While coding and de-identifying are both methods for protecting the confidentiality of research data/specimens, they are two distinctly different processes. Each has implications during the course of IRB review and the lifecycle of a study.

“De-identified” means the data/specimen cannot be related or attributed to a specific individual, either directly or indirectly, which means there is no reason to believe the data/specimen could be used to identify an individual. As the federal regulations do not specifically define data elements that could be used to identify subjects, IRBs routinely defer to the 18 identifiers listed in the Health Insurance Portability & Accountability Act (HIPAA), regardless of whether the research contains health information or is conducted within a covered entity.

“Coded” means the information that might readily identify a subject has been replaced with a number, letter, symbol or combination thereof (i.e., a code) and there is a key linking the code to the subject’s identifiable information. Therefore, the data/specimens could be directly linked back to the individual.

When is Coded Data Considered De-Identified?

Guidance on Research Involving Coded Private Information or Biological Specimens from the Office for Human Research Protections (OHRP) indicates OHRP considers coded data/specimens to be identifiable. The only exception to this is when: 1) data/specimens were originally collected for a purpose other than the current project; AND 2) members of the study team do not have access to the key linking subject codes with identifiable information.

Implications for IRB Review of Secondary Use of Data– Initial Review

Research involving the use of data/specimens collected for some other purpose, or secondary use of data/specimens, may be deemed not human subject research or reviewed as exempt or expedited, depending on how identifiers are accessed and collected. For example, research involving the secondary use of a dataset, would be:

- Deemed not human subjects, if the data was (or will be) collected by someone who is not part of the study team and the current study team has no access to links or identifiers;
- Exempt, if the data is pre-existing at the time of the IRB submission, and the data is recorded for the purposes of the current research without identifiers (i.e. the study team may have access to identifiers but does not record any identifiers in the research dataset);
- Expedited, if the project involves recording links or identifiers as part of the proposed research (e.g., utilizing a medical record number to link data from two separate sources)

IRB Submission Tip #1:
Don’t try to fit a square peg into a round hole! Your decision to collect or record identifiers should not be based on IRB review level, but rather what you need to conduct to your research.

(Continued on page 2)
De-Identified & Coding (Continued)

Implications for IRB Review - Confidentiality of Data

All research projects evaluated against the criteria for approval defined in 45 CFR 46.111 (i.e., research that undergoes expedited or full board review), must include adequate provisions for maintaining the confidentiality of data. Typically, at a minimum, the IRB would want to ensure that the data collected during the research is coded and stored in a secure manner in order to meet this criterion.

Study teams wishing to de-identify data/specimen to provide further protection are encouraged to do so, as long as this method is appropriate given the nature of the research (i.e., there is no intention to collect additional prospective data/specimen from any given subject that would need to be linked back to the original data/specimen provided).

IRB Submission Tip #2:
Pay close attention to the terminology used in your study protocol and IRB application! “De-identified” and “coded” are often used interchangeably even though they are not one in the same. Inadvertently using the wrong term could ultimately result in compliance problems.

Implications for IRB Review - Study Closure

Per OHSP Policy 502, a study is considered complete when subjects are no longer being recruited (or data/specimens being collected), subjects are no longer being followed, the primary data analysis is complete according to the protocol, and identifiers are removed from the analysis dataset. For closure purposes, identifiers within the dataset can either be destroyed or the dataset can be coded with the code maintained in a separate location.

IRB Submission Tip #3:
Do I need to keep the RSRB application open in order to continue analyzing data? As long as the primary data analysis according to the study protocol is complete, you can close the study and continue analysis, provided the dataset you continue to work with is coded or de-identified.

Save the Date! Upcoming Educational Opportunities

OHSP Research Education & Training Framework:
(The training opportunities identified below are described in further detail here)

Research Boot Camp
Wednesday, October 21st, 8:00am-12:00pm
Medical Center Room 2-7544
To register, please email Kelly Unsworth

Core Training
Core Training will resume in January 2016.

Achieving High Quality Clinical Research Seminar Series
October 27: Not Just Another Acronym: What the NPRM Could Mean for You
November 17th: Multi-Center Research
All seminars are held from 12:00-1:00pm in Helen Wood Hall Auditorium (1W-304).

