Navigating HIPAA Compliance in Human Subject Research (Part 2)

The Health Insurance Portability and Accountability Act (HIPAA) aims to safeguard health information and includes provisions under which a covered entity may use or disclose protected health information (PHI) for research purposes. To fulfill the requirements set forth in this act, the Department of Health and Human Service (HHS) constructed the HIPAA Privacy Rule and the HIPAA Security Rule (45 CFR 160 & 45 CFR 164).

Last quarter, the Office for Human Subject Protection Newsletter reviewed requirements and best practices primarily concerning the Privacy Rule, which focuses on how PHI is utilized. This quarter, we’ll focus on the requirements set forth in the Security Rule, which focuses on how electronic PHI (e-PHI) is safeguarded.

**HIPAA Security Rule Basics**

Generally, the Security Rule requires covered entities to:

1) Ensure the confidentiality, integrity and availability of all e-PHI that is created, received, maintained or transmitted by the covered entity;

2) Protect against reasonably anticipated threats to the security or integrity of e-PHI;

3) Protect against any reasonably anticipated unauthorized use or disclosure of e-PHI; and

4) Ensure covered entity workforce compliance with the ruling.

The Security Rule further defines several administrative, technical and physical safeguard standards that covered entities must meet, yet the ruling also recognizes the changing landscape of advancing technologies and the range in size, structure and applicability of the ruling to various covered entities. The ruling therefore provides covered entities flexibility in how these standards are implemented. The additional standards, in summary, include:

- Designating a security official for the covered entity;
- Implementing policies and procedures concerning risk analysis and management, sanctions for non-compliance, system activity review, e-PHI access controls, facility access controls, workstation security, device and electronic media security and controls, audit controls, e-PHI transmission security, e-PHI integrity protections, and incident reporting and management; and
- Workforce oversight and training (including security awareness and reminders, protection from malicious software, log-in (continued on page 2)

**What is PHI?**

PHI is defined as any individually identifiable information that is created or received by a health care provider that relates to: a) the past, present or future physical or mental health or condition of an individual; b) provision of health care to an individual; or c) the past, present or future payment for the provision of health care to an individual.
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(continued from page 1) monitoring, and password management).

The University of Rochester Medical Center (URMC) and Affiliates’ Information Security Policies incorporates these standards, as well as other healthcare-focused security standards and best practices (e.g., 21 CFR 11, JCAHO, etc.).

So, what do I need to do to comply?

Typically, when study teams consider how they’ll safeguard their research data (including any e-PHI) they primarily consider who will have access to the data and where that data will be stored. It’s important to recognize however, that because of the nature of the risks related to e-PHI, safeguarding e-PHI extends much further beyond these two factors; your ability to safeguard e-PHI depends on appropriate day-to-day use of electronic media, both at work and during your personal time.

Key day-to-day expectations and best practices related to the protection of e-PHI, defined in the URMC and Affiliates Information Security Policies, include:

- Keep all information system passwords confidential; DO NOT share passwords.
- Access only job-related information; DO NOT view/alter family member, friend, or acquaintance information.
- Log off or lock (via screen saver password) unattended workstations/computers.
- Encrypt all mobile/portable devices including smartphones, tablets, laptops, digital recorders and flash drives.
- Only store e-PHI via encrypted portable media/laptop/computer, network drive or approved cloud storage (note that Box.com and Microsoft OneDrive are the only approved cloud storage platforms).
- Present research findings in a de-identified format; beware of data.

What is a ‘Covered Entity’?

A covered entity is defined as a health plan, a health care clearinghouse, or a health care provider who transmits any health information in electronic form in connection with a standard transaction. The University of Rochester Medical Center (URMC) & Affiliates covered entity includes over 22 local healthcare facilities/entities (for a full list see the URMC & Affiliates Notice of Privacy Practices). Individuals working in any of the facilities/entities that are part of the URMC & Affiliates covered entity are considered part of the covered entity, regardless of whether they provide direct clinical care to patients (e.g., all individuals working at Eastman Dental, irrespective of their role, are part of the covered entity).

