Initial Review

To comply with the federal regulations covering the protection of human subjects in research studies conducted by NSU faculty, staff, and students, all funded and unfunded research proposals involving potential risk to human subjects must be examined by the IRB.

The research associates, who serve as alternate IRB representatives for the Abraham S. Fischler College of Education (FCE), have the responsibility to determine the appropriate level of review for the study and to assure that all the necessary IRB documents are included and appropriately completed.

No research activities may begin until after you have received official notification of approval from the FCE's IRB representative (for studies qualifying for a center level review) or NSU's IRB (for studies requiring an expedited or full review). **You may not recruit participants (nor distribute consent forms) until you have received IRB approval**. IRB approval is valid for one year from the date it is granted. **For a complete discussion of university policies and procedures, please review NSU's Institutional Review Board Web site at http://www.nova.edu/irb/**

The following individuals serve as IRB representatives for FCE:

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Types of Review

College/Center Level Review

This level (previously labeled as Exempt Research) is reserved for research that represents no more than minimal risks to participants and does not involve special populations (such as the mentally retarded, some types of studies with children, prisoners, etc.). The purpose of this review is to determine if research is in keeping with the exempt categories as defined by regulation and thus exempt from Expedited or Full Review. Research that falls into one of the categories below may be reviewed at Center Level:

- Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- Research involving watching public behavior of children, where the investigator does not take part in the activities, can be reviewed at the center level. (Note: surveys or interviews cannot be center-level reviewed.)
- Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed

to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

- Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

It should be noted that only members of the IRB may determine that a study is exempt from Expedited or Full Review. Any member of the IRB reviewing a study at the Center Level may consult with the Chair of the IRB or other members of the Board in needed.

Expedited Review

In some circumstances, if there is no more than minimal risk, expedited review can be conducted even on studies involving minors. In the following circumstances, the center-level representative and the IRB chair (or another IRB member that the chair designates) may review the study. The categories for expedited review are the same as in adult studies, but the blood collection limits differ. Research involving collection of PHI that is approved by both the parents and child with appropriate consent/assent forms can use expedited review. The categories for expedited review are:

- Surveys/interviewing of children, or observation of public behavior involving children when the researcher participates in the activity being observed.
- Surveys that request information that potentially expose the informant to criminal or civil liability or are extremely personal in nature in which the likelihood of associating the individual with the responses is very small.
- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture, not to exceed 50 ml or 3 ml per kg (whichever is less) in an 8 week period, and collection may not occur more frequently than 2 times per week.
- Collection of hair and nail clippings in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
- Collection of excreta and external secretions including sweat or uncannulated saliva.
- Collection of both supra-and sub-gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic

scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

- Recording of data from subjects using noninvasive procedures routinely employed in clinical practice, excluding X-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. Examples include-the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, diagnostic infrared imaging, doppler blood flow, and electroretinography. Subjects can participate in moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- Voice, video, digital or image recordings made for research purposes, such as investigations of speech defects. For example: An audio tape on which subjects are asked to speak common words for the purpose of measuring voice timber would qualify for Expedited Review. A tape of a therapy session with a patient would not qualify for Expedited Review. Although the research involved an audio tape, the sensitive nature of the contents would require a Full Review.
- Research on individual or group behavior characteristics of individuals, (such as studies of perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies when the research does not qualify for center-level review.
- Research on drugs or devices for which an IND/IDE is not required.

Additionally, Expedited Review may be used when there are minor changes in previously approved research during the period (one year or less) for which approval is authorized.

The IRB is responsible for determining what does or does not meet the criteria for Expedited Review, and the IRB may always require a study to go on for Full Review even though it may initially qualify for Expedited Review. Expedited Review may be carried out by the IRB Chair or by one or more reviewers designated by the Chair from among members of the IRB. When conducting an Expedited Review, IRB members may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after a full IRB review has been conducted. All IRB members must be advised of research proposals that have been approved using expedited procedures at the next regularly scheduled meeting.

Full Review

Full review by the entire IRB panel is reserved for studies that have potential risk to human subjects. This may include but is not limited to:

- Research that involves the administration of drugs or other substances to subjects where an IND/IDE are required,
- Research that materially affects the pregnancy of a woman or the health/well-being of fetuses in utero.
- Research involving subjects with life-threatening physical conditions.
- Research involving physically intrusive procedures.
- Research which previous experience (by the particular investigator or other investigators) has been shown to create a potential of risk to subjects.
- Research that may result in a significant level of psychological or physical stress.
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use) when there is a possibility that the subject could be identified.
- Research involving prisoners.
- Research that places protected populations (such as children, mentally retarded individuals, mentally ill individuals, patients with medical disorders) at more than minimal risk.
- Research involving waivers of any HIPAA regulations.