**Common Rule Change Implementation Plan**

The federal rules governing human research, called the Common Rule, was originally adopted in 1991 by the U.S. Department of Health and Human Services and 15 other Federal Departments and Agencies. Following a one-year delay, the revised Common Rule will go into effect on **January 21, 2019**.

The following is a brief highlight of those changes that will directly affect you as part of the research community. Investigators should fully read this email to remain compliant with the Revised Common Rule. Updated policies, investigator guidelines, and templates will be posted on the IRB website [http://irb.ufl.edu/](http://irb.ufl.edu/). The IRB will provide a “Brown Bag” in-service on the new Common Rule; a notice is forthcoming.

**Continuing Review**

1. The Revised Common Rule removes the requirement for continuing review for minimal risk research (i.e., research approved as Expedited) unless the research is FDA-regulated (i.e., involves an IND, IDE, or HUD). If the study is FDA-regulated, then there is **no** change, and yearly continuing review is **required**.

2. When the new rules go into effect, new research approved as Expedited, will not automatically require continuing review by the IRB unless it is FDA-regulated. The IRB may require continuing review for special circumstances such as studies involving a conflict of interest, IRB reliance, or prior compliance concerns.

3. In order for the University to keep track of active minimal risk studies, as of **January 21, 2019**, protocols approved as Expedited will include an every 3-year “Status Report.”
   - Every three years the PI will receive an automated email from the myIRB software asking to indicate if the study is still active.
   - If the PI indicates a study is completed, the myIRB system will automatically close the study.
   - If the PI indicates that the study is ongoing, then email reminders will be sent every 3 years until the study is closed by the investigator.
   - The PI will receive an email at 45 days, 30 days, and 7 days before each 3-year anniversary date. If the IRB does not hear back from the PI, the study will be administratively closed on the 3-year anniversary date.

**Important Note:** Even when continuing review is not required, investigators remain responsible for updating the IRB about adverse events and other unanticipated problems, seeking IRB approval for changes to personnel, protocol amendments, recruitment materials, etc.
Informed Consent

1. There are a few changes to the informed consent rules; the following two changes affect investigators and study teams directly:
   - The PIs have already been notified of the changes to the informed consent for studies that actively recruit and are federally funded.
     - Section #5 of the standard consent template for IRB 01 and 03 only has been changed to require a concise summary of "key information" that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to join the research.
     - There is also a statement required to be added to section #7 of the consent to inform subjects of the potential use of their de-identified data.
     - As of January 21, 2019, all protocols using the IRB 01 and 03 standard consent template must use this new template regardless of funding or funding source.

2. The standard consent for IRB-02, and for the brief consent, banking consent, waiver of documentation of consent forms do not require the new “concise” summary section.

3. As of January 21, 2019, all consent forms will no longer have an expiration date as part of the “Stamped” consent form. The stamp will only contain the date the IRB approved the consent form and thus will serve to indicate which is the most current consent form. If you revise your consent, a new approval date will be stamped. As always, using the most currently approved version of your consent form is critical when consenting study subjects.

4. All federally funded clinical trials must post a copy of the consent form on a government website (e.g., ClinicalTrials.gov). The posting must occur after study enrollment is completed, and no more than 60 days after the last study visit by any subject.
   - UF’s ClinicalTrials.gov office will post the relevant informed consents and will work collaboratively with the appropriate offices within the Institution to identify any contractual, intellectual property or export control issues, to appropriately redact sensitive information from the consents (when needed).

Chart Review Research

The Revised Common Rule broadens the types of research that qualify for the exemption. Rules related to several exempt categories, including most chart review studies have been revised. These changes to exemption will apply to research regardless of funding or funding source. One change in the revised Common Rule is that private information and biospecimens no longer have to be in existence before the start of the research. Under the revised rule, for example, a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future could qualify for this exemption if the study meets other criteria.

Another change is that if an investigator records information about individuals in a non-identifiable manner, the investigator must not attempt to re-identify or contact those research subjects. The myIRB software has been revised and will guide you as you submit your protocols.
Categories that are no longer considered human research
Under the definition of research, the rule identifies activities that do not meet the definition of research including: “Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research and historical scholarship)...that focus directly on the specific individuals about whom the information is collected.”; public health surveillance activities authorized by a public health authority to assess onsets of disease outbreaks or conditions of public health importance.; and certain criminal justice and intelligence activities.

