The revised Common Rule went into effective on January 21, 2019. The implementation of the revised regulations allows more research involving the secondary use of data/records/biospecimens to be deemed exempt. Previously, this type of research could only be exempt if the information/biospecimens were: a) pre-existing at the time of proposal submission; and b) publically available or recorded by the study team without retaining any identifiers. Under the revised Common Rule, the requirement for information/biospecimens to be existing at the time of research proposal has been eliminated. Secondary research of data/records/biospecimens can now be deemed exempt when:

- The review involves ‘secondary research’ only (meaning the information/biospecimens were originally collected for some other purpose); and
- One of the following criteria are met:
  
  A. The information/biospecimens are publicly available;
  
  B. The information (including information about a biospecimen) is recorded in a manner that the identity of the subjects cannot be readily ascertained (either directly or indirectly through links/codes), the investigator does not contact the subject, and the investigator will not re-identify subjects;
  
  C. The research involves only the collection and analysis of identifiable health information regulated by the Health Insurance Portability and Accountability Act (HIPAA); or
  
  D. The research is conducted by or behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research activities.

While these criteria seem relatively straightforward, it’s important to keep them in mind as secondary use or retrospective review protocols are developed. If Institutional Review Board (IRB) personnel cannot validate that these criteria are met, the research may require revision or may require a different level of IRB review. To facilitate IRB review, (continued on page 2)

What Does ‘Exempt’ Mean?

Exempt research is a regulatory classification that requires initial review by an Institutional Review Board (IRB) to determine that it meets specific regulatory-defined criteria. Once deemed ‘exempt,’ no further review is required, as long as the research remains the same. All modifications to exempt research must be submitted to the IRB prior to implementation to confirm the research continues to meet the criteria for exemption. ‘Exempt’ does not mean that the research is exempt from IRB review. Rather, ‘exempt’ means that once the IRB has confirmed the research is exempt, the research is then exempt from further review by the IRB (i.e., continued review) and consent requirements.
Retrospective Chart Reviews in the Era of the Revised Common Rule (Continued)

(continued from page 1) ask yourself if the following are clearly described in your study protocol:

- What is the source of the information/biospecimen and does the study team have access to that source? Perhaps biospecimens are collected from a department’s specimen repository under another IRB protocol. Perhaps the data will be retrieved from an online government database. Perhaps you will receive a dataset from a commercial entity. Is that source available to the public or available upon request. Furthermore, is access to the information/biospecimen limited or restricted and if so, how is the information/biospecimen going to be obtained? Understanding the source of the information/biospecimen and an investigator’s access to that source is critical to determine whether a proposal meets the criteria for exemption.

- Is the use of information/biospecimens truly ‘secondary’? The divide between what information/biospecimens were originally collected and why (i.e., the primary collection) and what will be used now for the retrospective review (i.e., the secondary use) is often muddy. This leaves IRB personnel unsure in determining if the protocol under review is truly ‘secondary’, so it is crucial to be clear about where data/biospecimens are coming from and why they were originally collected.

- Is the dataset identifiable? Protocols submitted to the IRB often waiver between indicating that data is de-identified and coded. Though these terms are similar they do not have the same meaning (see the 2015 OHSP Q4 Newsletter for more information on de-identification vs. coding). Each term may have different regulatory requirements, so interchanging them leaves the IRB unsure of the level of review for the study. Of note, it’s important to understand that, in some cases, collecting identifiable information is permissible (categories A, C and D listed above) while in other cases, collecting and maintaining identifiable information may bump the research to a different level of IRB review.

- Is the data collection sheet that supplements the study protocol consistent with the information described in the study protocol? If the research is (continued on page 3)

What If My Retrospective Review Doesn’t Meet the Criteria for Exemption?

