

## INFORMED CONSENT CHECKLIST BYU HRPP

The purpose of this checklist is to provide support for IRB Principal Investigators when writing the consent forms for their studies. This checklist can be used for all submissions (new, modifications, and renewal) that research subjects.

**Project Title:** Enter text.

**IRB#:** Enter text.

**Principal Investigator:** Enter text.

| INTRODUCTION                                                                                                                                                                                                                                                                                                           | YES                      | NO                       | N/A                      |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|
| 1. Why were they chosen                                                                                                                                                                                                                                                                                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. A statement that the study involves research                                                                                                                                                                                                                                                                        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. An explanation of the purposes of the research                                                                                                                                                                                                                                                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. The expected duration of participation (include active & follow-up)                                                                                                                                                                                                                                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Number of visits                                                                                                                                                                                                                                                                                                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PROCEDURES                                                                                                                                                                                                                                                                                                             | YES                      | NO                       | N/A                      |
| 1. Description of procedures including <ul style="list-style-type: none"> <li>Procedures at each visit matches the protocol.</li> <li>Procedures clearly described and organized (in lay language)</li> </ul>                                                                                                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| RISK                                                                                                                                                                                                                                                                                                                   | YES                      | NO                       | N/A                      |
| 1. Reasonably foreseeable risks/discomforts                                                                                                                                                                                                                                                                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Reasonably foreseeable of the procedures                                                                                                                                                                                                                                                                            | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| BENEFITS                                                                                                                                                                                                                                                                                                               | YES                      | NO                       | N/A                      |
| 1. Reasonably expected benefits to subjects/others                                                                                                                                                                                                                                                                     | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Appropriate alternative treatments defined (if applicable)                                                                                                                                                                                                                                                          | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| CONFIDENTIALITY STATEMENT                                                                                                                                                                                                                                                                                              | YES                      | NO                       | N/A                      |
| 1. Injury statement (if applicable), including (if more than minimal risk: <ul style="list-style-type: none"> <li>Description of available compensation</li> <li>What treatment consists of, if applicable</li> <li>Who to contact for a research related injury</li> <li>24-hour emergency contact number?</li> </ul> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Participation statement, including: <ul style="list-style-type: none"> <li>Participation is voluntary</li> <li>Refusal to participate will involve no penalty or loss of benefits</li> <li>Subjects may stop participation at any time- without penalty/loss of benefits</li> </ul>                                 | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Who to contact for information about research                                                                                                                                                                                                                                                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Contact for questions about research subject's rights                                                                                                                                                                                                                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| COMMENTS                                                                                                                                                                                                                                                                                                               |                          |                          |                          |

| Additional Elements, as Appropriate:                                                                                                                                      | YES                      | NO                       | N/A                      |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|--------------------------|--------------------------|
| Research may involve unforeseeable risks to the subject                                                                                                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Risks to pregnant women/ embryo/ fetus or nursing baby                                                                                                                    | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Costs/additional costs to subject from participation                                                                                                                      | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Circumstances under which the subject's participation may be terminated without regard to the subject's consent                                                           | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Payment for participation described (pro-rated, reasonable)                                                                                                               | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Procedures for orderly termination of participation                                                                                                                       | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Medical /scientific terminology defined                                                                                                                                   | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| A statement that significant findings during the course of research that might affect the subject's willingness to continue participation will be provided to the subject | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The approximate # of subjects in the study                                                                                                                                | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Legal guardian consent, if needed                                                                                                                                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Comments:</b>                                                                                                                                                          |                          |                          |                          |
|                                                                                                                                                                           |                          |                          |                          |
| <b>Reviewer:</b>                                                                                                                                                          | <b>Date:</b>             |                          |                          |