Single IRB Review
You are probably aware that as of January 25, 2018, all multi-center NIH-funded studies require the investigators to use a single IRB review for the domestic sites. Additional information is posted at http://irb.ufl.edu/sirb.html.

Starting in January 2020, single IRB review for studies conducted or supported by other federal agencies will be required as well.
Impact of the Changes on Research approved before and after January 21, 2019:
1. All new protocols approved after January 21, 2019, will be approved under the new Common Rule, regardless of study risk, funding, or funding source.
2. Other than as stated above regarding revised informed consent forms there will be no other changes to the Full Board protocols as it relates to the new Common Rule.
3. All Expedited protocols regardless of funding or funding source approved before January 21, 2019, will still be required to provide a “Continuing Review” based on its expiration date. Upon review of these continuing reviews, IRB approval will be with a “Status Report” only unless under FDA oversight or as otherwise determined by the IRB. At that time, the standard consent form must be revised to the new format.

myIRB System
January 21, 2019, is both the effective date and the compliance date for the new Common Rule. Therefore, the software changes require us not to accept chart review submissions nor consent form changes for the new consent form sections between January 10, 2019, and January 21, 2019. Any such submission received between this timeframe will be sent back to the PI to resubmit under the new rules. Please contact the IRB office at 352-273-9600 with any questions or concerns.

SRMC Update
Pending SRMC review was a hard stop for all Full Board submissions. After a meeting with the SRMC leadership in mid-December, it has been determined that we’ll apply the same process to expedited studies with the following exception. If a study is a student project, with a student PI and no Cancer Center resources are involved, the submission can be pushed forward as it’ll only receive an administrative SRMC review.

This change will also affect revisions that introduce SRMC relevant elements (cancer diagnosis, aims, and outcomes) to the study. myIRB will be modified in the future to introduce additional questions on the revision application SmartForm, pending SRMC’s input.
Common Rule changes to items #5 and #7 of the ICF

1. Item #5 of the ICF is meant to be an overview of the key information essential to decision making regarding study participation. Item #7 should contain explicit details, however, it should not just be a “copy and paste” from item #5, nor just contain the template paragraph.

If your study is minimal risk where the details seem to be nothing more than a “copy and paste” between items #5 and #7 (i.e., blood draw studies, or behavioral studies), then the Brief ICF with HIPAA might be more appropriate for your project. This form can be found on the IRB-01 website at [http://irb.ufl.edu/irb01/forms/forms-2.html](http://irb.ufl.edu/irb01/forms/forms-2.html). Please note, however, that this form is not intended to be a verbal consent. All study specific information must be inserted beneath each of the bulleted items and elsewhere as indicated in the form so that subjects are provided all elements of informed consent.

2. If your study does not involve the collection of biospecimens, this can be removed from the template paragraph in item #7 of the new Common Rule ICF as shown below.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

The requirement is only to tell folks that if samples were collected, that they could be used for future research.

---

**Education**

UF IRB Brown Bag Series

**Implementation of the New Common Rule**

January 16<sup>th</sup> 2019, 12-1:30 p.m.
Communicore C1-15

**Presented by**
Peter Iafrate, Pharm.D. IRB-01 Chair
&
Ivana Simic, Ph.D. Asst. Director of UF IRBs

**Program Description**

1. Describe changes regarding federal regulation on human subjects research
2. Identify requirements for the PIs regarding both currently approved studies and those that are submitted after the implementation date
3. Describe changes in the myIRB software as it relates to these new regulations

**Contact Hours**

UF Health Shands is a CE Provider recognized by the Florida Board of Nursing (FBN# 50-1790). Participants who attend this activity will be awarded ---- contact hours from the Florida Board. You must attend the entire program in order to receive credit.

For additional information, or to RSVP, contact Jamie Mayfield at 352-273-6093 or e-mail jmayfield@ufl.edu.