Recruitment and Consent Discussions

Trish Lindstrom & Triana Nagel

Consent Process

The informed consent process is the **critical communication** link between the prospective human subject and an investigator, **beginning** with the initial approach of an investigator to the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study.

No man is good enough to govern another man without that other's consent. - Abraham Lincoln

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Three key features

1. Disclosing to potential research subjects information needed to make an informed decision;

2. Facilitating the understanding of what has been disclosed; and

3. Promoting the **voluntariness** of the decision about whether or not to **participate** in the research.

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Goals of the consent process

- Give the subject **information** about the research
- Make sure the subject has **time** to consider all options
- Answer all of the subject's **questions** before the decision is made
- Make sure that all information is **understood** by the subject
- Obtain the subject's voluntary informed **consent** to participate
- **Continue to inform** the subject throughout the research study
- **Continue to re-affirm subject consent** to participate throughout the research study

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Language

- Consent documents **must be clearly written and understandable to subjects.**
  - Scientific, technical, and medical terms must be in lay terms.
  - It is recommended that the consent be written at the 8th grade reading level.
  - When enrolling minors in a study, related recruitment materials must reflect the reading level of minors.

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Language

- Consent may **not** include **exculpatory language**, that is, language that appears to waive subjects' legal rights or appears to release the investigator or anyone else involved in the study from liability for negligence.
- Furthermore, consent must be provided in the language of the subject or alternatively a translator and the "short-form" can be used.

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Types of Consent

- Consent
- Parental Permission
- Assent
- Verbal
- Short Form
- Information/Fact Sheet
- Waiver of Documentation of Informed Consent
- Waiver of Elements of Informed Consent

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Written Consent Process

Obtaining written consent from a potential subject is more than just a signature on a form.

- Use as a guide for the verbal explanation of the study.
- The subject's signature provides documentation of agreement to participate in a study, but is only one part of the consent process.
- The consent document must not serve as a substitute for discussion.

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The role of the investigator

- The consent process benefits from a collaborative effort.
- Ultimately, the PI is responsible for ensuring that staff are using appropriate IRB-approved consent documents and correctly obtaining subject consent.

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Investigator responsibilities

- Obtain consent **before** initiating study-specific procedures.
- Provide a **quiet, comfortable, and private setting** for the consent process whenever possible.
- **Explain** the consent process to the subject.
- Make sure the subject has **time to consider** all options; allow subject to take the form home before signing (whenever possible).
- Consider the **subject's reading abilities**.
- **Answer all questions.**

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Investigator responsibilities

- To the extent possible, make sure the subject **understands enough information** about the research study to give consent and that they are **free from coercion or other undue influence**.
- Since the consent process continues throughout the subject's participation in the study, **consent should be informally verified on a continuing basis.**
- **Significant new information** must be given to the subject, and continuing consent documented in some way; for example, new risk information presented to the subject in an addendum to be signed by subjects who agree to continue to participate.

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Issues to consider

- Is the subject alert and, in your opinion, able to read and understand the language in the consent form?
- If the subject was unable to read the consent form, and limited or non-readers were allowed to participate, did you have an impartial witness present for the entire process?
- If the subject is not fluent in English, was an approved translation of the consent form provided in the primary language of the subject? Was there also a bilingual translator present to assist with the informed consent process? Note: a translator alone is not considered adequate.
- Was the subject under any pressure (for example, family pressure, lack of medical insurance) to participate in the research? Was this discussed?
- Did the subject take time to carefully read the consent form, or read it along with you?

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Explanation of the research

Investigators (or IRB approved designees) must use the following steps in order to orient the potential subject to the purpose of the research and why they might wish to participate:

Step One: The investigator (or IRB approved designee) must explain the study to the potential subject verbally, providing all pertinent information (purpose, procedures, risks, benefits, alternatives, privacy and confidentiality, participation, etc.), and must allow the potential subject ample opportunity to ask questions.

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Explanation of the research

Step Two: Following this verbal explanation, the potential subject should be provided with a written consent form and afforded sufficient time to consider whether or not to participate in the research. "Sufficient time" can range from hours to days, depending on how long it reasonably takes to evaluate the procedures, risks, potential benefits, and alternative treatments.

Step Three: After allowing the potential subject time to read the consent form, an investigator listed on the consent form should meet with the potential subject and answer any additional questions s/he may have.

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Subject comprehension

It is critical that the investigator not only fields questions but also asks questions.

