### What is the Common Rule?

The **Common Rule** is subpart A of the regulations that govern the protection of human subjects (45 CFR 46). Subpart A defines basic protections including IRB review of research, IRB function and operation, criteria for IRB approval, general requirements for informed consent and provisions for assurances of compliance. The subpart has been coined the ‘Common Rule’ as several other Federal departments/agencies beyond HHS have codified identical requirements in their chapter of the Code of Federal Regulations.

### Exempt Research

Currently, the Common Rule identifies 6 exemption categories. Under the revised Common Rule, these categories were clarified, expanded or, replaced and 2 additional categories were added, for a total of 8 exemption categories under the new Common Rule. The use of exemption categories as they pertain to subparts B, C and D were also clarified as follows:

- **Subpart B (Pregnant Women, Fetuses & Neonates)** – Each exemption category may be applied
- **Subpart C (Prisoners)** – Exemptions do not apply, except for research aimed at a broader population that may incidentally include prisoners
- **Subpart D (Children)** – Only exemptions falling under revised categories 1, 4, 5, 6, 7 and 8 may be applied. Exemptions falling into category 2 may only be applied when the research involves educational tests or observations of public behavior when the Investigator does not participate in the activities being observed.

**Exempt Category 1:** Exempt Category 1 currently includes ‘research conducted in established or commonly accepted educational settings, involving normal educational practices such as: (i) research on regular and special educational instruction strategies; or (ii) research on the effectiveness of the or the comparison among instructional techniques, curricula, or classroom management methods’. The exemption has not changed significantly, (continued on page 2)

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A summary of the Common Rule revisions most pertinent to study teams were presented by the Office for Human Subject Protection (OHSP) during their September 27, 2017 seminar (a copy of the slides and a video of the presentation are available on the OHSP website). Further clarification of these changes, with applicable case studies (as appropriate), are provided below.
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(continued from page 1) except that it adds a restriction, indicating that the research cannot ‘adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction.’ This addition is principally meant to limit activities that might draw significant attention away from the routine delivery of educational curriculum.

Exempt Category 2: Exempt Category 2 includes ‘research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior’. Under the current rule, the collection of information that is both identifiable and sensitive in nature is excluded (‘sensitive’ meaning that disclosure of the information may place the subject ‘at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement or reputation’). This exemption was revised significantly to now permit the collection of both identifiable and sensitive information but requires the Institutional Review Board (IRB) to conduct ‘a limited IRB review’.

Exempt Category 3: Exempt Category 3 currently provides provisions for research involving educational tests, surveys, interviews and observations of public behavior of elected or appointed public officials. As this type of research will now fall under category 2, category 3 was replaced with a NEW exemption category: ‘research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection’. The exemption category further clarifies that ‘benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the Investigator has no reason to think the subjects will find the interventions offensive or embarrassing’. Deception of study subjects is permitted within this exemption, but the subject must agree prospectively that he or she will be unaware of or misled about the nature or purposes of the research. The exemption also requires ‘limited IRB review’ if the information collected is both identifiable and sensitive. (continued on page 3)

Exemption Case Study #1: An Investigator wants to interview adult couples in long-distance relationships. Multiple interviews and surveys will be conducted over a 12-month period. The data will be identifiable and includes potentially sensitive questions about relationship dynamics.

Under current regulations, the inclusion of identifiable data that could potentially put subjects at harm would require this study undergo either an expedited or convened board review with continued IRB monitoring (i.e., continuing review) because it does not meet exemption requirements. Under the revised Common Rule, this study might be eligible for exemption under Category 2.

Exemption Case Study #2: To assess smart phone distraction, subjects will be asked to play a video game of varying complexity on a smart phone while simultaneously listening to pre-recorded lecture passages of various lengths. Following each passage, subjects will be asked to recall questions on the content of the passage.

Given the video game manipulation, under the current regulations, this study would require expedited or convened board review. Under the revised Common Rule, this study might be eligible for exemption under the new Category 3 provided that the intervention period is brief in duration, the video game content is harmless, and that only adult subjects will be enrolled (Category 3 does not allow for enrollment of minors).
Exempt Category 4: Exempt Category 4 permits secondary use of data or biospecimens for research purposes. Under the current rule, the data and/or biospecimens utilized in the research must be pre-existing (meaning they exist at the time the research is proposed) and must be either publically available or the information recorded by the study team must be de-identified. Under the revised Common Rule, this category no longer requires data or biospecimens be existing at the time of research proposal and further provides for conducting research with identifiable health information subject to HIPAA regulations.