No. Big. Deal! With the revised Common Rule in place, the IRB review process for retrospective reviews is still relatively simple. When a proposal does not fit an exemption category, the review of the research is typically ‘bumped up’ to an expedited review level, which means the IRB coordinator and board chair will conduct the review on behalf of the full board, and the protocol may need to be revised to include a waiver of consent. During the review, the IRB board chair will confirm that the research meets the criteria for IRB approval (45 CFR 46.111) and determine whether continuing review of the research is required.

The most important aspect is for the study team to accurately describe the study activities and ensure the necessary information/biospecimens are collected to meet the aims of the research, and to let the IRB determine the review level. Modifying procedures or data collection points in order to fit the research into an exemption category may cause more problems in the long-run, if the data collected for analysis is compromised.
Retrospective Chart Reviews in the Era of the Revised Common Rule (Continued)

(continued from page 2) undergoing review by the local IRB, the Research Subjects Review Board (RSRB), a data collection sheet identifying the specific data points that will be collected as part of the retrospective review is required to be submitted with the study protocol. Frequently, the RSRB finds the information described in the study protocol does not match the data points identified in the collection sheet, which then requires clarification. The protocol, for example may state the data is de-identified but the data collection sheet includes identifiers. Protocols will also often list all data collection points, in addition to the data collection sheet, but the two documents are inconsistent. To avoid this, it’s best practice to indicate generally the type of data being collected in the study protocol, leaving specific data collection points to be listed on the data collection sheet.

- If information regulated under HIPAA is being collected, has a waiver of HIPAA authorization been requested and is it justified? Use of protected health information regulated under HIPAA for the purposes of research still needs to comply with HIPAA requirements (category C listed above). For retrospective reviews, this typically involves requesting a waiver of HIPAA authorization and while the waiver is often requested, the justification for the waiver is either not provided or inadequate, thereby making the waiver request unacceptable for IRB approval.

As a final best practice, to ensure all of the necessary points described above are addressed when submitting to the RSRB, study teams are strongly encouraged to utilize the specimen and record review protocol template. The protocol should be completed as directed and, in the event, a section is not applicable, simply enter ‘N/A’ to identify it as such. Eliminating a section or leaving a section blank leaves IRB personnel questioning whether the section didn’t apply or just wasn’t completed.

Questions about retrospective reviews? Contact your IRB Coordinator.

Research QI ‘Gold Star’ Award

The QI division is recognizing Melissa Sturge-Apple, PhD and BriAnna DiLuigi for their quality work on the ‘Project FLIGHT’ study. This vibrant study team is a part of Clinical and Social Sciences in Psychology. They received the OHSP-QI ‘Gold Star’ award for demonstrating attention to regulatory compliance and protocol adherence, a good consenting process and Investigator oversight, and high quality, organized study-related documentation.

Congratulations
A Data and Safety Monitoring Plan (DSMP) must be designed based upon the complexity and the risks of the study. There are inherent risks in human subject research and those risks need to be minimized as much as possible to ensure subject protection and safety. For minimal risk studies, the monitoring could encompass an assessment by the Investigator, for example. However, sometimes a study needs an independent reviewer, such as a Medical Monitor or Monitoring Committee. An example of a Data and Safety Monitoring Board meeting agenda is demonstrated in Image 1.

The Data and Safety Monitoring Plan should include the following information, at a minimum:

- individual(s) responsible for monitoring;
- process for and expected timing of conducting the monitoring;
- mechanism for documenting the monitoring and findings; and
- who will be notified of any monitoring activity outcome (e.g., IRB, sites).

Resources: OHSP Policy 506 Data & Safety Monitoring; NIH: Data and Safety Monitoring Plan Writing Guidance; CTSA Collaborative DSMB Workgroup - DSMB Training Manual;

More Changes! Click IRB Recently Upgraded

The Office for Human Subject Protection went live with a relatively significant upgrade to Click® IRB on Friday, June 7th. The upgrade primarily affected the submission process for studies undergoing review and approval by an external Institutional Review Board (IRB), e.g., WIRB, Advarra, or an external institutional IRB. In the previous Click® IRB system, these submissions required a two-step process. First, a study record was created to indicate the study will be reviewed by an external IRB, and the smart form collected information about the study as a whole (e.g., protocol, certificate of confidentiality). Second, a participating site record was created. Within the participating site smart form, the study team provided information specific to the local, University of Rochester site (e.g., local consent form and recruitment materials, research locations, any local site-specific protocol addendums). With the upgrade, these two submission records (or smart forms) were streamlined into one comprehensive record (all existing submissions were automatically converted to the new, single submission record).