HIPAA requirements only apply to research conducted under a covered entity (e.g., URMC, Highland Hospital, Mt. Hope Family Center, etc.). When all study team members are part of the covered entity, HIPAA compliance is required. Conversely, if no members of the study team are affiliated with the covered entity then HIPAA requirements do not apply to the research. If, however, the study team is comprised of both members of the covered entity and members who are not part of the covered entity (e.g., River Campus faculty or staff), the entire study team must comply with HIPAA when PHI is collected as part of the research.
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(continued from page 2) that is not categorized as ‘identifiable’ but may, in combination with other data, become identifiable.

- Inventory (all assets) to ensure proper tracking/updates (e.g., desktop computers, laptops, tablets, software, smart phones, etc.).
- Dispose of broken or unwanted electronic media/devices via the University’s Equipment Recovery Program to ensure retained PHI is rendered unusable, unreadable and undecipherable.
- Beware of phishing! Avoid opening unrecognizable or questionable links/attachments in emails and surfing to unknown websites.
- Only communicate with subjects via e-mail after have provided explicit consent to e-mail communications (see the OHSP 2017 Q1 Newsletter); encrypt all e-mails containing e-PHI.
- DO NOT send PHI via text message; text messaging is not a secure method of communicating with subjects and is generally not permitted.
- DO NOT share PHI on social media.
- Report suspected security incidents to your HIPAA security official.

In addition, if PHI is going to be shared outside of URMC as part of a research study, a security questionnaire should be completed by the recipient organization, and a data transfer agreement may be required.

Additional Resources
- URMC & Affiliates HIPAA Security FAQs
- HHS HIPAA for Professionals: Summary of the HIPAA Security Rule

Tips for Closing a Study

You’ve collected all the necessary data and performed the primary data analysis, it may be time to close the study… Now what? Here are a few tips to help you ‘dot all the I’s and cross all the T’s’:

When should I close a study?

A completed progress report updates the IRB on the conduct and outcomes of the study and indicates that the study was completed as planned in the study protocol; meaning, interventions, data collection, data analysis, and other activities as described in the protocol are complete. If the primary analysis of the study is complete, but the Investigator continues to conduct additional analysis, the study can be closed if identifiers are removed from the active analysis database and stored in a separate location. A study progress report can be submitted at any time; study staff do not need to wait for a continuing review or the end of the study approval period to submit a progress report to close the study.

If any of the following six conditions apply, do not file a progress report to close the study. Such studies must remain active and continue to receive ongoing IRB review and approval:

1) Enrollment continues, or
2) Research-related interventions and/or (continued on page 4)
Tips for Closing a Study

(continued from page 3) follow-up is being conducted, or
3) Subject follow-up is ongoing, or
4) Biological specimens containing personally identifiable information are being maintained in a repository that has been approved as part of this study or upon which further analysis or research is planned, or
5) Data analysis or manuscript preparation involves the use or access to personally identifiable information, or
6) If there is an external study sponsor and the sponsor has not provided permission to close the study with the IRB.

Don’t close a project too early. Once a Study Progress Report is processed to close a study, no further research related activity can occur; no additional data (either identifiable or coded/linked) may be collected. Contact with subjects for research purposes is no longer permitted.

When a study ends, is closed, canceled for any reason, or prematurely ends, you must complete a progress report in the RSRB On-line Submission System (ROSS) which serves as notification that IRB continuing review of the study is no longer needed.

How to Submit a Closure Form in ROSS?

- Initiate a Continuing Review form.
- Note ‘no’ when asked if you wish for the study to remain open.
- Select status (Completed, Study closed before completion, Study has not been/will not be conducted).
- Enter date completed and supply a reason if selecting ‘Study closed before completion’ or ‘Study has not been/will not be conducted’.
- Complete enrollment, demographic information, study staff, and subject concerns or withdrawals.
- Enter study findings and risk/benefit assessment.