Exempt Category 5: Exempt Category 5 involves research on the evaluation/examination of public benefit or service programs (e.g., Medicare, Social Security). While this exemption category is rarely utilized locally, it was expanded to include provisions for listing the research on a publically accessible Federal website.

Exempt Category 6: Exempt Category 6 includes taste and food quality evaluations and consumer acceptable studies. This exemption category is the only one that remains unchanged with the revised Common Rule.

Exempt Category 7: Exempt Category 7 is NEW under the revised Common Rule and permits storage/maintenance of identifiable private information and/or identifiable biospecimens for future secondary research use provided broad consent for such storage is obtained and the IRB conducts a limited IRB review. For this exemption, limited IRB review is required and includes determining that the study protocol provides adequate provisions for: a) obtaining broad consent; b) documenting or waiving documentation, if appropriate, of broad consent; and c) protecting the privacy of the subject and confidentiality of the data when/if the methods for storing or maintaining collected information/biospecimens change.

Exempt Category 8: Exempt Category 8 is also NEW under the revised Common Rule and involves the utilization of identifiable private information or identifiable biospecimens for which broad consent was obtained and documented. Limited IRB review is required to verify: a) adequate provisions for protecting the privacy of subjects and maintaining the confidentiality of the data have been provided; b) the proposed research is within the scope of the broad consent originally obtained from the subjects; and c) the Investigator does not intend to return individual research results.

Informed Consent

HHS regulations currently include provisions for obtaining informed consent, (continued on page 4)
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(continued from page 3) disclosing necessary content (or elements) during the consent process, documenting consent and altering the consent process. While the current requirements largely remain intact, substantive additions were included.

New ‘Key Information’ Presentation
Under the revised Common Rule, with the exception of broad consent, the ‘informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject...in understanding the reasons why one might or might not want to participate in the research’. The new requirement further indicates that the information must be organized and presented in a way that facilitates comprehension.

While further guidance from the federal government pertaining to what is considered ‘key information’ and how to best present that information is still pending, based on discussion in the preamble of the revised Common Rule, this information will be presented as the first section and will minimally include information pertaining to:

- Consent being sought for research;
- Voluntary participation;
- Purposes of the research;
- Study procedures and duration of participation; (continued on page 5)

Exemption Case Study #3B:
An Investigator wishes to analyze samples of lung tissue.

Under current regulations, the review of this study would depend on when and how samples of the lung tissue are collected. If the samples are pre-existing, were not collected by the Investigator, and are provided to the Investigator in a de-identified format, the study would likely be deemed not human subject research. If the samples were pre-existing, the Investigator has access to identifiers but completes the research in a manner where no identifiers are recorded, the study would likely be deemed exempt under Category 4. Alternately, if samples are collected prospectively or if the samples/date are recorded in an identifiable manner, the study would require expedited or convened board review.

Under the revised Common Rule, the Investigator could follow the traditional routes described in the paragraph above, or, if discarded tissues were obtained using a broad consent (i.e., via a repository study deemed exempt via Category 7), the analysis of the tissue could be deemed exempt via Category 8 regardless of identifiability.

What is Limited IRB Review?
‘Limited IRB review’ is a new function included in the revised Common Rule. This type of review is required for certain exemption determinations and is, most notably, intended to ensure adequate provisions are made for protecting the privacy of subjects and maintaining the confidentiality of data (though, in some cases, as with exemption categories 7 and 8, additional review parameters are defined).

How Will the Revised Common Rule Effect Studies Already Approved at the Time of Implementation?
Institutional Review Board (IRB) determinations made under the prior Common Rule will continue to be approved under that Common Rule. Ultimately, this means that the research will continue unchanged, with review requirements continuing just as they had prior to the revised Common Rule effective date.
• (continued from page 4) Reasonably foreseeable risks and benefits; and
• Alternatives to participation.

New Elements of Consent
Under the revised Common Rule, consent must include whether or not the data/biospecimens collected in the research study may be used for future research. The consent must include a statement indicating that:

• collected information/biospecimens may be de-identified and used for future research without additional consent from subjects; or
• collected information/biospecimens will not be used for future research.

