REQUEST FOR MULTIPLE PROJECT EXEMPT STATUS

(for faculty use only)

Research activities involving human subjects in which there is minimal or no risk and in which the only involvement of human subjects would be in one of the categories described on the back of this form may be exempt from IRB expedited or full board review. Projects that qualify for exempt status must, however, receive IRB certification that they 1) qualify for exempt status in accordance with federal regulations, and 2) are designed to ensure that the rights and welfare of human subjects are protected.

Exempt certification of each individual student project is not necessary for courses at MSU in which 1) students are required to design and conduct their own "mini" projects to be completed by the end of the term, 2) when the subject matter will clearly fall within the exempt category, and 3) there will be no publication of results. Instead, the instructor may use this form to obtain a multiple project exempt certification for the course at the beginning of each term in which the course is taught.

Project Design Requirements - Criteria for exempt certification require that projects meet minimum standards set forth in federal regulations covering human subject research. Of primary importance are the basic elements of **informed consent,** which must be communicated **in writing** to each prospective subject. This may be accomplished by a cover letter or information sheet attached to the materials to be distributed. The only exceptions to such written communication are telephone surveys or face-to-face interviews, when the elements of informed consent may be given orally. In such cases the student must develop a written script of the oral presentation. The basic elements of informed consent are described on the attached page.
For exempt certification of multiple class projects, submit this completed form to the Office of Research & Sponsored Programs, along with a brief description of the general subject matter to be pursued by the students (e.g., textiles and clothing surveys, studies in early American folklore).

Exceptions - In cases where a student's project might result in publication of data, or if the instructor, student, or other MSU employee thinks he/she might want to retain the data for his/her own additional research, exempt certification must be obtained for that specific student project before the student collects his/her data.

Please complete the following:

Instructor's name_____Dept._____

Course Title & No._____

Beginning date for which exempt certification is requested:

Assurance of Compliance: As the instructor responsible for the above named course, I will review each project to ensure that it falls within the qualifications of exempt status described on the back of this form. I will also make every effort to ensure that each student conducting a research project communicates to prospective subjects or respondents the required elements of informed consent in a manner appropriate to his or her project (cover letter, information sheet, oral presentation).

Signed:_____Date_____

Chair Signature:_____Date_____

Funding agencies supporting this research:_____

(A copy of the funding proposal for each agency identified above MUST be attached to this proposal when submitted.)

For IRB Office use: Protocol Number _____

Date Received _____ Approved under category _____ Not Approved _____

Comments:_____

Exempt status certification:_____

IRB Authorized signature date

Revised 1/6/10

IRB Proposal Checklist For All Proposals

In addition to filling out one of the IRB forms (i.e. exempt, expedited review, full board review) please provide the following information so that the Committee can obtain a good sense of your proposed research and review the proposal in a timely fashion.

Please Note: Depending on the status that you have applied for the outline may be brief or detailed.

I. IRB Form (front & back sides) must be completely filled out or it will be returned without review.

II. Introduction:

☐ **A. Purpose of Research/Research Questions**

☐ **B. Brief Literature Review** (no more than 2 pages)

III. Research Methods:

☐ **A. Sample/Technique**

1. How will the researcher gain access to the population? (sample technique)
2. Who is the population? (for example: age, race, gender, etc.)

☐ **B. Data Collection Instruments** (surveys, questionnaires)

1. Provide a copy of the instrument and how you will use it to collect your data

☐ **Note: Field Observations:** If this is part of the data collection-describe how this will be done and if the participants are aware of being observed (i.e. are the participants in a public or private setting?)

SEE NEXT PAGE FOR HUMAN PROTECTION ISSUES

IV. Human Protection Issues (if any):

☐ **1. Confidentiality** (how will this be assured?)

☐ **2. Where will the researcher keep the raw data?**

☐ **3. Voluntary Participation-** the subject can withdraw at any time by stating, "I no longer want to continue". Should be stated in the written consent form.

☐ **4. Informed Consent- (see page 6)**

Examples of informed consent should be provided in your IRB proposal in appendix

Informed consent should include:

- Description of project
- Potential Benefits/Risks to participants
- How information will be used, secured, and how long the data will be kept before destroying it
- The research process-what the participants can expect step by step (including tape recording or video recording)
- Confidentiality/Anonymity
- Voluntary-participants may withdraw at anytime

☐ **5. Additional Information on Informed Consent:**

Depending on the nature of the study, it may be necessary to obtain written/signed consent from the agency and guardian(s) where you are accessing the participants that indicate their agreement and understanding that the study is being conducted.

