U-MIC TRANSCRIPT
Secondary Use Applications

The purpose of this presentation is to examine what secondary use is as it relates to human subjects research and when the secondary use application type in eResearch is applicable.

There are three objectives:

- Identify and define secondary use,
- Review when secondary use of data, records, or specimens requires IRB review and approval and
- Finally to understand the applicability of and procedure for using the Secondary Use application in eResearch.

What is secondary use?

- Secondary use is the analysis of existing data, records, or specimens which were originally collected for another purpose; that original purpose could be another research study or for clinical care.
- Existing means that the data must "be on the shelf" at the time the current research is proposed.

The application type you submit to the IRB for the review and approval of a secondary use research project will depend on the nature of the research. There are 3 eResearch application types that apply to the secondary use of existing data, records or specimens:

- Exempt Human Subjects Research
- Activities Not Regulated as Human Subjects Research and
- The Secondary Use of existing data, records, or specimens that contains identifiable information.

Exempt Research means the project:

- Meets the regulatory definition of research involving human as defined by OHRP and FDA and
- Meets one or more of the 6 federally recognized exemption categories.
- An example of exempt secondary use research is a retrospective chart review if the information is publically available or recorded by the investigator in a way where subjects cannot be identified. This type of research meets exemption category 4.
- Note, however, that HIPAA regulations may apply.

Exempt Research has its own application type in eResearch section 1-1.1, "Exempt Human Subject Research". The IRB must verify the exemption BEFORE the secondary use research can begin.

Activities Not Regulated as Human Subjects Research means that the project does not:

- Meet the regulatory definition of research, AND/OR
- Involve human subjects

Often, there is no IRB requirement for the submission of a not regulated activity, but IRBMED can issue a formal not regulated determination for study team convenience; this may be a requirement for publication in some journals. For a formal determination, use the "Activities Not Regulated As Human Subjects' Research" application type in eResearch.

Examples of secondary use research that are not regulated activities include:

- Research where all of the data is public, meaning data is from public use data sets. For Example, US census data or data from the National Center for Educational Statistics
- Research using coded biological specimens or coded private information if the specimens or data were not collected for the proposed study, the investigators cannot readily ascertain the identities of the individuals from whom the specimens were obtained either directly or through a coding system, and the investigator is not a researcher or collaborator on the specimen and/or data provider's research.
- HIPAA regulations may still apply.

To use the "Secondary Use of Existing Identifiable Data/Records/Specimens" application type in eResearch:

- The research must be purely retrospective,
- The data, records, or specimens must exist at the time the research is proposed, and
- The data and/or specimens must be identifiable.

This is the only scenario in which this application type should be used.

To complete a secondary use of existing identifiable data/records/specimens application type in eResearch:

- from your home workspace
- select "Create New Study"

Once a new application is started, complete the standard study information, including:

- Study title
- Study team members and
- A summary of the project.
- When choosing an application type in question 1-1.1, select the "Secondary Use of Existing Identifiable Data/Records/Specimens" and the eResearch smart form logic will route you through all of the required sections of secondary use application.

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In section 3, indicate what analysis functions that will be performed at U-M. For secondary use studies using identifiable data this will typically be secondary data collection, primary or secondary analysis, and storage. Typically "coordinating center" is not an applicable selection because secondary use studies are not usually part of a multi-site research projects.

Informed consent is required in order to use data or specimens obtained from an individual for research purposes. However, obtaining informed consent can be difficult when conducting secondary use research because there isn't any interaction or intervention with the subject.

Therefore, it is appropriate to request a waiver of informed consent in section 10.3 of the application, indicating that the request is for a waiver of informed consent for all of the project in 10-3.

Complete section 10-3.2, affirming that the request for a waiver of informed consent appropriately meets the regulatory criteria. A waiver of informed consent can only be granted if: the research involves no more than minimal risk to the subjects, the waiver or alteration will not adversely affect the rights and welfare of the subjects, the research could not practicably be carried out without the waiver or alteration and whenever appropriate the subjects will be provided with additional pertinent information. A secondary use research project generally meets all four of these regulatory criteria.

Section 11 contains questions regarding the confidentiality, security, and privacy of the research to be conducted.

- Answer question 11.1 regarding access to identifiable data; answer "yes" that the study team will have access to data that is linked to a subject's identity by name or other identifier or code since you are completing this application based on the fact that you are using previously collected data/specimens that contain IDENTIFIABLE information.
- Complete the remaining questions to clarify how subject's privacy and confidentiality will be protected. In question 11.3 only select the security measures that the study team is able to utilize; IRBMED expects that whatever security measures are selected in 11.3 are being followed. Note, that IRBMED encourages study teams to encrypt identifying/sensitive information if it will be electronically accessed and stored; especially if the data will be stored on portable devices.
- Question 11-1 asks about the data set you will be creating for your secondary use research project. Complete 11-1 indicating: how the data identifies the subject, how long identifiers will be retained, how data will be stored, and who has access to the data.
- Typically the dataset you create will indirectly identify the patient/subject.

In Section 24 identify the source of the data you are using to perform your secondary use research.

- The IRB commonly reviews secondary use studies where the existing data is being collected from MiChart or CareWeb.

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- Note, question 24.3 asks what identifiers are contained in the source data set and not the specific data you are collecting for your research project. The data you are collecting will be included on your data collection sheet which you will upload in section 44 of the application.

When a waiver of informed consent is requested a corresponding HIPAA waiver should also be requested if you are using or disclosing protected health information for research purposes. Thus, you will need to complete section 25 of the application regarding PHI and HIPAA.

- Complete questions 25-1.1 indicating what PHI will be used as part of the research and
- Complete 25-1.2, explaining why the PHI is the minimum necessary to conduct the research.

Complete questions 25-1.3 and 25-1.3.2, requesting a waiver of HIPAA Authorization.

- Specifically, in 25-1.3 select "HIPAA Authorization will not be obtained from any subjects" for the same reason informed consent will not be obtained from subjects.
- In 25-1.3.2, indicate that you are requesting a full waiver of HIPAA authorization. The other options are only selected when HIPAA authorization is not required from subjects.
- And in section 25-2.1, request a waiver of HIPAA authorization for the entire project and
- Complete 25-2, affirming that the waiver is appropriate, once again stating that the regulatory criteria necessary for the IRB to grant a waiver of HIPAA Authorization have been met.

If you have any questions regarding secondary use research please contact IRBMED.

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