Waiver of Informed Consent when Using Medical Records or Other Secondary Data or Specimens

UNC-CH OHRE Guidance Document

External and Internal Use

This guidance has been provided by the UNC-Chapel Hill Office of Human Research Ethics (OHRE). This document is intended to provide guidance to investigators regarding the information needed for the IRB to grant a full waiver of informed consent under 45cfr46.116(d) when a study involves the use of secondary data and/or specimens.

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1 CRITERIA FOR A WAIVER OF INFORMED CONSENT OVERVIEW

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent, under 45cfr46.116(d), provided the IRB finds and documents that **ALL** of the following criteria are met:

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.

Additional Criteria

Two additional "criteria" are not specific to the waiver but must be addressed in order to receive IRB approval:

5. The risk to privacy is reasonable in relation to the importance of the knowledge to be gained.
6. Please explain why it would not be possible to conduct the study with only de-identified data.

Information to consider when responding to each criteria

1. The research involves no more than minimal risk to the subjects.

Identify all risks associated with the research. Typically, a breach of confidentiality is the primary risk associated with medical record review and with the use of existing identifiable data or specimens. Discuss steps to minimize these risks. Specifically, discuss the sensitivity of the data and the confidentiality protections in place to protect the data and minimize a breach of confidentiality. This response should reflect and build upon information provided by the investigator in sections A.9. ("Identifiers") and A.10. ("Confidentiality of the data") of the application.

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

a. Explain why the waiver will not adversely affect subjects' rights. Patients have a right to privacy regarding their medical records. The impact of the research on this right must be minimized to the extent possible. Minimizing the impact can be achieved through the use of an honest broker (such as the CDW) that extracts the data, or by placing clear limitations on individuals within the research team who will engage in data extraction from the medical records. The latter option requires the investigator making the request to clearly identify the steps and/or strategies that will be used to limit exposure of the patient's ***entire*** medical record during the data extraction process (for example, what training has the data extractor completed that will reduce the likelihood of unintended exposure of elements of the record that are not essential to the research? What methods will be used to record the data without creating and maintaining additional hard copies of PHI?).
b. Explain how the waiver will not adversely affect subjects' welfare. Regarding the concept of welfare, the investigator must consider several factors depending on the original source of the data.
    i. For medical record review: Consider the impact of record review on a patient's ongoing clinical care; in addition, consider the psychological, physical, social, economic, and legal implications of a breach that would result if the private information placed in the research record became known outside the research team. The waiver request should identify any specific data that is considered sensitive in nature and address specific concerns about a breach of confidentiality regarding those sensitive data.
    ii. For secondary data or specimen use:
        1. *Data collected as part of a prior research study in which subjects provided informed consent*. Explicitly address how the proposed use of the data/specimens is consistent with what subjects agreed to when signing the consent form for the original study. Specifically, consider (1) what the original consent allowed or limited regarding sharing data/specimens with other researchers (e.g., research limited to specific medical conditions, sharing limited to de-identified data only) and (2) if identifiers will or will not be shared with researchers who were not involved in the original study. The proposed secondary use should be related to the disease, condition, or other general topic consistent with language in the original study consent document. If the current study involves sharing identifiers outside the study team and this plan contradicts language in the original consent, the investigator must address the potential adverse effect on subjects' rights.

2. *Data collected for administrative or other non-research purposes and consent was not obtained*. Consider how a subject may feel about their data being used for research purposes. Consider whether the research purpose is consistent with the original intent of the individual who provided the data. Consider the expectation of privacy associated with the original data provision and the sensitivity of the research. If the sensitivity of the research topic is inconsistent with the expectation of privacy of the individual (for example, using photos of college applicants in a study of risky sexual behavior), the research could be done but consent could not be waived.

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

Carefully consider the principle of Respect for Persons within the context of the proposed study. Is the study entirely retrospective or does it involve prospective data collection that might offer an opportunity to consent subjects and obtain HIPAA authorization? Describe the real (not presumed) barriers to obtaining consent, understanding that having limited financial resources to support the consent process does not justify the waiver. Answer the following questions:

a. Is contact information of potential subjects readily available?
b. Is the contact information likely reliable? Consider the age of the records and the likelihood that the contact information is outdated.
c. Are potential subjects likely to be deceased or lost to follow-up?
d. How many records are required to review? Would the resources required to obtain consent from all subjects exceed reasonable expectations of any research team? (For example, the study is a case-control cohort design involving hospitalized patients, and the sample size estimate indicates 200,000 cases are needed to answer the research question.)
e. Are subjects geographically dispersed? Consider the feasibility of the research team obtaining consent from individuals located outside the local catchment area.
f. Will subjects be burdened? Consider whether the consent process:
    i. Necessitates an unreasonable time burden on subjects.
    ii. Creates additional risk to subjects in the form of the collection of unnecessary identifiable information (i.e. name, phone number, signature on a consent or HIPAA form).

4. **Whenever appropriate, the subjects will be provided with additional pertinent information after participation.**
    a. Submit a debriefing form if the waiver request is specific to the use of deception or withholding information.
    b. Describe why this criterion is not applicable for fully retrospective studies.
    c. For secondary analysis of prospectively collected data, consider providing subjects a brochure or information sheet that includes information such as:
        i. that subjects' data will be included in the research
        ii. what data will be included in the research
        iii. the purpose of the research
        iv. ow they may reach the investigator if they have questions/concerns about the research
        v. instructions for having their data withdrawn if they wish
        vi. how they may reach the IRB in case they have questions or concerns about their rights as a research subject
5. **The risk to privacy is reasonable in relation to the importance of the knowledge to be gained.**

    Briefly, recap the risk to privacy by discussing the nature of the data (sensitive or not) AND justify this risk with a clear assertion of the greater public good that the research will realize. Be specific about the nature of the knowledge to be gained.

6. **Please explain why it would not be possible to conduct the study with only de-identified data.**

    Non-identified information should be used whenever possible in order to respect subjects' interests in protecting the confidentiality of their data and/or biospecimens. Clearly describe why identifiers are needed (e.g., to link data across time, IDs are variables of interest, etc.).

2 WHAT IS NOT A SUFFICIENT JUSTIFICATION?

1. This is a retrospective chart review only with no more than minimal risk. This only speaks to risk level and does not provide information about any other criteria.
2. Since there is minimal risk and an observational study it would be pointless to obtain consent. This only speaks to risk level and does not provide information about any other criteria.
3. Requiring informed consent will slow down the process and I need to graduate in 6 months. This only addresses cost, convenience, and speed to the investigator. Convenience cannot be used to justify the waiver.
4. Requiring informed consent will lead to a lower participation rate and will bias the data. Although this may be true, biasing of data is an issue inherent to all research. In addition, this justification implies that participants could be consented which means that it is not impracticable and not giving subjects an opportunity to say make a decision to participate if practicable, violates the principal of respect for persons.
5. Requiring informed consent would place undue cost and burden on the research team. Although this may be true, it is the responsibility of the researcher to be qualified and have the resources to conduct the research the proposed. As previously mentioned, cost, convenience, or speed to investigators alone is not acceptable as a justification to not obtain consent from subjects.