On January 21, 2019, the revisions to the Common Rule (the ‘Federal Policy for the Protection of Human Subjects’), issued by the Department for Health and Human Service (HHS), went into effect. By and large, the revision that has been the most challenging to implement is the new requirement concerning the presentation of ‘key information’ at the start of the consent form. The revised regulations state:

“Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.”

While there is no specific guidance from HHS’s Office for Human Research Protections (OHRP) on how to comply with this requirement, the preamble to the final rule published in the Federal Register indicates that OHRP generally expects this new requirement can be satisfied by including a brief description of the following at the beginning of a consent form:

- “the fact that consent is being sought for research and that participation is voluntary;
- the purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research;
- the reasonably foreseeable risks or discomforts to the prospective subject;
- the benefits to the prospective subject or to others that may reasonably be expected from the research; and
- appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.”

Based on this recommendation, the RSRB revised their consent form templates prior to the January 21, 2019 compliance date to include template ‘key information’ bullet points. The key to utilizing the ‘key information’ template is to bear in mind that the bullet points are guidance only; bullet points may be added or removed as necessary based on the nature of the research.

When drafting consent forms, study teams should strive (continued on page 2)
Keys to ‘Key Information’

(continued from page 1) for a ‘happy’ balance between meeting the additional requirements, without creating significant duplication and making the consent form unnecessarily long or more complex. The goal of the ‘key information’ is to facilitate decision-making by providing critical information to the subject ‘up front’. For higher risk or more involved research, the ‘key information’ should be relatively brief, concise and focused, providing a short summary of crucial elements of information that are further explained in the consent form (e.g., identifying the most important or the most severe risks instead of all risks). For simple research, with limited procedures, the ‘key information’ may be quite minimal as highlighting multiple benign points in an already brief document will not likely aid in the decision-making process. In some cases, as stated in the preamble to the final rule, “if the information included at the beginning of the consent form satisfies both [key information requirements and the elements of consent]… more generally, the information in the beginning need not be repeated later in the body of the informed consent.” For example, for a minimal risk study requiring only a short interaction with the subject (e.g., brief interview or survey completion), it may not be necessary to duplicate a concise statement of duration of participation (e.g., ‘your participation in this study will last about 30 minutes’) and/or benefit statement (e.g., ‘you will not benefit from being in this study’), as this would not require further explanation in the body of the consent document, provided the statement(s) is provided as a ‘key information’ bullet.

Additional considerations to bear in mind when drafting ‘key information’ include the following:

- The University of Rochester is only applying the revised Common Rule (‘2018 Requirements’, as identified in the STUDY workspace in Click IRB) to new research approved on or after January 21, 2019 (all studies approved prior to that date remain under the old, pre-2018 Common Rule requirements), and do not require ‘key information’ in the consent form. As such, the Research Subjects Review Board (RSRB) is not requiring that ‘key information’ be added via modification to studies approved prior to January 21, 2019, unless a sponsor or other entity is requiring the revision.

- ‘Key information’ requirements do not apply to research deemed exempt; ‘key information’ does not need to be included in consent documentation (e.g. information letters) for such research.

- In the event a consent template is provided by a sponsor or coordinating center for local IRB review and approval, study teams may defer to the ‘key information’ identified by the sponsor or coordinating center. DO NOT insert duplicative ‘key information’ bullets merely because these bullets are included in the RSRB consent templates. Providing two sets of ‘key information’ defeats the goal of facilitating subject understanding.

Questions about the ‘key information’ requirement? Contact your IRB Coordinator.
confirmed and documented (i.e., subject screening).

The manner in which subjects are screened and enrolled into research will ultimately depend on the nature of the research, though the process will generally fall into one of the following scenarios (see Figure 1):

A) A potential subject is identified and eligibility is confirmed (e.g., via record review and/or oral history/interview with the subject) prior to obtaining informed consent.

B) A potential subject is identified, informed consent is obtained for study participation and the subject undergoes screening following consent (subjects found to be ineligible during screening are then withdrawn from the research).

C) A potential subject is identified and informed consent for screening procedures only is obtained. Enrolled subjects then undergo screening procedures and subjects found to be eligible for participation go on to provide informed consent for study participation (subjects found to be ineligible are withdrawn).

**Consent for Screening**

A key, yet often overlooked, factor in planning for screening provisions is considering whether informed consent must be obtained from potential subjects prior to the conduct of screening procedures. Similar to the age-old chicken and egg dilemma, screening often becomes a question of which comes first, screening or consent?

