The Continuing Review submission form in the Click® IRB review platform requires study activity to be reported through research milestones (Question #2). These milestones differ from how study status was formerly identified in the Continuing Review form in the RSRB Online Submission System (ROSS). Therefore, we must change how we think about reporting study activity.

Research milestones in Click® IRB are identified and described in Table 1 on page 9. When selecting the applicable research milestone, keep the following points in mind:

- **Research milestones reflect the typical lifecycle of an overall study.** Generally, the conduct of research involves: 1) enrolling subjects; 2) conducting study procedures; 3) collecting data; and 4) analyzing data. The first four research milestones identified in Click® IRB reflect these four basic steps and, as such, should be selected in order, over the course of the research as each milestone is achieved (i.e. completed in its entirety). Once all four milestones have been achieved, Click® IRB programming will facilitate IRB closure. The two additional (continued on page 2)

### Defining & Reporting Subject Enrollment

Along with research milestones, subject enrollment must be reported when active research requires continuing review. Determining when a subject is ‘enrolled’ however, can be challenging as use of the term can vary depending on the nature of the research and who you’re communicating with (e.g., an Institutional Review Board [IRB] vs. a study sponsor).

The Research Subjects Review Board (RSRB) considers a subject enrolled in the research once they have provided consent to participate. For simple studies, determining enrollment should be relatively straightforward – all subjects who have provided written or verbal consent should be counted as ‘enrolled’ and the number reported as ‘enrolled’ should be consistent with your study documentation (e.g., the number of maintained signed consents, the number of subjects identified on an enrollment log, the number of completed surveys).

For studies that involve screening procedures (i.e., where a subject undergoes study-specific procedures to validate eligibility [e.g., oral medical history or blood draw]), reporting enrollment can be a bit more complicated. As a general rule of thumb, subjects should be counted as ‘enrolled’ after written or verbal consent to perform the screening procedures is provided. For example:

- When a medical or academic record is reviewed to confirm eligibility prior to subject recruitment and/or consent, the subject should only be counted as ‘enrolled’ when eligibility is confirmed and they consent to participate. If a subject’s medical or academic record is reviewed and they are determined to be ineligible and (continued on page 3)
(continued from page 1) research milestones listed in Click® IRB (‘remaining study activities are limited to data analysis’ and ‘study remains active only for long-term follow-up of subjects’) fall into a study’s lifecycle but, if selected, implicate specific IRB review pathways for research involving greater than minimal risk. Moreover, the wording of the last two milestones do not represent an endpoint or achievement. Rather, they are active, ongoing phases of the research (i.e., they may be selected when a study is within the course of the phase, not necessarily when the phase has been achieved/completed).

- **All applicable research milestones should be selected.** If no milestone has been achieved, no boxes should be checked (e.g. study is currently enrolling). This confirms the study’s progress at the time of each continuing review and facilitates appropriate timing of study closure. Failing to select a milestone that was previously achieved implies that steps in the research have been skipped or the research is moving ‘backwards’ in the lifecycle, which is only accurate in very rare circumstances.

- **Research milestones should reflect the progress of the study overall, not the progress of individual subjects or cohorts.** A milestone should only be selected when the milestone is achieved for all aspects of the research. This includes all subjects, all sub-studies, and all cohorts, as described in the study protocol. Individual subject status is no longer required to be routinely reported, with the exception of withdrawals, which are collected as part of Question #4. It is also possible that additional information regarding individual subject statuses may be requested by the Research Subjects Review Board (RSRB).

- **Some milestones include two statements (separated by ‘OR’), select the research milestone if either statement applies to the research.** The research milestones are phrased in this manner to accommodate different types of research with varying subject engagement and to facilitate closure of approved studies that will not be completed. Generally, the first statement applies to traditional types of research where subjects enroll in the research and actively participate in study procedures. Whereas, the second statement applies to other types of research with no subject engagement (e.g., concept or umbrella studies) or when the research was approved but will not be conducted and submitted for closure.

- **Use the ‘Comments’ field to clarify, when necessary.** The ‘Comments’ field in Question 5 of the continuing review form may be used when it is necessary to provide additional information about research milestones.

