

National Institute for Direct Instruction

Institutional Review Board

Policies and Procedures

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National Institute for Direct Instruction Institutional Review Board Policies and Procedures

The National Institute for Direct Instruction (NIFDI) has an Institutional Review Board charged with reviewing research procedures to assess any possible risks to research subjects and to ensure that the procedures provide appropriate protections for these subjects. The Board is guided by principles of the Belmont Report, which outlined key ethical principles of respect for persons, beneficence and justice.¹ The IRB and its membership have been registered with the U.S. Department of Health and Human Services (DHHS) (IRB0004995, renewing an earlier Assurance (FWA00008914)). Members of the IRB submitted in the documentation sent to HSS are Dr. Jean Stockard, NIFDI Director of Research (Chair), Dr. Linda Carnine, Dr. Kurt Engelmann, Christine Wlaschin, Dr. Geoff Colvin, Cristy Coughlin, Dr. Douglas Carnine, Jerry Silbert, and Dr. John Lloyd.

The paragraphs below summarize federal regulations regarding protection of human subjects and then describe the policies and procedures that NIFDI will use when analyzing data that has been provided from other sources and when gathering data from subjects. The goal of the procedures is to minimize any risk to subjects that might arise from the research process and maximizing possible benefits. While NIFDI does not have any federal grants at this time, we will follow the federal procedures to help ensure that our activities fall within the norm of established scientific activities. Appendices provide details on categories of review used by HHS and a sample of a NIFDI informed consent letter.

Federal Guidelines Regarding the Protection of Human Subjects

The full text of federal guidelines regarding the protection of human subjects may be found at <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>. The regulations define the procedures that should be used to review research protocols and establish guidelines for determining the extent of the review process.

A key element of the review process includes determining the extent of risk that subjects face when participating in a research project. The Department of Health and Human Services defines Minimal Risk as meaning “that 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.”

Research projects are divided into three categories: 1) those that are exempt from review by an IRB, 2) those that can be handled through an expedited process, and 3) those that must be reviewed by a full committee. The criteria for exempt and expedited projects are included at the end of this report in Appendices A and B. As described more fully in Appendix A, activities that are exempt from review include those in which research occurs in established educational

¹ See the full text of the report at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>. A discussion of the history surrounding the development of the report can be found at <http://www.hhs.gov/ohrp/belmontArchive.html>.

settings and involves research on the effectiveness of instructional and management methods, research involving the use of educational tests (unless data are recorded in a way that could identify subjects and the responses would put the subjects at risk), and research involving existing data and records if information is recorded in a manner that cannot be linked to the subjects. If the research involves no more than minimal risk to subjects and involves audio or video recording of subjects or other types of research in which subjects will not be anonymous, it falls into the expedited category, as described more fully in Appendix B.

Informed consent is required with all projects, whether involving exempt and expedited reviews. When survey data are obtained from children, both parental consent and child assent are required. Depending upon the situation, it may be possible to use a form of “passive consent,” where parents are fully informed of the research and given the option to opt out of participation. The decision regarding whether to use “active” or “passive” consent should be made in conjunction with the school district and schools involved.²

It is anticipated that virtually all of the research conducted by NIFDI will involve minimal risk for subjects. The work almost always involves the collection and/or analysis of achievement data already routinely gathered in classrooms and, occasionally, gathering additional data regarding views of the educational process or experiences. The procedures that will be used to ensure protection of subjects within this context of minimal risk are outlined below. Any projects that are judged to go beyond the usual pattern of work and are not included in the list of expedited procedures and projects in Appendix B should be taken to the full IRB committee for review.

Procedures to be Used with Intact Data Sets

NIFDI is often provided with data sets from school districts and schools around the country containing data regarding academic achievement for students using Direct Instruction and other curricula. These data fall into the exempt category and will not require any committee review.