Asking questions can further the discussion, elicit questions from the potential subject, prompt the potential subject to think more carefully about the study, and help the investigator decide whether the person has adequately understood the study.

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Subject comprehension

Useful questions will be open-ended and non-directive. Ex:

- "Just so that I'm sure you understand what is expected of you, would you please explain to me what you think we're asking you to do?“
- "What is the possible benefit to you of participating in this study? What are the possible risks?"
- "Can you describe what the alternatives to participation in this study are?”

In contrast, close-ended questions do not further discussion and tend to bring it to a stop, so they should be avoided. Ex:

- "Do you understand?“; "Do you have any questions?“; "Do you see that there are some risks to taking this drug?"

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Never

perform any study-related procedures before signed consent has been obtained.

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Dissent

In all research, whether the subject has consented himself, the IRB has waived consent, the IRB has approved consent by an LAR or the subject has appointed a research proxy **dissent is ALWAYS honored**. If the subject refuses to participate in portions of or all of the research - even though the subject is decisionally impaired - dissent is honored.

Participation in research cannot be forced or coerced.

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Tools an investigator might use

- Consent Form Pamphlets or other reading materials*
- Internet information*
- Instruction sheets*
- Audio-visual presentations*
- Charts or diagrams*
- Discussions
- Consultation with others

** These items require IRB review before use.*

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Developing a recruitment plan

Recruitment Letters

- When recruiting potential subjects from among their own patients, investigators must consider the possibility that their patients may feel obligated to participate because they are being asked by their treating physician.

Advertisements

- Few participants will take part in research unless they can identify with and understand its validity and relevance. Consequently, an adequate, clear and concise explanation must be provided.

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Advertisements

ANY advertisement used to recruit subjects should be limited to:

- The name and address of the clinical investigator and/or the research facility and the IRB number of the study;
- The condition under study and/or the purpose of the research;
- In summary form, the criteria that will be used to determine eligibility for the study (a complete list of eligibility criteria is not required);
- A straightforward and truthful description of the benefits or burdens (e.g. as applicable, payments, no cost treatment, the percentage of subjects who will receive a placebo) to the subject for participating in the study;
- The time or other commitment required of the subjects;
- The location of the research and the person or office to contact for further information.

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Advertisements

These requirements apply regardless of whether the advertisement is in print, on the radio, on television, social media, or on the Internet, with the exception that it is not required that the IRB number be read aloud for radio and TV ads.

http://www.fda.gov/RegulatoryInformation/Guidances/ucm126428.htm

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Advertisements

- Do not use the phrase “Free medical treatment”
- Do not call the intervention a new treatment, medication, drug, device, etc.
- If the study is a blinded multi-armed investigational drug study, describe the study arms in the following manner. “You will receive a pill (or patch, injection, etc.). This pill (or patch, injection, etc.) may contain the study drug, an inactive substance call a placebo…(continue listing any other possible interventions). You have a 1 in “X” chance of receiving the study drug.”
- When submitting an advertisement for review, indicate the media used and whether any subsequent advertisements in different media are planned.

Significant new findings, re-consent

- Obtaining a signature on a consent form does not complete the consent process.
- Maintaining informed consent requires that subjects be provided with any new information that arises during the course of the study
  - changes to the research plan, change in risk/benefit profile, the results of related research, etc. that may affect a subject's decision whether or not to continue participation in the study.
- When such information arises, the investigator may submit a modification request to revise the consent form and memo that briefly describes what changes have been made since the subjects last provided informed consent.
- Subjects must sign the updated consent form.

Significant new findings, re-consent

In some cases where new information arises during or after the research has begun, full re-consent may not be necessary or appropriate.

Written or verbal notification to subjects or no action at all may be acceptable.

- The significance of the information and the likelihood that it might affect subjects' willingness to continue participation
- The subjects' progress in the research (e.g. active study treatment vs. long-term follow-up)
- Whether there is a possibility of intervention (now or in the future) based on the new information
- Whether re-consent would require unnecessary inconvenience for subjects and/or excessive administrative burden for study staff
- Whether re-consent might create additional anxiety for subjects

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Significant new findings, re-consent

Investigators are authorized to act in the best interest of subjects with regard to relaying new information to subjects prior to IRB approval.

- If an investigator finds it appropriate due to the critical nature of the new information, subjects may be contacted and informed at the next reasonable opportunity, and given an opportunity to withdraw from the study.

