THE UNIVERSITY OF ARIZONA
Research, Discovery & Innovation

UA New Common Rule Implementation

The New Common Rule - What does it all mean?

This guide serves to assist University of Arizona researchers to understand the New Common Rule ('new rule') and how it will be implemented at the University of Arizona. This is not an exhaustive list of the changes in the new rule, but highlights the areas of most importance to researchers.
Some changes will result in a reduction of burden while others will present additional work for investigators and the IRB.

Implementation Date

Topic	Rule change and UA Implementation
Implementation Date	The new common rule applies to federally funded or supported projects approved after the implementation date of July, 19, 2018. All new IRB submissions in July 19, 2018 will be approved under the new rules. These projects will be pre-reviewed by the HSPP staff and prepared for IRB approval starting on July 19, 2018.
Projects approved prior to the implementation date are grandfathered under the old rule	All projects reviewed and approved prior to the implementation date remain under the old rule. These projects retain their existing level of review and all other IRB requirements, including continuing review requirements. Grandfathered projects will be provided information on transitioning to the new rules at the time of continuing review (if applicable).

Definitions

Topic	Rule change and UA Implementation
Definition of Research	The new rule explicitly removes four categories of activities from the rule jurisdiction: • 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 Since 2012, the UA has allowed for flexibility in reviewing the above categories outlined by recognizing that these activities are not within the IRB's scope. There will be no change locally as a result of this clarification in the rule.
Definition of a Clinical Trial	The old rule provided no definition of a clinical trial. The new rule defines a clinical trial 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. The UA HSPP provide guidance on the interpretation of this definition.
Definition of Benign Behavioral Intervention	The old rule provided no definition of benign behavioral interventions. The new rule defines a benign behavioral intervention 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 2015, the UA has allowed for flexibility in reviewing benign behavioral interventions by recognizing these activities pose very little to no risk to subjects. These activities have been reviewed under the flexible exempt category 7. With the new rule, the flexible exempt category will no longer be needed.

Exemptions, including limited IRB review

Topic	Rule change and UA Implementation
Exempt project determination	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. The (*) items represent the change for revised categories. **REVISED** Exempt category 1 – research in educational settings *Revised to include 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 *Revised to include limited IRB review for privacy and security of data and that 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 *Revised to remove word 'existing' and to allow for a HIPAA exemption

	*Information must be publicly available, or not identifiable by the investigator directly or through links, the investigator will not contact subjects, and will not re-identify subjects; **REVISED** Exempt category 5 – research and demonstration projects conducted or supported by a federal department or agency *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	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 UA has for the last two years 'flexed' studies that involve benign interventions that are not federally funded or supported. These flexed studies have already

	received exempt approval. Now federally funded or supported studies that involve benign interventions will receive exempt status, but they will be subject to a limited IRB review to assess the privacy of subjects and confidentiality of data. There can be no deceptive research with benign interventions unless the deception is authorized by the subject first.
Limited IRB review	The old rule did not contain the concept of limited IRB review for exempt research. The new rule outlines several exempt categories that require an increased level of review by the IRB; either for data security and privacy protections, or for confirmation of broad consent elements and return of research results. 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 8The 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 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. 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. Both the UA and Banner Health will require a waiver of authorization be granted by the IRB upon submission of the request for access to the PHI, or the individual's written authorization is obtained.
Exempt amendments	Exempt research 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 a change and extension of IRB scope. New guidance will be issued outlining the expectations.

Expedited Review

Topic	Rule change and UA Implementation
Expedited review categories	There is no change to the expedite categories under the new rule. 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 stop sending projects to the full committee even if they are on the list of minimal risk activities. The burden will be on the IRB to document that the activities involve greater than minimal risk. The UA will continue to treat minimal risk activities as expedite review and will work with the IRB to educate on this new interpretation of the expedite categories.
Continuing review requirement for expedited, minimal risk studies	Projects approved after the implementation date will no longer be subject to a continuing review, unless the IRB finds and documents the need to require a continuing review to enhance the protections of research subjects. Expedite research will be given a three-year expiration date only so that the Human Subject Protection Program can update its records.

eliminated	The UA IRB may require 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 rule. Moving a project to the new rule means the entire new rule applies. This may require revisions to the informed consent, reconsent of subjects, 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 HSPP.
Single IRB (sIRB) review for multi-site studies	The UA has allowed since 2010 for single IRB review of for-profit research and on a case-by-case basis for all other research. The new rule requires that all multi-site (meaning more than one site) conduct sIRB review. The sIRB is determined by the prime awardee and the federal agency supporting the study. 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 UA will create guidance and frequently asked questions about charging for sIRB review, the scope of the review, etc. The new rule allows for exceptions from sIRB review, such as for Native American collaborative research. This is consistent with the UA's ABOR policy on consultation with Native American tribes.

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

Topic	Rule change and UA Implementation
Informed Consent requirements	The informed consent requirements have been highly modified. A brief explanation of the changes are noted, with more detailed explanation in the following sections: • Significant changes to the content, organization, and presentation of information and process to facilitate a subject'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 UA IRB, in consultation with Banner Health for BH-related research, will create a new informed consent template that meets the expectations of simplicity, clarity, and comprehension.
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 will be

	appropriate. Investigators may also request broad consent. There are several key points when using broad consent: • There are different elements of informed consent from traditional informed consent. The elements are: o Risks, benefits, confidentiality, voluntariness, and whom to contact; o Whether identifiable information or specimens will be sold for commercial profit and whether the subject will or will not share in this commercial profit; o Whether research may involve whole genome sequencing; o General description about the types of research that will be done with the identifiable information or specimens; o 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; o Time information will be stored and maintained, and stored and used for research; o Unless told otherwise, a statement that individuals will NOT be informed of the details of any results of studies; and o Unless told 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.

Other items of interest

Topic	Rule change and UA Implementation

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 biospeicmens. 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 rule, therefore, the old rules still apply
Newborn Screening Act	With the implementation of the new rule, the New Screening Saves Lives Reauthorization Act of 2014 is no longer be effective. Secondary research with nonidentified newborn blood spots will be treated in the same way as secondary research with any other type of nonidentifiable biospecimen. This research is no longer considered research with human subjects under the new rule.