IRB should review for potential harm may result from potential damage to the subjects' educational advancement.

**NEW** Exempt category 3 – *research involving benign interventions. This research cannot involve deception unless the deception is authorized by the participant*

**REVISED** Exempt category 4 – secondary research for consent is not required of identifiable private information or identifiable biospecimens. This category is revised to remove word ‘existing’ and to allow for a HIPAA exemption. The exemption requires that information must be publicly available, or not identifiable by the investigator directly or through links, the investigator will not contact subjects, and will not reidentify participants.

**REVISED** Exempt category 5 – research and demonstration projects conducted or supported by a federal department or agency. This exemption is revised to allow for easier applicability

**Unchanged** Exempt category 6 – taste and food evaluations

**NEW** Exempt category 7 – storage and maintenance for secondary research for which broad consent is required involving identifiable private information or identifiable biospecimens

**NEW** Exempt category 8 – secondary research or which broad consent is required involving use of identifiable private information or identifiable biospecimens for secondary research use

## Exempt research and vulnerable populations

**Pregnant Women** – All exemptions may apply if the condition of the exemption is met.

**Prisoners** – None of the exemptions apply, except for research aimed at involving a broader subject population and only incidentally includes prisoners.

**Children** – Exemptions (d)(1) and (d)(4-8) may involve children. Exempt (d) (2) (research on educational tests, surveys, interviews or observations) may include children, but:

- Exempt (2)(i) and (ii) only apply to educational tests or observation of public behavior when the investigator(s) do not participate in the activities being observed;  
and
- Exempt (2)(iii) is not applicable to research with children. This exemption is where the investigator can readily ascertain the identity of the child.

## Benign behavioral intervention

This is a new definition and a new category of exemption (d) (3) – 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. Examples include: play an online game, solve puzzles under various noise conditions, decide how to allocate a nominal amount of cash between individuals, and listen to various prompts to identify sounds.

The IRB has been flexible in review of studies that involve benign interventions when the research is not federally supported. With the change in regulations, federally supported benign interventions will be reviewed in this way with the additional limited IRB review to assess the privacy of subjects and confidentiality of data. Deception cannot be used unless the deception is authorized by the participant in advance.

### Limited IRB review

Previously the regulations did not include provisions for limited review for exempt research. The new regulations outline exempt categories that require an increased level of review by the IRB; either to ensure that there are adequate protections for data security and privacy or for confirmation that the broad consent elements and return of research results are considered during the review process. The exempt categories subject to limited IRB review are:

- Exempt (d)(2) research involving interviews, observations, surveys, interviews that are identifiable
- Exempt (d)(3) research involving benign interventions that are identifiable (directly or through links) and the responses may be damaging to the subject's reputation, financial standing, employability, educational advancement, criminal or civil liability.
- Exempt (d)(7) involving storage or maintenance of identifiable private information or biospecimens for secondary research for which broad consent is not required
- Exempt (d)(8) involving secondary research for which broad consent is required

Limited review .111(a)(7) for data security and privacy is applicable to exempt categories 2, 3, and 8. The Office for Human Research Protections will provide additional guidance that will provide more details about what is expected for this review.

- The extent to which identifiable private information is or has been identified and the risk that such de-identified information can be reidentified;
- 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.

Limited IRB Limited IRB review .111(a) (8) is only applicable to exempt (d) (7) involving storage or maintenance of identifiable private information or biospecimens for secondary research for which broad consent is not required.

This limited IRB review requires the IRB to determine:

- Broad consent is obtained for the storage, maintenance, and secondary use;
- Broad consent is appropriately documented or waiver of documentation is appropriate; and,
- Adequate provisions are in place to protect the privacy of subjects and confidentiality of data if there is a change in the way the identifiable private information or identifiable biospecimens are stored or maintained

### **HIPAA exemption for identifiable secondary research of PHI that was collected for some other purpose or intent than the proposed study**

Informed consent is not required for research limited to identifiable secondary research utilizing Protected Health Information (PHI), including identifiable biospecimens (exempt category 4). *A HIPAA authorization is required for future and secondary use, or a waiver of authorization is granted by the IRB/Privacy Board.*

A waiver of authorization must be approved by the IRB upon submission of the request for access to the PHI unless the individual's written authorization is obtained.

