What’s New with the Final Rule?
(Or, how I learned to stop worrying and embrace the upcoming regulatory changes)

The Final Rule published by the U.S. Department of Health and Human Services on January 19, 2017 does not contain the sweeping changes that were previously proposed. However, the Final Rule does provide some helpful revisions to provide clarification and reduce administrative burden. Implementation of the Final Rule is slated for January 19, 2018.

Here is a brief overview of some of the more notable changes:

Revised Human Subjects Definition

Although the criteria for what constitutes human subjects research has not changed, the actual text has. The definition of “human subject” has been changed to include “identifiable biospecimens” as well as how data and/or biospecimens have been collected or will be used.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

The definition of “research” has also been expanded to list activities that are specifically deemed not to be research (e.g., oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions).

Impact: Provides greater clarification on definition.

New & Revised Exempt Categories

Minor revisions to existing categories

There have been some minor revisions to the following categories:

Exempt 1: Now includes a statement that the research cannot “adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.”
Impact: Provides clarification on risk.

Exempt 2: Includes a clarification that the data may involve visual or audio recording as well as a carve-out that allows for the collection of sensitive, identifiable data to be collected as long as a “limited review” is conducted by the IRB.
Impact: Allows for sensitive, identifiable data to be determined as exempt.

**Exempt 4:** This category has been revised to also include biospecimens, as well as special carve-outs for HIPAA-covered data, federally conducted research, and federally generated data. 
Impact: Provides greater clarity on what is allowable under this category.

**Exempt 5:** The revision provides further clarification about what are “research and demonstration projects that are conducted or supported by a Federal department or agency.” To note, research that is reviewed under this category has always been quite rare.  
Impact: Provides clarification on what is allowable under this category.

**New Exempt Categories**

**Exempt 3:** This is a new category specific to “benign interventions” involving adults that allows for deception under certain conditions. Data may also be sensitive and identifiable as long as a “limited review” is conducted by the IRB. 
Impact: “Benign interventions” are currently reviewed as expedited review, as there is no current exempt category that this activity would fit in. With the Final Rule, this type of research would be permitted as an exempt review.

**Exempt 7:** This new category is specifically for identifiable data and/or biospecimen repositories as long as a “limited review” is conducted by the IRB.  
Impact: Repositories are currently reviewed as expedited review, as there is no current exempt category that this activity would fit in. With the Final Rule, this type of research would be permitted as an exempt review.

**Exempt 8:** This new category pertains to the use of identifiable data and/or biospecimens from a repository as long as certain conditions are met. 
Impact: The review of secondary use of identifiable data is currently reviewed as expedited review, as there is no current exempt category that this activity would fit in. With the Final Rule, this type of research would be permitted as an exempt review.

**Limited Review**

Limited review is a new Final Rule activity that is designed to dovetail with several of the exempt categories. In essence, limited review provides a safeguard for activities that fall *slightly* outside the spirit of the exempt categories. By conducting a limited review, the IRB has the opportunity to weigh in on research that may include potential risk and to ensure that safeguards are in place prior to confirming the exempt determination. Limited review is outlined for the following areas:

- To ensure that broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of the regulations that pertain to informed consent;
- To verify that broad consent is appropriately documented or a waiver of documentation is appropriate;
- And, if there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Impact: Includes a special type of review to accompany some exempt categories for research that was not previously permitted to receive an exempt determination.
Broad Consent
As outlined in the Final Rule, broad consent is geared toward repositories for which the primary purpose is secondary research use, with the understanding that later use is not exactly known; broad consent is permitted as an “alternative” to the standard informed consent requirements. While some of the traditional elements are still required, additional elements that are specific to secondary research use such as commercial profit, whole genome sequencing, whether sharing will occur, return of results, and the length of time that the data and/or biospecimen may be stored have been added.

Impact: While broad consent will now be a requirement for the collection of data and/or biospecimen for secondary use, it provides a great deal more protection in terms of informing those who provided the data and/or biospecimen.

No More Continuing Review
Annual continuing review requests are no longer required in the following circumstances:

- Research eligible for expedited review
- Research reviewed by the IRB in accordance with the limited IRB review
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study: (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Impact: Reduction of administrative burden while not compromising human subject protections; any change to the research or unanticipated event that occurs is still required to be reported to the IRB.

Informed Consent Considerations

New language/Clarity
Consent forms must be clearer and more focused and many of the added changes are intended to emphasize that information must be provided to facilitate a potential subject’s understanding of why one would participate or not.

Basic and Additional Elements
The following elements have been added:

- If the research involves the collection of identifiable private information or identifiable biospecimens, a statement on whether the identifiers might be removed and information or biospecimens could be used for future research without additional informed consent;
- A statement that 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 about whether clinically relevant research results, including individual research results, will be disclosed to subjects;
- A statement about whether the research project might include whole genome sequencing.

Impact: Provides a great deal more protection in terms of informing those who provided the data and/or biospecimen and is not too much additional work for researchers or IRB reviewers.
Single IRB Review

When more than one institution is involved in a research study, the regulations define this as a “cooperative research project.” In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects; however, this creates a situation where there are multiple IRBs involved, asking for multiple things, and creating an environment of duplication of effort.

In an effort to streamline the process and prevent duplication of effort, the use of one IRB for cooperative research will be required (a.k.a. “Single IRB” or “sIRB”). However, there are certain restrictions on this requirement:

1) A Federal department or agency must be supporting or conducting the research;
2) The institutions that are involved must be located in the U.S.; and
3) The research sites must be located in the U.S.

The Final Rule regulation also goes on to mention types of research that are not subject to this requirement:

1) Cooperative research for which more than single IRB review is required by law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe), or
2) Research for which any Federal department or agency supporting or conducting the research determines and documents that the use of a single IRB is not appropriate for the particular context.

Of note, the implementation of the sIRB requirement will not occur until January 20, 2020! However, don’t forget that the NIH has also imposed a sIRB requirement which has an implementation date of September 15, 2017 for NIH funded multi-site clinical trials.

Impact: As the University-Area IRB regularly enters into reliance agreements when more than one institution is involved, not much change would occur. However, this may be a major impact for researchers if a selected reviewing IRB charges for their services if these costs have not been budgeted. This impact may also be major to the University-Area IRB if they are chosen as the IRB of record. This would place demands in so far as amount of time invested and additional workload.