HUMAN SUBJECTS RESEARCH NEWSLETTER
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Health Information Portability and Accountability Act HIPAA

Follow up to Non-Federal Exempt 7 Category

In April 2015, we rolled out a new exemption category "Non-Federal Exemption 7" for "research collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, where this information is personally identifiable or coded." This new category was developed as part of a national flexibility initiative to streamline chart review projects that included directly identifiable or coded data.

The HIPAA regulations that govern how protected health information (PHI) is obtained and used for research purposes are very specific. The criteria for a Waiver of Authorization has to be fully documented and approved through the IRB expedited review process. The current review conducted for the Non-Federal Exemption #7 research projects does not meet HIPAA requirements, so we need to make some adjustments to this process.

Going forward, projects that require identifiable or coded PHI can no longer apply for exempt review. The IRB is currently working with the Integrity and Compliance Department at the University of Vermont Medical Center (UVM Medical Center) to create a new standardized form for chart review projects requiring identifiers or codes that satisfies HIPAA requirements. There will be a special notice when that is available, along with instructions.

During the interim, for any data extracted from the medical record, you must submit the Common Protocol Cover form, Human Subjects Protocol form, and the Request for Waiver of Consent/HIPAA/Documentation form for an expedited review.

Changes to the Protocol Exemption Review and Determination form

This form has been revised to help direct researchers to submit for the appropriate review type. We have not completely removed the exempt 7 category as it does apply to data collection projects when there is no PHI, such as review of student records.

Changes to the Request for Waiver of Consent/HIPAA/Documentation form

We have updated the form to include additional elements required by HIPAA regulations. Please download the revised form from our forms page.

Changes to the Written HIPAA Authorization template

The Integrity and Compliance Department at UVM Medical Center has conducted a review of the HIPAA Authorization template and expanded the list of people/entities of where data could potentially be shared. Any new protocols going forward must include the new template. It may be tailored to specific research projects as appropriate.

Research Manual Changes

Summary of Major Changes Since 07/15 Version

Manual Sections

5. Training Requirements

Note: PIs and Faculty Sponsors, if applicable, that are listed on protocols that are deemed to be Exempt or Not Human Subjects are required to take the training, but other listed key personnel are not required to take the training.

8.A.1.j. Human Subject Protections

Compensation Guidance when Minors are Involved (New)

8.B. Legally Effective and Prospectively Obtained Informed Consent and Documentation of Consent (Update)

2. Children in State Custody (Wards of State) The following has been added to this section "If a child has begun research procedures with the consent of a parent but is subsequently placed in the custody of DCF while undergoing research interventions, consent must be sought again from the appointed advocate for the child at DCF in order to continue participation in the research." HIPAA has been updated throughout this section.

8.B.1.b. Children Reaching Legal Age of Consent While Enrolled in a Study Policy (clarification)

The IRB developed a sample consent form for "Continued Participation in a Research Study" that should be used when consenting the now-adult subjects. Since this document was created by the IRB, it does not require the IRB approval stamp. However, if you wish to change the contents, an amendment would be required prior to use.

8.B.3. Informed Consent Process for Non-English Speaking Individuals (replaced)

This entire section has been revised.

Appendices

O. Guidance on Research Data Management in Human Subjects Research (revised)

Provided definition of sensitive data and clarified the protections necessary when moving data via email or external devices.