



Minnesota Department of Health
 Institutional Review Board
 85 East Seventh Place, PO Box 64882
 St. Paul, MN 55164-0882

RE-REVIEW OF PREVIOUSLY APPROVED RESEARCH

Title of Study or Project _____ IRB Identification Number _____

Project Description _____

Date of Initial IRB Approval _____ Last Re-Review Date _____ Next Scheduled IRB Review _____

Check if PI has changed

Name of Principal Investigator _____ Phone Number _____

Address (Street or P.O. Box) _____ City _____ State _____ Zip _____ E-Mail/Internet Address _____

Complete **EITHER** Section I **OR** Section II

SECTION I This study does **NOT** require re-review because:

- It is no longer in progress.
- It was never started. (Grant funding was denied, did not meet criteria, etc.)
- The MDH IRB has deferred to another IRB, which recently re-reviewed and approved the study on (date): ____ / ____ / ____
 By: _____ (See Section III)

Other
 (Specify): _____

SECTION II For studies that require re-review. **NOTE: If any question in this section is answered yes, it is possible the proposal will need to go through a full IRB review.**

1. How many subjects have been entered into the study? _____

1a. Is active recruitment of participants still occurring? YES NO

1b. What stage is the project in?

Finalizing design and procedures

Data collection

Data analysis

Report writing

Other (explain): _____

2. Briefly describe progress to date, plans for the next year, and any change in expected completion date for the study.

3. Have you received notice of or are you aware of any adverse events or unanticipated problems involving risks to subjects or others, including breach of confidentiality, withdrawal of study subjects, or complaints about the study?

Yes

No

If Yes, please describe on an attached sheet.

4. Has there been any recent literature, findings, or other relevant information, especially information about risks associated with the research, which study subjects should be aware of since last reviewed by the IRB in _____?

Yes

No

If Yes, describe on separate sheet.

If Yes, have study subjects been informed of these findings?

Yes

No

If No, why not?

5. Have there been any changes in the informed consent form since the last review by the IRB in _____?

Yes

No

If Yes, please submit 3 UNBOUND copies of the revised form. Use highlight or track changes to show revisions.

6. Have there been any significant changes from the original protocol or in previously reviewed instruments (e.g., questionnaires, surveys, etc.)?

Yes

No

If Yes, please describe on an attached sheet and include 3 UNBOUND copies of the changed protocol or instruments. Use highlight or track changes to show revisions.

SECTION III

1. Has this proposal been reviewed or approved by another IRB?

Yes

No

If Yes, list name, organization, and phone number of IRB contact and date of review.

Name and Organization of IRB Contact:	Phone Number of IRB Contact: (include area code)	Date of Review:
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Signature of Principal Investigator

Date