Not Able to Attend? Miss a Previous Seminar?
Live streaming of seminars is typically available through the CTSI. Presentation materials and videos of previously recorded seminars are also available on the OHSP and CTSI Websites.
Top 10 Tips to Survive a FDA Audit

You were just notified that the Food and Drug Administration (FDA) will be inspecting your study. How should you prepare? First things, first: take a deep breath! While the thought of an inspection can be overwhelming, there are several steps you can take to prepare and ease the anxiety:

1) Don’t panic! You know the study well and work on it every day.

2) Ensure you have all of the information you need—Who is conducting the inspection? What is their contact information? When does the Inspector plan to be on-site? Which studies will be inspected? Who should be available during the inspection for interview? What type of inspection will be conducted? What specific documents need to be available? (Review the Bioresearch Monitoring Program on the FDA website.)

3) FDA inspections can be announced or unannounced. Announced inspections are study-directed and typically occur at a high enrolling/high participation site after an application is submitted for marketing approval. Unannounced inspections are usually in response to complaints or to investigate possible regulatory violations.

4) Notify the study sponsor, the study monitor, all study staff, and ancillary staff (e.g. pharmacy, clinical research center). Consider contacting the OHSP-QI team for a site assessment/readiness review – another set of eyes is often valuable!

5) Re-familiarize yourself (and your study team) with the study protocol, investigational product, recruitment and informed consent process, and significant research events.

6) Keep study documentation up to date and organize your essential documents for review. Ensure you have all versions of the study protocol and consent forms, IRB approvals and communications, the Investigator’s Brochure(s), evidence of study team training and experience (i.e., CVs, licenses, human subjects and protocol-specific training), financial disclosure forms, delegation log, screening and enrollment log(s), source documentation, investigational product accountability logs, adverse event documentation, etc. Use a checklist if needed to ensure all documents are available and have Standard Operating Procedures available for review, if applicable. Label, label, label – lead the inspector to what they need to find in the study documentation.

7) The Inspector(s) will need a quiet, uninterrupted space with access to all study-specific regulatory files including lab manual(s), investigational product files, and all subject research charts (including screen failures). When reserving the space for the inspectors, consider the location and what they might be able to overhear in the vicinity. Consider reserving a separate work space for associated study staff to prepare and store documents needed for the audit.

8) Plan to meet the Inspector(s) in a central location and escort them to their work space. When the Inspector(s) arrive, they will present their identification badge and a Form 482 (Notice of Inspection). Study staff will then be briefed on the anticipated daily schedule.

9) The Investigator should set aside time each day to talk with the Inspector(s) to review findings. Answer questions as simply as possible. (continued on page 4)
Top 10 Tips (Continued)

(continued from page 3) State only the facts: be concise, direct, and to the point. Listen actively and ask for clarifications; comply with requests. If the Inspector(s) requests copies of documents, make two copies so a file can be made for your own reference. Make corrections immediately whenever possible. Remember: the FDA can look at and review anything. It is okay ‘not to know’ and need to review documents, get back to the reviewer, or refer them to the appropriate individual. Take notes on the questions asked for future reference. The FDA may issue a Form 483 (Inspection Observations), if indicated.

10) An FDA Audit Reminder Card template is available in the OHSP-QI’s Study Documentation Toolbox (see the Documentation/Note to File Samples section). Keep one posted by your phone for quick reference. An FDA Audit Preparation Resources Checklist can also be found here.

Food for Thought

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

- Scientists Who Cheat (Editorial. [2015, June 1]. The New York Times.)
- Serious Risks About Existing Drugs Aren’t Given to Trial Participants (Silverman, E. [2015, July 29]. The Wall Street Journal.)
- Registered Clinical Trials Make Positive Findings Vanish (Woolston, C. [2015, August 13]. Nature.)
- Nine Explanations for Why The FDA is Approving Almost Every New Drug Application (Herper, M. [2015, August 25]. Forbes.)

Research QI ‘Gold Star’ Award

The QI division would like to recognize Loisa Bennetto PhD, Laura Soskey, and Paul Allen for their quality work on the ‘Auditory Attention and Localization in Children with Autism Spectrum Disorders’ trial. This dynamic study team is part of the Department of Clinical and Social Sciences in Psychology.

