



# PI Transition Requirements

## ***What does transitioning to the new rules mean for your research project?***

Transitioning to the new 2018 human subject rules is not hard. In fact, it will be simpler in the long run. It is important to note that projects that transition to the new rule must adopt the WHOLE rule, not parts of the rule. The table below outlines the basic changes for each review level and a separate discussion regarding informed consent. Please discuss with the Human Subjects Program staff what the new rules mean for your project.

### **Exempt Projects:**

There is no need to transition these projects to the new rule. Exempt projects remain exempt.

### **Expedite Projects:**

At continuing review, projects will be assessed to see if the project meets the new exempt criteria. If the project can be made exempt, then the investigator will need to undergo a limited IRB review for data security and privacy protections for identifiable data.

Projects that are not exempt remain expedite. The IRB will assess the following:

- A review for data security and privacy protections.
- Assessment of the informed consent to see if the project requires some new elements of informed consent for keeping identifiable data and repository research.
- Changes to the organization and format of consent documents (unlikely for most expedite or minimal risk research).
- Reconsent for subjects may be required if any of the new consent elements are added to the consent.

Expedite research that transitions to the new rule will NOT have a continuing review in most cases. The removal of the renewal requirement is a significant reduction in burden, even if there are increased data security or consent requirements. Some projects the UA has determined should still have a renewal. These include:

- Projects involving Native Americans
- Serious or continuing non-compliance determination for the PI or co-PI over the last two (2) years
- Projects that have an ongoing conflict of interest (COI) management plan
- Projects that do not authorize the deception first

All other requirements, such as amendments and reporting obligations, stay the same.

### **Full Committee:**

- Any project reviewed at full committee will be reassessed for data security and privacy protections regardless of switching to the new rule.
- Increased informed consent requirements as outlined below.



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**Informed Consent:**

Informed consent changes impact all projects, however, full committee projects will experience the most change. Most expedite informed consents are already short and brief enough that not many changes would be necessary. Should the project transition to the new rules the following may be required:

- 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;

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. Reconsent of existing subjects will be required if these additional elements are necessary. The 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.*

**Single IRB review:**

Projects that are federally funded or supported will be required to transition to a single IRB of record. This is complicated due to needed conversation with colleagues at other institutions. Please review the 'single IRB' guidance document on the Human Subject Protection Program website for more information.