

**UNIVERSITY OF ALABAMA INSTITUTIONAL REVIEW BOARD
FOR THE PROTECTION OF HUMAN SUBJECTS**

IRB Project # _____ Date _____

IRB Project Title _____

**CHECKLIST FOR IRB
(Office for Research)**

Does IRB member have a conflict of interest with project? Yes No
Name _____

Date Submitted from Investigator _____

Date Reviewed by OR _____

Assessment and Minimization of Risk:

- Assessment of level of risk (check appropriate category):
 - no risk:
 - minimal risk [The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.]:
 - greater than minimal risk but has potential direct benefit:
 - greater than minimal risk and no direct benefit but has potential to yield generalizable knowledge about the subjects disorder or condition:
 - if risk is greater than minimal, are the risks reasonable in relation to the potential benefits? Yes No

- Are the risks:
 - Physical
 - Psychological
 - Social
 - Economic

- Have risks for all subjects been minimized via use of an appropriate research design? Yes No
- Has safety been maximized for all subjects? Yes No

Assessment of Subject Population/Recruitment:

- Is the proposed subject population equitably distributed (e.g. gender, religion race, and ethnic group)? Yes No
- Are inclusion and exclusion criteria appropriate? Yes No
- Does the study include vulnerable subjects? Yes No
Indicate (**circle**) vulnerable subjects to be enrolled:
minors,
pregnant women,
prisoners,
fetuses,
mentally disabled individuals,

economically or educationally disadvantaged persons

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|--------------------------|--|-----|----|
| <input type="checkbox"/> | Are additional safeguards in place to protect vulnerable subjects? | Yes | No |
| <input type="checkbox"/> | Are all subjects' rights and welfare protected? | Yes | No |
| <input type="checkbox"/> | If minors are to be enrolled in the study will assent be obtained? | Yes | No |

Privacy/ Confidentiality

- | | | | |
|--------------------------|--|-----|----|
| <input type="checkbox"/> | Is private medical/psychiatric information being requested (e.g. in questionnaires) about Individuals other than the subjects? | Yes | No |
| <input type="checkbox"/> | Will privacy and confidentiality of research records be adequately protected? | Yes | No |
| <input type="checkbox"/> | Are ALL procedures in protocol stated in consent? | Yes | No |

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|--------------------------|---|-----|----|
| <input type="checkbox"/> | Is this FDA regulated research? | Yes | No |
| <input type="checkbox"/> | Will an investigational drug(s) be used? | Yes | No |
| | <input type="checkbox"/> Is there an IND? | Yes | No |
| <input type="checkbox"/> | Will an investigational device(s) be used? | Yes | No |
| | <input type="checkbox"/> Is it a significant risk device? | Yes | No |
| | <input type="checkbox"/> Is it a non-significant risk device? | Yes | No |
| <input type="checkbox"/> | Will research coordinators be employed for this study? | Yes | No |

Consent Document:

- | | | | |
|--------------------------|--|-----|----|
| <input type="checkbox"/> | <i>Has the PI requested a modification in the consent process (waiver of informed consent)?</i> | Yes | No |
| <input type="checkbox"/> | <i>Has the PI requested a modification in the documentation of informed consent (waiver of signed consent)?</i> | Yes | No |
| <input type="checkbox"/> | Does it fulfill all 4 requirements for a waiver? | Yes | No |

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

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|--------------------------|---|-----|----|
| <input type="checkbox"/> | Does it fulfill 1 of the 2 requirements for a documentation waiver? | Yes | No |
|--------------------------|---|-----|----|

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Approval of Consent Waiver/Modification

Signature _____

<input type="checkbox"/> Study Title on informed consent document	Yes	No
<input type="checkbox"/> Are the 8 basic elements of informed consent incorporated (see below)?	Yes	No

The Eight Required Basic Elements of Informed Consent:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A statement that describes the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

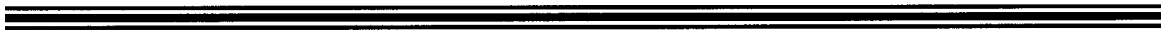
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

<input type="checkbox"/> Are the 6 additional element of informed consent incorporated where appropriate (see below) ?	Yes	No
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The Six Additional Elements of Informed Consent:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.

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|--------------------------|--|-----|----|
| <input type="checkbox"/> | Will the consent document be understandable to an individual with an 8th grade education? | Yes | No |
| <input type="checkbox"/> | Will the potential subject be approached for informed consent / assent in an appropriate manner? | Yes | No |
| <input type="checkbox"/> | Are ALL AEs in protocol stated in consent ? | Yes | No |



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|--------------------------|--|-----|----|
| <input type="checkbox"/> | If project approved, should approval be: | | |
| <input type="checkbox"/> | for one year | Yes | No |
| <input type="checkbox"/> | if no, limited to _____ | | |
| | Duration or # of subjects | | |

Approval Signature _____