

REC Checklist for Initial Review

Title of Research:

Principal Investigator.....

Primary Reviewer for the REC.....

Social Value

- | | Yes | No | N/A |
|--|--------------------------|--------------------------|--------------------------|
| 1. Does the research have the potential to enhance the future health of society? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Has the community been involved with the planning of the research? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Scientific Design

- | | | | |
|--|--------------------------|--------------------------|--------------------------|
| 3. Has a scientific committee approved the research? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| If No, are the elements of the study design (e.g., hypothesis, objectives, sample size, statistics, etc.) adequate to produce valid results? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Will the research be performed by qualified investigators and at proper facilities? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Does the study involve a placebo group and if so, is there justification for including such a group? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Does the control group adequately represent the local standard of care? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Are the experimental procedures adequately described? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 8. Are there any other scientific issues that need to be addressed? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Subject Recruitment

- | | | | |
|---|--------------------------|--------------------------|--------------------------|
| 9. Is it clear who will be enrolled as research subjects or whose records will be used in the research? | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 10. Is the selection of subjects fair and equitable?
(Consider purpose, setting, inclusion and exclusion criteria) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

	<u>Yes</u>	<u>No</u>	<u>N/A</u>
11. Does the study has the potential of enrolling subjects who might be decisionally impaired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes			
a. will there be proxy consent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. should the investigator assess the capacity of subjects to make their own decisions?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the study involve any vulnerable groups? (<i>e.g., pregnant women, & fetuses, children, prisoners, decisionally impaired, institutionalized, socially or economically disadvantaged individuals, employees, students</i>)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If Yes:			
a. If so, are additional safeguards needed to protect the rights and welfare of the vulnerable groups?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. If yes, state which ones are needed.....			
.....			
.....			
13. Does any compensation for participation (e.g., financial, prospects of free medical care, etc.) represent an undue inducement to participate?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Does the recruitment setting present any potential for coercion?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Were all recruitment materials submitted? (<i>Posters; brochures; contact letters; TV, radio, newspaper ads</i>)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Are the recruitment materials acceptable as submitted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Risk/Benefit Analysis</u>			
<u>Risks</u>			
17. Are there physical or medical risks related to study participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Are there psychological or emotional risks related to study subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Are there social, economic, or legal risks related to study participation?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Are there risks to society in general?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Are risks adequately minimized?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. If not, how can risks be further minimized?			
.....			
.....			
23. What is the risk level of the research? <input type="checkbox"/> Minimal Risk <input type="checkbox"/> Above Minimal Risk <input type="checkbox"/> Too Risky			

	<u>Yes</u>	<u>No</u>	<u>N/A</u>
<u>Benefits</u>			
24. Are there potential direct benefits to individual research subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Are there potential benefits for the future health of society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Will the community/country benefit from the results of the research after the research is over?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. Has any post-trial agreements been developed with the sponsor/investigators?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Analysis of Risks and Benefits</u>			
28. Are the risks to subjects reasonable in relation to the anticipated benefits to the subjects and/or society?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Confidentiality:</u>			
29. Are there adequate safeguards to protect subject privacy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Are there adequate provisions to protect the confidentiality of the data?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Stored Tissue Samples</u>			
31. Will there be any storage of tissue samples (blood/tissues)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. Will there be any genetic analysis of the stored tissue samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
33. Will a code be used to label the stored tissues?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes, will the code contain any information that can potentially identify the subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
34. Will subjects have the option to withdraw their samples at any time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
35. How long will the samples be stored? _____			
36. Based on questions 32-35, are there safeguards to protect the privacy and confidentiality of the stored samples and the information from the stored samples?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Will any stored samples be shipped out of the country?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Yes No N/A

Informed Consent:

38. Is the researcher requesting access to records without informed consent?
If yes, explain why this is justifiable:

39. Is the informed consent checklist completed and is the consent form adequate?

40. Is the short consent form needed for individuals who are illiterate?

Safety Monitoring

41. Are there procedures to monitor the safety data (reasons for withdrawal/discontinuation) collected to ensure the safety of subjects?

42. Is there a Data and Safety Monitoring Board (DSMB?)

43. Are there any planned interim analysis?

RECOMMENDATION:

Approval

List non-binding suggestions, if relevant:

Approval with Modifications

List modifications

Deferral

List issues:

Disapproval

List issues:

Signature of Primary Reviewer

Date

Investigator Application Form

1. Name of Researcher:.....
2. Name of Institution/ Department:.....
3. Address of Researcher:
.....
a. email: :.....
b. Phone number: Mobile:
c. Fax number:.....

