Institutional Review Board: Policies and Procedures

PURPOSE

All surveys and other research that are conducted within IMSA or by IMSA faculty, staff, or students must be approved by IMSA's Institutional Review Board (IRB). Functionally, this means contacting the chair of the IRB, which operates out of the Office of Institutional Research. The IRB coordinates the federally mandated Human and Animal Subjects Review functions for IMSA.

According to federal regulations, "This policy applies to all research involving human subjects." Although some research at IMSA is exempt from more than a cursory review by the IRB (therefore not requiring review by the full IRB committee), the IRB must make that exemption decision according to law. If the research is in violation of such regulations, failure to obtain prior approval can result in the immediate suspension or discontinuation of the research. In general, research involving human subjects and intended to contribute to generalizable knowledge by scholarly presentation or publication requires at least an expedited review by the IRB. An **Exempt from Annual Review Application** has been developed which individuals may submit to the IRB in case of exempt research studies.

Furthermore, the IRB is mandated to review all research because the level of surveying and other researching conducted upon IMSA students and faculty already is burdensome. Additional uncontrolled research, which may be duplicative, otherwise unnecessary, or less than optimally designed, creates the risk that none of the research efforts of this education laboratory will be taken seriously by its potential subjects. The research staff can help with research design as well as provide alternatives, such as examination of existing records and past studies.

The "Policy for Research with Human and Animal Subjects" is the formal document which regulates all internally- and externally-based research sponsored in part or in whole by IMSA. The purpose of the policy is to minimize intrusion and disruption for the students and educators of IMSA and to protect the rights and welfare of human and animal subjects used in research projects. The policy is issued in conjunction with IMSA's "Research with Human and Animal Subjects: Policies and Procedures" manual, which incorporates federal human subject protection guidelines in its detailing of appropriate research protocols.

Thank you from the staff of the IRB and the Office of Institutional Research.

October 2017

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I. Overview

The mission of the Illinois Mathematics and Science Academy (IMSA) is to transform mathematics and science teaching and learning by developing ethical leaders who know the joy of discovering and forging connections within and among mathematics, science, the arts, and the humanities by means of an exemplary laboratory environment characterized by research, innovative teaching, and service.

The Board of Trustees recognizes that a vigorous and educationally valid program of research and curriculum development is requisite for the achievement of IMSA's mission and legislative charge.

Researchers throughout Illinois and the nation are invited to participate in the research and development activities of IMSA. Research projects that reflect the state of the art in theory and practice and enhance the professional development of both students and educators are encouraged for submission. Collaborative research efforts that not only inform but involve students and educators in the design and implementation of the research process are of special interest.

All research and development activities will be coordinated in a manner to minimize intrusion and disruption for the faculty, staff, and students of IMSA. Furthermore, IMSA has the responsibility for:

- protecting the rights and welfare of human and animal subjects used in research projects conducted at this institution or under the direction of any employee or agent of this institution, whether funded or not, and regardless of the source of funding.
- educating students about their responsibility to protect the rights and welfare of human and animal subjects in their research.

In compliance with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Research Subjects (45 CFR 46, as amended), IMSA has established an Institutional Review Board (IRB). The processes and structures established by the IRB are designed to define and standardize the reviews of research proposals involving the use of human and animal subjects which are deemed to be of value but may place such subjects in at-risk situations.

All research projects involving the use of human and animal subjects conducted by IMSA faculty, staff and/or students or sponsored in part or in whole by IMSA must be reviewed and approved by the IRB, in accordance with the Research with Human and Animal Subjects: Policies And Procedures manual located in the Office of Institutional Research. All IMSA faculty, staff, students, and other individuals conducting research projects that are sponsored in part or in whole by IMSA, shall be responsible for complying with the procedures described therein. Staff of the IRB and the Office of Institutional Research shall be responsible for advising others of their responsibilities and for addressing questions and concerns that may arise.

IMSA shall be guided by the ethical principles regarding all research involving humans as subjects as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research."

