

IRB Update

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Waivers of Informed Consent and Documentation of Informed Consent

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Waivers of informed consent and waivers of documentation of informed consent are necessary (and valuable) for certain types of research where it is impracticable to obtain written informed consent.

The National Jewish Health IRB had previously provided a single form for requesting waivers of informed consent and documentation of informed consent but recognized that researchers were unsure how to complete the form. The IRB has now divided the application form into two separate forms for waiver of informed consent and waiver of documentation of informed consent. Each form has different questions and directions to assist researchers.

The most common need for a waiver of informed consent occurs in chart review studies. There is no contact with subjects but members of the research team may need access to information that would identify individuals directly or indirectly through coding systems.

The most common need of a waiver of documentation of informed consent is for telephone screening. The IRB can approve a process by which verbal informed consent is obtained prior to recording information about a prospective subject's eligibility for a trial. There are also circumstances by which a subject can provide verbal consent to withhold specific medications prior to the first research visit, so long as the IRB feels that withholding would not adversely affect subject safety and prospective subjects will be instructed to reschedule the research visit if they require use of the medication during the planned withholding period.

A listing of the regulatory criteria with examples and explanations of appropriate responses is provided on pages 3 and 4.

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Need for Informed Consent when Children reach the age of majority

Wendy Charles

Informed consent should be viewed as an ongoing process throughout the duration of a research project. When a child reaches the age of majority (age 18 in Colorado), the prior parental permission and child assent are not equivalent to legally effective informed consent for the now-adult subject. Investigators should seek and obtain the legally effective informed consent for the now-adult subject for any ongoing interactions or interventions with the subjects.

While most researchers do plan to obtain informed consent for ongoing interactions with now-adult subjects, few are aware that the same legal requirement to obtain informed consent exists after subjects' completion if the research continues to meet the regulatory definition of "human subject research." For example, the Office for Human Research Protections (OHRP) has specified that the definition of "human subject research" includes the analysis of specimens or data for which the subject's identity is readily identifiable to the investigator(s), directly or indirectly through coding systems.

For OHRP's guidance for obtaining informed consent from children who reach the age of majority in human subject research, please review: <http://answers.hhs.gov/ohrp/questions/7270>.

The requirements for HIPAA Authorization are different. A parent's authorization for use and disclosure of a child's health information remains in

effect after the child reaches the age of majority. It is not necessary to obtain HIPAA authorization from a now-adult subject.

The IRB offers a few strategies for managing data/specimens when children reach the age of majority and there is no ongoing interaction:

- 1) Obtain written informed consent from the now-adult subjects. Permissible options may include face-to-face contact, mail, scan, or fax.
- 2) Strip all identifiers from that subject's data/specimens and destroy the code key so that the data no longer meet the federal definition of a "human subject."
- 3) The IRB may consider, if appropriate, a waiver of informed consent in order for certain research activities to continue.

The IRB requires submission of a plan that describes how the requirement for informed consent will be addressed when a child involved in human subject research reaches the age of 18. Depending on the nature of research and the timing of a child's completion relative to his/her 18th birthday, the IRB may recommend a combination of the strategies listed above.

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Please remember

Photocopies

The IRB no longer requires 20 copies for full committee submissions! Full committee review is conducted by reviewing scanned copies of submissions. Because the IRB still relies on paper records for filing and stamping, we request a signed original submission and two complete photocopies of the original. While the photocopies may be double-sided, we request that each discrete document is photocopied individually so that last page of one document is not copied to the first page of the next document.

Internal Grant Reviews (IGRs):

To facilitate the IRB's congruency evaluation, please provide a copy of the grant proposal or progress report for any IGR associated with a specific IRB-approved research study. Please remember that the IRB requests 48 hours to process any IGR that lists an IRB-approved study. (This amount of time allows IRB staff to compare the content of the grant proposal or progress report to the IRB-approved protocol.) However, when IRB review is "pending," any IRB staff member can sign the IGR immediately.

Example of a Waiver of Informed Consent

The following example is from:

Elliott, MM. Research without consent or documentation thereof. In: Bankert EA, Amdur RJ (ed.), *Institutional Review Board: Management and Function*. Sudbury, MA: Jones and Bartlett: 2006.

