



Research Regulator

Protecting Human Participants in Research



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In Focus: Informed About Consent?

Consent, Assent, Parental Permission, Oral, Written, Short-Form, Videotape, Audiotape, Online, Waiver, Waiver of Signature...

The Belmont Report states, “Because the subject’s ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the [consent] information to the subject’s capacities.”

To ensure that you have not only met your ethical obligation to provide true informed consent, but also to satisfy the IRB, ask yourself the following questions:

Have I provided a complete description of the potential subject population such that the IRB can easily determine the appropriate language, literacy and cultural needs for my protocol?

Why is this important? A random sample based on census data of 100 people in Cleveland would include 34 minorities, 11 persons living below the poverty level, and at least 7 who do not speak English as their first language. Simply stating inclusion and exclusion criteria rarely provides enough information for IRBs to make appropriate consent determinations.

Do my research team and I have enough time and resources to devote to obtaining informed consent?

Clearly describe in your protocol the resources you have available. In other words, have you estimated, based on your current research program, the number of people who would need to be consented in the next 6 months to meet your research goals? Do you have the time and resources needed to actually meet that goal? For example, if you need to recruit

100 subjects and you predict that you will have a 50% success rate, you will need to provide consent to at least 200 people. If the process takes 2 hours per person, the amount of time needed for the consent process alone for the study will be 400 hours or 10 normal work weeks.



If I am not obtaining consent, have I described how the other members of my team will be trained to do so?

CREC certification should be considered only as a baseline in human subject protections training. In recent years research has been conducted on whether

supplementing the consent process with such methods as streamlined forms, additional written information, videos, computer-assisted learning and post-testing, actually improves understanding and comprehension. Findings suggest that while supplementation does not lower comprehension or willingness to participate, significant improvements in understanding and comprehension are also not seen. What the research has shown is that those participants who were able to spend more time in a discussion with a staff person knowledgeable about the study (not necessarily the PI) had a more comprehensive understanding on which to base their decision.

Encouraging your staff members to practice on you or others is an effective way to ensure that they are ready to acquire consent from subjects. Prepare clear guidelines as to what you consider to be adequate and comprehensive consent, including how to identify extenuating circumstances which would require your staff to involve you or another team member in the process.

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Congratulations on acquiring Full AAHRPP accreditation to:

The Cleveland Clinic

The MetroHealth System

and

University Hospitals Case Medical Center

For information on AAHRPP accreditation, see:

<http://www.aahrpp.org/www.aspx>





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Do I have a clear plan to protect the confidentiality of the study records and to ensure data integrity over time?

Some points to consider in securing and maintaining documentation of consent:

- Documentation of consent (i.e., signed consent documents) should be maintained for no less than three years after the completion of the study (IRB protocol termination). Prior to the initiation of any study, investigators should have a clear understanding of any additional requirements (i.e., FDA, sponsor, state...) and outline in the protocol how, where and for how long consent documentation will be maintained.
- Consent documentation should not be limited to the initial consent form. Copies of any re-consenting documents, letters to subjects, e-mails, etc. should be maintained in case questions arise concerning the consent process or the overall research project. For example, the University's research misconduct policy states that allegations can arise from research conducted during the six years prior to the time of the allegation.
- Normally, consent documentation should be kept separately from the research record in order to protect confidentiality. Study data cannot be considered coded if a copy of the signed consent is in the same folder or electronic file.
- Confidentiality is key when storing consent documentation. Investigators can maintain electronic files (i.e. scanned copies); however, they must ensure that these



Using a Short Form for Informed Consent

The ideal way to acquire documentation of informed consent from all research participants is to have them read an informed consent document written in language understandable to them, receive answers to questions, and sign the consent document. However, in some circumstances, there may be the potential to involve a few individuals who speak one of a variety of different languages. The Belmont Principle of Justice would indicate that it is inappropriate not to grant these individuals the opportunity to participate simply because of a language barrier. On the other hand, it can be difficult to predict each language that may be spoken by potential participants in some areas.

A practical solution to this dilemma can be the use of the "Short Form" (45 CFR 46.117(b)). The Short Form is a short, generic IRB-approved document translated into the language understood by the potential participant stating that the elements of informed consent (see IRB 101 on Page 4) have been presented orally.

A translator is given an IRB-approved written consent summary to read to the participant. The translator is responsible for reading the short form and written summary word-for-word, and discussing the entire English-version consent form with the subject. A witness must be present for this process, which in some cases may take more than an hour. The participant only signs the short form, but is given a copy of both the short form and the summary to keep.