Examples of additional informed consents:

1. School age children- permission from the principal, school superintendent, parents, and any other individual that has a legal interest in the child. *Research being conducted in the Minot School District requires permission from both the school principal and the assistant superintendent.
2. Inmates- permission from prison warden, director of corrections, and inmates
3. Adults who are developmentally disabled-permission from the director of the workshop, half-way house, and legal guardian/advocate (if applicable)

☐ **6. Qualifications of the Researcher:** Does the researcher have experience in working with the population? Provide a brief vita or resume'

Note: If the researcher is a student who will be supervising the student?

☐ 7. Changes in Protocol and/or Consent Forms

Researchers are responsible for notifying the IRB Chairperson of any substantive changes in research protocol or consent forms. Provide a copy of the changed consent forms and/or a letter explaining the research changes. This must occur 14 days prior to implementation

EXCEPTION: A protocol may be changed without prior IRB approval where necessary to eliminate apparent immediate hazards to subjects. However, the IRB Chairperson must be notified in writing of any such changes within 72 hours.

Researchers are also responsible for notifying the IRB of any injuries or unanticipated problems involving risks to subjects within 72 hours in writing to:

Dr. Brent Askvig, Chair
NDCPD
Memorial Hall 234A
701-858-3052

☐ 8. Annual Reports-(attached to packet):

A brief report for on-going research projects (longer than 1 year) is required.

INFORMED CONSENT

REQUIREMENTS/CRITERIA FOR DIFFERENT STATUES OF RESEARCH PROJECTS

Note: The criteria below constitute general guidelines in that they are meant to cover different statuses of research projects (full board, exempt, expedited). The criteria for specific research projects may be described in more detail or less detail, depending on the nature of your particular project. The following are the minimum required elements of informed consent. Investigators are free to include additional information at their discretion.

The U. S. Code of Federal Regulations governing research on human subjects (45 CFR 46.116) states that, *"... no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."*

I. Types of Projects to Which Informed Consent Applies.

Unless the IRB issues a specific waiver, the written informed consent of subjects is required for ALL research projects except those projects that qualify for certification of exempt status. Written informed consent of subjects may also be required in some projects that otherwise qualify for exempt status.

II. Minimum Required Elements of Informed Consent.

The following information must be communicated in writing to all research subjects or respondents before they agree to participate in a research project which involves human beings as subjects. The information may be incorporated into a cover letter or information sheet to be distributed with a questionnaire or other survey instrument. The IRB Office may, in certain cases, require that an investigator develop a consent form to be signed by each research subject. Additional elements of informed consent may be required by the IRB Office for some projects.

1. a statement identifying yourself and your affiliation with Minot State University;
2. an invitation to participate in the study as part of a research project;
3. an explanation of the purposes of the research, the expected length of time of the subject's involvement, a description of the procedures to be followed, and identification of any procedure which are experimental in nature;
4. a description of any benefits to the subject or others which may reasonably be expected from the research;
5. a description of compensation for participation (money, extra course credit, etc.), if any;
6. a statement describing the subject's anonymity or the extent to which confidentiality of records identifying the subject will be maintained;
7. the names, addresses, and phone numbers of the people;
8. an assurance that participation is voluntary and that the subject may withdraw from participation at any time.

Suggestion: give a copy of your informed consent statement to each subject to keep for their information.

III. Additional Provisions.

A. Oral Consent

Under special circumstances, the IRB may approve an **oral consent document** that states that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. The oral consent document must include:

- the reason the investigator had to use the oral form,
- the date of the communication of consent requirements to the subject(s),
- information about whether the communication was in person or over the telephone,
- any possible questions or comments from the subject(s) raised during the communication.

B. Waiver of Elements of Informed Consent

There may also be some circumstances (e.g. a very unique, unprecedented nature of the project) under which the IRB may approve a **consent procedure which does not include**, or which alters, some or all of the elements of informed consent. The investigator must justify in writing any request to waive the elements of informed consent.

C. Informed Consent for Minors

When research subjects are **under the age of 18**, the written consent of one or both parents is required for projects for expedited or full board review, and for some projects that otherwise would qualify for exempt review.

D. Storage of Informed Consent Forms

Signed copies of informed consent forms must be **maintained** by the principal investigator and be **stored** in a secure manner. Unless otherwise specified by federal and/or state regulations, retention of the signed consent forms is for a period of at least three years beyond the termination of the study. If the investigator resigns or graduates from Minot State University before the end of the designated period, the informed consent forms must be maintained by the department of record, unless otherwise specified.