OHSP Policy Update: Change to Study Expiration Dates Determination Policy

Historically, the Research Subjects Review Board (RSRB) policy has been to retain the date of study expiration date from year-to-year to make it easier for study teams to remember the timing of study expiration. For example, a study approved on 1/17/2019 for one year would expire on 1/16/2020 and then each subsequent year the study is re-approved (1/16/2021, 1/16/2022, etc.). To retain this date, the RSRB could not formally review and reapprove a continuing review until the study was within 30 days of expiration, in order to keep the resulting approval period within one year, as required by the regulations. (continued on page 2)

More Changes! The Revised Common Rule is in Effect

The Department of Health and Human Services (HHS) revisions to the Common Rule (the ‘Federal Policy for the Protection of Human Subjects’) went into effect on January 21, 2019.

How Does this Affect Existing Research?

In consult with leaders and peers within the field of human subject protection, the Office for Human Subject Protection (OHSP) has determined that the revised regulations will only apply to research approved on or after January 21, 2019. The ‘old’ (pre-2018) common rule requirements remain in effect for all research approved prior to January 21, 2019. Meaning, regulatory revisions will not affect existing approvals; previously approved research will continue to be conducted as approved. Study teams can verify what regulatory requirement applies to their research from the study homepage in Click® IRB (see Image 3 on page 3).

How Does this Affect Research Approved After January 21, 2019?

Research approved on or after January 21, 2019 will be subject to the new regulations, with the largest impact affecting Institutional Review Board policies and procedures. From a study team standpoint, the need-to-know revisions are as follows:

- Additional elements are required in the consent form. The Research Subjects Review Board (RSRB) revised their consent form templates accordingly in Spring 2018 to begin introducing the new required language. Study teams should continue to use the updated consent form templates provided by the RSRB for all new research submitted.

- More studies will qualify for exemption (see OHSP Policy 501 and the associated Guideline for Exempt Status Determination). (continued on page 3)
OHSP Policy Update: Change to Study Expiration Dates Determination Policy

(continued from page 1) With the recent implementation of the Click® IRB review platform and the ability to submit a modification and continuing review as one, comprehensive submission, the RSRB’s practices concerning expiration date retention has been updated. **Effective January 21, 2019, the RSRB will no longer retain study expiration dates from year-to-year (OHSP Policy 501).** This allows modifications submitted with a continuing review to be reviewed immediately, rather than waiting until the study is within 30 days of expiration, thus delaying approval and implementation of submitted modifications.

**Practically speaking, what does this mean for the study team?**

- Study expiration dates will change from year-to-year depending on when a continuing review is submitted and re-approved by the RSRB (see Image 1).
- Once a continuing review (or combined modification/continuing review) is submitted to the RSRB, the submission will be reviewed in a timely manner, regardless of the existing expiration date.
- Approval periods will not change; studies that require continuing review will continue to be re-approved for one year or for the board-determined approval period.
- Continuing review notifications will still be provided at 90, 60 and 30-days prior to study expiration. Please note however, these notifications are not specifically labeled with the expiration timing; study teams must check the system to determine the date of expiration.
- Study teams must continue to be cognizant of providing enough time for the RSRB to conduct their review of the research, particularly for research requiring review by the convened board. Nonetheless, study teams should also be mindful that routinely submitting continuing reviews particularly early will result in an expiration date ‘creep’, whereby expiration dates will sneak forward into the calendar year (see Image 2).

Questions concerning these updates? Contact your RSRB Specialist.
More Changes! The Revised Common Rule is in Effect

- (continued from page 1) Continuing review will no longer be required for every expedited study.
- Approved clinical trial consent forms will need to be posted on a public website (though this is not required until after the trial is closed to enrollment).

These changes will be reviewed in further detail at the February 14, 2019 UR-HRPP Educational Forum (12-1pm in Helen Wood Hall Classroom 1W-509; remote attendance details will be provided via the OHSP email distribution list). Summaries of the revised regulations are also available for your review in the Office for Human Subject Protection’s 2017 Q4 Newsletter. Additional resources include:
- Office for Human Research Protection’s Revised Common Rule Q&A
- Collaborative Institutional Training Initiative’s Final Rule Resources

PI Proxy Designation: What Do I Need to Know?

The Office for Human Subject Protection (OHSP) recently went live with a new IRB review platform, referred to as Click® IRB. The new software includes several features that were not previously available, one of which is the Principal Investigator (PI) Proxy designation.

The PI Proxy designation allows study team members to act on the Principal Investigator’s behalf in the Click® IRB system. More specifically, this means individuals assigned as a PI Proxy can do everything the PI can do, including submit modifications and continuing reviews, respond to clarifications, and receive notifications concerning submissions (e.g., when the IRB requests clarification or a continuing review deadline approaches).