Recall the regulations for the protection of human subjects require study teams to obtain informed consent before involving a potential subject in research. Also recall a ‘human subject’ is defined by the regulations as a ‘living individual about whom an investigator…(i) obtains information or biospecimens through intervention or interaction…or (ii) obtains, uses, studies, analyzes or generates identifiable private information or biospecimens.’ As such, provisions for consent must be addressed for screening procedures when screening involves:

- Obtaining (i.e., recording, logging, tracking, or otherwise documenting) identifiable information (e.g., recording a name, date of service, or other identifier in a screening log); or
- Conducting study-specific screening procedures (e.g., collecting a blood sample, conducting a physical or neurological exam that is not part of routine care).

If screening does not require the acquisition of identifiable information (e.g., the study team verbally queries the subject or the medical/academic record is reviewed for eligibility without recording any identifiable information, at any point) or the conduct of study-specific procedures, consent for study participation can be obtained following confirmation of eligibility (scenario A above).

When consent for screening is required, study teams have traditionally mimicked scenarios B or C described above whereby screening procedures are either incorporated into the overall study consent (scenario B) or a separate screening consent, in some cases a verbal consent script, is created to obtain consent for screening procedures only (scenario C). In other rare instances, a waiver of consent may be justified.

Under the revised Common Rule, (continued on page 4)
Provisions for Subject Screening

(continued from page 3) effective January 21, 2019, study teams now have the additional option of requesting a consent exception for certain screening procedures. The revised Common Rule states:

“An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining eligibility of prospective subjects without the informed consent of the prospective subject or of the subject’s legally authorized representative, if either of the following conditions are met:

1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.”

This means that study teams can request an informed consent exception via their study protocol for the IRB to approve, in lieu of obtaining consent for screening purposes provided the screening procedures meet the conditions identified within the regulations (i.e., screening only involves accessing records/stored biospecimens or obtaining information through oral/written communication). Note, however, not all screening procedures will align with these conditions (e.g., collecting blood samples, conducting physical exams). If the study protocol requires screening procedures that do not meet the requirement for a consent exception, informed consent (either written or verbal) must be obtained prior to conducting the screening procedures.

In addition to consent, study teams conducting research under the University of Rochester Medical Center’s covered entity must further consider how they will comply with the Health Insurance Portability and Accountability Act (HIPAA) when screening procedures require the collection of identifiable health information (see OHSP Policy 708 HIPAA Privacy Rule for additional information):

- When consent for screening is obtained in writing (either in the overall study consent or a separate screening consent form), HIPAA authorization is routinely included within the consent document.
- When consent for screening is obtained verbally, an altered HIPAA authorization must be requested via the study protocol (an ‘altered’ authorization is required when authorization is obtained verbally because, per HIPAA requirements, authorization requires written agreement or a signature).

- When a consent exception or waiver are requested, either a waiver of HIPAA authorization must be requested via the study protocol or the information collected during the screening process must be limited to a limited data set with a data use agreement in place, if the information will be disclosed outside the covered entity.

Conducting Screening Procedures

Ensuring consent is appropriately obtained for subject screening, when necessary, is only one piece of the subject screening puzzle. Quality improvement, monitoring and inspection reports often site study teams for findings related to enrolling ineligible subjects into the research and/or inadequately documenting subject eligibility. Additional best practices related to subject screening include:

- When identifying inclusion and exclusion criteria in the study protocol, be specific and objective. Consider all possibilities including but not limited to: age, sex, race, diagnosis requirements, method of diagnosis, treatment (continued on page 5)
Research QI ‘Gold Star’ Award

The QI division is recognizing PI’s David Adler, MD and Kian Merchant-Borna, MPH, MBA, and Research Coordinator Sarah Dermady for their quality work on the ‘cobas® vivoDx MRSA Clinical Utility Protocol No. VIV-MRSA-431’ study. This vibrant study team is part of the Industry-Sponsored Research Program in the Division of Emergency Medicine Research. They received the OHSP-QI ‘Gold Star’ award for demonstrating attention to protocol adherence, respect for the subjects, good consenting processes, Investigator oversight, and high quality, organized study-related documentation.

Congratulations!

Provisions for Subject Screening

(continued from page 4) requirements, existing or previous conditions and therapies, concomitant and disallowed medications, disease severity, pregnancy and fertility, cognitive function, language fluency, ability to perform specific study-related functions/procedures, and ability to provide informed consent.

- To simplify the screening process, state inclusion and exclusion criteria only once within the protocol; do not include inverse criteria in each respective criteria list. E.g., if only English-speaking subjects will be enrolled, this criterion only needs to be identified in either the inclusion or exclusion criteria list; do not list ‘English-speaking’ in the inclusion criteria and ‘Non-English speaking’ in the exclusion criteria. Similarly, the process for screening subjects should only be described once in the study protocol. Repeating descriptions of study procedures across multiple sections of the study protocol (e.g., repeating screening procedures in the recruitment methods, consent process and study procedures section) can set study teams up for error when/if the repeated descriptions are not consistent.