Additional disclosures that must be made, when applicable, include:

• A statement that a subject’s biospecimen 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 will (if known) or might include whole genome sequencing.

New Broad Consent Option
Revised regulations allow for broad consent, in lieu of ‘traditional’ informed consent, when the research involves the storage, maintenance and secondary research use of identifiable private information and identifiable biospecimens. In this context, a ‘broad consent’ is less specific/restrictive than traditional consent as it provides open-ended permission to utilize the information/biospecimens under the provisions defined within the study protocol and consent. When utilizing broad consent, the revised regulations specify that the following information (elements) must be disclosed to subjects:

• A general description of the types of research that may be conducted;
• A description of the identifiable information/biospecimens that might be used in the research, whether sharing of identifiable private information/biospecimens might occur, and the types of institutions/researchers that might conduct research with the information/biospecimens;

• The period of time that the information/biospecimens will be stored and maintained;
• An explanation of whom to contact for answers to questions and whom to contact in the event of research-related harm; and
• Unless otherwise provided: a) a statement that subjects will not be informed of the details of any specific study (continued on page 6)

Do These Changes Apply to FDA-Regulated Research?

No. These changes do not apply to FDA-regulated research. Unlike other Federal departments/agencies that have adopted the Common Rule, the FDA has not; they have their own regulations pertaining to the protection of the human subjects (21 CFR 50 and 21 CFR 56). Per the 21st Century Cures Act enacted by the FDA in December 2016, it is expected that the FDA will work to harmonize regulations with HHS within 3 years enactment of the Act. So it is possible that these changes may apply to FDA-regulated research in the future.
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(continued from page 5) that might be conducted using the information/specimen; and b) a statement that neither clinically relevant results nor individual research results will not be disclosed.

Furthermore, note that:

- From a clinical standpoint, at this time, the UR does not intend to implement broad consent globally for secondary use of patient information/biospecimens. Investigators may however choose to utilize this process for information/biospecimens collected for research purposes (e.g., data/biospecimens collected through other approved research).
- Utilizing broad consent is provided as an alternative to the current process. Investigators may still choose to conduct secondary research with information/biospecimens through the mechanisms currently utilized.

Additional Requirements in Waiver and Alteration of Consent

Currently, Common Rule regulations permit IRBs to waive or alter: a) general requirements of informed consent; or b) basic/additional elements of consent. Waivers and alterations of consent are typically requested with studies involving secondary use of information or biospecimens or deception. Waivers or alterations of consent are only permitted when the IRB finds that:

- The research involves no more than minimal risk to subjects;
- The waiver or alteration will not adversely affect the rights and welfare of subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Under the revised Common Rule, an additional criteria pertaining to research involving the use of identifiable private information or identifiable biospecimens has been added: the research could not practicably be carried out without using such information or biospecimens in an identifiable format. So, for example, if an Investigator wanted to conduct a chart review study, in addition to the original waiver of consent criteria, the investigator would also need to justify that the data would need to be collected in an identifiable format. Collecting a medical record number might be justified if the study required linking subject data between two separate databases. Conversely, if linking the two databases wasn’t necessary and dates were the only identifier being collected (continued on page 7)

What is the RSRB Doing to Prepare for the Revised Common Rule Effective Date?

Continuing efforts are underway to make necessary changes required to implement the revised Common Rule as they pertain to OHSP policies and guidelines, the RSRB Online Submission System (ROSS), and internal procedures. While extensive changes are required in order to implement the revised Common Rule, most of these changes (e.g., exempt and continuing review revisions) cannot be applied until the effective date of January 19, 2018. In the interim, revised review pathways and testing are being conducted in ROSS and policy revisions drafted.

Revisions pertaining to the informed consent process (i.e., presentation of ‘key information’ cover sheets and additional elements) may be implemented prior to the January 19, 2018 effective date as these serve additional protections beyond what is currently required. Key information cover sheets and policies revisions are currently in final format and will be communicated to the UR research community in the very near future.
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(continued from page 6) for the purposes of age calculation, the waiver might not be justifiable as age calculation can occur at the time of data recording (meaning age can be collected in lieu of the date, thereby eliminating the need to collect an identifier).

