Waiver of Informed Consent

IRB Board Member Training
March 2018

THE UNIVERSITY of NORTH CAROLINA at CHAPEL HILL

45 CFR 46.116 (c) or (d):

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that . . .

45 CFR 46.116 (c)

The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:

(1) (i) public benefit or service programs;

(2) (ii) procedures for obtaining benefits or services under those programs;

(3) (iii) possible changes in or alternatives to those programs or procedures; or

(4) (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

The research could not practicably be carried out without the waiver or alteration.

45 CFR 46.116 (d)

(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; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

2 Additional Provisions to Receive IRB Approval for the Waiver

(5) The risk to privacy is reasonable in relation to the importance of the knowledge to be gained.

(6) It is not possible to conduct the study with only de-identified data.

What Constitutes an Adequate Justification?

Research is no more than minimal risk

1. Identify *all* risks associated with the research (note, typically, a breach of confidentiality is the primary risk associated with medical record review and with the use of existing identifiable data or specimens).

2. Discuss steps to minimize these risks.
   - ❑ Sensitivity of the data
   - ❑ Protections in place to protect the data and minimize a breach of confidentiality. Build upon information in sections
     - A.9. - “Identifiers”
     - A.10. - “Confidentiality of the data”

No adverse effect on rights

How will the researcher minimize the impact of the research on patients' right to privacy regarding their medical record?

Describe the following, as relevant:

- ❑ CDW to retrieve data and provision it to the investigator
- ❑ Honest broker maintains the data set and restricts access to limit exposure of PHI and reduce the possibility of deductive disclosure
- ❑ Properly train study personnel on data search limitations
- ❑ Record data w/o creating additional hard copies of PHI

No adverse effect on welfare – *medical record review*

1. Consider if/how the records review will impact ongoing clinical care
2. Consider the psychological, social, legal implications if the private information placed in the research record became known outside the research team
3. Address specific concerns about a breach of sensitive data

No adverse effect on welfare – *secondary data or specimen use*

1. Data from prior study – is the proposed use consistent with what subjects agreed to when signing the consent form for the original study?
    1. Is sharing restricted to certain individuals or methods?
    2. Is sharing restricted to study certain diseases?
2. Administrative/non-research data obtained w/o consent for research use –
    1. How might a patient feel about their information used for research?
    2. Is the sensitivity of the research topic inconsistent with the expectation of privacy? (e.g., using photos of college applicants in a study of risky sexual behavior)

Practicability – what are the real barriers?

1. Is contact information readily available?
2. Is contact information likely reliable?
3. Deceased or lost to followup?
4. How many subjects needed (20 versus 20K)?
5. Are subjects geographically dispersed?
6. Would the consent process create added subject burden or risk?
   - ❑ Time added to an already lengthy SOC clinic visit
   - ❑ Collection and maintenance of identifiable information
     - Recording and storing name, phone numbers
     - Signed consent and HIPAA forms

Provide subjects with additional pertinent information after participation

1. Debriefing form if deception used
2. Brochure of information sheet if conducting secondary analysis of prospectively collected data
    - Patients information will be included in the research
    - The purpose of the research
    - How patients may reach the investigator if they have questions/concerns about the research
    - Istructions for having their data withdrawn if they wish
    - IFB contact info for questions or concerns about their rights as a research subject

Risk to privacy is reasonable

1. Recap the risk to privacy, especially regarding sensitive data

2. Justify the risk
   - ❑ Clearly describe the greater public good the research will realize
   - ❑ Be specific about the nature of the knowledge to be gained

Impossible to conduct the study using de-identified data only – why are identifiers needed?

1. Link data across time
2. Personal identifiers, such as home address, is a variable of interest to the research question (e.g., geographic distribution important to understand environmental factors)

Insufficient Justification

1. This is a retrospective study with no more than minimal risk.

2. Requiring informed consent will

   - ❑ Slow down the process and I need to graduate in 6 months.
   - ❑ Lead to a lower participation rate and bias the data.
   - ❑ Place undue cost and burden on the researchers