NCNM Institutional Review Board (IRB) IRB Exemption and Expedited Review Petition Form

Exempt Status Research

Research is eligible to be reviewed for Exempt status by an IRB committee member if it involves very minimal or no risk to participants. In general, research that does not propose to disrupt or manipulate the normal life experiences of participants, incorporate any form of intrusive procedures, or involve intentional deception will be exempt from full Committee review.

Please note that ***all of the rights and protection afforded to human subjects in research are required in Exempt status cases.*** *In short, research with Exempt status* ***is exempt only from full Committee review.*** *Investigators engaged in human subjects research that qualifies for Exempt status* ***must still complete a full application and prepare an informed consent statement.***

Research that involves protected classes or vulnerable populations (such as prisoners, pregnant women, mentally disabled persons, research by a faculty member on his/her own students) is never Exempt.

Expedited Status Research

Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the entire IRB. The term "expedited" does ***not*** *mean a review is quicker or conducted with less rigor. It means fewer reviewers are required for approval.*

In general, research may be considered for Expedited review if it involves no more than minimal risk, does not include intentional deception, does not employ vulnerable populations or sensitive topics, and includes appropriate consent procedures. Please note that ***all of the rights and protection afforded to human subjects in research are required in Expedited status cases.*** *Investigators engaged in human subjects research that qualifies for Expedited status* ***must still complete a full application and prepare an informed consent statement.***

To be considered for Exempt or Expedited status, research must fall into one of the categories listed below. However, the IRB may determine that a Full Committee review is necessary if the research poses risks or ethical concerns.

Please complete this form and submit it to the IRB Liaison with all required documents for initial IRB review.

Research Study Title: _____

Principal Investigator (PI): _____

PI Telephone Number: _____ **PI email: _____**

Submission with Petition for Exemption, this project is:

- ☐ Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- ☐ Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior.
- ☐ Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- ☐ Research and demonstration projects which are designed to study, evaluate, or otherwise examine public benefit or service programs.
- ☐ Taste and food quality evaluation and consumer acceptance study.

Please Note: Survey/Interview Procedures are Non-Exempt under Any of the Following Conditions:

a. *Responses are recorded in such a manner that the participant can be identified, either directly or through linked identifiers.*

b. *Responses, if they become known outside the research setting, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, or reputation within the community.*

c. *Research deals with sensitive aspects of participant's own behavior, such as illegal conduct, use of alcohol, drugs or other addictive substances.*

d. *Questions ask about sexual attitudes, preferences, or practices.*

e. *Questions request information pertaining to a participant's psychological well-being or mental health.*

f. *Research involves HIV status information.*

Submission with Petition for Expedited Review, this project is:

- ☐ A clinical study of drugs for which an investigational new drug application is not required.
- ☐ Research on medical devices for which an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- ☐ Research involving collection of blood samples by finger stick, heel stick, ear stick, or venipuncture per the Office for Human Research Protections expedited review guidelines.
- ☐ Research involving prospective collection of biological specimens for research purposes by noninvasive means.
- ☐ Research involving collection of data on subjects 18 years of age or older through noninvasive procedures routinely employed in clinical practice.
- ☐ Research involving materials that have been collected, or will be collected solely for non-research purposes.
- ☐ Research involving collection of data from voice, video, digital, or image recordings made for research purposes.
- ☐ Research on individual or group characteristics or behavior; or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Additional Notes:

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_____ _____

PI Signature Date

Review Date: _____ **IRB Number:** _____

Institutional Review Board Decision:

- ☐ IRB Exemption Approved

If an exemption is approved, file this form along with all proposal documents where they can be easily accessed and identified.

- ☐ IRB Exemption Not Approved (Please see comments on original documents.)

If the exemption is not approved, the IRB Liaison will contact the PI to inform them that the study has not been exempted and will be reviewed by the IRB.

- ☐ IRB Expedited Review Approved (Please see comments on original documents.)

If an expedited review is approved, file this form along with all proposal documents where they can be easily accessed and identified.

☐ IRB Expedited Review Not Approved (Please see comments on original documents.)

If the expedited review is not approved, the IRB Liaison will contact the PI to inform them that the study has not been approved for expedited review and will be reviewed by the full IRB.

_____ _____

IRB Chairperson Signature Date