

THE INSTITUTIONAL REVIEW BOARD (IRB)

An Institutional Review Board (IRB) is a committee that, according to federal law, must evaluate the potential physical or psychological risk of research involving human and animal (vertebrates) subjects. All proposed human and animal research must be reviewed and approved by an IRB before experimentation begins. This includes any surveys or questionnaires to be used in a project. *NOTE- Vertebrate animals, as covered by these rules, are defined as live, nonhuman vertebrate mammalian embryos or fetuses, tadpoles, bird and reptile eggs within three days (72 hours) of hatching, and all other nonhuman vertebrates (including fish) at hatching or birth.

An IRB at the school or ISEF Affiliated Fair level must consist of a minimum of three members. Additional members are recommended to avoid conflict of interest. The IRB should include:

- a) The science fair coordinator or science teacher
(May NOT be the student's classroom or sponsoring teacher!)
- b) The school principal or administrator and
- c) One of the following: a psychologist, psychiatrist, medical doctor, or school (registered) nurse.

Each school site must establish an IRB to handle human and animal related science fair or science festival projects. This will eliminate the need for approval (only elementary and middle schools) of these studies from anyone other than your school.

Animal studies must conform to the International Science Animal Experimentation rules. For information on the rules and the forms contact our Scientific Rules Committee Chairman, Dr. Simmonds at simmonds@ix.netcom.com.

Two basic questions need to be asked:

- 1) Are students involved in the study? If, Yes, then you need to have parent permission slips before conducting the research (Each site is responsible for making your own).
- 2) Are animals involved? If, Yes, and the animal(s) could be harmed, in any way, then you need to have a veterinarian check the condition of the animal(s) prior to conducting the research. (Keep all original paper work)

All projects involving animals or humans require approval by the school site IRB prior to the start of any experimentation and the Site Fair Director must retain the original.

Risk Assessment

No more than minimal risk exists when the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical or psychological examinations or tests.

1. Physical Risks
 - a. Exercise other than ordinarily encountered in DAILY LIFE would be considered more than minimal risk
 - b. Ingestion, tasting, smelling, or application of a substance would typically be considered more than minimal risk. However, ingestion or tasting projects that involve commonly available food or drink should be evaluated by the IRB who will determine risk level based upon the nature of the study
 - c. Exposure to any potentially hazardous material would be considered more than minimal risk
2. Psychological Risks
 - a. A research activity (e.g. survey, questionnaire, viewing of stimuli) or experimental condition that could potentially result in emotional stress would be considered more than minimal risk.

All Elementary and Middle School projects must have a copy of their IRB taped to the back of the left side of the project along with copies of all necessary consent forms from all subjects and guardians (place in a clear sheet protector or folder attached to the back) or a copy of the veterinarian's examination of the animal, if required. **Display and Safety will not approve projects that do not meet this requirement.**

ALL REQUESTS FOR APPROVAL BY THE FAIR'S SCIENTIFIC REVIEW COMMITTEE and/or INSTITUTIONAL REVIEW BOARD MUST BE INTO THE SCIENCE FAIR DIRECTOR BY FRIDAY, DECEMBER 18, 2009 (UNLESS SPECIAL CONSIDERATION IS OBTAINED FROM THE FAIR DIRECTOR).

All high school projects requiring an IRB must send an APPROVED IRB copy to the Regional Fair Director *on or before Friday, January 29, 2010.*

INSTITUTIONAL REVIEW BOARD

APPROVAL FORM

Student(s) Name(s): _____

Grade: _____ Science Teacher: _____

Title of Project: _____

Brief Description of Project: _____

Teacher: Please sign here if you feel this form is neat and readable, and proposes a viable Science Fair Project that follows the scientific method and in which neither animals nor humans will be harmed.

Science Teacher Approval Signature: _____

IRB Waiver of Written Informed Consent for Human or Animal Participation

The IRB may waive the requirement for documentation of written informed consent/assent/parental permission if the research involves **only minimal risk and anonymous data collection and if it is one of the following:**

- Research involving normal educational practices b) Research on individual or group behavior or characteristics of individuals where the researcher does not manipulate the subjects' behavior and the study does not involve more than minimal risk.
- Surveys, questionnaires, or activities that are determined by the IRB to involve perception, cognition, or game theory and do NOT involve gathering personal information, invasion of privacy or potential for emotional distress.
- Studies involving physical activity where the IRB determines that no more than minimal risk exists and where the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in DAILY LIFE or during performance of routine physical activities.

If there is any uncertainty regarding the appropriateness of waiving written informed consent/ assent/parental permission, it is strongly recommended that documentation of written informed consent/assent/parental permission be obtained.

For School/Site Use Only:

HUMAN or ANIMAL SUBJECTS
Permission Slips needed? ___ Yes ___ No (Keep slips with the project)
Check-up of Human or Animal Subjects required by Doctor, school nurse or Veterinarian? ___ Yes ___ No If yes, Doctor's, Nurse's or Veterinarian's (before and after experimentation) check-up must be attached to back of project display.

APPROVALS –

Principal / Administrator Signature

Date Reviewed

School Nurse / Doctor Signature

Date Reviewed

Science Fair Coordinator Signature

Date Reviewed