Navigating the Land of Research Rules

Janine Richardson, RN, CCRC
Director, HRPP
East Tennessee State University

DISCLAIMER

NEITHER THE PUBLISHER NOR THE AUTHORS ASSUME ANY LIABILITY FOR ANY INJURY AND OR DAMAGE TO PERSONS OR PROPERTY ARISING FROM THIS WEBSITE AND ITS CONTENT.
Navigation Tool: Chart Reviews

Consider which map to use: exempt or expedited.

Key note: As a PI, you may request an exempt review or expedited review, however, the IRB Chair (or designee) will make the final determination for exemption status.

Navigation Tool: Chart Reviews

Advantages of exempt studies (exempt from federal rules governing research)
- faster turn-around time by IRB
- less consent documentation
- continuing review is not required
Exemption Category #4

• 45 CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

• To qualify for the above 45 CFR 46 (101) (b) category 4 exemption, data, documents, records or specimens must already exist at the time the research is proposed.

Exemption Category #4 – 2 Important Requirements

• 45 CFR 46.101(b)(4): Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Exemption Category #4 – Important Requirements

• 45 CFR 46.101(b)(4):
  The recorded data includes no identifiers.

Note that identifiers can be accessed, but not recorded.

Exemption Category #4 – Important Requirements

• 45 CFR 46.101(b)(4):
  The recorded data includes no identifiers.

Example: A hospital can provide access to medical records with identifiers. As long as the investigator does not record identifiers or links to identifiers, this would meet this qualification.
<table>
<thead>
<tr>
<th>Exemption Category #4 – Important Requirements</th>
<th>Exemption Category #4 – Important Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 45 CFR 46.101(b)(4): The recorded data includes no identifiers.</td>
<td>• 45 CFR 46.101(b)(4): The recorded data includes no identifiers.</td>
</tr>
<tr>
<td>It is not enough to simply not record names. Links to identifiers that make a study not exempt can include, for example, the medical record number, phone number, or the date of surgery with a rare disease.</td>
<td>No identifiers means there is NO WAY that you could track your data back to an individual even if you wanted to.</td>
</tr>
<tr>
<td>Exemption Category #4 – Important Requirements</td>
<td>Exemption Category #4 – Important Requirements</td>
</tr>
<tr>
<td>• 45 CFR 46.101(b)(4): The recorded data includes no identifiers.</td>
<td>• 45 CFR 46.101(b)(4): Research involving the collection or study of existing data,</td>
</tr>
<tr>
<td>In order for your project to be even considered under this criteria, you must clearly describe what data you will record in your IRB application.</td>
<td>To qualify for the above 45 CFR 46 (101) (b) category 4 exemption, data, documents, records or specimens must already exist at the time the research is proposed.</td>
</tr>
</tbody>
</table>
Exemption Category #4 – Important Requirements

- 45 CFR 46.101(b)(4): Research involving the collection or study of existing data,

Existing means ALL the data exits at the time you submit the application to the IRB for review.

Exemption- all 6 categories

- Note: Research that is determined to be exempt from IRB review is not exempt from protection of human subjects.

All exempt research is subject to human subject protections and ethical standards.

ETSU’s Ethical Standards for Exempt Studies

1. The research holds out no more than minimal risk to the participants.
2. The selection of participants is equitable.
3. If the study includes recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.
ETSU’s Ethical Standards for Exempt Studies

4. If the study includes interactions with participants, there is a consent process that discloses such information as:
   – that the activity involves research
   – a description of the procedures
   – that participation is voluntary
   – the name and contact information for the investigator

5. The research has adequate provisions to maintain the privacy interests of participants.

Navigation Tool: Chart Reviews

What if your chart review study design will not potentially meet exempt criteria?

Request an expedited review rather than exempt.

Navigation Tool: Chart Reviews

Requests for Waivers of Informed Consent:
The rules allow informed consent to be waived ONLY under very specific conditions.

Requests for a waiver of informed consent must be justified on the basis of those conditions.

45 CFR 46.116(d) (Must meet all four criteria detailed below) (not applicable to research subject to FDA regulation)

• 1. The research involves no more than minimal risk to the subjects; and
• 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects and
• 3. The research could not practically be carried out without the waiver or alteration and,
• 4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
• 3. The research could not practicably be carried out without the waiver or alteration.

In other words, WHY can’t you get informed consent?

(You have to get unless you can’t, and if you can’t, why not?)

• Note: The criteria for waiver of HIPAA Authorization are similar and also require detailed justification.

Includes:
The research could not practicably be carried out without the waiver because .......

The research could not practicably be carried out without access to and use of PHI because ......

(You have to get unless you can’t, and if you can’t, why not?)
Navigation Tools: Case Studies

Consider which map to use: human subject research or not human subject research

Key note: Activities that constitute human subject research are determined by the ETSU and ETSU/VA IRB. The IRBs delegate this decision to the IRB Chair or Vice Chair.

Navigation Tools: Case Study

• The IRB has the sole authority to make a final determination of whether a proposed activity is human research according to DHHS or FDA regulatory definitions. Unless you are familiar enough with these regulations to be certain that the activity does not represent human research, the activity should be brought forward to the IRB for a determination.

• Example:
  • Retrospective review of a patient’s medical records for use in an educational setting. The data will be de-identified.
  • Submit to IRB: NO
Navigation Tools: Case Study

• Example:
  • A single subject study with clear intent, before recruiting or interacting with the participant, to use data that would not ordinarily be collected in the course of daily life. The intent is to report and publish the case study.
  • Submit to IRB: YES

• Exception: If any aspect of the case is unusual enough that the patient might be identifiable even though normal patient identifiers are removed, then it should be submitted.
  • Submit to IRB: depends on conditions above

Navigation Tools: Case Studies

• For case reports involving more than one patient, IRB should be consulted (by submitting a Form 129) to determine whether the case report is research.
  • If the proposed case report activity involves 4 or more patients, it must be submitted as human subject research.
Navigation Tools: Case Studies and Other Activities

• Complete and submit Form 129 to request a determination of whether you need IRB approval for a proposed activity
• Last form on the forms page, http://www.etsu.edu/irb/formsdoc.html

Navigation Tool: Clinical Studies

Consider which map the IRB will use:
Clearly delineate what is standard of care and what is research in your proposal.

Key note: The IRB will evaluate risks and benefits of the procedures.

Navigation Tool: All Studies Involving Pregnant Women/Fetuses

Design according to the map of additional protections for this vulnerable population.

Key note: The rules require additional detailed protections, in addition to the standard ones.
Navigation Tool: All Studies Involving Pregnant Women/Fetuses

Examples:
- Any risk is the least possible for achieving the objectives of the research;
- Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.
- See policy 15 for all requirements.

Current Ethical Issue

Newborn blood samples

Current Ethical Issue

Newborn blood samples

Recent litigation: Texas and Minnesota

Current Ethical Issue

Michigan Deliberative Jury

Results: 87% supported general idea of using spots for research (conditioned upon addressing of concerns).

Current Ethical Issue

Concerns:

A. Consent
- Distinguish between screening and consent for research
  - Opt in? Opt out?
- Consent for what?
  - 80% said parents should have option of choosing to limit what kinds of research may be done.
- From whom?

B. Privacy
- Safeguards for de-identification important (can DNA be really de-identified?) What if something clinically relevant to an individual is found?
- Public resource or private property?
- Concerns regarding who had access