### **Exempt amendments**

Exempt research that is subject to **limited IRB** review will be required to submit amendments to research projects to determine if there are changes that affect the limited review. This is initially no change to the ASU IRB scope as amendments have routinely been submitted for changes to exempt approvals only when a proposed changes alters the exempt status. Moving forward this may reduce the scope of review as studies determined to meet exemption that do not require limited review will no longer require the submission of amendments unless the exemption becomes invalid based on scope changes to the research implementation. Additional guidance will become available regarding the IRB expectation.

### **Expedited Review Categories**

There is no change to the expedite categories under the new regulations. The Federal Government will assess the categories every four years. The rule clarifies that projects involving only activities on the list of expedited categories should be treated under expedited review unless the IRB determines and documents that the study involves more than minimal risk.

The intent of the federal regulation is for IRBs to review only those studies that are greater than minimal risk by the convened IRB. The IRB will be responsible for documenting that the activities proposed involve greater than minimal risk.

The IRB will continue to treat minimal risk activities as expedite review and will work to educate staff and researcher on the interpretation of the expedite categories.

## **Continuing review requirement for expedited, minimal risk research**

Research approved after the implementation date will no longer be subject to annual continuing review, unless the IRB finds and documents the need to require continuing review to enhance the protections of research participants. Expedited research will be given a five-year expiration date only so that IRB records can be updated.

The IRB will required continuing review for minimal risk research when the research involves:

- Native Americans;
- Principal Investigator (PI) or co-PIs who have received a determination of continuing or serious non-compliance in the past two years;
- As determined by the IRB because of a change in risk, protection or inclusion of subjects, or other concerns that require increased oversight;
- Projects that involve deception that is not prospectively authorized; or
- A conflict of interest management plan exists.

Existing projects will be assessed at the next continuing review to determine if they should transition to the new regulations.

Moving a project to the new regulations means and requirements apply. This could require revisions to the informed consent, re-consent of participants, and increased data security and privacy standards for these existing studies. Investigators offered the opportunity to transition might decline after an assessment of the burden change and conversation with the IRB.

## **Single IRB (sIRB) review for multisite studies**

The IRB has increasing implemented single IRB review of research. The sIRB may be determined by the prime awardee and the federal agency supporting the study or offered as a burden reducing effort.

The implementation date of sIRB review is three years from the implementation date of the rule (January 19, 2020). Note that the NIH single IRB policy is effective January 25, 2018.

The new rule allows for exceptions from sIRB review when special circumstances apply that require more institutional oversight.,

## **Informed Consent, including Broad consent and waiver of consent and waiver of documentation**

The informed consent requirements have been significantly modified. A brief explanation of the changes are provided with more detailed information in the subsequent sections:

- Significant changes to the content, organization, and presentation of information and process to facilitate an individual's decision about whether to participate;
- Changes to the basic and additional elements of consent;
- Creation of the concept of broad consent;
- Changes in the criteria for the waiver or alteration of consent;
- New provisions that allow IRBs to approve research for which investigators obtain information or biospecimens without consent for the purposes of screening, recruiting, or determining the eligibility of prospective subjects provided certain conditions are met; and
- Requirement to post\* to a federal website a copy of the IRB approved version of the consent form.

\*Only one posting is required per multi-site study, which can be done by the sponsor. This only applies to clinical trials that are conducted or supported by a federal department or agency. The website has yet to be developed.

The IRB will develop new informed consent templates that meets the expectations of simplicity, clarity, and comprehension as needed.