New Provisions for Subject Screening

Under the current regulations, studies that require collecting information or testing existing biospecimens for the purposes of screening, recruiting or determining eligibility are typically handled in one of two ways. Most often, informed consent is obtained for subjects to undergo screening procedures (either via written or oral consent). Less often, consent is waived to obtain information, until eligibility is confirmed and informed consent obtained.

The revised regulations now specifically address screening processes, providing a consent exception (not to be confused with a waiver). The revised regulations state: ‘An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects without informed consent of the prospective subject… if either of the following conditions are met:

- The investigator will obtain information through oral or written communication with the prospective subject; or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.’

Key considerations pertaining to this provision include:

- Complying with the circumstances set forth in the regulation. Not all screening procedures will meet the criteria defined in the exception. Interviewing a potential subject about their medical history, completing a quality of life measure, or accessing pre-existing information from the medical record would be permissible. Whereas undergoing study-specific procedures beyond that defined criteria, such as collecting a blood sample or undergoing an electrocardiogram would require full informed consent.

- IRBs will review this exception as part of the entire IRB application and protocol and as such, the exception is still subject to the criteria for approval (45 CFR 46.111). Consideration must be paid to how privacy will be protected and confidentiality maintained for those undergoing screening procedures, including both subjects that will go on to provide consent to participate in the research and those who fail screening procedures.

Clinical Trial Consent Posting

The revised Common Rule now requires IRB-approved consent forms for clinical trials conducted or supported by a Federal department/agency be posted on a ‘publically available Federal website’. (Note that the regulations define a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions [which may include placebo or other control] to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes”). One IRB-approved consent form used to enroll subjects must be posted (on a yet-to-be-determined website) by the awardee (or Federal department/agency conducting the research) after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subjects.

Examples of studies that would require posting include: a) a phase 1, 2 or 3 study (continued on page 8)
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(continued from page 7) of an investigational drug sponsored by the NIH; b) a stress-relief interventional sponsored by the Department of Justice; or c) a weight loss smart phone application intervention sponsored by National Science Foundation. Observational studies that do not manipulate or change the subject’s environment that might include surveys, interviews, focus groups, or data abstraction would not require posting, as they do not include an intervention.

Documentation of Consent

Under current regulations, unless a waiver of documentation of consent is granted, it is generally expected that consent will be documented in writing (meaning the subject physically signs the form in indelible ink). The revised Common Rule now specifically indicates that documenting consent via an electronic signature is now acceptable, though the requirement to provide a copy of the signed form remains. (Note that, for FDA-regulated research, further requirements concerning electronic signatures are defined by 21 CFR 11.)

The waiver of documentation of consent criteria has also been expanded to provide alternative mechanisms for documenting consent when subjects are members of a culture or community where signing forms is not the norm (e.g., a culture that routinely uses thumb prints in lieu of signatures). The additional criteria requires that the research presents minimal risk of harm to subjects to be eligible and there must be an appropriate alternative for protecting subject (i.e., consent is still obtained and documented in a manner appropriate to the culture/community).

Continuing Review

Traditionally, the Common Rule required that all research approved through the expedited or convened board procedure undergo continuing review at least annually. While IRBs may determine continuing review is needed under certain circumstances, under the revised Common Rule continuing review will not be required when:

- The research is reviewed and approved under an expedited or limited IRB review; or
- The research is reviewed and approved by the convened board and progresses to the point where only follow-up clinical data from standard clinical care procedures is being assessed or only data analysis is taking place.

For example, an IRB reviews a study that involves blood collection and medical record data abstraction via the expedited review pathway and deems it minimal risk; under the current regulations this would require continuing review at least annually. Under the revised Common Rule, the IRB can determine that continuing review is not required. This, in turn, means that the study would not be assigned an expiration date. On the other hand, if there were a circumstance that might warrant annual (or more frequent) review – perhaps the population is vulnerable or the Investigator has a history of non-compliance – the IRB could require annual reviews to more closely monitor the research, and an expiration date would be assigned to the research.

While this reduces some reporting requirements on the part of the Investigator, it’s essential to understand that requirements pertaining to other IRB reporting requirements remain unchanged; amendments and reportable events must still be submitted. Similarly, the revised regulations do not limit the IRBs ability to monitor the research, which may include new/additional requests to confirm study status to account for ongoing research (continued on page 9).
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(continued from page 8) and an increase in OHSP Quality Improvement review activity to ensure human subject protection and compliance.