Reminders

- If the Investigator is serving as the lead investigator or the University of Rochester is the coordinating center, the study must remain open as long as the coordinating center is still receiving, studying, using, or analyzing identifiable private information from other sites (even if local interventions, interactions, observations, and data gathering is complete).
- Principal Investigators who are departing the UR are expected to close or transfer their projects to a new PI prior to leaving the university.
- Principal Investigators of student projects should ensure students submit a Study Progress Report prior to graduation/leaving the university.

Record Retention

Data from the completed study should be stored and protected in the manner approved by the IRB and consented to by the research subject to maintain the privacy and confidentiality of the subjects. Whenever possible, the data should be permanently de-identified.

Also, at a minimum, per federal regulations (45 CFR 46.115(b) and 21 CFR 56.115(b)), investigators must maintain research records for three years beyond the completion/termination of the study. Investigators should be aware that other laws and requirements (e.g., funding agency) may require a longer record retention period.

Serious Adverse Events or Unanticipated Problems Learned After Study Closure

(RSRB Policy 901, Section 8.10 and RSRB Policy 801)

The Principal Investigator must report to the IRB any information learned after study closure that could affect subject safety or care, including, but not limited to serious adverse events or unanticipated problems reported by the Sponsor or others responsible for study monitoring.

Footnotes:

i  http://ora.research.ucla.edu/OHRPP/Documents/Policy/11/Study_Closure.pdf

ii  https://hso.research.uiowa.edu/closing-study
When you hear the words ‘subject education’, what comes to mind? The most obvious answer is the consent process. Informed consent is an important, necessary step in the research process that involves informing subjects about the details of their potential participation in a study and ensuring they understand the information provided. How well subjects are informed about those details and how much of that information the potential subject understands can affect whether the subject ultimately decides to enroll in the research.

Subject education can also have a much broader effect on critical factors related to the success of the research, beyond just the informed consent process. Harper and Neurer (2009) identify education as a factor of successful recruitment and retention. Potential subjects may become aware of opportunities to participate in research but if they’re unaware of what study participation typically involves or what mechanisms are in place to protect them, they may not be inclined to pursue the opportunity. Similarly, if subjects don’t have a clear understanding of what their participation will entail they may be more inclined to withdraw or drop out early.

More broadly speaking, subject education can also affect the quality of the data collected. Ultimately, you want a dataset that is as complete and accurate as possible. This is affected not only by your ability to retain subjects but also enhance the subject’s ability to complete study procedures. Consider, for example, a survey with vague, unclear instructions, a confusing study visit schedule, or miscommunications concerning expectations or on a specific study task – these factors can skew your data.

Its best practice to think through where supplemental subject education can be provided during the protocol development phase of the research. Harper and Neurer (2009) identify the following to consider:

- “Who needs to be educated about which aspects of the study (e.g., the subject, family member, parent, caregiver, treating physician)?
- What tools or materials are needed to supplement the informed consent document?
- What training is needed for site personnel? For subjects and families? For influencers?
- What are the most effective means of training these individuals?
- What questions will subjects have about the study?
- How well are site personnel positioned to respond to participant questions?”

Supplemental subject educational materials often come in the form of brochures, instruction or information sheets, newsletters, blogs, infographics or short videos. The content of these materials may be study-specific or, in some cases, it may be broader, including general information on research participation, the disease or condition under study, or how to find the study site.

General education materials that are readily available for study team use are accessible via the University’s Office for Human Subject Protection and Clinical & Translational Science Institute as well as the Department of Health and Human Services, the Center for Information & Study on Clinical Research Participation, CenterWatch and the National Institutes of Health.

Note that prior to use, all subject education material must be reviewed and approved by an Institutional Review Board.