Common study status scenarios and applicable research milestones are provided in Table 2 on page 10; see additional Frequently Asked Questions related to continuing review on page 7. When in doubt of which research milestones apply at the time of continuing review, or for questions, contact your **IRB Coordinator**.

Defining & Reporting Subject Enrollment

(continued from page 1) therefore are never approached to participate in the research, they should not be counted as ‘enrolled’.

- When a subject is verbally asked questions to validate eligibility, prior to written or verbal consent, the subject should only be counted as ‘enrolled’ when eligibility is confirmed and they consent to participate. If a subject is verbally queried prior to written or verbal consent and they are determined to be ineligible and therefore consent is never obtained, they should not be counted as ‘enrolled’.

- When a subject provides written or verbal consent to undergo formal screening procedures (e.g., physical exam, neurocognitive assessment), the subject should be counted as ‘enrolled’ regardless of whether eligibility is confirmed via the screening procedures. In the event, a subject provides consent and is subsequently determined to be ineligible, they should not be counted as ‘enrolled’.

My protocol permits subjects to participate in the research more than once. How should these subjects be counted in enrollment totals?

First and foremost, the study protocol should specifically indicate when an individual subject is permitted to participate in the research more than once. The circumstances for allowing this participation will depend on the nature of the research, as will how subjects should be counted in enrollment totals. Generally, subjects should only be counted once toward the enrollment total. In the event an individual subject’s participation in the research, is counted more than once in the enrollment total (e.g., a study that allows screen failures to re-screen for participation after a specific waiting period or if the individual participates in a study more than once and signs a new consent form each time they enroll), the protocol should clarify how enrollment totals are being determined, and how subjects will be counted if they enroll in the study multiple times.

Who is considered ‘enrolled’ when consent is waived?

For studies involving a secondary data analysis, chart reviews and/or specimen analysis approved with a waiver of consent, subjects should be counted as ‘enrolled’ when they have been identified as eligible for the study and the study team plans to collect or use their data/specimens.

What about withdrawals?

As stated above, a subject is considered enrolled in the research once they have provided consent to participate. Activities that occur following consent – subject withdrawal, investigator-initiated subject withdrawal, lost to follow-up, or subject death (due to causes related or unrelated to study participation) – do not affect how enrollment totals are calculated. E.g., if 10 subjects are enrolled and 1 subject withdrawals, 10 subjects should still be reported as ‘enrolled’.

To report withdrawals (both subject withdrawals and investigator-initiated subject withdrawals) in Click® IRB, leave the ‘NO subjects withdrew from the study’ checkbox in Question 4 of the Continuing Review form UNCHECKED and insert a comment, explaining the withdrawal, into Question 5 or attach additional supporting documentation in Question 6 (see Image 1).

If you have questions regarding how enrollment should be reported at the time of continuing review, contact your IRB Coordinator.

Image 1. Withdrawal Reporting
Office for Human Subject Protection (OHSP) Policy 201 Education Program requires all researchers engaged in human subject research re-certify human subject protection training through the Collaborative Institutional Training Initiative (CITI) every 3 years. Before the implementation of Click IRB, OHSP provided email notification of pending training expiration directly to staff by email. In October 2018, this practice changed to allow CITI to directly email notifications to the researchers. Unfortunately, it has recently come to OHSP’s attention that not all users are receiving these notifications and, for those who are, the notification may be overlooked.

OHSP staff is in the process of notifying all internal research staff with human subject protection certifications that expired after October 1, 2018. While it is the responsibility of individuals to keep track of when their certification will expire, OHSP does recognize that the email notification is a helpful tool in maintaining compliance. As such, OHSP has created a note to file for researchers to use to document any unexplained lapses in certification, the potential root cause, and the steps OHSP is taking to address the error to maintain in their study files.

To ensure receipt of future notification, please verify the contact information identified in CITI profiles. Upon registration, all CITI users are assigned a ‘Member Profile’ and an ‘Institutional Profile’ for each institution they are affiliated with: notification emails from CITI are sent to the user’s ‘Preferred Email’ identified within their Member Profile and the Click® IRB-CITI integration is facilitated via the ‘Institutional Email Address’ identified within user’s University of Rochester Institutional Profile. Ensuring the contact information in both profiles is accurate is essential in receiving notifications regard upcoming expirations in human subject protection training.