The IRB shall encourage and promote constructive communication among students, faculty, and staff, as well as the human subjects, in order to maintain a high level of awareness regarding the safeguarding of the rights and welfare of the subjects. Correspondence concerning human and animal subject research and requests for additional information should be directed to the IRB, in care of the IRB committee chair, located in Office of Institutional Research, for review and response.

II. Definitions

Some of the following definitions contain quotations of language included in the federal regulations to guide researchers and other interested parties in determining the necessity for review.

Research: A systematic investigation... designed to develop or contribute to generalizable knowledge.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information.

Animal Subject: Any life form in the animal phylum Chordata.

Intervention: Both physical procedures by which data are gathered (e.g., drawing blood) and manipulations of the subject or the subject's environment that are performed for research purposes. This includes gathering information that if made public, may be harmful to the research subject.

Interaction: Communication or interpersonal contact between researcher and subject.

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

Minimal Risk: The risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. (See the AERA table: Summary of Harms and Ameliorative Measures.)

Consent: An explicit affirmative agreement, oral or written, to participate in research. Failure to object cannot be construed as consent. If a research subject is a minor (under the age of 18 years of age), then consent is usually provided by the parent or guardian of that individual.

Informed Consent: Consent obtained 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.

Assent: Minors (individuals under the age of 18 years old) usually may not legally consent to participation in research as a research subject. However, this does not mean that they should not be fully informed of the purposes and risks, if any, of the proposed research; their assent to participate should be obtained, along with parent consent.

Legally Authorized Representative: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved.

Research Protocol: Procedures and rules for dealing with the subject and the records derived from the subject.

Internal Research: Designed, conducted, or sponsored by IMSA faculty/staff.

External Research: Designed, conducted, or sponsored by researchers who have no staff status with IMSA; this includes mentorship in which work is conducted by IMSA students using other IMSA students as research subjects, on the IMSA campus.

III. Guidelines Governing Review of Applications

There are three levels of IRB review of research involving the use of human and animal subjects: Exempt, Expedited Review, and Full Board Review. These categories are assigned according to the level of known or potential risk to the subjects, the degree of confidentiality, the use of deception, whether the research will be used to contribute to generalizable knowledge (for example, presented at a conference or published), and so forth.

Exempt Projects

Exempt proposals must be forwarded to the IRB chair, or designee, who is responsible for reviewing the preliminary determinations of researchers and for making final institutional determination whether research protocols qualify for exemption from coverage under 45 CFR 46.101(b) (see items 1 to 6 below). Research determined to be exempt may be undertaken upon such determination.

If, upon being notified of the existence of a research study in progress, the IRB Chair, or designee, determines that a proposal assumed to be exempt should have been reviewed as nonexempt, the project will be discontinued pending expedited or full board review, as appropriate. Attempts shall be made to review the proposal and resolve differences expeditiously so that the project is not unnecessarily delayed or interrupted.

In order to be considered exempt, the research must be classified as internal research (as defined in section II) and covered in one or more of the following categories per federal regulations:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
    a. research on regular and special educational instructional strategies, or
    b. 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:
    a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    b. 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, as described earlier if:
    a. the human subjects are elected or appointed public officials or candidates for public office; or
    b. 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 researcher 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:
    a. public benefit or service programs;
    b. procedures for obtaining benefits or services under those programs;
    c. possible changes in or alternative to those programs or procedures; or
    d. 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:
    a. if wholesome foods without additives are consumed, or
    b. 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.

NOTE: Any external research, as defined in Section II, will require at a minimum expedited review, even if it otherwise meets the exempt status requirements. Also, if the project is otherwise exempt, audiotaping or videotaping of the subjects will not affect that determination. For policy on non-exempt projects involving taping, see "Video/Audiotaping Procedures", Section V below.

Research involving human subjects conducted by IMSA students' on-campus as part of mentorship requires at a minimum expedited review.

Research involving any human subjects conducted by IMSA students off-campus as part of mentorship, not utilizing IMSA resources or research subjects, does not require IMSA's IRB review or notification. Instead, this research must follow the off-campus mentorship site's IRB policies and procedures.