### **Informed Consent Elements**

**NEW** required element of informed consent for studies involving collection of identifiable private information or identifiable biospecimens. One of the following statements must be in the informed consent:

- A statement that the identifiers might be removed from the information, and after such removal, the information could be used for future research studies or distributed to another investigator for future research without additional informed consent; **OR**
- A statement that the subject's information or specimens, even if identifiers are removed, will not be used or distributed for future research.

**NEW** additional elements of informed consent will be required of applicable research studies. These additional elements are:

- 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;
- A statement regarding whether clinically relevant research results; including individual research results, will be disclosed to subjects, and if so, under what conditions; and
- For research involving biospecimens, whether the research (if known) or might include whole genome sequencing.

### **Broad consent**

Broad consent is an option to obtain consent for studies involving storage, maintenance, and secondary use of identifiable data or specimens. Broad consent is not in addition to traditional informed consent, but separate from traditional informed consent.

Projects will be assessed on a case-by-case basis as to whether broad consent is required. Investigators may also request use of broad consent. There are items to consider that apply when broad consent is used:

Broad consent should consider the following elements:

- Risks, benefits, confidentiality, voluntariness, and whom to contact;
- Whether commercial profit and a determination that the participant will or will not share in the profit;
- When research involves the whole genome sequencing provide:
  - General description about the types of research that will be done with the identifiable information or specimens;
  - Description of the identifiable information or specimens that might be used in the research, whether sharing of such information will occur, and the types of institutions or researchers that might conduct research with the identifiable information or specimens;
  - Time period the information will be stored and maintained, and stored and used for research;
  - Unless explained otherwise, a statement that individuals will NOT be informed of the details of any results of studies; and
  - Unless explained otherwise, a statement that clinically relevant results will NOT be shared.
- When a participant withdraws their broad consent, the IRB cannot issue a waiver or alteration of consent to allow continued use of the identifiable information or specimens.
- The new rule allows waiver of a signature requirement (e.g. waiver of documentation) when a broad consent is used, so long as all the elements above are met. However, it is expected that use of a waiver of a signature for broad consent will be used rarely (e.g. for distinct cultural groups where signing documents is not the norm, or when the initial activity involved only oral communication through activities like a phone survey).

### **Waiver or alternation of informed consent**

The IRB is prohibited from waiving or altering consent when broad consent is used. If a participant withdraws their broad consent, the IRB is prohibited from waiving consent for use of any information collected.

Investigators will be required to provide justification for a **NEW** required element for obtaining a waiver of consent:

- If the research involves using identifiable private information or biospecimens, the research could not practicably be carried out without using such information in an identifiable format.
- Broad consent is appropriately documented or waiver of documentation is appropriate; and
- Adequate provisions are in place to protect the privacy of participants and confidentiality of data if there is a change in the way the identifiable private information or identifiable biospecimens are stored or maintained.

## **Other items of interest**

### **Screening, recruiting, or determining eligibility of prospective subjects**

The new rule specifically states that an IRB can approve access to identifiable information or identifiable specimens without the prospective informed consent of the subject for purposes of screening, recruiting, or determining eligibility if: •

- The investigator obtains information through oral or written communication with the prospective subject; OR
- The investigator obtains identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

A waiver of informed consent will no longer be required to access identifiable information for determining eligibility. However, a waiver of PHI authorization will still be required as the HIPAA rule does not

allow such access without prior written authorization or a waiver of authorization.

## **Other federal agencies**

FDA - No harmonization yet as required by 21st Century Cures Act. DOJ – Has not adopted the new regulations, therefore, the prior regulations apply.

## **Newborn Screening Act**

With the implementation of the new regulations, the New Screening Saves Lives Reauthorization Act of 2014 is no longer effective. Secondary research with nonidentified newborn blood spots will be treated as secondary research consistent with any research involving nonidentifiable biospecimens.

This research is no longer considered research with human subjects under the new regulations.

ASU thanks the University of Arizona Human Protection Program for their interpretation guidelines and acknowledges their original content as the basis for information in this document.