Important factors to note concerning the PI Proxy:
- The PI Proxy is limited to activities in the Click® IRB system. It does not extend beyond the limits of the review platform, nor does it alleviate the Principal Investigator of their oversight responsibilities.
- The PI Proxy can only be assigned by the Principal Investigator on an individual study, blanket assignments across multiple studies are not feasible. Any member of the study team can be a PI Proxy, (continued on page 4)
PI Proxy Designation: What Do I Need to Know?

(continued from page 3) multiple team members can be PI Proxy, and it can be assigned or revised at any time without action by the IRB (no modification is needed).

- The PI Proxy can only be assigned from the main study workspace in Click® IRB; the activity is not available on the modification or continuing review workspace. Instructions for assigning a PI Proxy are available in the study staff manual.

- Without the designation of a PI Proxy, only the Principal Investigator will be able to submit items for IRB review (including responses to clarification requests from the IRB).

- For those Principal Investigators who decide to assign study members the PI Proxy designation, OHSP suggests setting forth clear expectations among their assigned PI Proxies for how the designation should/shouldn’t be utilized. For example, rather than allowing free reign, a Principal Investigator may assign a PI Proxy with the expectation that only modifications or responses to clarifications from the IRB will be submitted on their behalf.

- For students acting as Principal Investigators on exempt research, it is expected that their faculty mentor/adviser be designated as a Co-Principal Investigator and be assigned as PI Proxy.

- Upon submission of initial applications, the submitter is required to certify their acknowledgment of the responsibilities and requirements of a Principal Investigator. Therefore, it is generally expected that the Principal Investigator will always submit the initial submission of a new study application themselves.

Should you have any questions concerning assignment of the PI Proxy, please contact the Office for Human Subject Protection.

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Research QI ‘Gold Star’ Award

Heather Adams, PhD and her hard-working research team including Mr. Kristen Bonifacio and Ms. Alyssa Thatcher represent our ‘Gold Star’ research site for this quarter. The members of the University of Rochester Batten Center (URBC) and the members of the UR Tourette Research Group demonstrated attention to regulatory compliance/protocol adherence, and have high quality, organized study-related documentation with exceptional Investigator oversight.

Congratulations!
Good Documentation Practice—Consenting

Good Documentation Practice (GDP) is a term the pharmaceutical industry, in particular, uses to describe best practices surrounding research documentation and its maintenance. Some GDP standards are supported by law or regulation, while others are corporate policy or simply current expectation (or ‘good practice’), and not formally supported by regulation.

Below are some Good Documentation Practices for Consenting:

- Practice the consent discussion with a colleague prior to meeting a potential subject; consider questions prospective subjects may ask and plan for addressing challenges that may arise. Building confidence in the consent process is key. Each subject will be a little different so possibly practice with several colleagues to get perspectives from different individuals.

- Provide the prospective subject with a copy of the consent form to read the information beforehand. Each person has a comfort level with how much risk they tolerate and personal information they agree to share. Subjects need time to make an informed decision.

- Consider using tables and charts to aid in describing the schedule of study procedures. Some studies are complicated and this will assist in assuring the subject understands the research and is voluntarily participating.

- After discussing the content of the consent form, ask the prospective subject open-ended questions and encourage them to repeat their understanding of the study and to ask questions. Obtaining consent is a continuous dialogue between the research team and the subject throughout study participation and the research team should assess whether the subject understands the study and can describe what is being asked.

- Use a consent form checklist to guide the consenting discussion; an example can be found in the QI Study Documentation Tool Box. It is important to discuss each of the items addressed in the consent form prior to obtaining signatures.

- Obtaining consent should always happen prior to any study procedures.

- Note the consent discussion in the research chart and/or medical record, as appropriate. A template is available here. Consistent with a study’s IRB approval, document consent and/or other information in the subject’s electronic health record, as it can be beneficial for the clinical team to know a subject is in a research study.

- Conduct a quality check on each completed consent form, especially at the beginning of a study and after a consent form modification is approved by the IRB. Self-audit templates are available here. A second-set of eyes on a completed consent form is invaluable. It is much better to find errors when they happen, rather than weeks or months later when an outside auditor may be reviewing the consent forms.

- Secure all pages of the original, signed consent form in a locked area. A consent form is the document that enters a person into a research study and having the documentation is imperative.

- Remember: consenting is an on-going process that continues throughout the duration of the study!

Contact OHSP-QI any time to schedule your team for a study start-up consultation, which includes a review of consenting expectations.
What is a concept study?