- To aid in the screening process, as appropriate, create reference cards, ‘cheat sheets’ or flowcharts for study team members to quickly reference eligibility criterion and scripts for study teams to follow when verbally screening potential subjects.

- Ensure your study documentation demonstrates your compliance with the screening process described in the study protocol, confirms subject eligibility, and accurately identifies screening outcomes (e.g., withdrawal in the event a subject is found to be ineligible).

Administrative Study Closures

For all studies which have lapsed in approval in the Click IRB system the RSRB will begin implementing, immediately, a process that will restrict review for any new submission by the PI of the lapsed study. This means that new study submissions will not be reviewed by the RSRB until the lapsed study has been brought up to a state of compliance (i.e. either study closure through a CR or submission of CR to proceed with the study).
Updates, Reminders & Announcements

Independent IRBs: Who’s on Deck?
An independent Institutional Review Board (IRB) is an IRB that functions autonomously from (i.e., they are not affiliated with) a research organization or research institution. For many years, the only independent IRB the Research Subjects Review Board (RSRB) would defer to for the review of research (typically only for industry-sponsored research) was the Western IRB (WIRB). Over the past couple of years however, in response to the push for further use of single or central IRBs for the review of multi-site research and impending Common Rule revisions concerning cooperative research, the RSRB has expanded the number of reliance agreements in place with independent IRBs. The following independent IRBs may be utilized for the review of multi-site research (as requested by the study sponsor), for:

- Advarra (including Schulman, Quorum, and Chesapeake IRB)
- Western IRB

As a reminder, all submissions to IRBs other than the RSRB (i.e., external IRB submissions) are required to undergo administrative/institutional review by the RSRB any applicable Ancillary Committees prior to submission to the external IRB. Instructions for submitting external IRB studies in Click® IRB for RSRB review are available in the Click® IRB: Study Staff Manual. Questions concerning these submissions should be directed to the RSRB Reliance Coordinator.

OHSP Newsletter Index
Need help on a specific Research Subjects Review Board or research-related topic? Training a new study team member? Keep archived Office for Human Subject Protection (OHSP) Newsletters in mind. OHSP has been providing the University of Rochester research community information on salient research topics via the newsletter for over 5 years and while some of our processes/practices have changed over time, a considerable amount of content still applies. A searchable index of key newsletter articles, that continue to be pertinent, is available on the OHSP newsletter website. Examples of notable articles that were previously circulated include: The Ins and Outs of Re-consenting; Navigating HIPAA Compliance in Human Subject Research (Part 1 & Part 2); De-identified & Coded: One in the Same?; Top 10 Tips to Survive a FDA Audit; Note to Files: Not Always the Solution to the Problem; Tips for Closing a Study; Tabled Studies vs. Stipulations for Approval: Implications for the Study Team; Subject Recruitment Plans: Key Concepts for IRB Review; and Data & Safety Monitoring Plans: Considerations for Plan Development & Compliance.

Adding External Study Team Members in Click® IRB
Based on the nature of a specific study, it may be necessary for study teams to include members that are unaffiliated (or external) to the University of Rochester (i.e., the study team member is not a faculty member, staff or registered student). External study team members can be added to new and existing research in Click® IRB by uploading documentation of their human subject protection training (see the instructions provided in the Click® IRB: Study Staff Manual for how to do so). Note however that adding individuals in this manner does not provide them access to the study, meaning they will be unable to access study materials and/or have the ability to create submissions in Click® IRB; access to study materials must be provided via alternative mechanism, as appropriate per role, by the internal study team (e.g., shared folder on Box.com).

On the very rare occasion that external study team members require access to Click® IRB, the study team can sponsor a University of Rochester Guest Account for the external study team member. Generally, this access should only be necessary when the external study team member will be responsible for creating and/or editing submissions in Click® IRB; guest accounts should not be sponsored for external study team members for the sole purposes of adding individual to research and providing them access to study materials.
Study Start Up Consultations Gaining National Recognition

OHSP Quality Improvement (QI) has demonstrated that Study Start Up (SSU) consultations 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. The data demonstrate an average of 4.3 findings per review when an SSU occurred compared to an average of 5.1 findings per review when an SSU did not occur. Studies with an SSU had fewer findings in key areas related to subject safety, specifically consent-ing, data and safety monitoring, adverse event assessment, protocol compliance, and regulatory adherence. Since April 2015, OHSP-QI has conducted 236 Study Start Up consultations, approximately 4.4 per month.