Furthermore, be aware that removing courses from your CITI training curriculum, will prevent reminder notifications. When/If additional training is required in CITI (e.g., Good Clinical Practice, Responsible Conduct of Research, or Animal Care and Use training), select ‘Add Courses’ to add the additional training; (continued on page 5)
External IRB Study Start-Up Consultations

You just completed the External IRB approval process for your new study but how do you know you are adhering to all applicable regulations when you are relying on a Non-UR IRB?

In addition to SSU for RSRB-approved studies, OHSP-QI is pleased to announce the addition of External IRB Study Start-Up (SSU) Consultation to our services. The primary goal is to assist Investigators and study staff in adhering to their local responsibilities when an external IRB is reviewing your research study, as well as, ensuring protections for UR subjects enrolled in research. Even though the UR may defer IRB review to an external IRB for the regulatory review, the UR remains responsible for the conduct of the study and human subject safety.

Upon request, after IRB approval but prior to enrolling subjects into the study, the OHSP-QI staff is available to evaluate study documentation (e.g. regulatory binder, data collection forms, source documents) and work with the Investigators and study staff to identify and comply with the Reviewing IRB’s determinations and policies. For example, we can detail your approved oversight plan, demonstrate ways to be compliant with your protocol, and evaluate risk areas for the Investigator, the subjects, and the UR. After the consultation, OHSP-QI will provide a written assessment, educational materials/references, support, and study tools.

OHSP-QI has demonstrated that providing SSU consultations to study teams increases overall compliance in human subject research. Study teams who utilized this service had fewer high-risk findings and improved ratings upon internal review compared to those who did not. For further details on this project, refer to our ‘Quality Improvement Study Start-Up Consultations Improve Protocol Compliance’ poster.

Study Start-Up Consultations are free and fully customizable to study team needs. Please contact OHSP-QI to schedule a study start-up consultation.

Resources:
- OHSP Study Start-Up Consultation Website;
- OHSP Study Start-Up Consultation Information Memo;
- OHSP Policy 504 IRB Reliance ad Collaborative Research;
- OHSP Guideline for Relying IRB

CITI Reminder Notifications

(continued from page 4) Do not remove courses. If ‘Remove Courses’ is selected, the individual will be un-enrolled in the training; and any automatic enrollment in refresher courses and notification emails will be prevented.

Finally, please be mindful of reading e-mail communications from CITI. As these notifications are new to most users, they can be easily overlooked; do not assume they are junk mail.

Should you have questions concerning these notification, please contact the OHSP Director of Research Education and Training.

Resources:
- OHSP Study Start-Up Consultation Website;
- OHSP Study Start-Up Consultation Information Memo;
- OHSP Policy 504 IRB Reliance ad Collaborative Research;
- OHSP Guideline for Relying IRB
Office for Human Subject Protection (OHSP) Policy 901 Investigator Responsibilities requires all investigators to ‘maintain documentation to support RSRB [Research Subjects Review Board] determinations.’ For research deemed exempt, this minimally includes the approved version of the study protocol, a copy of the RSRB submission, and the RSRB determination (approval) letter. For all other research (FDA and non-FDA regulated research), this further includes all IRB-approved documents (e.g., all approved versions of the study protocol, all watermarked versions of the consent form(s), all watermarked recruitment materials, etc.) and all IRB determination letters (for a complete list, see OHSP Quality Improvement’s Research Study Site File Documentation Requirements).