Generally, the IRB would need to see a compelling reason to approve the use of the short form. If, for instance, 30-40% of the study population is likely to speak Spanish or another single language, the IRB would expect the entire consent form to be translated into that language. However, if researchers have reason to believe that there may be just a few subjects who speak a particular language, the use of a qualified translator and the Short Form could be considered.

Additional guidance and a sample short form can be found on OHRP's website at: <http://www.hhs.gov/ohrp/humansubjects/guidance/ic-non-e.htm>.

documents are well protected. Such materials should **not** be stored in forms easily accessible via The Internet (i.e. open servers, e-mail accounts, etc.) or left unprotected (i.e. without appropriate passwords, encryption, etc.).

If you have questions about secure electronic document storage, please contact Thomas Siu, Case Chief Information Security Officer, at thomas.siu@case.edu. More information about electronic data security can be found at www.case.edu/its/security.

- Many of our affiliated hospitals require that a copy of the consent be kept in a subject's medical record. This should not be the sole copy of the consent as documents within the medical record can be lost or misplaced. The investigator is ultimately responsible for being able to provide documentation of consent for each subject enrolled in a study (unless an IRB has waived such requirements) and, therefore, should also have a separate original/copy.

How can I ensure that I obtain true informed consent and still

have a waiver or alteration approved by the IRB?

IRBs can approve alternative consent processes. However, they cannot do so without a specific request and appropriate justification from you.

Waiving or altering the normal consent process doesn't obviate an IRB's mandate to ensure that the subject has made an informed decision. In the absence of standard consent language and signatures, the IRB actually needs more information to ensure that the process is appropriate and complete. Investigators should provide detailed plans so that the IRB can make a clear determination if the process outlined in the protocol is acceptable.

We hope that this issue of *Research Regulator*, which concentrates on the process of informed consent, will provide you with helpful guidance in facilitating your research programs. It is important to remember that compliance is just a small part of our moral and ethical obligation to ensure true informed consent from our research subjects.

Remember: IRBs don't obtain consent, you do!





New to CREC???
Welcome!

Case Western Reserve University has developed the Continuing Research Education Credit (CREC) Program to provide documented training in the ethical conduct of human subjects research.

To become active in the CREC Program, one must successfully complete the Basic Course through the online education program, Collaborative Institutional Training Initiative (CITI). Once completed, CITI notifies Case and a CREC account is set up. Your CREC certification status is accessible to our affiliated IRB offices and to individuals who have a Case Network ID and password. Core Certification in the CREC Program is good for three years from date of completion and investigators are provided with a Certificate of Achievement.

The IRBs at Case and its affiliated hospitals will accept documented proof of training in the protection of human subjects in research from another institution for one year from date of hire. Within that year, researchers who will continue to be engaged in human subjects research are expected to complete the CITI Basic training and become CREC certified.

Please see the CREC webpage for more information: <http://ora.ra.cwru.edu/research/orc/crec/index.cfm> ❖

Social Science Spotlight
Acquiring Informed Consent for Internet Research

The Internet has provided some survey researchers the prospect of enrolling more participants in their projects; however, it has also eliminated the opportunity to initiate a traditional informed consent process.

Even though most survey research is considered to be minimal risk, the IRB still requires investigators to have a process in place to acquire informed consent.

Before the subject can participate in the research, he or she must be presented with a document that includes all the required elements of informed consent (Page 4, IRB 101).

Points to Consider

- The identity and age of participants are not easily verified with internet research. As such, it is possible that internet research with the potential to involve children or other vulnerable populations as subjects may not be approved by the IRB.
- If using a chat room, community board or forum, the IRB will require that authorization to use the venue is given from the webmaster of the site before consenting and data collecting. While The Internet is a public place, some users still consider their postings to be

private or intended for a targeted group. They may object to researchers observing their actions or soliciting them for participation in research.

Researchers must still obtain informed consent when using The Internet for data collection

Some examples of consent procedures that may be acceptable are given below:

Solicitation for participation through chat rooms, community boards or forums: The initial solicitation must indicate that the researcher has

received prior approval from the webmaster to post the request. Interested parties can then be directed to an informed consent page, as below.

Anonymous Surveys: The recruitment message can embody the informed consent language, including that completion of the survey implies consent to participate in the research.*

Identifiable or Sensitive Surveys: The subject can be taken to a screen that displays the informed consent document (ICD) and requires the individual to click "I Agree" or "I Do Not Agree". The participant must click "I Agree" before the survey can be taken.*

*The investigator must request that the IRB grant a waiver of written documentation of informed consent to use these methods. ❖

Regulatory Update:
OHRP Answers Frequently Asked Questions on Informed Consent

The Office of Human Research Protections (OHRP) has recently unveiled a new webpage of answers to frequently asked questions (FAQs) about informed consent.