The researcher plans to determine whether some specific blood chemistry values change in individuals undergoing clinically indicated abdominal surgery and if there is a correlation of changes with the increased incidence of complications after surgery. The researcher plans to review the medical records of all individuals who have undergone abdominal surgery in the past 2 years. From a preliminary estimate, there are about 5,000 abdominal surgeries performed per year at the hospital. The researcher will collect limited data for this research. The types of data to be collected include such items as the diagnosis before surgery, the type of abdominal surgery, specific blood chemistry values before the surgery, the same specific blood chemistry values after the surgery, a description of problems after surgery, and the age ranges of the individuals. The researcher will code the data so that only the researcher knows the link in the unlikely event the data must be verified for accuracy. The results of the research will not affect the clinical care of the individuals because the information will not be examined until after subjects leave the hospital.

In this example, the IRB may find that a waiver of informed consent is appropriate and that the criteria from 45 CFR 46.116(d) have been met based on the following:

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

The research involves minimal risk, as the review of subjects' medical records is for limited information. The information is not sensitive in nature, and the data are derived from clinically indicated procedures. There is an extremely low probability of harm to subjects' status, employment, or

insurability. The precautions taken to limit the record review to specified data and the coding of the data further minimize the primary risk, which is a breach of confidentiality.

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

The rights and welfare of the individuals would not be adversely affected because the clinically indicated surgical procedure and the associated blood chemistry values were already completed, regardless of the research. None of the results of the research would affect the clinical decisions about the individual's care because the results are analyzed after the fact. Subjects are not being deprived of clinical care to which they would normally be entitled.

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

The research could not be practicably carried out without the waiver. Identifying and contacting the thousands of potential subjects, although not impossible, would not be feasible for a review of their medical records for information that would not change the care they would already have received. Further, after two years, many subjects will have changed their telephone numbers or moved without providing forwarding addresses.

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

It would not be appropriate to provide these subjects with additional pertinent information about the results of the research as this study is exploratory and would have no effect on the subjects. The surgical procedure and care afterward have both been completed for these subjects. There is no anticipated benefit to subjects that would change what has already occurred.

Examples of Waivers of Documentation of Informed Consent

Under either of the two criteria in 45 CFR 46.117(c), an IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects.

Example applicable to 46.117(c)(1):

A researcher plans to interview homeless teenagers living in a shelter. The purpose of the research is to evaluate illicit drug use. The researcher plans to recruit subjects through flyers posted at the shelter. Potential subjects will contact the researcher directly. Informed consent will be obtained verbally. The interviews will be audiotaped, and the researcher will ask subjects to use a pseudonym during the interviews. Also, each subject will be assigned an ID# on the audiotape.

Regulation: That 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. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

Interpretation: OHRP notes that some subjects might refuse a copy of the consent form once signed out of concern that their possession of the form could compromise their privacy. This is fully consistent with the idea behind one of the bases for a waiver of the requirements for documentation of informed consent that harm would result to the subject if his/her identity were compromised by the documentation itself.

<http://answers.hhs.gov/ohrp/questions/7276>

Example rationale: The only record linking the subject to the research would be the consent document. The principal risk would be potential harm resulting from a breach of confidentiality if the consent documents were disclosed, purposefully or inadvertently.

Example applicable to 46.117(c)(2):

A researcher conducting a survey (that does not qualify for an exemption under 45 CFR 46.101(b)) mails a survey questionnaire to a random sample of adults. The survey materials clearly state that by responding to the questions and mailing the survey back, the recipients have agreed to participate.

Regulation: That 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. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Interpretation: if the IRB has approved this alteration of the consent process and has waived the need for documentation of consent, then such procedures are permissible under the regulations. By sending back a completed survey the recipient has implied that he or she consents to participate but has not signed an informed consent document. Although some might call this "implied informed consent," OHRP would consider this to be a permissible informed consent process if the IRB has approved the informed consent alteration and waived the requirement for documentation of informed consent.

<http://answers.hhs.gov/ohrp/questions/7249>

Example rationale: The survey presents no more than minimal risk of harm to subjects. The survey does not ask the subject to answer any sensitive questions and the subject is not asked to perform other activities. Normally, there is no requirement for written consent for completion of surveys outside the research context. By completing and returning the survey, subjects have consented to participate in the research.

Note: When designing an information sheet or invitation letter, OHRP does not require these materials to include all of the elements of consent listed at 45 CFR 46.116(a). Be aware that the NJH IRB has often required all (or nearly all) elements of informed consent for an information sheet or invitation letter if there will not be a verbal exchange of information (as in studies involving a mailed survey and there is no other contact).

The first example and rationales inspired by: Elliott, MM. Research without consent or documentation thereof. In: Bankert EA, Amdur RJ (ed.), *Institutional Review Board: Management and Function*. Sudbury, MA: Jones and Bartlett: 2006.