Southern Utah University Institutional Review Board
REVIEWER CHECKLIST
SUU IRB Documentation for Full Board Status

This form should be downloaded and opened with Adobe Reader or Adobe Acrobat.

Reviewer

Reviewer's College

Date

Reviewer's E-mail

Reviewer's Phone Extension

Title of Proposed Research

Principle Investigator (PI)

PI's E-mail

PI's College

Research proposals which meet one or both of the criteria below must receive a full board review:

- ☐ Participants are considered vulnerable
- ☐ The research involves more than minimal risk

Please answer each of the following questions, and for any No responses, provide comments below, in the comment section.

Risks and anticipated benefits are accurately identified, evaluated, and described by the principle investigator?

◯ YES ◯ NO ◯ N/A

Have special vulnerabilities among prospective subjects that might be relevant to evaluating the risk of participation been considered by the principle investigator?

◯ YES ◯ NO ◯ N/A

If the research involves the evaluation of a therapeutic procedure, has the risks and benefits of the research interventions been evaluated separately from those of the therapeutic interventions?

◯ YES ◯ NO ◯ N/A

Has every effort has been made to minimize risks and maximize the likelihood of benefits to participants?

◯ YES ◯ NO ◯ N/A

Have adequate provisions have been made for a continuing reassessment of the balance between risks and benefits?

◯ YES ◯ NO ◯ N/A

Are the risks are NOT so strong that they would warrant the use of a data and safety monitoring committee?

◯ YES ◯ NO ◯ N/A

Comments

Informed Consent

Will Investigators obtain signed consent in every case where it is required?

◯ YES ◯ NO ◯ N/A

Will Investigators obtain proof of ascent in every case where it is required?

◯ YES ◯ NO ◯ N/A

All conditions are in keeping with standards for voluntary and informed consent?

◯ YES ◯ NO ◯ N/A

Comments

Categories eligible for expedited review (Select YES or NO for each of the following)

Checklist Items

Required Elements for Informed Consent

Participants have been informed about *the investigator's name and position at SUU*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the purposes of the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the expected duration of the subject's participation*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the procedures to be followed in the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the type/nature of the questions, if using surveying/ interviewing methods*

◯ YES ◯ NO ◯ NA

Participants have been informed that *participation is voluntary. and that they may discontinue the study at any time for any reason without penalty, and that they may ask questions at any time.*

◯ YES ◯ NO ◯ NA

Participants have been informed that *they may skip any question they do not wish to answer, if a survey/interviewing method is being used.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any reasonable, foreseeable risks or discomforts.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any benefits to the participant which may reasonably be expected from the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *whether participation and the data collected is anonymous or confidential*

◯ YES ◯ NO ◯ NA

Participants have been informed about *who to contact for information or concerns regarding the study*

◯ YES ◯ NO ◯ NA

Participants have been informed about *whether or not compensation will be awarded and the details thereof.*

◯ YES ◯ NO ◯ NA

Participants have been informed that *study involves research.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any procedures which are experimental.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *alternative procedures or courses of treatment, that might be advantageous to the subject.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *who will have access to individual participant's data.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *when, how, and who to contact to obtain the results of the study.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *how to contact the SUU IRB.*

◯ YES ◯ NO ◯ NA

Comments, if any, about Required Elements of the Informed Consent

Other Considerations

The proposed explanations of the research provide an accurate assessment of its risks and anticipated benefits.

◯ YES ◯ NO ◯ NA

The possibility (or improbability) of direct benefit to the subjects is fairly and clearly described.

◯ YES ◯ NO ◯ NA

The language and presentation of the information to be conveyed is appropriate to the subject population (including a translation into a language other than English if applicable).

◯ YES ◯ NO ◯ NA

The timing of and setting for the explanation of the research is conducive to good decision making.

◯ YES ◯ NO ◯ NA

Nothing more can be done to enhance the prospective subjects' comprehension of the information and their ability to make a choice.

◯ YES ◯ NO ◯ NA

The individuals who will be explaining the research to potential subjects are identified.

◯ YES ◯ NO ◯ NA

The individuals who will be explaining the research to potential subjects are qualified

◯ YES ◯ NO ◯ NA

Someone in addition to or other than the investigator should and will be present.

◯ YES ◯ NO ◯ NA

Subjects will be reeducated and their consent acquired periodically.

◯ YES ◯ NO ◯ NA

The IRB need NOT monitor incoming data to determine whether new information should be conveyed to participating subjects.

◯ YES ◯ NO ◯ NA

Someone in addition to or other than the investigator should and will be present.

◯ YES ◯ NO ◯ NA

A waiver of some or all of the consent requirements is requested and the importance of the research justifies such a waiver

◯ YES ◯ NO ◯ NA

The research design cannot be modified to eliminate the need for deception or incomplete disclosure.

◯ YES ◯ NO ◯ NA

Subjects will be given more information after completing their participation

◯ YES ◯ NO ◯ NA

The nature of the disease or behavioral issue to be studied permits free consent

◯ YES ◯ NO ◯ NA

Incentives offered for participation are unlikely to unduly influence a prospective subject's decision to participate.