Answers are given to questions such as:

- Is a faxed copy of the signed consent or parental permission form acceptable to document informed consent?
- What happens if a child reaches the legal age of consent while enrolled in a study?
- When does compensating subjects undermine informed consent or parental permission?

- What should be considered in seeking informed consent from individuals with diminished decision-making capacity?
- What is the definition of guardian in the context of obtaining consent for research involving children?

Check out the FAQ page on OHRP's website to find the answers to these questions and more, as well as to explore the FAQs on other topics such as Research with Children, Investigator Responsibilities, and Prisoner Research. You can also suggest a question and provide feedback regarding the responses.

Link: <http://www.hhs.gov/ohrp/faq.html>



Did You Know...

There were 866 people who needed to get their CREC recertification by September 1, 2007. Congratulations to the 599 of you who have recertified. There are still 267 people whose certification has now expired.

Please be aware that any IRB actions will not proceed until you are recertified!!

See the CREC website for options: <http://ora.ra.cwru.edu/research/orc/crec/index.cfm> ❖

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Online submissions:
<https://mhirb.metrohealth.org/irb>

Mailing address:

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MetroHealth Medical Center
2500 MetroHealth Drive
Room 103, Rammelkamp
Cleveland, OH 44109

Questions or suggestions for
Research Regulator??? Contact Tracy Wilson-Holden at
368-6131 or tjw18@case.edu.

IRB 101: Elements of Informed Consent

Eight Required Elements

Unless a waiver or alteration of the informed consent process has been approved by the IRB, researchers are required by Federal regulations to inform potential research participants of the following information:

Element 1

- the study involves research
- the purpose of the research
- the expected duration of participation
- the procedures to be followed, including identifying any procedures that are experimental

Element 2

- any reasonably foreseeable risks/discomforts

Element 3

- any benefits to subjects or others

Element 4

- any alternatives to the research or treatment options that may be advantageous

Element 5

- the extent to which confidentiality of records will be maintained, if any

Element 6

(for research involving greater than minimal risk)

- whether compensation or medical treatment is available if injury occurs
- what the treatment consists of, or where further information can be obtained

Element 7

- whom to contact for answers to pertinent questions about the research and research subjects' rights

- whom to contact in the event of a research-related injury

Element 8

- participation in the study is voluntary
- refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled

Six Additional Elements (if applicable)

The regulations require that these additional elements be included when they are relevant to the study:

Additional Element 1

- The procedure or treatment may involve risks that are currently unforeseeable

Additional Element 2

- The circumstances under which the subject's participation may be terminated by the investigator

Additional Element 3

- Additional costs to the subject that may result from participation

Additional Element 4

- The consequences of a subject's decision to withdraw and the procedure to be followed to ensure an orderly termination

Additional Element 5

- Assurance that the subject will be informed of any significant new findings that may affect his/her willingness to continue participating

Additional Element 6

- The approximate number of subjects involved in the study

Take the CREC Quiz online at: crecquiz.case.edu **one credit**

1. Having a copy of the signed informed consent document in a patient's medical record is sufficient documentation of consent.
 - a. True
 - b. False
2. Use of a short form to acquire informed consent from non-English speakers replaces the need to have a translator.
 - a. True
 - b. False
3. Potential research participants must be told this in the informed consent form:
 - a. How long their participation will be
 - b. That participating will help them
 - c. Whom to contact if they are injured as a result of the research
 - d. Only a and c above
4. Study staff who acquire consent should typically:
 - a. Be CREC certified
 - b. Practice consenting on other staff first
 - c. Have written guidance on when to consult with others about whether the subject is truly able to provide consent
5. Which of the following is not true of internet research:
 - a. The Internet is a public domain, and as such all research done using The Internet does not require IRB review.
 - b. Most internet survey research is minimal risk
 - c. Investigators should usually request a waiver of written documentation of informed consent.
 - d. A chat room or community board's web master should provide the investigator written documentation that they agree to allow the site to be used for research purposes.

This quiz is available for credit until 5 pm on **Monday, December 31, 2007.**

Take the quiz for **ONE** credit at:
crecquiz.case.edu

Local IRB Contacts

- **Case Cancer IRB**
<http://casemed.case.edu/ora/irb/>
- **Case Social/Behavioral IRB**
<http://ora.ra.cwru.edu/compliance/>
- **The Cleveland Clinic**
<http://cms.clevelandclinic.org/body.cfm?id=158>
- **Louis Stokes Cleveland VA Medical Center**
**This site is currently under construction. For assistance, contact deborah.fox2@va.gov
- **MetroHealth**
<https://mhirb.metrohealth.org/irb>
- **University Hospitals**
<http://www.uhhospitals.org/tabid/1294/Default.aspx>