For further details on this project, refer to our ‘Quality Improvement Study Start Up Consultations Improve Protocol Compliance’ poster.

OHSP-QI is gaining national attention regarding their success of the SSU Consultation Program. Data was presented at three conferences in the last year:

- In April 2019 at the international annual meeting of the Society of Quality Assurance (SOA) in Atlanta, GA
- In May 2019 at the national annual conference for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) in New Orleans, LA, and
- A poster presentation in November 2019 at the national Public Responsibility in Medicine and Research (PRIM&R) Advancing Ethical Research Conference in Boston, MA.

Study Start-Up Consultations are free and fully customizable to study team needs. Upon request, after receiving IRB approval and prior to enrolling subjects, the OHSP-QI staff is available to provide guidance on best practices and to evaluate study documentation. The primary goal of an SSU is to assist study teams in their ability to achieve compliance applicable to their specific study and to further protect subjects participating in research. Please contact OHSP-QI to schedule a study start-up consultation.

Contact Information

**Department Administration**
Kelley O’Donoghue, Director OHSP (585) 273-4631
Nicole Mason, Director RSRB (585) 273-4574

**Research Education & Training**
Kelly Unsworth, Director (585) 275-5244

**Clinical & Regulatory Systems**
Thai Nguyen, Director (585) 273-4583
James Wanzenried, Sr. Programmer (585) 273-4579

**Quality Improvement**
Kathleen Wessman, Director (585) 273-2118
Jennifer Dolan, QI Associate (585) 276-5709

**Administrative Staff**
Janice Taylor, Administrative Asst (585) 273-4127

**RSRB Board Specialists**
James Filingeri, Board 1 (585) 273-2117
Kathleen Buckwell, Sr. Specialist, Board 2 (585) 275-7446
Suzanne Coglitore, Board 3 (585) 276-4578
Michelle Giglio, Board 4 (585) 273-4576
Katherine Zanibbi, Board 5 (585) 276-3856
Kristin Dauenhauer, Reliance Specialist (585) 273-4577
Jamie Biear, Assistant Specialist (585) 276-5544

**Main Office**
Phone: (585) 273-4127
Fax: (585) 273-1174
Website
www.rochester.edu/ohsp

**OFFICE FOR HUMAN SUBJECT PROTECTION**
3RD QUARTER, 2019
<table>
<thead>
<tr>
<th>Research Milestone</th>
<th>Description</th>
</tr>
</thead>
</table>
| 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;  
  • 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 2. Common Study Status Scenarios and Applicable Research Milestones in Click® IRB

<table>
<thead>
<tr>
<th>Study Status Scenarios</th>
<th>Applicable Research Milestones in Click® IRB</th>
</tr>
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<tbody>
<tr>
<td><strong>Studies Involving Subject Engagement</strong></td>
<td><strong>Studies Involving Secondary Data Analysis, Chart Reviews &amp; Specimen Analysis</strong></td>
</tr>
<tr>
<td><strong>Scenario A:</strong> Study is open to enrollment, but no enrollment has occurred.</td>
<td><strong>Scenario A:</strong> The study has not been initiated, but will be initiated in the future.</td>
</tr>
<tr>
<td><strong>Scenario B:</strong> Subjects have enrolled but the accrual goal has not been reached. Enrolled subjects are actively participating in study procedures (some or all enrolled subjects may have completed or discontinued study participation).</td>
<td><strong>Scenario B:</strong> Subjects/specimens for inclusion in the research have been identified; additional subject/specimen identification for inclusion may occur. Data collection or laboratory analysis on specimens may have begun but is not complete.</td>
</tr>
<tr>
<td><strong>Scenario C:</strong> Enrollment is complete for one, but not for all cohorts. Enrollment in open cohort(s) continues; enrolled subjects are actively participating in study procedures (some or all enrolled subjects may have completed or discontinued study participation).</td>
<td>N/A</td>
</tr>
<tr>
<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>N/A</td>
</tr>
<tr>
<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><strong>Scenario C:</strong> All subjects/specimens for inclusion in the research have been identified; no additional subjects will be identified. Data collection or laboratory analysis on specimens has begun but is not complete.</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; • Study remains active only for long-term follow-up of subjects</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>N/A</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; • All subjects have completed all study-related interventions OR not applicable</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. 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; • All subjects have completed all study-related interventions OR not applicable • Collection of private identifiable information is complete OR not applicable • Remaining study activities are limited to data analysis</td>
</tr>
</tbody>
</table>

### Table Notes:
- **N/A:** Not applicable

### Table Legend:
- *This will close the study.*