Historically, in the RSRB Online Submission System (ROSS), study team members could only access the current watermarked RSRB-approved documentation. With the implementation of Click® IRB, study team members can now access the historical watermarked documents, with one exception, as follows:

- All current watermarked RSRB-approved documents are available on the ‘Documents’ tab in the STUDY workspace (labeled ‘STUDY0000…’, see Image 2). Watermarked versions are available under the ‘Final’ heading (see Image 3).
- Historic watermarked (outdated) RSRB-approved documents are available on the ‘Documents’ tab of the applicable follow-on submission workspace (labeled based on the submission type, e.g., ‘MOD0000…’, ‘CR0000…’, ‘MODCR0000…’, etc.). For example, the documents approved with Modification #1 are available on the ‘Documents’ tab in the workspace of Modification #1.
- RSRB determination (approval) letters are available in the heading of the applicable workspace: original approval letters are on heading of the STUDY workspace and follow-on approval letters are on the heading of the applicable follow-on workspace (e.g., the approval letter for Modification #1 is available in the heading of the workspace for Modification #1). Additional RSRB determination letters (e.g., stipulation letters, request for changes letters) are available via the ‘History’ tab of the applicable workspace. Please note: all letters are labeled “Correspondence” regardless of the type of letter.

EXCEPTION: Once a follow-on submission is approved, the watermarked documents approved with the original RSRB approval are no longer accessible. This occurs because the documents approved with a follow-on submission copy to the study workspace to replace the previously approved documents. Study staff must be cognizant of downloading and maintaining the documents approved with the original RSRB approval in a timely manner (i.e., prior to submission of the first follow-on submission). In the event, a study team fails to download the materials approved a template note to file has been created for study teams and is available in OHSP Quality Improvement’s Study Documentation Toolbox.
When can I close a study with the IRB?

For studies reviewed by the Research Subjects Review Board (RSRB), per Office for Human Subject Protection Policy 502 Types of RSRB Submissions, a study is considered completed, and therefore may be closed with the RSRB, when subjects are no longer being recruited (or data/specimens being collected), no longer being followed, primary data analysis has been completed according to the protocol and results are available, and identifiers have been removed from the analysis dataset (e.g., identifiers destroyed or identified maintain in a separate dataset). Exceptions are as follows:

- Multi-site studies where the University of Rochester is an enrolling site only (i.e., the local site is not the coordinating center or lead site and is not responsible for data analysis) – Enrolling site studies can be closed once the site’s participation in the research is complete (i.e., subjects are no longer being recruiting, no longer (continued on page 8))

How do I temporarily suspend a study?

‘Suspending’ a study means that the study, or a specific component of the study (e.g., enrollment, a specific study procedure, or intervention administration) is halted. Routinely, this occurs because of a safety or non-compliance incident and a study sponsor, the reviewing Institutional Review Board (IRB), data and safety monitoring committee, or Principal Investigator (PI) determines that the study should be stopped for a period of time in order to investigate the incident and determine the best path forward. When the reviewing Institutional Review Board (IRB) decides that a study needs to be suspended for any reason, the IRB is required by federal regulation to report this determination to applicable institutional and regulatory authorities and the study sponsor (see Office for Human Subject Protection Policy 402 RSRB Meetings for additional information).

When the Research Subjects Review Board is the reviewing IRB and the PI, study sponsor or data and safety monitoring committee determine that the study should be suspended, it should be reported via the Reportable New Information (RNI) submission form in the Click® IRB platform. Suspensions should not be requested through a request for study closure via continuing review, as this does not allow the study to be reopened and modified to reverse the study suspension.
being following and all data collection and review [including data edits and queries] are complete) and the coordinating center or lead site has instructed the enrolling site to close the study with their reviewing Institutional Review Board (IRB).

- Multi-site studies where the University of Rochester is the lead site or coordinating center – When the University of Rochester acts as a lead site or coordinating center and is therefore responsible for the conduct of the research at each enrolling site, the lead site’s IRB cannot be closed until all enrolling site IRBs are closed and the primary data analysis is complete according to the protocol.

- Concept studies – A concept study is a type of IRB submission that allows for IRB review and approval of a protocol that is still in development. Protocols are only approved in this manner when the funding agency provides a period of time prior to the research for protocol development. Once the protocol is fully developed it must be submitted as a new IRB submission, following approval of which, the original concept study can be closed.

- Umbrella studies – An umbrella study provides funding for multiple studies, submitted under separate IRB submissions. Umbrella studies can be closed once all IRB submissions for each study falling under the umbrella study has been closed.

- Studies reviewed and approved by an external IRB – Studies undergoing review and approval by an IRB other than the RSRB (e.g., Advarra, WIRB, or another institution’s IRB), can be closed per the reviewing IRB’s requirements.