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Methods for re-consent and/or notification

1. Re-consent using an updated APPROVED version of the original consent form. Best reserved for extensive changes to the study design, procedures, or risks. A cover letter and/or a system for showing subjects what has changed (e.g. highlighting new information) may help improve subject comprehension.

2. Re-consent using an addendum to the original consent form. This may be useful when new information is limited to a relatively narrow topic, such as new or modified risks.

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Significant new findings, re-consent

3. Re-consent using a letter with signature. When subjects are not scheduled for an in-person visit and the nature of the information does not necessitate a personal conversation (because it's a clear or simple change or little action is required), researchers may send subjects a letter and ask them to return a signed acknowledgement. The letter should include a contact phone number that subjects may call if they have questions.

4. Oral Re-consent. Oral re-consent may also precede written re-consent when necessary to relay time-sensitive critical information to subjects.

5. Notification via letter or conversation. Information unlikely to change a subject's willingness to participate in the study may not warrant re-consent. Oral or written notification, depending on the circumstances (such as whether the subject is scheduled for a visit in the near future), may be sufficient.

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Scenario 1: A potential subject must change or stop taking a certain medication in order to be eligible for a study.

- **Issues to Consider:** Changing medications to make a subject eligible for a study is considered an intervention for research purposes. Consent is required **before** any research interventions may take place.
- **Solutions:** Obtain consent for study participation before making any changes to the subject's medications. Ask for a protocol exception from the sponsor and IRB for a potential subject who is technically ineligible but may benefit from the study.

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Scenario 2: A study has two separate consent forms, one for the screening phase and one for the experimental treatment phase. The Legally Authorized Representative (LAR) who signed the screening consent on behalf of the subject is not available to sign the second consent. Does the same LAR have to sign all consent forms for a study?

- **Issues to Consider:** Determining who may serve as an LAR involves considering a hierarchy of possible individuals and their availability. If a preferred LAR is not available, someone else, such as next of kin, may serve as an LAR. Therefore, the most appropriate LAR may be different at different points in the study. Keep in mind that the LAR must be informed about all aspects of the study, not just the portion for which he or she is being asked to provide consent.
- **Solutions:** The LAR signing the second consent form may be different than the first as long as he or she meets the criteria for being an LAR under IRB and OHSU institutional policy and is fully informed about all aspects of the study that may influence the decision to consent on behalf of the subject.

LAR

- Not specifically designated by subject to make research decisions
- Subject didn't assign a proxy before he/she lost capacity
- Restricted to family members and legal guardians
- Assumption that family in best position to know what the subject would want (substituted judgment) or decide in subject's best interest
- "An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research *"45 CFR46.102©; 21CFR50.3(k)*
- Sequence of kinship: spouse, adult child, parent, sibling…
- LAR consent from spouse obtained whenever possible; if incapable or can't be reached in a reasonable time, document and move down the line of kinship

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Example: If a subject reaches the age of majority during the study do they need to provide consent in order to remain in the study?

- Not specifically designated by subject to make research decisions
- Subject didn't assign a proxy before he/she lost capacity
- Restricted to family members and legal guardians
- Assumption that family in best position to know what the subject would want (substituted judgment) or decide in subject's best interest
- "An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in research *"45 CFR46.102©; 21CFR50.3(k)*
- Sequence of kinship: spouse, adult child, parent, sibling…
- LAR consent from spouse obtained whenever possible; if incapable or can't be reached in a reasonable time, document and move down the line of kinship

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Temporary decisional impairment

If the research calls for enrollment of decisionally-impaired subjects (i.e. comatose) who may later become able to consent then arrangements must be made to consent the subjects as soon as they are able. The wishes of the subject always supersede those of the LAR.

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Scenario 3: A child presents as a potential subject for a clinical trial, and parent permission is required to enroll the child. The parent is out of town and cannot be physically present for a consent discussion. The IRB has not waived any elements of consent or documentation.

- **Issues to Consider:** The parent still must be fully informed about the study, and all regulatory elements of consent must be present. Documentation of consent is also required.
- **Solutions:** The consent discussion can be conducted over the phone. The consent form must be provided to the parent, signed, and a copy must be returned to the investigators. This can take place via mail, fax, or email. The child may not be enrolled until documentation is complete.

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Scenario 4: A study involves screening a large number of subjects, so phone screening takes place before a subject is asked to come in for a first study visit.