Expedited Review

For all nonexempt research protocols, the subcommittee shall determine whether the research protocol meets the criteria necessary for an expedited review process or should be subject to a full board review.

The eligibility of some research for review through the expedited procedure is in no way intended to negate or modify the policies of this institution or the other requirements of 45 CFR 46. The expedited review procedure may be used to review minor changes in previously approved research during the period for which approval is authorized. The only other research for which an expedited review procedure may be used is that which involves no more than minimal risk to the subjects and in which the only involvement of human and animal subjects will be in one or more of the following categories:

1. Collection of: hair and nail clippings, in a non-disfiguring manner
2. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice, which involves no deception. This includes 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 an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

3. Video/audio recordings made for research purposes such as investigations of speech defects.
4. Moderate exercise by healthy volunteers. In order for review of a project to be expedited under this category, a justification of the classification of the exercise as "moderate" must be provided.
5. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
6. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the researcher does not manipulate subjects' behavior and the research will not involve stress to subjects.
7. Research on devices for which an investigational device exemption is not required.

Any other category specifically added to this list by DHHS and published in the Federal Register.

Expedited Review shall be conducted by the subcommittee, who may exercise all of the authorities of the IRB except that the reviewers shall refer any research protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewers may also refer other research protocols to the full committee whenever the reviewers believe that full committee review is warranted.

When the expedited review procedure is used, the subcommittee conducting the review shall inform IRB members of research protocols which have been approved under the procedure. At a convened IRB meeting, any member may request that an activity which has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue. The determination of the IRB will be conveyed to the researcher following the meeting.

Full Board Review

When the IRB chair, or designee, has received a research proposal involving more than minimal risk to the subjects that does not fall within the expedited review category, the proposal is referred to IRB for a Full Board Review.

The IRB shall have the responsibility to review and the authority to approve, require modification in, or disapprove all activities or proposed changes in research based on the IRB’s determinations as to whether each of the following requirements are satisfied:

1. Risks to subjects are minimized:
    a. by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
    b. whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB shall not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.
3. Selection of subjects is equitable. In making this assessment the IRB shall take into account the purposes of the research, the setting in which the research will be conducted and shall be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and be appropriately documented, in accordance with, and to the extent required by 45 CFR 46. 116. Documentation of such informed consent must be submitted to the IRB prior to approval.
5. Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
6. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Research protocols scheduled for review shall be distributed to all members of the IRB prior to the meeting. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the meeting.

A majority of the members of the IRB constitutes a quorum and is required in order to convene a meeting for the review of research protocols. An IRB member whose concerns are primarily in nonscientific areas must be present at the convened meeting before the IRB can conduct its review of research. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has an interest, except to provide information requested by the IRB.

In cases where research activities were initially approved under expedited procedures and subsequently reviewed by non-expedited procedures, the decisions reached at the convened meeting shall supersede any decisions made through the expedited review process.

IV. Review Procedures

Project Submission and Approval Process:

It is the responsibility of the Principal Investigator to know and comply with the review procedures of the IRB. Should the researcher be a student enrolled at IMSA, the adult sponsor of the research (e.g., teacher or other staff member) will assumes responsibility for the proposed activity as the Principal Investigator on record with the student researcher serving as a Co-Investigator. All internal and external researchers (faculty, staff, and students) should be familiar with their obligations in regards to the protection of the subject(s) from risks incurred as a result of participating in the research. Therefore, prior to obtaining IRB approval, the Collaborative Institutional Training Initiative (CITI) training program must be completed. Completion certificates must be submitted along with the Application for Institutional Review of Research. Researchers and research supervisors are responsible for submitting all research involving human and animal subjects to the IRB Chair. When it is not clear whether the research involves human and animal subjects, researchers and/or research supervisors should seek assistance from the IRB or the Office of Institutional Research in making this determination.