Cooperative Research

Cooperative research, as described by the regulations, are those projects that ‘involve more than one institution.’ Under the current regulations, each individual institution is responsible for complying with the Common Rule and ensuring adequate safeguards are in place to protect subjects. The regulations further indicate that participating institutions may choose to enter into a joint review arrangement whereby sites rely on another IRB to review and approve the research.

Under the revised Common Rule, institutions located in the United States engaged in cooperative research with Federal funding must rely upon review and approval by a single IRB. Exceptions will be permitted only when: a) review by an additional IRB is required by law (e.g., tribal law passed by the official governing body of an American Indian tribe); or b) the Federal funding agency determines that the use of a single IRB is not appropriate based on the nature of the research.

Of note, this is the only Common Rule revision with an extended effective date of January 20, 2020. Furthermore, the National Institutes of Health (NIH) released a similar policy in June 2016, with a January 25, 2018 effective date. Understanding what policies and regulations apply to specific research projects is essential for compliant implementation:

- Grant applications submitted to the NIH on or after 1/25/2018 with multi-site research must include a plan for single IRB. E.g., a UR investigator is submitting an application to the National Institute of Allergy and Infectious Disease on February 2nd to conduct a vaccine trial at 10 sites within the United States. All 10 sites would be required to defer to the same Reviewing IRB for review and approval of the research.

- Multi-site research that will be initiated on or after 1/20/2020 that is funded by a Federal agency (other than the NIH) must undergo single IRB review. E.g., The University of Rochester is selected as an enrolling site for a study initiated by the University of Maryland. The multi-site, observational study is sponsored by the Department of Education. All enrolling sites would be required to defer to the same Reviewing IRB for review and approval of the research.

Note that Investigators planning to utilize the Research Subjects Review Board (RSRB) as the Reviewing IRB for multi-site research are required to meet with the OHSP and RSRB Directors prior to grant submission to ensure adequate budgeting and study monitoring have been accounted for.

Additional resources, guides and recommendations pertaining to the revised Common Rule are available through the Secretary’s Advisory Committee on Human Research Protections (SACHRP) and the Collaborative Institutional Training Initiative.

Stay Informed!

Extensive changes to current practices and policies are coming. To help ensure a smooth transition, please remain cognizant of OHSP communications and training opportunities. OHSP communications will primarily be relayed through their email distribution list. If you do not currently receive these emails, please contact Kelly Unsworth to be added.
As protocols become increasingly complex, so do the assurances and agreements that they require. Unfortunately, navigating what types of agreements are required, based on the nature and scope of a research proposal, can be confusing. Below is a quick tutorial of the most commonly used agreements among UR Investigators. Bear in mind, obtaining Institutional Review Board (IRB) approval does not equate to executing/obtaining any of the agreements identified; IRB approval must still be obtained. Furthermore, in some cases, an agreement may still be required even though IRB approval isn’t (e.g., when a proposal does not meet the definition of human subject research).

