General Considerations

One significant outcome of the Nuremberg medical trials was the establishment in 1947 of the Nuremberg Code, which set forth ten principles for conducting research involving human subjects. The first of those principles states, "the voluntary consent of the human subject is absolutely essential." Thus, no investigator may involve a human being as a subject in research, as defined in this policy and procedure manual, unless the investigator has obtained the subject's informed consent. The process of informed consent is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e. his or her consent is voluntary. Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this manual.

Additionally, the researcher should be aware that litigation against the University is always a possibility. From this perspective, even an ethical informed consent is not sufficient. Rather, we need an ethical informed consent which is legally valid and the legal validity of which can be demonstrated should such a need arise.

Researchers are to use consent forms that have been stamped by either the center representative or the IRB as permitted.

The researcher should also be aware that signed informed consent form documents must be retained for a minimum of three (3) years from the date the study is concluded (or longer depending on the requirements of certain funding agencies).

Types of Informed Consent Forms

There are four types of consent forms. Please note that the IRB has provided two different templates for the Adult/General Consent Form and for the Parental Consent Form (these instructions are applicable to both templates):

Adult/General Consent Form

Used for subjects 18 years and over who are capable of giving informed consent. This includes most adult subjects. In some cases, parents are participating in a study while their child is not. The Adult/General Consent Form would be the appropriate choice. If parents are giving consent for both their child to participate in a study and agreeing to participate themselves at the same time, the Parent/Guardian Consent Form should be used.

Consent Forms should be written at a readability level commensurate with
the proposed subjects. It is recommended that consent forms not exceed the 8th grade reading level in most cases.

Child Assent Form

For children between the ages of age 7 and 12, an assent form is used which is written in a simpler format with language appropriate to the youngest child in this age range; however, it still contains the major required elements. This form is used in conjunction with the Parent/Guardian Consent Form. For children under 7, the same information needs to be conveyed but may be done orally at the child’s level of development. The oral explanation of the study to the child should be attested to by the parent on the Parent Consent Form when a written assent is not possible. Infants and children unable to understand do not need a written assent.

You will note that the IRB has provided model assents at two different readability levels. Researchers are encouraged to consider the population of their study as they develop their assent forms. These model forms are suggestions. Researchers are also encouraged to use readability tools available in many word-processing software such as MSWord. See Readability Tool instructions on the following IRB Web site (http://www.nova.edu/irb/manual/forms.html). Remember that the consent forms should be written for the readability level of the youngest participant and/or the lowest grade/readability level.

Adolescent Assent Form

Used when subjects are in the age range of 13-17. The Adolescent Assent Form is generally the same as for the adults except it is written in language appropriate to the youngest teenager to be included in the study. This form is used in conjunction with the Parent/Guardian Consent Form.

You will note that the IRB has provided model assents at two different readability levels. Researchers are encouraged to consider the population of their study as they develop their assent forms. These model forms are suggestions. Researchers are also encouraged to use readability tools available in many word-processing software such as MSWord. See Readability Tool instructions on the following IRB Web site (http://www.nova.edu/irb/manual/forms.html). Remember that the consent forms should be written for the readability level of the youngest participant and/or the lowest grade/readability level.

Parent or Guardian Consent Form

Anytime a subject under 18 is used consent must be obtained from the parent or guardian. This form is again similar to the Adult/General Form. However, rather
than saying “you” the subject is referred to as “your child.” This form would also contain information regarding any parental/guardian participation in the study. If the study requires a guardian of an adult to provide consent it should read “your ward.”

Consent Forms should be written at a readability level commensurate with the proposed subjects. It is recommended that consent forms not exceed the 8th grade reading level in most cases.

Studies may need to use only one or several of these forms, depending on the groups involved in the research. For example, if different procedures are used for teachers and parents, use two different consent forms.

**General Requirements for the Consent Form**

All sections described below must be included in every consent form. The length or applicability to a given study may vary, but the sections must appear in the standard order listed on the example document layouts. This allows the IRB to see quickly that the researcher has considered all elements of the consent form.

- The first page of the consent form should be on Nova Southeastern University letterhead, except in cases of collaborative projects when the letterhead from a hospital, university, etc. is acceptable. All letterhead must be the original, not a copy and not digitally created. All proposed consent forms must be submitted on NSU letterhead as well. Please contact your Center Representative for NSU letterhead.

- The consent form should be in language understandable to the subject or his or her legal representative. It must be written in a consistent voice: either first, second, or third person (not a combination). In general, the consent form should be in second person (“You are being asked to participate…..”). The consent language of the child or adolescent assent should account for the ages of the subjects. For subjects who would better comprehend the consent form in their native language the consent must be provided in a translated version.
• Translations and Translation Services

For protocols that may be reviewed at the Center Level or Expedited Review Level the IRB will permit researchers to translate consent materials and instruments themselves and submit the original English and Spanish versions for review by the designee of the IRB chair. Such translations should not be submitted until the English version of consent materials is approved. The translation does not have to be conducted by a certified translator. For documents translated into all other languages, the IRB requires that the documents be translated by a certified translator unless the Chair can identify a member of the IRB or an appropriately trained individual who is able to check the translation. Please contact your center representative or the IRB office regarding other languages.