For studies undergoing review by the RSRB, as described in the article on page 1, Click® IRB will prompt study closure once the milestones necessary for study closure are reached.

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OFFICE FOR HUMAN SUBJECT PROTECTION
3RD QUARTER, 2019

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<tr>
<th>Research Milestone</th>
<th>Description</th>
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| Study is permanently closed to enrollment OR was never open to enrollment           | • **Study is permanently closed to enrollment:** All subjects (in all sub-studies and all cohorts, if applicable) have been enrolled in the research; no additional subjects will be enrolled in the future. Note: When considering secondary data analysis studies, chart reviews, and specimen analysis, ‘enrollment’ refers to records or specimens accessed/used.  
  -OR-  
  • **Study was never open to enrollment:** A) The study does not involve subject enrollment (e.g., concept or umbrella studies); or B) The study never began (no subjects were enrolled and no data was collected) and the continuing review is being submitted to close the study. |
| All subjects have completed all study-related interventions OR not applicable (e.g., study did not include interventions, no subjects were enrolled) | • **All subjects have completed all study-related interventions:** All subjects (in all sub-studies and all cohorts, if applicable) have completed all study procedures. Note: In this case, the word ‘intervention’ should be broadly applied to encompass all study-related procedures and interactions (e.g., surveys, interviews, or task completion); the use of the word ‘intervention’ here is not limited to manipulations of the subject or subject's environment.  
  -OR-  
  • **Study-related interventions are not applicable:** A) The study does not involve active engagement or participation of subjects (e.g., secondary data analysis, chart reviews, and specimen analysis); B) The study does not involve subject enrollment (e.g., concept or umbrella studies); or C) The study never began (no subjects were enrolled and no data was collected) and the continuing review is being submitted to close the study.  
  Note: Generally, this milestone should only be true when the following additional milestone has been achieved (and selected in Click® IRB):  
  - Study is permanently closed to enrollment OR was never open to enrollment. |
| Collection of private identifiable information is complete OR not applicable (no subjects were enrolled) | • **Collection of private identifiable information is complete:** The collection and/or receipt of all identifiable data and specimens is complete (including the collection/receipt of coded data and specimens); no further data collection, editing, or queries will occur.  
  -OR-  
  • **Collection of private identifiable information is not applicable:** A) The study does not involve subject enrollment (e.g., concept or umbrella studies); or B) The study never began (no subjects were enrolled and no data was collected) and the continuing review is being submitted to close the study.  
  Note: Generally, this milestone should only be true when the following additional milestones have been achieved (and selected in Click® IRB):  
  - Study is permanently closed to enrollment OR was never open to enrollment; and  
  - All subjects have completed all study-related interventions OR not applicable. |
| Analysis of private identifiable information is complete OR not applicable (no subjects were enrolled) | • **Analysis of private identifiable information is complete:** Analysis of identifiable data, as described in the study protocol, is complete (including the analysis of coded data).  
  -OR-  
  • **Analysis of private identifiable information is not applicable:** A) The study does not involve subject enrollment (e.g., concept or umbrella studies); or B) The study never began (no subjects were enrolled and no data was collected) and the continuing review is being submitted to close the study.  
  Note: Generally, this milestone should only be true when the following additional milestones have been achieved (and selected in Click® IRB) and the intention is to close the study:  
  - Study is permanently closed to enrollment OR was never open to enrollment; and  
  - All subjects have completed all study-related interventions OR not applicable; and  
  - Collection of private identifiable information is complete OR not applicable. |
| Remaining study activities are limited to data analysis                             | All subjects (in all sub-studies and all cohorts, if applicable) have been enrolled; all study-related interventions, procedures and interactions are complete; and all data have been collected but the analysis of the data, as described in the study protocol, is not yet complete.  
  Note: This milestone should only be true when the following additional milestones have been achieved, minimally (and selected in Click® IRB):  
  - Study is permanently closed to enrollment OR was never open to enrollment; and  
  - All subjects have completed all study-related interventions OR not applicable. |