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| Federalwide Assurance (FWA)                           | A written declaration confirming an institution’s commitment to comply with the requirements set forth in 45 CFR 46 (as well as the terms identified in the assurance document). | • Institutions engaged in human subject research conducted or supported by the Department of Health and Human Service (HHS)  
• Note that FWAs pertain to institutions, not IRBs; external awardees and/or sub-contractors engaged in the research are required to file their own FWA with HHS. | Institutional Official  
(via Office for Human Subject Protection)                                                   |
| Confidential Disclosure Agreement (aka Non-Disclosure Agreement) | A legal contract between two parties (e.g., sponsor and investigator) defining information that will be shared between the two parties and restrictions on wider dissemination. | Industry-sponsored clinical trials (note that this agreement is executed during the site selection phase of the research; prior to Clinical Trial Agreement execution) | Office of Research and Project Administration                                                      |
| Clinical Trials Agreement                              | A legal contract that manages the relationship (e.g., responsibilities, risk allocation, protection of legal/intellectual property) between a study sponsor and the institution conducting the clinical trial. | Clinical trials sponsored via mechanisms other than grant funding | Office of Research and Project Administration                                                      |
| Data Use Agreement                                     | A legal contract required by the HIPAA Privacy Rule for the transfer of limited data sets that sets forth terms for maintaining the confidentiality of the shared data. | Sharing of a limited data set (a ‘limited data set’ includes protected health information [PHI] that excludes direct identifiers, but may include city, state, 5-digit zip code, and dates, and other unique codes that are not direct identifiers) | Office of Research and Project Administration                                                      |
| Material Transfer Agreement                            | A legal contract that governs the transfer of materials between entities, including the scope of work as well as the rights/obligations regarding intellectual property, ownership, publication, confidentiality and research results. | Projects that require the transfer tangible material (e.g., biological materials such as cell lines and vectors, data, software, chemical compounds) between entities | Office of Research and Project Administration                                                      |
| Reliance Agreement (or IRB Authorization Agreement)     | A written agreement that provides a mechanism for an institution engaged in research to delegate IRB review to another IRB. | Human subject research proposals requesting IRB review by an external IRB (i.e., other than the Research Subjects Review Board) | Office for Human Subject Protection / Institutional Official |
The purpose of the Office for Human Subject Protection’s Division of Quality Improvement (OHSP-QI) is to assure the rights and well-being of human subjects are protected, assess subject research risk areas, and provide resources to the University of Rochester’s research community. OHSP-QI meets these obligations primarily by conducting on-site reviews and Study Start-Up Consultations.

The primary principles of an on-site review includes assessing compliance with applicable regulations and UR policy/procedures, assisting sites to be ‘audit-ready’, and providing resources/education. Approximately 85 reviews are conducted annually throughout the University.

We decided to turn the tables on the QI reviewers and put them under the spotlight:

**How many hours does it take to complete the entire process from when the study is identified for review until the final report is issued?**

The complete process takes about 30 hours. However, the on-site portion of the review is, on average, three hours. The duration is dependent on the complexity of the study and quantity of subjects.

**What is the most common finding across all reviews?**

Last year, 73% of the reviews conducted had an incomplete regulatory file with missing documents. The construction of the regulatory file starts with the protocol intent, and in some cases the project funding. A regulatory file can be either hard copy or electronic, or a combination of both, but must contain all versions of IRB actions including:

- All approval letters (initial, amendments, and continuing reviews).
- All approved study protocols (final/approved version is best practice).
- All IRB-watermarked documents: consents, recruitment materials, and releases.
- For a comprehensive list of expected documents, click [here](#).

**Can you describe what a Study Start-Up (SSU) Consultation entails?**

A typical SSU is conducted after IRB approval and before subjects are enrolled, is free, takes about one-hour, is fully tailored to the newly approved protocol, and is comprised of study-specific discussion surrounding applicable regulations and the regulatory file, consenting, and overall protocol adherence. A Study Start-Up Consultation is intended to assist Investigators/study staff in achieving compliance with research regulations, policies, and guidelines applicable to their specific study and to further protect subjects who participate in research.

**What is a Quality Management Plan (QMP)?**

A QMP is a detailed strategy implemented by those conducting the research outlining how errors will be identified, assessed, and corrected during the conduct of a study. Through a consultation, OHSP-QI will help you to identify needs, risks, and strategies. Time, commitment, and resources will be considered, however a site-specific QMP may ultimately save time and resources by identifying and potentially preventing incidents of non-compliance. A QMP can be developed for a single study, a group of studies, or all studies.

Contact OHSP-QI any time for additional questions or to schedule your team for a study start-up or quality management plan consultation.
Recent ROSS Updates

Several updates/modifications have been made to the RSRB Online Submission System (ROSS) over the past quarter to better accommodate the ever-changing landscape of the human subject research conducted at the UR and to prepare for the implementation of the revised Common Rule. Major updates include:

**Study Site Identification**

Section 63 of ROSS has been updated to better delineate site engagement when utilizing non-UR sites to conduct research. Rather than simply asking whether non-UR sites will be engaged in the research, questions 63.2, 63.3 and 63.4 respectively identify non-UR sites where: a) only UR staff is engaged in the research; b) both UR and non-UR staff are engaged in the research; and c) RSRB is acting as the Reviewing IRB for the non-UR site. Answering yes to any of these questions will direct study teams to complete a non-UR site profile that provides additional details about the site (e.g., site name, site contact, and letter of support or site IRB approval). See Image 1 below.