OHSP Education & Training Framework Opportunities

The Office for Human Subject Protection’s Division of Research Education & Training continues to work toward enhancing the number of training opportunities that study team members can complete online. A summary of online training opportunities, available for study team members to complete at their convenience and based on their needs and/or role, is available below. Additional details pertaining to these opportunities is available on OHSP’s Division of Research Education & Training website. Note that training currently available in MyPath will eventually transition to Blackboard to facilitate training access to all research personnel. Questions? Contact Kelly Unsworth.

<table>
<thead>
<tr>
<th>Training</th>
<th>Description</th>
<th>Learning Platform</th>
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<tr>
<td>Orientation to Conducting Human Subject Research</td>
<td>Introduces basic University of Rochester (UR) policies and required review processes concerning human subject research. Highlights resources available at the UR for designing and implementing study protocols.</td>
<td>MyPath</td>
</tr>
<tr>
<td>Research Boot Camp</td>
<td>Applies the basic human subject protections introduced via CITI training and the Orientation course above to conducting research at the UR. Includes training videos on basic protocol development, IRB review processes, informed consent and post-approval considerations.</td>
<td>MyPath &amp; Blackboard</td>
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<tr>
<td>Core Training</td>
<td>Distinct learning modules aimed at cultivating an advanced understanding of major responsibilities related to conducting human subject research: Study Design, Principal Investigator Oversight, Study Operations, Recruitment &amp; Retention. <strong>Additional modules coming to Blackboard later in 2018</strong></td>
<td>MyPath, MyPath, Blackboard</td>
</tr>
<tr>
<td></td>
<td>Informed Consent, Investigational Products, Subject Safety, Essential Documentation, Quality Management &amp; Non-Compliance</td>
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Research Modernization Project Update

As part of the ongoing Research Modernization Project, the Office for Human Subject Protection has been working very hard over the last 3 months with Huron to document software requirements and to prepare the test site for the UR’s new IRB review software (as a reminder, an overview of the project is available in OHSP’s Q2 Newsletter).

A primary aspect of preparing for the new software is to determine what data will be moved from the current ROSS system to the new system. Number #1 on the list is the users and research personnel. **When we move research personnel over, we will exclude those individuals whose human subjects training has expired more than 6 months ago.** Therefore, we are asking all research teams to take extra effort in the coming months to evaluate the list of research personnel on their active non-exempt research studies, specifically to ensure the list is current. Please contact individuals who have expired and let them know that they need to update their CITI training to remain on the study, and remove those individuals no longer working on the study via an amendment to study personnel. Performing these activities will help to ensure that “clean” data is transferred into the new IRB review system. If you have any questions concerning this, please contact your Specialist.
Research QI ‘Gold’

The QI division is recognizing Hyekyun Rhee, PhD and Annette Grape, PhD for their quality work on the PLASMA (Peer-led Asthma Self-Management Program for Adolescents): A Multi-site Project study.

The study team has a detailed, multi-focal Quality Management Plan in place which demonstrated excellent quality improvement and assurance activities, served a challenging subject base in several states, demonstrated attention to regulatory compliance/protocol adherence, had exceptional subject recruitment/retention practices, and conducted excellent research with high quality, organized study-related documentation. This energetic study team is based in the School of Nursing.

Congratulations!

Common Rule Requirements

The U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies have issued a Final Rule to delay for an additional 6 months the general compliance date for changes recently made to the revised Federal Policy for the Protection of Human Subjects (AKA the Common Rule). All but three of the final provisions go into effect in January 21, 2019. The following three burden-reducing provisions are optional until January 2019:

1) The revised definition of “research,” which deems certain activities not to be research;
2) The allowance for no annual continuing review of certain categories of research; and
3) The elimination of the requirement that institutional review boards review grant applications or other funding proposals related to the research.

The UR will not adopt the three provisions early due to the implementation of the new IRB review system currently underway.

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