They received the OHSP-QI ‘Gold Star’ award for their attention to regulatory compliance/protocol adherence, demonstrating great respect for the subjects and their families, and stellar Investigator oversight.

Congratulations!
Did You Know...

- RSRB Board 01 has a new Regulatory Specialist! OHSP is pleased to welcome Randall Buermann, MPH, CRA to our staff as Regulatory Specialist for RSRB Board 01. Effectively immediately, Linda Palm-Montalbano, RN, CIP, will transfer to RSRB Board 03. Not sure who your specialist is? See OHSP’s Who’s My Specialist webpage.

- Faculty Advisors and/or Dissertation Chairs listed as the Principal Investigator (PI) on a RSRB application for study projects (including projects that might be conducted at unaffiliated sites and international studies) are **required** to oversee the conduct of all research activities, including the training and education of **ALL** research staff. Although the PI may delegate responsibilities, as appropriate, he or she must maintain oversight responsibilities. For additional guidance on PI responsibilities, please refer to OHSP Policy 901 and the associated Summary of Responsibilities for: Exempt Research, Non FDA-Regulated Research, and FDA-Regulated Research.

- As part of the University of Rochester’s Human Research Protection Program (UR-HRPP) re-accreditation process, site visitors were on-campus September 30th – October 2nd. During this time, members of the UR-HRPP, including senior leadership, key personnel from offices who oversee the conduct of research, board members, principal investigators and study coordinators were interviewed to ensure everyday practice within the UR-HRPP is consistent with our policies and guidelines. **Many thanks to those who participated in the interview process!**

Frequently Asked Questions

**I’m not sure what “IRB of Record” means in Section 95 of the ROSS application. How do I fill this section out?**

“IRB of Record” refers to the Institutional Review Board (IRB), RSRB or WIRB for example, that will be responsible for both the initial and ongoing approval of a research study. Most research conducted at the University is reviewed and approved by the RSRB. When researchers are requesting the RSRB be the IRB of Record, Section 95 of the RSRB Online Submission System (ROSS) application (“Is this study being submitted for review by the RSRB as the IRB of Record?”) should be answered “Yes.”

In some circumstances, studies may be reviewed and approved externally by an Institutional Review Board (e.g., WIRB). While the RSRB will conduct an administrative/institutional review of this research to ensure institutional policies are followed, initial and ongoing approval will ultimately be determined by the designated external IRB (i.e., the IRB of Record). Note that studies can **only** be reviewed externally with approval from the Office for Human Subject Protection (OHSP). This requires an IRB Reliance Agreement or IRB Authorization Agreement (See OHSP Policy 504 RSRB Reliance for Review). Therefore, Section 95 of the ROSS *(continued on page 6)*
Frequently Asked Questions (Continued)

(continued from page 5) application should only be answered “No” when one of these agreements exists and the designated external IRB is listed in the drop down list. Study teams wishing to submit studies to an external IRB other than WIRB, must contact the RSRB office prior to submission for consideration (an IRB Reliance Agreement with WIRB is pre-existing).

I've completed an application for a new study but there's no option/link to submit it to the RSRB. What am I missing?

New applications can only be submitted by Principal Investigators (PI). Study Coordinators, Co- or Sub-Investigators will not have the option to submit a brand new application but will be able to “Request Application Signoff”. Selecting this option in the ROSS will send an e-mail notification to the PI notifying him or her that the application is ready for their sign-off and submission.

If a PI is missing the option to “Submit Application” on the study’s homepage, verify whether you’ve indicated that the application is complete. This can be verified within the application by navigating to the “Application QA” page from the drop down menu. The question “Is this application completely filled out?” must be answered “Yes” in order for the PI to sign-off on the application.

I've made changes to a new application in response to board review. Does the PI need to submit these or can the study coordinator do this?

All new applications and continuing reviews must be submitted by the Principal Investigator. If clarifications or changes are requested after initial review by the RSRB, study team members with appropriate ROSS access (e.g., a co-investigator or study coordinator) may submit these changes directly to the RSRB; submission by the PI is not required.