**Automated Withdrawal of Stagnant New Applications**

In December of 2016, the RSRB implemented a policy providing the RSRB the option to withdraw initial submissions if the Investigator is non-responsive to RSRB requests after 90 days. Policy 502 Types of RSRB Submissions, states in Section 5.1.1, “Initial submissions that are incomplete, or for which the Investigator is nonresponsive to RSRB requests, may be withdrawn from consideration for RSRB approval after 90 days of inactivity, or at the discretion of the RSRB Director”. The withdrawal process was initially implemented manually, where RSRB staff proactively initiated the withdrawal process. This process has since been automated within the ROSS as follows:

- Initial study applications submitted for review prior to October 1, 2017, which have had no activity by the study team for more than 90 days, will be administratively withdrawn from ROSS.
- For studies submitted on or after October 1, 2017, Investigators will receive automated notifications from ROSS after approximately 60 days of no activity and again after 90 days of no activity. The 60 day notification will indicate there has been no action in response to RSRB requested changes and the 90 days notification will indicate that the initial submission has been administratively withdrawn.

In both cases, to keep a study active, a (continued on page 13)
Recent ROSS Updates

(continued from page 12) ‘state change’ is required to re-set the 90-day clock, meaning the study team must send the application back to the RSRB to reset the 90 day window, even if just to provide an update to the RSRB.

New Forms Required for Surgical Pathology & HURC Ancillary Committees

If your research requires review by Surgical Pathology or Radiation Safety (HURC) and you select either of these options in Section 62 (Ancillary Committee Reviews) of the ROSS application, there are new forms that require completion in order to aid the ancillary committees review process. Access to each respective form is hyperlinked within the committee description provided in ROSS; completed forms then need to be uploaded into the application (see Image 2 below). If this form is missing during initial review by the RSRB, your Specialist will return the application to request that you complete and upload the form in order to continue the review process.

Western Institutional Review Board (WIRB) Submissions

As of September 1, 2017, the RSRB will no longer submit the WIRB application on behalf of the study team. All studies must still be submitted in ROSS to complete the institutional review (and any other applicable ancillary committee reviews). Once the study team receives notification that institutional review is complete, the study team must complete the WIRB Connexus application, upload a copy of the RSRB review cover memo, and submit the study to WIRB. Please review the revised Guideline for Submission to WIRB for instructions on this new process.

Study Personnel Sections

More than a year ago, the RSRB implemented the ‘amendment light’ process, simplifying the process for requesting study personnel changes. With this, Sections 9.3 and 85.1 that identify study personnel became ‘read only’ and a new Section 1.7.2 (Other Study Personnel) was created. As it has been more than a year since Sections 9.3 and 85.1 have been in use, they are now not visible in the ROSS application.

OHSP Core Training Update

The Office for Human Subject Protection’s Division of Research Education & Training is delighted to announce that Core Training Module 1: Study Design and Core Training Module 2: Principal Investigator (PI) Oversight are now available in MyPath. These courses are components of OHSP’s Education & Training Framework. Remaining modules that constitute the OHSP’s Core Training will follow suit and become available online over the upcoming year. Instructions for accessing the courses in MyPath are available here: Study Design and PI Oversight.
Food For Thought

Please note that the articles included in this feature by no means represent OHSP’s current viewpoints; they are merely meant to provoke thought and conversation on issues concerning human subject research.

- Toy, S. (2017, July 25). 45 years ago, the nation learned about the Tuskegee Syphilis Study. Its repercussions are still felt today. USA Today.

Research QI ‘Gold Star’ Award

The QI division is recognizing Bogachan Sahin, MD and his study team members for their quality work on the ‘FLUORESCE: Fluoxetine for Visual Recovery after Ischemic Stroke’ study. This vibrant study team is based in the Division of Stroke and Cerebrovascular Disorders, Department of Neurology.

The study site received the 4th Quarter, 2017 OHSP-QI ‘Gold Star’ award for their commendable work in serving a challenging subject base, demonstrating attention to regulatory compliance/protocol adherence, Investigator oversight, exceptional subject safety practices, and conducting excellent research (following the guidelines) with high quality, organized study-related documentation.

Congratulations!

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