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Consent Process

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

- The consent document is to be used as a guide for the verbal explanation of the study.
- The consent document should be the basis for a meaningful exchange between the researcher and the participant.
- The participant'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.

See HRPP Policy Manual [4] Ch 12 Informed Consent and Assent for policy on the consent process, waivers, consent of vulnerable populations, assent, etc.

The entire informed consent process involves giving a participant adequate information concerning the study, providing adequate opportunity for the participant to consider all options, responding to the participant's questions, ensuring that the participant has comprehended this information, obtaining the participant's voluntary agreement to participate, and continuing to provide information as the participant or situation requires. To be effective, the process should provide ample opportunity for the researcher and the participant to exchange information and ask questions.

- Basic Research Consent Requirements [5]
- General Requirements for Informed Consent [6]
- Observation of the Consenting Process [7] (checklist)

Consent Templates, Glossary, and Suggested Language

- Consent form templates and samples are available, tailored to research with different characterisics. See Forms & Templates [8].
- Glossary - According to federal guidelines, consent form langauge should be suitable for the general public, written at the 8th grade level. The resources below translate commonly used scientific words into lay language

that may be more easily understood:
  - Lay Language Glossary [9]
  - Clinical Trials Terms [10]
  - Commonly Used Acronyms [11]

- Suggested Language
  - National Comprehensive Cancer Network (NCCN) Informed Consent Language Database [12]
  - Research Involving Diagnostic Use of Ionizing Radiation [13]

Documenting Consent

Written, signed consent should be sought unless there are compelling reasons to seek an alteration or waiver of consent or waiver of documentation (e.g., signature). See:

- Consent Form Do's & Don'ts [14] (a practical guide)
- Regulations for Waiver or Alteration of Consent Requirements [15]

Surrogate Decision Makers

When participants who lack the capacity to consent are included as research participants, federal human subjects regulations require that consent for research be obtained from the subject?s ?legally authorized representative? (see Research Surrogate Decision Makers [16]).

Parental Permission

When children are included as research subjects, in most circumstances parental permission must be obtained (see Parental Permission [17] (pdf) and IRB Guidance For Investigators on Consent for Protocols Involving Children and Consenting Minors [18]).

Non-English Speaking Partcipants; Translating the Consent Document

Stanford University is located in a culturally diverse region. Investigators are encouraged to recruit and include all segments of our community in research, including individuals whose primary language is not English.

Participants who do not speak English should be presented with a consent document written in a language understandable to them. The Stanford HRPP and OHRP strongly encourage the use of a full consent form translated into the participant?s language whenever possible. Written consent documents should embody, in language understandable to the participant, all the elements necessary for legally effective informed consent.

When all of the participants in a study (i.e., the target population) are anticipated to be non-English speaking, a full translated consent is necessary, and it is important that consent forms be translated accurately. Procedures for ensuring accurate translation should be described. For more information contact:

- Translation Services at Stanford Hospital and Clinics at (650) 721-7457
- Interpreter Services at Lucile Packard Children?s Hospital at (650) 497-8371
- To contact or schedule an interpreter, call (650) 723-6940, page (24/7) 17726, or email interpreterservicesSHC@stanfordmed.org [19].

Federal regulations permit use of a Short Form Consent Process [20] under certain circumstances, when approved

by the IRB.
Translated short form consent templates [21] are available in many languages.

Special Stanford University Situations

Bing Nursery School Studies

The Bing Nursery School was constructed as a laboratory school in 1966 with a grant from the National Science Foundation and a gift from Dr. Peter S. Bing and his mother, Mrs. Anna Bing Arnold. The purpose of the school is to provide a laboratory where undergraduates at Stanford can learn first-hand about child development and where faculty members and graduate students can conduct research in child development.

Each individual study posted on the school Study Board is reviewed and approved separately by the IRB, but parental permission is obtained from parents at the beginning of each school year, allowing their child to participate in research studies conducted at the school. Parents can choose to have their child 'opt-out' of individual studies.

Psychology Pool and Q-Day

Once a year, on Questionnaire Day (Q-Day), students in the Psychology Department Subject Pool are asked to complete a packet of pre-selection forms and surveys. Students tell the Pool about themselves and their preferences, noting information such as gender, age, handedness, or political affliation and beliefs. Researchers may then recruit participants based on these demographics. Students enrolled in psychology classes sign up to participate in a variety of minimal risk studies, either for classroom credit or for payment. Each study is separately approved by the IRB.

Links
[1] https://rco.sites.stanford.edu/panels/hs/forms/consent/non-english
[2] https://rco.sites.stanford.edu/panels/hs/consent/forms/short-form-consent-process
[3] https://rco.sites.stanford.edu/panels/hs/forms/consent/assent-process
[4] https://stanfordmedicine.box.com/shared/static/l2u7ynl9ixc2trf39ku796jjgzkcxsgf.pdf
[5] https://stanfordmedicine.box.com/shared/static/efb7eagptdvfp4j6ih6bfs438iaewss2.pdf
[6] https://stanfordmedicine.box.com/shared/static/abnw9zaduffrrj48okqf0bdsue8m83iz.pdf
[7] https://stanfordmedicine.box.com/shared/static/azmq9212ujg6cmhjmmrix8fleeho8df7.doc
[8] https://researchcompliance.stanford.edu/panels/hs/forms/forms-templates
[9] https://stanfordmedicine.box.com/shared/static/c55fwg30hr0w92awpbfgk3jaca7o6w0x.pdf
[10] https://stanfordmedicine.box.com/shared/static/war1ui5kbqi26t4l3juig76dujx0wti8.pdf
[11] https://stanfordmedicine.box.com/shared/static/ujcj7g1l52o0sjtepb31by8709083brh.pdf
[12] http://www.nccn.org/icl/default.aspx
[13] https://ehs.stanford.edu/manual/radiation-protection-guidance-hospital-staff/guidance-preparing-research-proposals-involving
[14] https://stanfordmedicine.box.com/shared/static/htaj9twheowi56dzuznte6whbp86bfhp.pdf
[15] https://stanfordmedicine.box.com/shared/static/6s5bimwuqdan2k5zxr3kbzdghctjgbx8.pdf
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[18] https://stanfordmedicine.box.com/shared/static/tnxkpep2r6fzptdglt6jkgibopype0zt.pdf

[19] mailto:interpreterservicesSHC@stanfordmed.org
[20] https://researchcompliance.stanford.edu/panels/hs/consent/forms/short-form-consent-process
[21] https://researchcompliance.stanford.edu/panels/hs/consent/forms/short-form-consent-process#temps