eRESEARCH | REGULATORY MANAGEMENT

Edit: Application -

Save Exit Hide/Show Errors Print Jump To Continue

Note *(0 Notes Total)* Previous Next

01-1.2 Scope of Secondary Use Research

Completion of this section is required based on the response provided to question 1-1.1.

Projects involving only analysis of data and/or biospecimens require different levels of review, depending on identifiability of information accessed, identifiability of information recorded, and whether other federal regulations apply to the research. The following questions will help the IRB determine the appropriate type of review.

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1* This research will involve analysis of (select all that apply):

- [x] Data [Require Section 24]
- [x] Biospecimens [Require Section 18]

1.1* Will the study involve human embryonic stem cells (hESCs) or induced pluripotent stem cells? [Require Section 19]

○ Yes ● No Clear

Answer is usually "No."
If "Yes," HPSCRO (Human Pluripotent Stem Cell research Oversight) committee will also need to review & approve outside of eResearch.

1.2* Will genetic analysis be performed on any specimens acquired in conjunction with this study? [Require Section 20]

○ Yes ● No Clear

2* Does the source of the data or biospecimens require an IRB review and approval of the project - full committee or expedited review rather than an exempt or not regulated?

○ Yes ● No Clear

Answer is usually "No."
MiChart data: answer "No."
Biospecimen analysis **with** associated identifiable data recorded: Answer "Yes."

A few examples -

- Health and Retirement Study (HRS) "Restricted Data"
- National Health and Aging Trends Study (NHATS) "Restricted Data"
- National Longitudinal Study of Adolescent to Adult Health (Add Health) "Restricted Contractual Data"
- Some datasets obtained through BioLINCC (NHLBI)
- Some datasets obtained through dbGaP, based on Data Use Certification.

2-part question - "Yes" only if BOTH are true

3* Are or were any study team members on this project also involved with the direct collection of the data/biospecimens from subjects and still have access to subject identifiers either directly or via the key to the code linking to subject identifiers?
(e.g. part of another study, part of an ongoing study involving interaction/intervention with subjects, managing a repository in which the specimens are stored)

● Yes ○ No Clear

For data/specimens generated for non-research purposes, answer is usually "No."
Do not answer "yes" just because researchers are clinicians who may have contributed to the electonic medical record.

4* Can subject identity be readily ascertained (directly or through links) in the data/biospecimens *accessed or received* by study team members on this project?
This means that the **information accessed or received** includes **direct identifiers** (name, address, email, phone number, social security number, student ID, medical record number), **indirect identifiers** (i.e. data elements that could be combined to identify an individual, such as dates, employment history, etc.), or a **code that can be linked back to the subject.**

● Yes ○ No Clear

4.1* Will the study team members *record* direct, indirect or coded subject identifiers that could be linked back to the subject for ANY of the data/biospecimens?

● Yes ○ No Clear

Look for ways to get the data you need **without** direct chart review - answer "No" to these questions if you can!
Useful - Data Office Consultation and Self-Serve Data Tools

To best protect data confidentiality, subject privacy, and University interests, **researchers should handle FEWER rather than more identifiers**.

5* Will data from the proposed activity be submitted in an application to the FDA for an IDE (Investigational Device Exemption) or In Vitro Diagnostic (IVD) device approval? [Require Section 16]

○ Yes ● No Clear

Answer is usually "No."
"Yes" requires *comprehensive IRB review and approval* due to FDA regulations.

For guidance, contact MICHR IND/IDE Investigator Assistance Program.

6* Does the research analysis target prisoners as the subjects of the research? [Require Section 38]

○ Yes ● No Clear

Answer is usually "No."
Status as a prisoner is not relevant (or available) in most secondary-use-only studies. If it is necessary to know which data obtained is from prisoners, *comprehensive IRB review and approval* is required, as additional safeguards must be in place for this vulnerable population.

Research targeting prisoners as a subject population is subject to additional human subjects protection regulations and requirements. For definitions and further information, see U-M HRPP Operations Manual Part 7.

