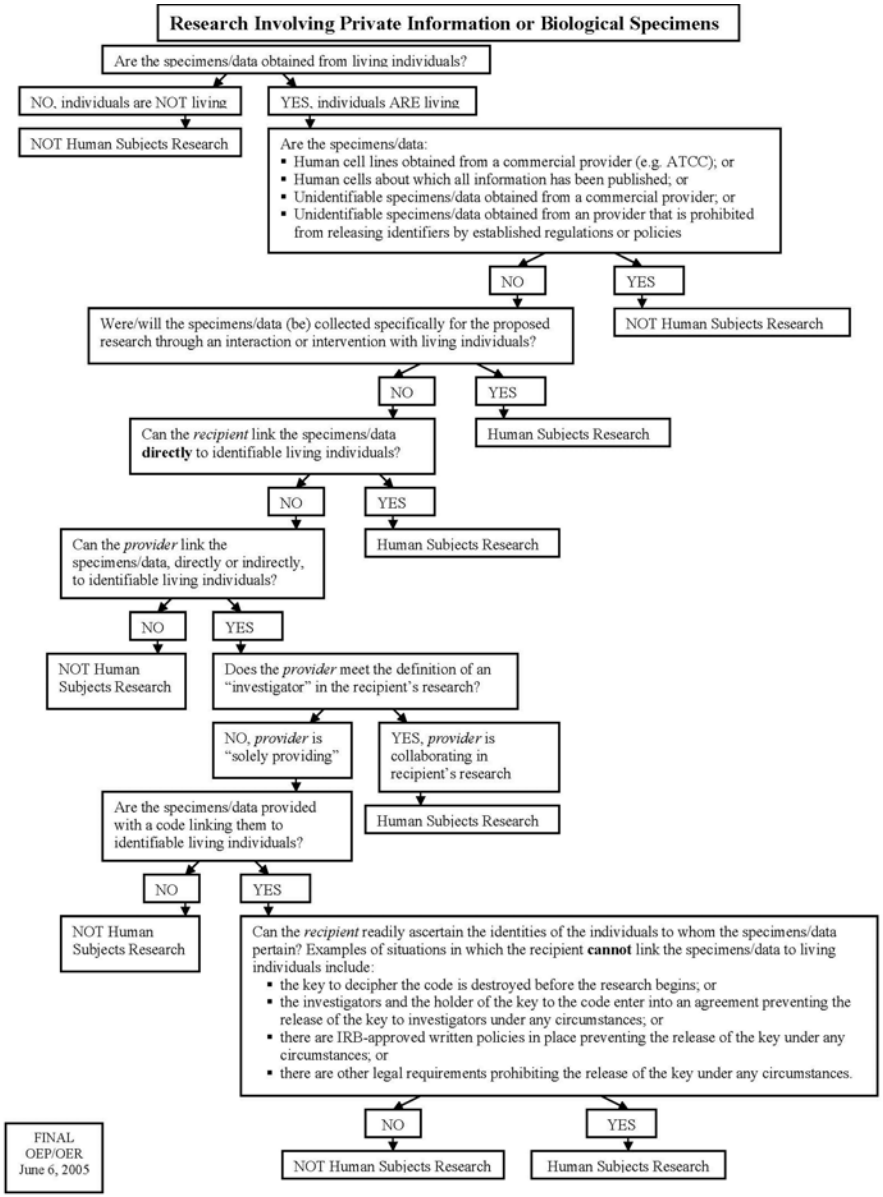
Regulatory Requirements for Biospecimen Research

NIH Decision Chart



NORTHWESTERN UNIVERSITY

Is it Research?

- 45 CFR 46.102 (d)

Research means a **systematic investigation**, including research development, testing and evaluation, designed to develop or contribute to **generalizable knowledge**.

Are Human Subjects Involved?

- 45 CFR 46.102 (f)

Human subject means a **living individual** about whom an investigator (whether professional or student) conducting research obtains

1. Data through **intervention or interaction** with the individual,

OR

2. **Identifiable private information**

What is Considered Identifiable Private Information?

- information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
- information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)
- the identity of the subject may readily be ascertained by the investigator or associated with the information

What about Coded Data / Specimens?

- Can the researcher “readily ascertain” the identity of the specimen donor?
- Are procedures in place that prevent a researcher from being able to associate coded data/specimen with the individual?
  - Agreement between researcher and holder of key prohibiting release of key
  - IRB-approved written procedures for data management
  - Other legal requirements

Exemption #4 - 45 CFR 46.101 (b)

- 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.

So…

If the activity in question

- Is research
- Does involve human subjects
- Does not qualify for exemption

The regulatory requirements in 45 CFR 46 apply

- IRB review and approval
- Review by institution
- Informed Consent or Waiver

Criteria for IRB Approval (45 CFR 46.111)

- **Risks** to subjects are **minimized**
- **Risks** are **reasonable** in relation to anticipated **benefits**
- Selection of subjects is **equitable**
- **Informed consent** is **sought** from each subject
- **Informed consent** is appropriately **documented**
- All Authorized Research Personnel have completed **human subjects training**

And when appropriate:

- data collection is monitored to ensure subject safety
- privacy and confidentiality of subjects is protected
- additional safeguards are included for vulnerable populations
- approval/permission obtained from non-public project sites to use the site
- subjects are fully debriefed if deception used

Informed Consent / Waivers

The basic elements of informed consent as described in 45 CFR 46.116 are required unless:

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

Documentation of Informed Consent

Informed consent must be documented as described in 45 CFR 46.117 unless:

- the **only record linking the subject and the research** would be the consent document and the principal risk would be potential harm resulting from a **breach of confidentiality**.

OR

- the research presents no more than **minimal risk** of harm to subjects and involves **no procedures for which written consent is normally required** outside of the research context.

References

45 CFR 46:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

OHRP Guidance on Research Involving Coded Private Information or Biological Specimens:
http://www.hhs.gov/ohrp/policy/cdebiol.html

NIH Frequently Asked Questions: Human Subjects Research- Human Specimens, Cell Lines or Data:
http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm

Resources

Main IRB Office number (Chicago): 312-503-9338

http://irb.northwestern.edu/

OHRP webinar: Research Use of Human Biological Specimens and Other Private Information
http://www.youtube.com/watch?v=yp5GzAmXlPM&list=SP5965CB14C2506914&index=6

OHRP Guidances: Biological Materials & Data
http://www.hhs.gov/ohrp/policy/biodata/index.html