| Study remains active only for long-term follow-up of subjects                     | All subjects (in all sub-studies and all cohorts, if applicable) have been enrolled and the only remaining study-related procedures for active subject is limited to long-term follow-up only. Per HHS Office for Human Research Protections guidance, long-term follow-up includes:  
  - “Research interactions that involve no more than minimal risk to subjects (e.g., quality of life surveys); and  
  - Collection of follow-up data from procedures or interventions that would have been done as part of routine clinical practice to monitor a subject for disease progression or recurrence, regardless of whether the procedures or interventions are described in the research protocol”.  
  Long-term follow-up does not include “research interventions that would not have been performed for clinical purposes, even if the research interventions involve no more than minimal risk” (HHS guidance).  
  Note: This milestone should only be true when the following additional milestone has been achieved (and selected in Click® IRB):  
  - Study is permanently closed to enrollment OR was never open to enrollment. |
<table>
<thead>
<tr>
<th>Study Status Scenarios</th>
<th>Applicable Research Milestones in Click® IRB</th>
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<tbody>
<tr>
<td><strong>Studies Involving Subject Engagement</strong></td>
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<tr>
<td><strong>Scenario A</strong>: Study is open to enrollment, but no enrollment has occurred.</td>
<td>N/A</td>
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<tr>
<td><strong>Scenario B</strong>: Subjects have enrolled but the accrual goal has not been reached.</td>
<td>N/A</td>
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<tr>
<td>Enrolled subjects are actively participating in study procedures (some or all enrolled subjects may have completed or discontinued study participation).</td>
<td>study remains active only for long-term follow-up of subjects.</td>
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<td><strong>Scenario C</strong>: Enrollment is complete for one, but not for all cohorts. Enrollment in open cohort(s) continues; en-rolled subjects are actively participating in study procedures (some or all enrolled subjects may have completed or discontinued study participation).</td>
<td>study remains active only for long-term follow-up of subjects.</td>
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<td><strong>Scenario D</strong>: Subjects have enrolled and were reported at the time of a previous continuing review, but no additional subjects were enrolled during the current reporting period; the study is continuing to enroll subjects. Enrolled subjects are actively participating in study procedures (some or all enrolled subjects may have completed or discontinued study participation).</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
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<td><strong>Scenario E</strong>: Subject enrollment is complete (in all sub-studies and all cohorts, if applicable); no additional subjects will be enrolled. Enrolled subjects are actively participating in study procedures (some subjects may have completed or discontinued study participation).</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
</tr>
<tr>
<td><strong>Scenario F</strong>: Subject enrollment is complete and remaining study procedures for all active subjects (in all sub-studies and all cohorts, if applicable) are limited to long-term follow-up only (see description of 'long-term follow-up' in Table 1).</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
</tr>
<tr>
<td><strong>Scenario G</strong>: Subject enrollment is complete and all subjects (in all sub-studies and all cohorts, if applicable) have completed all study procedures; no additional study procedures will be performed. Receipt of additional data may continue as test/procedure results are calculated/reviewed and/or data edits, queries or cleaning is completed.</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
</tr>
<tr>
<td><strong>Scenario H</strong>: Subject enrollment is complete and all subjects (in all sub-studies and all cohorts, if applicable) have completed all study procedures. Data analysis has begun but is not complete. Additional data edits, queries or cleaning may still take place.</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
</tr>
<tr>
<td><strong>Scenario I</strong>: Subject enrollment is complete and all subjects (in all sub-studies and all cohorts, if applicable) have completed all study procedures. No additional identifiable or coded data/specimens will be collected and/or accessed. Data analysis has begun but is not complete.</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
</tr>
<tr>
<td><strong>Scenario J</strong>: Subject enrollment is complete and all subjects (in all sub-studies and all cohorts, if applicable) have completed all study procedures. No additional identifiable or coded data/specimens will be collected and/or accessed. Data analysis, as described in the study protocol, is complete. Any further analysis of data will be limited to the analysis of de-identified data sets.</td>
<td>study is permanently closed to enrollment OR was never open to enrollment;</td>
</tr>
</tbody>
</table>

Table 2. Common Study Status Scenarios and Applicable Research Milestones in Click® IRB