Demonstrations of the update were provided prior to the upgrade, a recording of which is available in Blackboard. The Study Staff Manual has also been updated accordingly.

Data and Safety Monitoring Documentation

Image 1. DSMP Documentation

The Office for Human Subject Protection - 2nd Quarter, 2019
I need to add a study team member to an application but can't find them in Click® IRB. What should I do?

The short answer to this question is contact the Office for Human Subject Protection, but before doing so you should:

- Verify that the individual you’re trying to add is an internal faculty, staff or student member. External study personnel are generally not provided user accounts for Click® IRB; they should be added manually as external study team members as directed on page 14 of the Click® IRB Study Staff Manual.

- Verify that the individual you’re trying to add has completed the University’s required human subject protection training via the Collaborative Institutional Training Initiative (CITI). Human subject protection training completed in CITI for another institution does not meet the University’s training requirements, though credit for that work can typically be transferred into one of the University-accepted training modules (questions regarding this can be directed to Kelly Unsworth).

Click® IRB will automatically assign a user account to individuals who complete one of the University of Rochester’s CITI human subject protection courses and are recognized as faculty, staff or a student per the University’s Human Resources (HR) and student databases. The ability of the programming to ‘recognize’ an individual depends on 2 key components: 1) whether the individual has entered an accurate, University of Rochester email address in the Institutional Email Address field CITI; and 2) whether the individual exists in the University’s staff/student databases with an appropriately assigned identification number (e.g., Student ID or URID). The process will fail (meaning, an account will not get created) when the institutional email address entered into CITI does not match with the information in the University’s databases. More specifically, this process can fail when:

- An individual is not paid faculty or staff or a registered student;
- An individual has not been assigned an appropriate identification number (per their staff/student designation);
- An inaccurate email address is entered as the Institutional Email Address in CITI (e.g., Rochester is misspelled in the email address or a personal email account is entered).

Note: In some cases, entering a personal email may be accurate for University of Rochester students provided their personal email address is consistent with what is on file with the University.

FAQs

How Do I Verify and Update my Information in CITI?

Upon registration, all CITI users are issued at least two profiles that include their contact/demographic information. The Member Profile includes your name, residence, preferred email addresses and password information. This profile remains available to you regardless of how many institutions you might affiliate or unaffiliate with throughout your career within CITI. Users are also provided an Institutional Profile for each institution they might affiliate with within CITI. This profile includes institution-specific information such as department, research role, degree, and institutional email address. The institutional email address entered within a University of Rochester Institutional Profile is critical for facilitating access to Click® IRB and ensuring all CITI training is documented in Click® IRB.

To verify and update the information included within your University of Rochester Institutional Profile within CITI, do the following:

1) Log-in to CITI and click on your name in the upper right corner. Select ‘Profiles’ from the resulting drop down menu.

2) Scroll down and select ‘Edit Profile’ adjacent to University of Rochester under the ‘Institutional Profiles’ heading (do not select the ‘Member Profile’ – the information entered here does not facilitate the CITI/Click® IRB integration).

