Common Rule Anxiety

# Questions

## What were the changes to the Common Rule?

1. Here is a summary of the changes:
   1. There are new requirements regarding information that must be given to prospective research subjects as part of the informed consent process.
      1. Informed consent must begin with a concise and focused presentation of the key information needed to assist in the understanding of why one might or might not want to participate in the research.
   2. Allows use of broad consent.
      1. Broad consent may be sought under specific conditions as an alternative to traditional informed consent.
         1. Broad consent is required for exemptions 7 and 8.
         2. WTAMU has adopted the provisions of broad consent and will allow use of broad consent when applicable.
   3. Establishes new exempt categories. Please take the time to review the new exempt categories as there were major changes to this section (45 CFR 46.104).
      1. There are now eight exempt categories instead of the previous six.
         1. Combined some categories, clarified some concepts, and added three new exempt categories (3, 7, and 8).
            1. Category 3 is for research involving benign behavioral interventions.
            2. Category 7 is for storage or maintenance for secondary research requiring broad consent.
            3. Category 8 is for secondary research requiring broad consent.
   4. Creates single IRB requirements.
      1. US-based institutions engaged in cooperative research must use a single IRB for that potion of the research that takes place within the US.
         1. Established agreements and gives those agreements authority under the rule (.103(e)).
   5. Added Limited IRB Review.
      1. Put in place to ensure adequate protections for identifiable private information and identifiable biospecimens.
      2. No continuing review is required for protocols under Limited IRB Review.
         1. WTAMU will still require annual updates of research activities.
   6. Removes continuing review for certain research activities.
      1. WTAMU will still require annual updates of research activities.
   7. Clarifies some concepts.
      1. Three new definitions
         1. Clinical Trial
         2. Public Health Authority
         3. Written, In Writing
      2. Four revised definitions
         1. Human Subjects
         2. Identifiability
         3. Legally Authorized Representative
         4. Research
      3. Provided guidance on activities deemed “not research”. Please take time to review these activities in your determinations of IRB applicability.
         1. To summarize: certain scholarly and journalistic activities; health surveillance; collection of information for criminal justice purposes; and operational activities in support of national security and homeland defense as provided in the Final Rule are not considered research.
      4. Changes to “Vulnerable”
         1. Pregnant women and physically disabled individuals are no longer considered vulnerable to coercion or undue influence.
         2. “Mentally disabled persons” has been replaced with “individuals with impaired decision-making ability”
   8. FWA’s no longer a check in the box.
      1. FWA required if the research is:
         1. Federally funded.
         2. Conducted by a federal agency.
      2. FWAs no longer a declaration of ethical principles
   9. Renumbering of a few provisions
      1. Section titles and scheme had minimal reorganization
         1. Some provisions have been relocated (ex: Provisions for exemptions moved from .101 to .104)
         2. Some areas were re-organized (ex: definitions are now alphabetized.)

## How do the changes to the Common Rule impact the investigator?

Most of the changes to the Common Rule were put in place to reduce burden on investigators and improve the rule by clarifying some concepts. As an investigator the changes you will need to become familiar with are:

1. Activities “deemed not research”
2. Changes to informed consent, including the addition of broad consent
3. Exempt categories and their applicability to Subparts B, C, and D (research with pregnant women, neonates, fetuses, prisoners, or children)
4. Applicability to limited IRB review (used with exemptions 2c, 3c, 7, and 8)
5. Please note research covered under other rules, procedures, or directives (ex: FDA under 21 CFR 50 and 56) will require adherence to additional requirements.

## Where can I find additional information?

1. Look for new forms, decision trees, and information at [www.wtamu.edu/IRB](http://www.wtamu.edu/IRB)
2. Participate in training specifically focused on the new Common Rule at [www.citiprogram.org](http://www.citiprogram.org)
3. Contact the IRB Chair or AR-EHS at 806.651.2270 or AR-EHS@wtamu.edu