

## Consent Form Checklist for Adult & Parental/Legal Guardian Consent Forms

This checklist will help you be sure that you have included all the required elements in the consent form(s).

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| <b>Heading</b>                              | <input type="checkbox"/> North Park University (and any other University or Institution as appropriate)<br><input type="checkbox"/> "Consent to Participate as a Research Subject Form" (or "Parental permission/Informed Consent" or "Assent to Participate")<br><input type="checkbox"/> Title – specific to study and subject group<br><input type="checkbox"/> Investigator name(s), title(s), department/division affiliation(s), telephone number(s)<br><input type="checkbox"/> "Investigator's Statement" heading (use statement provided in template as appropriate for adult or parental consent)<br><input type="checkbox"/> Paragraph about what a consent form is   |
| <b>Purpose of the Study</b>                 | <input type="checkbox"/> "Purpose of the Study" heading<br><input type="checkbox"/> Statement of purpose of research   |
| <b>Description of the Study</b>             | <input type="checkbox"/> "Description of the Study" heading<br><input type="checkbox"/> Use of word "study," "research," or "investigation" to describe activity<br><input type="checkbox"/> Description of study design (i.e., field research, survey, placebo-controlled, cross-over, blinding, etc.)<br><input type="checkbox"/> Time commitment<br><input type="checkbox"/> Examples of sensitive and personal questions<br><input type="checkbox"/> Use of medical or other personal records<br><input type="checkbox"/> Description of blood or other tissue amounts in lay terms, where appropriate<br><input type="checkbox"/> Statement that subject may refuse to answer questions or other survey items   |
| <b>Potential Risks Stress or Discomfort</b> | <input type="checkbox"/> "Potential Risks, Stress, or Discomfort" heading<br><input type="checkbox"/> Description of reasonably foreseeable risks, stresses, and discomforts<br><input type="checkbox"/> How side effects will be handled; to whom to report, etc.<br><input type="checkbox"/> If radiation, state amount of exposure and level of risk  |
| <b>Potential Benefits</b>                   | <input type="checkbox"/> "Potential Benefits" heading<br><input type="checkbox"/> Realistic statement of possible benefits or no benefits, to subject and society<br><input type="checkbox"/> Statement that subjects, themselves, may not benefit from this study (if appropriate)  |
| <b>Alternative Methods of Treatment</b>     | <input type="checkbox"/> "Alternative Methods of Treatment" heading (if appropriate)<br><input type="checkbox"/> Alternatives to study participation, including no treatment   |
| <b>Confidentiality</b>                      | <input type="checkbox"/> "Confidentiality" heading<br><input type="checkbox"/> Description of extent of confidentiality/anonymity<br><input type="checkbox"/> Who will have access to identifiable data<br><input type="checkbox"/> Where will confidential data, etc., be stored (We recommend that you state it will be stored in locked file in the investigator's office or other appropriate setting).<br><input type="checkbox"/> If data will be linked, i.e., will master file with identifier information to numeric codes. be stored in a separate locked file?<br><input type="checkbox"/> How long identifiable data will be retained (NPU IRB Policy is 7 years)<br><input type="checkbox"/> Description of how data will be destroyed after the completion of the study (The NPU IRB recommends that you shred all identifying and original hard copy data. Videotapes and other |

photographs should be erased or shredded, unless you have been approved by the IRB to keep the videotapes and photographs for educational purposes after the completion of the study with the subject's and parent/legal guardian's consent(s).

- ☐ Statement that confidentiality will be maintained to the extent allowed by law
- ☐ If appropriate, you have stated that all additional researchers in the study will be trained in all confidentiality measures of the study

**Incentives to Participate**

- ☐ "Incentives to Participate" heading
- ☐ State what is being offered, amount of incentive, and what is required to obtain incentive
- ☐ Statement if incentive is not offered for participation

**Costs and/or Compensation for Participation**  
**Compensations for Injury**

- ☐ "Costs and/or compensation for participation" heading
- ☐ State if costs associated with participation
- ☐ If costs involved, description of remuneration/costs, pro-rated compensation
- ☐ "Compensations for Injury" heading (if study is more than minimal risk)
- ☐ Statement of whether medical treatments are available if injury occurs
- ☐ Description of who will bear financial responsibility for adverse effects and where further information can be obtained
- ☐ Whom to call if subjects have an adverse event

**Voluntary Nature of Participation**

- ☐ "Voluntary Nature of Participation" heading
- ☐ Standard statements that participation is voluntary and that subjects are free to withdraw from study at any point in time without penalty (use statement provided in template as appropriate for adult or parental consent)

**Questions about the Study**

- ☐ "Questions about the Study" heading
- ☐ Whom to call with questions about the study
- ☐ "If you have questions about your rights as a subject, contact the Institutional Review Board at IRBChair@northpark.du or call at: (find the current IRB chair's phone number and insert here)"

**Subject's Statement:**

- ☐ "Subject's Statement" heading
- ☐ Standard statement (use statement provided in template as appropriate for adult or parental consent)
- ☐ Subject's signature, printed name and date line
- ☐ If appropriate, parent/guardian/legally authorized rep. signature, printed name and date line
- ☐ Researcher's signature, printed name and date line

**Other:**

- ☐ Appropriateness of language for intended population (8th grade or lower)
- ☐ Legibility of form (use font size no smaller than 10)
- ☐ When videotaping, audio taping or taking pictures, a statement agreeing to being videotaped or audio taped along with a checkbox or space for signature, must be included on the consent form, usually at the end of the document, before the signature lines.

**\*\*See the Institutional Review Board Guidelines for additional elements of consent.**