A concept study is an idea (concept) for a research study, which is submitted for IRB review prior to the development of a complete protocol.

A concept study application allows for IRB review and approval of a protocol still in the concept stage of development. It is a specific mechanism for review of a funded study which provides a period of time (and sometimes funding) for the full development of the study protocol, study measures and consent forms.

Under a concept study submission there can be no data collection and/or human subject engagement. Data collection, subject recruitment and enrollment is contingent upon submission of a fully developed protocol for IRB review and approval.

What’s the difference between the approval and effective date?

As defined in OHSP Policy 501, the approval date is the date the IRB decision was made to either approve or approve with modifications/stipulations the item under review (i.e., new study application, modification or continuing review). An effective date is the date IRB decision takes effect; it is the first possible date the research can be performed (or modification implemented) following notification from the IRB.

Depending on the determination the IRB makes, these dates may or may not be the same. When a submission is approved outright and no modifications/stipulations are required to secure approval, the approval and effective date will be the same. However, when modification/stipulations are required for approval, the effective date will be later; it will reflect the date the required modifications/stipulations were reviewed and accepted by the IRB.

What does ‘filling the shell’ mean?

In preparation for go-live with the new Click® IRB review platform, the Office for Human Subject Protection (OHSP) needed to determine what, if any, studies would migrate from the RSRB Online Submission System (ROSS) into Click® IRB. It was determined early in the implementation process that the RSRB would not be able to function optimally with active reviews occurring in both platforms. Based on needs concerning board meeting management, reporting requirements and compliance, it was ultimately determined that all active research approved via an expedited or convened board review process would be transferred into Click® IRB. These studies, that migrated from ROSS into Click® IRB, then became referred to as ‘legacy studies’.

Given the requirements set forth in the new Click® IRB platform, the data migrated into Click® IRB for each legacy study was minimal. The data fields are different between the two platforms and OHSP did not want to risk migrating inaccurate data. Only a ‘shell’ of basic study information from each legacy study was transferred into Click® IRB. Therefore, following ‘go-live’, study teams were required to populate missing data fields and documents within the new legacy application in Click IRB (i.e., ‘filling the shell’). Generally, this process includes uploading current versions of previously approved unwatermarked study documents, identifying funding sources, validating study team member roles, and answering questions related to conflicts of interest, research locations, use of investigational products (drugs/devices) and ancillary reviews. Step-by-step instructions for completing this process are available in the OHSP 2018 Q4 Newsletter.
Frequently Asked Questions (Continued)

What documents get watermarked in Click® IRB?
With the implementation of the new Click® IRB review platform, and to accommodate the revised Common Rule regulations, the Research Subjects Review Board (RSRB) has recently updated their practices concerning documents that get watermarked upon approved (see Table 1). As of ‘go-live’ with Click® IRB, all consent form and recruitment materials are minimally watermarked with a RSRB approval date. Consent forms, parental permission forms, consents to procedures/data use for deception studies and short forms are further watermarked with an expiration date (note that in some cases, if a study does not require continuing review per the revised Common Rule, the expiration date may appear blank).

Watermarking occurs via programming within the Click® IRB platform, based on the category selected by the study team when a document is uploaded. For example, when a document is uploaded and the document is identified as a consent form in the category field, the document will be watermarked with both an approval and expiration date. Whereas, if the document is identified as an information sheet, it will only be watermarked with an approval date.

As the process is now automated, RSRB staff do not have the ability to move or adjust where the watermark appears. The watermark will always appear in the lower right-hand corner of the document. As such, study teams should be cognizant of leaving the right-hand side of all document footers blanks, with at least a 1-inch footer.

Questions about the watermark? Contact your RSRB Specialist.

Table 1. RSRB Watermarked Documents

<table>
<thead>
<tr>
<th>Watermarked with Approved Date &amp; Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consent Form</td>
</tr>
<tr>
<td>• Parental Permission Form</td>
</tr>
<tr>
<td>• Consent to Procedures/Data Use (Deception Research)</td>
</tr>
<tr>
<td>• Short Form</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Watermarked with Approved Date Only</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Assent Form &amp; Assent Script</td>
</tr>
<tr>
<td>• Consent Addendum</td>
</tr>
<tr>
<td>• Information Sheet</td>
</tr>
<tr>
<td>• Verbal Script</td>
</tr>
<tr>
<td>• Recruitment Materials (Brochure/Flyer/Poster, Recruitment/Information letter, Email, Telephone or Announcement Script, Social Media Post, SONA, Research Match, Radio/TV or Newspaper Ad, ‘Other’ Recruitment Materials)</td>
</tr>
</tbody>
</table>

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