In most cases these data sets do not contain any personally identifying information, such as children’s names or birthdates. When the data provided by a district contain such information, the sets that are used for analysis are stripped of personally identifiable information, replacing identifiers with a unique identification code. Publications regarding the data never identify individual children. School districts and schools may be identified if the entities are large enough that individual teachers or children cannot reasonably be identified (e.g. when there are multiple schools, each with several teachers, in the analysis) and when knowledge of the location of the district provides important contextual information (e.g. larger urban districts). The identity of smaller districts will be disguised unless those districts and/or schools allow or request that NIFDI mention their name in publications.

Procedures to be Used When Data are Gathered by NIFDI Personnel

When data are gathered by NIFDI personnel the staff members will develop a summary of the research procedures that will be used. This summary should include, either in the body or

² When intact data sets are given to NIFDI by schools or school districts, parental consent will not be obtained. It is assumed that the schools and/or districts have authority to transmit the data.

as an appendix, a discussion of the procedures that will be taken to ensure that benefits to individual participants are maximized and any risks are minimized. The discussion must include 1) a description of all subjects in the study (e.g. teachers, students, parents), 2) a description of any possible risks that they might encounter and ways in which these risks are minimized, and 3) procedures for obtaining consent for participation in the study, including appropriate letters of consent and procedures for obtaining child assent.

The procedures will be reviewed by at least two members of the IRB committee to ensure that risks to participants are minimized. An example of a letter of informed consent that explains a study and requests parental permission for a child to participate is included as Appendix C of this document. The letter would be customized to fit the needs of school districts participating in specific research projects.

Appendix A

Research Activities that are Exempt from Review as Determined by HHS Policy

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

- (1) 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.

- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures 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.

- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph [\(b\)\(2\)](#) of this section, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- (4) 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.

- (5) 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.

- (6) 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.

Source: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.408> (see paragraph 46.101) (b)

Appendix B
Categories of Research That May Be Reviewed by the Institutional Review Board (IRB)
through an Expedited Review Procedure, per HHS Policy¹

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](#) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children², considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101\(b\)\(4\)](#). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101](#)(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) where no subjects have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

¹ An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in [45 CFR 46.110](#).

² Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402\(a\)](#).

Retrieved from: <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> (December 8, 2008)

Appendix C
Sample Informed Consent Letter for Use in NIFDI-Sponsored Research Projects

Dear Parents:

The (School District) is collaborating with the National Institute for Direct Instruction, based in Eugene, Oregon, U.S.A., to test a computer-based reading instruction program called “FUNNIX.” We are asking your permission to allow your student to participate in this study.

The purpose of the research is to compare the gains in reading achievement that children experience in FUNNIX with the progress made in their regular classroom. In the study, children will be randomly assigned to study reading using the FUNNIX computer program under the guidance of a school staff member or to continue with their regular reading instruction. Students’ reading achievement will be individually tested both at the beginning and the end of the study, and the researchers will examine achievement data that are already gathered in the classrooms. As part of the study students will also be asked to fill out a very short questionnaire regarding their attitudes toward reading and school.

There are no known risks associated with the curriculum. Other studies indicate that children learn as much, if not more, with the FUNNIX program as with other programs. This study may benefit your student by enhancing his or her achievement. In addition, your child’s participation in the study will help the school district assess whether FUNNIX should be used with more children in years to come.

Both the school district and the researchers will do everything they can to protect your student’s privacy. Numbers will be assigned to each child’s information. When the researchers analyze the data they will not know the names of any of the children who participated.

Your decision to allow your child to participate in the study is voluntary. You may choose for your child not to participate, and you may withdraw your consent for your child to participate at any time. You will not be penalized in any way should you decide not to participate or allow your child to withdraw from this study.

If you have any questions or concerns about this study or if any problems arise, please contact Jean Stockard, Director of Research at the National Institute for Direct Instruction (toll free, 877-485-1973) or (district contact person). Thank you for attending to this matter.

Sincerely,
Signed by district contact person

Parental Consent
Study of FUNNIX Reading
National Institute for Direct Instruction and the (School District)
(Date)

I have read the explanation of the study of FUNNIX Reading Instruction and

_____ DO give permission for my child to participate.

_____ DO NOT give permission for my child to participate.

Child's name

Parent or Guardian name

Parent or Guardian signature

Date