3) Update your email (and other necessary information) in the profile accordingly and save your changes by selecting ‘Update’.
RSRB Welcomes New Director & Staff

The Research Subjects Review Board (RSRB) is thrilled to congratulate Nicole Mason, MS, CIP, who has accepted the position of Executive Director of the RSRB, effective March 1, 2019. Nicole was hired into the RSRB as an Assistant Regulatory Specialist in August 2011 and responsible for the review of exempt research and institutional review of research deferred to Western IRB. In November 2013, Nicole was promoted to Regulatory Specialist II and responsible for the review and management of Board 05 with specific departments in Pediatrics, Emergency Medicine, Orthopedics, and Imaging Sciences. She obtained her Certified IRB Professional designation in October of 2015, and while working at the RSRB went back to school at the University of Rochester to obtain her Master’s in Health Care Organization Management and Leadership.

Congratulations are also in order for the following individuals in the RSRB:

- **Suzanne Cogliatore**, who was promoted to Board 03 Regulatory Specialist in December of 2018,
- **Katherine Zanibbi**, who joined the RSRB as the Board 05 Regulatory Specialist in May of 2019, and
- **Jamie Biear**, who joined the RSRB as the Assistant Specialist in May of 2019.

CITI Updates and Reminders

The Collaborative Institutional Training Initiative (CITI) is now providing new course formatting options for learners electing to complete the Social-Behavioral-Educational Researchers training to fulfill their human subject protection training requirements. On a module-by-module basis, learners will be able to select either an audio-visual format, ideal for learners who prefer a visual narration of the course content, or ‘classic’ formatting, for learners who prefer to read course content at their own pace. At this time, only learners completing the initial (basic) Social-Behavioral-Educational Researchers training are provided this option. Updates to refresher and Biomedical Researcher courses are forthcoming.

Additionally, as a reminder, effective October 2019, email notifications pertaining to human subject training refreshers are now generated directly from the Collaborative Institutional Training Initiative (CITI), not the Research Subjects Review Board. Reminder emails are sent 30 and 7 days prior to training expiration. Please be mindful of reading email communications from CITI; if they are repeatedly deleted, they may begin to filter into your junk email folder and can easily be overlooked. To ensure you receive the notification, users should verify they have accurate contact information identified in their profile within CITI (see the FAQ on page 5). In the event an individual’s training lapses, they should cease all involvement in human subject research activities until the refresher training is completed.

OHSP Newsletter Index

The Office for Human Subject Protection (OHSP) now has a searchable Newsletter Index available on their website. The index includes a listing of all currently applicable content from previously distributed OHSP Newsletters. Listings are arranged by topic area with the article title, type (e.g., brief reminder, FAQ or full article), and issue date identified. To search the index, press Ctrl + F on your keyboard and type in the content you wish to search for in the search box provided. Study teams are encouraged to use this resource, in addition to existing OHSP Policies and Guidelines, when IRB-related review questions arise.
Why is the Expiration Date Field Blank for my Study in Click® IRB?

Expiration (or approval end) dates are blank when continuing review of the research is not required. Federal regulations do not require continuing review when the research is deemed exempt, when the project does not involve human subject research, or when the project involves human subject research but the University of Rochester is not engaged. In addition, per the Revised Common Rule effective 1/21/2019, continuing review may not be required for research reviewed via an expedited review path.

When continuing review is not required, the approval end date in the study workspace (Image 2) and the expiration date in the Research Subjects Review Board (RSRB) watermark (Image 3), if applied, will be left blank. As a reminder, some types of consent documents (primarily consent forms and parental permission forms) are watermarked with both an approval and expiration date field, while other types of consent documents (e.g., information sheet) are only watermarked with an approval date. For a complete listing of the types of watermarked documents, please see Quick Reference Guide on watermarked documents in the Click® IRB Study Staff Manual.

Of final note, when continuing review is not required, study teams are still responsible for submitting all revisions to the research (i.e., to the study protocol or other IRB-approved document) to the RSRB for review and approval prior to implementation (see OHSP Policy 901 Principal Investigator Responsibilities), and are required to notify the RSRB when the study is completed. This is accomplished by submitting a Continuing Review (CR) report to close the study. For instructions on how to complete the CR to close the study, please see page 24 in the Click® IRB Study Staff Manual.

FAQ

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