- **Issues to Consider:** Obtaining private information about an individual over the phone for research purposes requires consent (and authorization if the information is Protected Health Information [PHI]). However, it is generally considered minimal risk and eligible for a waiver of documentation of consent and a waiver of authorization.
- **Solutions:** Ask the IRB for a waiver of documentation of consent and a waiver of authorization that will apply to the phone screening portion of the study only. Obtain verbal consent for the screening over the phone. If a subject comes in for a visit, obtain fully documented informed consent and authorization at that time.

Scenario 5: A study involves conducting a focus group. It would be more efficient to obtain consent by explaining the study to the entire group at the same time.

- **Issues to Consider:** Focus groups are often considered minimal risk and eligible for a waiver of documentation of consent. In asking individual potential subjects for consent, be mindful of the fact that other members of the group may influence their decision if they are being asked to agree to participate while others are present or are not given a confidential opportunity to ask questions.
- **Solutions:** In some cases, it may be appropriate, with an IRB-approved waiver of documentation of consent, to conduct a group consent discussion that includes group Q & A, but each individual must be given the opportunity to decline participation. When group research involves sensitive issues or information or controversial methods, it may be necessary to provide a private opportunity for each individual to have questions answered and indicate his or her decision about participation.

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Scenario 6: Study subjects are asked to take an online survey. There is no plan to initiate any personal or telephone contact with the subjects.

- **Issues to Consider:** Surveys are often considered minimal risk and eligible for a waiver of documentation of consent. However, there is still an opportunity to inform subjects about the study and their choice in participating, so a waiver of consent is not appropriate.
- **Solutions:** Before subjects access the online survey, an "information sheet" should be viewable (for instance, an email or web page with a link at the bottom to enter the survey) that includes the basic elements of informed consent. It should also include an email or phone number so that subjects can contact the investigators with questions. Subjects can indicate willingness to participate by completing the survey.

Analyst Calls

If a subject reaches the age of majority during the study do they need to provide consent in order to remain in the study?

Minors who were initially enrolled with parental/guardian permission and then reach the age of majority must provide legally effective consent if the project continues to meet the definition of research involving human subjects. This includes interacting or intervening with the subject or having access to private identifiable information.

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Consent of a non-English-speaking subject

- Using a fully translated, IRB-approved consent form with a translator present to facilitate the discussion; or
- Using verbal translation of the consent form and asking the subject to sign a short form in his or her own language. This process requires:
- A witness to observe the consent discussion *(may be the translator)*;
- The signatures of the subject and the witness on the short form; and
- The signatures of the person obtaining consent and the witness on the full consent form.
  - The translator may not be the subject's family member.

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Preparing the IRB Submission

- The consent process is fully described in the protocol, IRQ, or other study documents, including a description of:
  - How subjects will be recruited;
  - How the consent discussion will take place (e.g. in person, over the phone, etc.);
  - Any specific requirements or limits on the time, place or manner for obtaining consent (e.g. before a subject receives a drug that may affect judgment; waiting period between the consent discussion and asking for signature; etc.); and
  - If a waiver or alteration is being requested for some or all parts of the informed consent process, justification for the waiver or alteration.

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Preparing the IRB submission

- The person(s) who will obtain consent from subjects are designated in the IRQ as having this responsibility.
- The consent document complies with all OHSU template and standard language requirements and is uploaded to the eIRB.
- All recruitment materials are uploaded to the eIRB
- For studies anticipating participation by subjects who do not speak English, alternate language materials, such as a short form consent document or a translated consent form, are uploaded to the eIRB. A translator's certificate or memo describing the translator's credentials is required if the translated document is not available on the IRB forms website.

Ongoing Responsibilities

- A copy of the signed consent document is maintained in the research record.
- A copy of the signed consent document is uploaded to the subject's medical record if the study is FDA-regulated or involves clinical procedures.
- The subject is informed throughout the study of any new risks or other information that may change his or her willingness to continue participation.
- Modifications to the consent process and/or consent document are approved by the IRB before they take effect, unless it is in the subject's best interest to be informed of a change sooner.
- Consent/re-consent of the subject or consent from a subject's LAR, as appropriate, is sought if the subject's capacity to consent changes during the study.

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Important Reminders

Do **NOT** use an unapproved (unstamped) consent form.

Do **NOT** use an expired consent form.

Changes will be made to the consent document during the course of the study. It is the PI's responsibility to ensure that the individual signs the latest version of the consent document.

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Questions?

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Mark your calendars!

IRB Myths Busted

January 24th, 2013
11:30am to 12:30pm
UHS 8B60

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