◯ YES ◯ NO ◯ NA

There are adequate procedures for monitoring the consent process.

◯ YES ◯ NO ◯ NA

Arrangements need NOT be made for the IRB or its representative observe the consent process.

◯ YES ◯ NO ◯ NA

Comments, if any.

Selection of Subjects

The burdens of participating in the research will fall on those most likely to benefit from the research.

◯ YES ◯ NO ◯ NA

The solicitation of subjects avoids placing a disproportionate share of the burdens of research on any single group.

◯ YES ◯ NO ◯ NA

The nature of the research requires or justifies using the proposed subject population.

◯ YES ◯ NO ◯ NA

If there are groups of people who might be more susceptible to the risks presented by the study (and who therefore ought to be excluded from the research) the procedures for identifying such individuals are adequate.

◯ YES ◯ NO ◯ NA

To the extent that benefits to the subjects are anticipated, they are distributed fairly.

◯ YES ◯ NO ◯ NA

There are no other groups of potential subjects with a greater need to receive any of the anticipated benefits.

◯ YES ◯ NO ◯ NA

To the extent that participation in the study is burdensome, these burdens are distributed fairly.

◯ YES ◯ NO ◯ NA

The proposed subject population is not already so burdened that it would be unfair to ask them to accept an extra burden.

◯ YES ◯ NO ◯ NA

All special physiological, psychological, or social characteristics of the subject group which pose special risks for them have been identified.

◯ YES ◯ NO ◯ NA

It is NOT possible to conduct the study with other, less vulnerable subjects.

◯ YES ◯ NO ◯ NA

The selection process does not overprotect potential subjects who are considered vulnerable (e.g., children, cognitively impaired, economically or educationally disadvantaged persons, students of researchers, seriously ill persons) so that they are denied opportunities to participate in research.

◯ YES ◯ NO ◯ NA

The subjects are susceptible to pressures, and every effort has been made to reduce the pressures or minimize their impact.

◯ YES ◯ NO ◯ NA

Special safeguards are included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, persons with physical or mental illness, and persons who are economically or educationally disadvantaged).

◯ YES ◯ NO ◯ NA

Comments

Privacy & Confidentiality

If one or more participant's identity is known to investigator(s), adequate measures have been taken to protect their identity.

◯ YES ◯ NO ◯ NA

The research does NOT involve observation or intrusion in situations where the subjects have a reasonable expectation of privacy.

◯ YES ◯ NO ◯ NA

Are the investigator's disclosures to subjects about anonymity/confidentiality adequate?

◯ YES ◯ NO ◯ NA

The investigators do NOT want to review existing records to select subjects for further study.

◯ YES ◯ NO ◯ NA

The investigator(s) will NOT be collecting sensitive information about individuals.

◯ YES ◯ NO ◯ NA

Documentation of consent should NOT be waived in order to protect confidentiality.

◯ YES ◯ NO ◯ NA

Comments, if any, about Privacy & Confidentially

Method for Obtaining Informed Consent:

Is informed consent information to be presented in a manner which is clear to participants?

◯ YES ◯ NO ◯ NA

Is there exculpatory language which appears to waive participants' rights or release SUU from negligence?

◯ YES ◯ NO ◯ NA

Comments, if any, about Method for Obtaining Informed Consent:

Required Elements for Informed Consent

Participants have been informed about *the investigator's name and position at SUU*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the purposes of the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the expected duration of the subject's participation*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the procedures to be followed in the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *the type/nature of the questions, if using surveying/ interviewing methods*

◯ YES ◯ NO ◯ NA

Participants have been informed that *participation is voluntary. and that they may discontinue the study at any time for any reason without penalty, and that they may ask questions at any time.*

◯ YES ◯ NO ◯ NA

Participants have been informed that *they may skip any question they do not wish to answer, if a survey/interviewing method is being used.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any reasonable, foreseeable risks or discomforts.*

◯ YES ◯ NO ◯ NA

Participants have been informed about *any benefits to the participant which may reasonably be expected from the research*

◯ YES ◯ NO ◯ NA

Participants have been informed about *whether participation and the data collected is anonymous or confidential*

◯ YES ◯ NO ◯ NA

Participants have been informed about *who to contact for information or concerns regarding the study*

◯ YES ◯ NO ◯ NA

Participants have been informed about *whether or not compensation will be awarded and the details thereof.*

◯ YES ◯ NO ◯ NA

Are the incentives offered are reasonable, based upon the complexities and inconveniences of the study and the particular subject population?

◯ YES ◯ NO ◯ NA

It is NOT necessary for the IRB to monitor subject recruitment to determine whether coercion or undue influence is a problem.

◯ YES ◯ NO ◯ NA

Comments, if any, about Required Elements of the Informed Consent

Decision:
Based on the above materials this proposal should be:

◯ Accepted as submitted
◯ Accept contingent on minor revisions
◯ Not be accepted

If minor revision are needed list below

If the proposal should not be accepted, provide the justification for this decision

Submit