IRB Common Terms and Definitions

All research involving human subjects, conducted under the auspices of Minot State University, by its researchers must receive review and approval by the **IRB** prior to initiation of the research.

The activity must meet both tests of the federal regulatory definition to require IRB review:
It must be Research and it must involve Human Subjects

Definitions

Anonymous Data: Data that by virtue of the method of collection can never be reasonably be connected with the person providing the data (for example, questionnaires that are returned by mail in envelopes with no return address or other identifying markers). There are no identifiers connected to the data and the researcher is unable to link data to any one individual.

Class Projects: Student project/presentation conducted solely in fulfillment of educational requirements for specific class do not require IRB approval. In this instance, class projects are not "generalizable." If the class project is to be presented to the public (i.e. during a poster session open to the public) an IRB Exempt Screening Form should be filled out for the Course Project by the instructor. If individual students wish to present the research to the public or to be "published" in the future it is required that an IRB Exempt Screening Form be filled out by the student.

Clinical Trial: Research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or b behavior health-related outcomes.

Confidential Data: Data is confidential when the researcher can link to a particular participant but will protect the privacy of the participant. Projects may collect data in a confidential manner but analyze and/or report it in an anonymous manner, or the data may be collected and analyzed on an anonymous basis. The consent information provided to participants should make these procedures clearly understood.

De-identified Data: To not be considered human subject research, the human data must meet one of the following standards:

- Exists without ANY personal identifiers or links to identifiers.
- Provided by a research repository (data bank, medial record system etc.) which takes responsibility for removing any identifiers, including a code linked to identifiers, prior to providing the data to the researcher. Research cannot be one of the parties responsible for collecting or maintaining the source material.
- Provided by a supplier who maintains a firewall security preventing recipients from receiving access to identifiers.

Disseminate: The sharing or distribution of results to those outside the University via the web, poster presentations, conferences, library placement, or publications. Note: "Dissemination" does not include the use of date for internal University System usage as long as the about criteria are met.

Generalizable: Designed to draw conclusions from the data, results are analyzed for predictive value, results can be applied to the larger population (i.e. application is not limited to the participants) or inform policy.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains information or biospecimens through intervention with the individual, and, uses, studies, or analyzes the information or biospecimens; **OR** obtains, uses, studies, analyzes, or generates identifiable private information that is not publicly available or identifiable biospecimens.

Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Identifiable private Information: Private information for which the identify of the subject is or may readily be ascertained by the investigator or associated with the information.

Interaction: Includes communication or interpersonal contact between investigator and subject (for example, interviews, focus groups, surveys – including mailed and on-line).

Intervention: Includes both physical procedures by which information or biospecimens are gathered. (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes. (for example, placement in one of three learning conditions, use of a room with and without a mirror present).

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, *legally authorized representative* means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Normal Educational Practices: Activities and data collected in the process of normal class activities and evaluations. The activity and thus the data is part of the existing course curriculum and would have been administered whether or not that data was collected.

Private Information: Includes 1) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, 2) information which has been provided for specific purposes by an individual and that the individual can reasonable expect will not be made public (for example, a school record).

Program Evaluation: Program evaluation activates are those for which the primary purpose of the evaluation is to assess the program – not to contribute or develop generalizable knowledge. The evaluation is a tool for monitoring and/or improving the program – IRB review would not be required. The program evaluation projects are not "generalizable".

Public Health Authority: An agency or authority of the United States, a state, or territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person **or** entity acting under a grant of authority or contract with such public agency, including the employees or agents of such public agency or its contractors or person or entities to whom it had granted authority, that is responsible for public health matters as part of its official mandate.

Publicly Available: Means available without restriction. "Publicly available" refers to sources such as public records. This does not include data sets from organization that are broadly available at cost to the research community as these are not generally available to the public at large.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge. Research includes work that is conducted either on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experimental methodologies, regardless of the content or routine nature of the topic and whether the work is preliminary in nature or a study proper. The following activities are deemed not to be research:

(1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
(2) Public health surveillance activities, including the collection and testing information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
(3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

Systematic: The implementation or utilization of specific methods of inquiry or data collection that is repeated with multiple participants. It is the proscriptive plan to incorporate data collection and analysis to answer a research question. Methodology alone does not determine the need for IRB approval.

Written, or in Writing: Purposes of this part, refers to writing on a tangible medium (e.g., paper) or in an electronic format.