4. Name(s) of Co-Investigator(s).....
.....
.....

5. Grade of Protocol

- | | |
|------------------------|--------------------------|
| Domestic | <input type="checkbox"/> |
| Multi-Centre within SA | <input type="checkbox"/> |
| International | <input type="checkbox"/> |

6. Title of the research.....
.....
.....

7. Type of research (check all that apply):

- | | |
|----------------------|--------------------------|
| Drug trial: | <input type="checkbox"/> |
| Surgical Techniques: | <input type="checkbox"/> |
| Invasive Techniques: | <input type="checkbox"/> |
| Devise Study: | <input type="checkbox"/> |
| Survey Study: | <input type="checkbox"/> |
| Blood sampling: | <input type="checkbox"/> |
| Review of records: | <input type="checkbox"/> |

8. Subjects of research:

- | | |
|-----------------------|--|
| Children (< 18 years) | <input type="checkbox"/> |
| Adults (≥ 18 years) | <input type="checkbox"/> |
| Vulnerable groups: | Yes: <input type="checkbox"/> No: <input type="checkbox"/> |

If yes, please describe:
.....
.....

9. Request is being made to waive informed consent: Yes: No:

If yes, please explain why:
.....
.....

10. The research is for the good of society: Yes: No:

11. Study Design (check all that apply):

- a. Phase Type: I: II: III: IV:
- b. Randomization: Yes: No:
- c. Placebo: Yes: No:
- d. Genetic sampling Yes: No:
- e. Other _____

12. Facilities for the research are available: Yes: No:

13. List the risks of the study:
.....
.....

14. List the potential direct benefits, if any, to the subjects:
.....
.....

15. Are the risks reasonable to the potential direct benefits to the subjects, if any, or to the knowledge to be gained? Yes: No:

16. Privacy & confidentiality of subjects are assured Yes: No:

17. It is clearly stated that the subject of the research could quit at anytime without penalty or loss of any benefits to which they would otherwise be entitled: Yes: No:

18. Informed consent form is attached: Yes: No:

Signature of Principal investigator Date

ELEMENTS OF INFORMED CONSENT

Checkboxes to be completed by reviewers

<u>Elements of Informed Consent:</u>	<u>Yes</u>	<u>No</u>	<u>N/A</u>
(1) Purpose of Research:			
A statement that the study involves research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
An explanation of the purposes of the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Expected duration of the subject's participation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A description of the procedures to be followed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Probability of random assignment to each treatment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Identification of any procedures which are experimental	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(2) Risks and Discomforts:			
A description of any reasonably foreseeable risks or discomforts to the subject	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(3) Benefits:			
A description of any benefits to the subject or to others, which may reasonably be expected from the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(4) Alternatives:			
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(5) Confidentiality:			
A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and, if relevant, that other agencies might inspect the records	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(6) Compensation for Injury:			
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(7) Research Questions:			
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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(8) Voluntary Participation:			
A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Additional Elements of Informed Consent (When Appropriate):

- (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.
-

Statement of Confidentiality

_____ [Name of REC] agrees, subject to the conditions below, to disclose information in confidence to _____ [Name of Recipient] relating to projects being evaluated by _____.

_____ [Name of recipient] agrees as follows with respect to the confidentiality of such information:

1. _____ will not disclose or use any such confidential information (other than to the extent reasonably necessary to perform obligations as directed by _____ [REC] _____) unless:
 - 1.1. the subject matter was already known to _____ prior to its disclosure to _____, as evidenced by written documents;
 - 1.2. the subject matter was or becomes generally public knowledge, or
 - 1.3. the subject matter is made known to _____ by a third party who by such a disclosure is not in breach of duty or obligation toward _____.
2. Neither _____ [recipient] nor _____ [recipient]'s agents or employees shall distribute or disclose any such confidential information without the prior written consent of _____ [REC].
3. For purposes of this Statement, _____ considers and will treat as confidential information all business, clinical, and procedural information shared by _____.

Signature of REC official

Signature of Recipient

Date

Date

Financial Conflict of Interest Disclosure Statement

It is important that the review of research not be biased or compromised by any conflicting financial interests or other potential or actual personal gain of a member. A conflict of interest arises when a member is or might be in a position to put his or her own interest before the best interests of research subjects. The term financial conflict of interest addresses when a REC member has a significant financial interest in an agency or company that is providing funding for a particular research project. It is recognized that many potential conflicts of interest do not constitute actual conflicts or might be acceptable with proper safeguards.

REC Member Disclosure and Certification:

Do you, your spouse, or dependent children have any financial interests related to the work to be conducted under the proposed project?

- No
- Yes, please complete the following:

A. Management:

Do you, your spouse, or children hold a position of management or employment with this entity?

- No
- Yes, please indicate the position _____

B. Income

Do you, your spouse, or children receive income from this entity?

- No
- Yes, please indicate the nature of the income and the amount:
 - Honoraria _____
 - Salary _____
 - Consulting _____
 - Other _____

C. Equity

Do you, your spouse, or your children hold an equity interest in this entity?

- No
- Yes, please indicate the nature of this equity (e.g., bonds, stocks, options, other) and the value of this equity interest _____

I acknowledge my responsibility to disclose any new reportable financial interests obtained during the term of the project. I certify that this is a complete disclosure of my financial interests related to the proposed project.

Signature.

Printed Name

Date