Research aimed at involving a broader subject population, which only incidentally includes prisoners, may not require additional regulation.

7* Does the research analysis include data/biospecimens from children? [For non-exempt research require Section 33-1]

○ Yes ● No Clear

By regulatory definition (45 CFR 46.402(a)), "Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." For further information, see U-M HRPP Operations Manual Part 7.

8* Is ANY identifiable information to be accessed, used, and/or analyzed defined as "Protected Health Information (PHI)" protected by HIPAA? PHI is:

- information about a subject's past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; **AND**
- maintained by a HIPAA-covered component (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).

[Require Section 25]

● Yes ○ No Clear

Answer for IRBMED applications is almost always "Yes."

Protected Health Information (PHI) includes one or more HIPAA identifiers.

Most data generated from clinical records is regulated by Health Insurance Portability and Accountability Act (HIPAA). HIPAA generally covers both data provided directly by a HIPAA "covered entity" and data provided by a central data broker and protected by contractual agreements.

8.1* To ascertain if ALL data are Protected Health Information (PHI) protected by HIPAA:

Answer Yes if

1. All study team members are Michigan Medicine faculty, staff, medical student(s) or professional trainee(s), and
2. All data are generated by or received from a HIPAA "covered entity, and
3. The study never involves sharing PHI outside the "covered entity" ("disclosing"), and
4. ~~If biospecimen analysis is involved: all biospecimens were obtained with research consent and HIPAA authorization~~

Answer No if

1. The study team includes collaborators from outside Michigan Medicine (e.g., LSA, SPH, Business School, or outside University of Michigan), and/or
2. Not all data source(s) are HIPAA "covered entities" (data is generated by or received from source(s) not subject to HIPAA), and/or
3. Patient-level data containing HIPAA identifier(s) will be shared outside a covered entity (CE) ("disclosed"), and/or
4. Identifiable biospecimens are used, ~~at least some of which were not obtained with research consent and HIPAA authorization.~~

○ Yes ● No Clear

Answer depends most on data source, and on study team affiliation.
For data generated from MiChart and reviewed entirely by Michigan Medicine personnel, answer "yes."
If there are central campus collaborators (including undergraduate research assistants), answer "no."
For ALL research with biospecimens, answer "no" (list #4 in this quesiion's guidance is out of date).

Answer "No" if:

- any study team members are outside a HIPAA "covered entity" (*e.g.* outside Michigan Medicine, such as U-M LSA, SPH, Business School, or not affiliated with U-M)
- some data is **not** defined as PHI (e.g. from a non-"covered entity" source; or research data from prior studies conducted outside a "covered entity")

9* Are all the data/records/specimens publicly available?
"Publicly available" is defined as information/biospecimens shared without conditions on use.

Note: Answer "no" if your research involves a Data Use Agreement or Material Transfer Agreement.

○ Yes ● No Clear

Answer is usually NO.

Questions 9, 10, 11 appear ONLY IF earlier answers have RULED OUT "Not Regulated" and "Exempt 4(iii)."
USUALLY this means *comprehensive IRB review & approval*, or sometimes "Exempt 4(ii)."

A few examples -

- archives in a public library

- if the only requirement for obtaining the information is paying a user fee, registering or signing in as a visitor to an archive.

10* Do you plan to recontact subjects?

For instance, would you recontact subjects in the event that the research reveals information of potential benefit to the subject or identifies a clinically significant, unexpected disease or condition; or do you want to recruit these same subjects for additional research studies?

Note: a "no" answer does not prevent an investigator from abiding by any legal requirements to return individual research results.

○ Yes ● No Clear

Must be consistent with 10-3.2, 5th subquestion.

11* Is the research being conducted on behalf of a federal department or agency, using government-generated or government-collected information obtained for nonresearch activities?

(This is rare at an academic institution; consult with the IRB.)

○ Yes ● No Clear

Answer is usually NO.

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