For protocols requiring a full review, all documents that are to be translated must be translated by a certified translator unless this is waived by the Full IRB.

The university recommends but does not mandate that researchers use the services of Student Services International, Inc. for the certified translations.

Student Services International, Inc
2455 East Sunrise Boulevard, Suite 200
Fort Lauderdale, FL 33304
954-565-8505 xt 29
fax 954-565-8718
www.talkinusa.com

Regardless of the translation service, documentation must be provided that states the translator is certified.

Translations should not be commenced until the IRB has approved the English version of the consent materials and instruments.

• If the research is externally funded, the funding agency should be listed under funding source.

• The title of the study and the name, address, and telephone number of the investigator(s) follow immediately after funding source. The Principal Investigator’s address and phone number, and the number of the IRB Office (954-262-5369) must appear on the consent form. If the principal investigator is a student, the address and phone number of his/her advisor(s)/clinical supervisor(s) must also appear on the form. If the
research is conducted as a setting where contacting the researcher or the advisor might be difficult (such as when the research is done out of state or in a prison) a local contact who the subject can easily reach should also be listed.

- Informed consent should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.

- Language that states that research files could be audited by regulatory agencies when appropriate.

- When required by the IRB, one or more of the following elements shall be provided to each subject:
  (a) Statement that procedure may involve unforeseeable risks to the subject;
  (b) Description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent;
  (c) Additional costs to the subject resulting from participation in the research;
  (d) Approximate number of subjects involved in the study.

- Use of authorized signature lines in addition to subject lines on the consent form may be required depending on the nature of the study and the types of subjects you plan to use. If a subject is represented by an individual (proxy) to make medical and/or research decisions this person would then be required to sign the informed consent form. If your study will only comprise individuals who are able to consent or assent to participate then there is no need for the authorized signature line and date and no need to provide space for a description of what the authorization is based upon. As a result, the consent/assent forms for such a study would only have the participant’s signature line/date and the witness’s signature line/date.

- **Audio/Video Taping**

  For all projects submitted to the IRB which include any form of audio recording of any portion of the research project, the following section should be included as the SECOND section of the consent (with optional areas filled in as appropriate for the proposed project). The wording should be simplified for child assents:

  **Is there any audio or video recording?**
This section should include information related to audio or video recording if it is applicable to the project proposed. If there is audio and/or video recording, please include the following paragraph:

“This research project will include audio (and/or video if applicable) recording of (SPECIFY WHAT IS BEING RECORDED AND HOW). This audio (and/or video) recording will be available to be heard by the researcher, the IRB, any granting agencies (IF APPROPRIATE also SPECIFY which agencies), and the following (SPECIFY: such as dissertation chair or committee, other researchers, classes, or no one else or as appropriate). The recording will be transcribed by (BE SPECIFIC, including “The recording will not be transcribed.” if no transcription will take place). The recording will be kept securely (SPECIFY WHERE AND HOW). The recording will be kept for XX months (SPECIFY) and destroyed after that time (SPECIFY HOW). Because your voice (or your image and your voice) will be potentially identifiable by anyone who hears (or hears and sees) the recording, your confidentiality for things you say (or do) on the recording cannot be guaranteed although the researcher will try to limit access to the tape as described in this paragraph.”

Frequently Asked Questions

- When are consent forms required?

Consent forms are required in all studies that collect information for or about human subjects except under the following conditions:

1. Research on a de-identified dataset (as previously defined)
2. Research on a limited dataset pursuant to a dataset agreement
3. Research or preliminary research authorized by a duly appointed privacy board
4. Research conducted using an anonymous survey to adults, where a statement about the voluntary nature of the survey is contained in the survey instructions

- Does the consent form always have to be signed?

In general, all consent forms must be signed. A copy is to be given to the subject as well after all of the signatures have been secured. Principal investigators must maintain a copy of the signed executed forms in their research records. The IRB may waive the requirement to obtain a signed consent form for some or all subjects if:

1. the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality, and
2. the research presents no more than minimal risk and involves no
procedures for which written consent is normally required. In cases where documentation is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research. For example, there are some surveys where the likelihood of any risk is minimal (such as a questionnaire about food preferences) and where the only information identifying the client would be the signature on the consent form. In such cases, instead of a signature line, the researcher may add at the end of the standard consent form, “I understand that my completion of this survey (or questionnaire) implies my consent to participate in this study.”

- **Do I always have to use the NSU consent form format?**

In general, the answer is yes; however, in cases where the study is being done in its entirety at another institution with a federally approved IRB, the researcher may request that he or she use the form of that institution. In such cases, the researcher must submit the alternate consent form along with approval from the other IRB. Such a request will be reviewed to see that the form meets NSU requirements although in a different format. In cases where the requirements are met, the alternate consent form may be used. In other cases, the IRB may suggest alterations to bring the form into compliance, or, if this is not possible, the use of two consent forms.

- **How long should I keep signed informed consent forms?**

Signed consent forms should be retained in a secure file for a minimum of three (3) years from the date the study was concluded. You should note, however that some funding agencies require a longer period of time. For multi-site studies, the date of study completion may exceed the date you stop the study at your local site. The date you must use to account for the three years is the date ALL research related to the study concluded.