Researchers must obtain approval prior to the start of data collection by completing either the "Application for Institutional Review of Research – Exempt from Annual Review Level I" or the "Application for Institutional Review of Research – Human Subjects Research Level II/III." Preliminary discussions concerning the proposed project are encouraged prior to formal proposal submission so that members of the IMSA community may assist in the design and direction of the proposed investigation. Once a proposal is submitted, the IRB Chair, or designee, will either designate the proposal as "exempt" or requiring further review (expedited review or full board review). If the IRB Chair, or designee, determines that the research is exempt, a copy of the application form is filed and the researcher can conduct the research. If the IRB Chair, or designee, desires further consultation, the application may receive an expedited review by a subcommittee of the IRB consisting of at least three members. This committee will evaluate ethical considerations, scientific merit, and risks, if any, to

the subject. Studies warranting careful scrutiny for the protection of human and animal subjects, as determined by the subcommittee, will be presented to the full IRB for full board review.

Research proposals will be evaluated based on:

- relevance to the mission of the Illinois Mathematics and Science Academy;
- contribution to education;
- quality of project design;
- potential to deliver a product for dissemination;
- appropriateness of qualifications of project staff;
- cost to IMSA (student, faculty, and staff time, materials, and so forth);
- minimal degree of participant risk, absence of pain or suffering;
- integration with overall research program at IMSA.

A copy of the abstract of each approved proposal will be place on the IRB website along with date of the approval.

Ongoing projects, unless exempt, must be reviewed at least annually. The IRB will require more frequent monitoring for research involving more than minimal risk to the subjects.

Principal investigators of all approved projects will be required to provide disclosure statements to all participants and to report project progress at intervals prescribed by the IRB. A final project report describing the outcomes/results and conclusions of the project will be reviewed and filed with the Office of Institutional Research within three months of the completion of the project and prior to the public release of any data or results. Public release of project results is subject to IMSA copyright policies and will acknowledge IMSA's participation and assistance in the project design and activities as well as cite any notes specific to IMSA deemed important to the interpretation of the research.

Additional Responsibilities of the Investigator:

Extension of Project Time Period: Researchers are responsible for reporting the progress of non-exempt research to the IRB Chair no less than once per year. If the project has been approved as exempt by the IRB, it needs no further review unless the researcher intends to modify the protocol in such a way that it is no longer exempt.

To obtain an extension of approval, beyond one year, of a project that has minor or no changes to the protocol, the researcher should notify the IRB Chair in writing no less than sixty (60) days prior to the date the project's original approval will expire. Any change in the protocol must be clearly indicated. Unless deemed necessary by the IRB Chair, extensions are not referred to the subcommittee or the full IRB for review. However, researchers are prohibited from continuing their research after a project's approval expiration date unless such an extension has been approved in writing from the IRB Chair. Continuation of approval without full review procedures is available on an ongoing basis.

Researchers should submit continuing applications in a timely manner to avoid interruption of their data collection. Researchers are also responsible for reporting promptly to the IRB Chair any injuries or any unanticipated problems which involve human research subjects or others.

Significant Changes in the Research Protocol: The IRB Chair should be immediately notified of proposed changes in a research activity. Changes in research during the period for which IRB approval has already been

given require IRB review and approval, except when the change is necessary to eliminate apparent immediate hazards to the subject.

V. Compliance with IRB Decisions

The IRB Chair shall keep researchers aware of decisions and administrative processing affecting their respective protocols and shall return all disapproved protocols to the researchers. Researchers shall be responsible for complying with all IRB decisions, conditions, and requirements.

If any members of the IRB become aware of research being conducted or about to be conducted with human and animal subjects, and if the research has not been brought to the attention of the IRB by the researcher(s), the researcher(s) will be immediately informed that the research cannot proceed, or must be suspended, and will be asked to contact the IRB Chair immediately to initiate the approval process. Such research will not resume until IRB approval has been received.

Applications submitted with the "Application for Institutional Review of Research – Exempt from Annual Review Level I" will be reviewed and responded to by the IRB Chair, or a designee, within three to five business days. If research requires either an Expedited or Full Board Review, the "Application for Institutional Review of Research – Human Subjects Research Level II/III" must be submitted at least three to four weeks prior to the expected start date of the research project in order to allow for sufficient time to review the request. Research requiring an Expedited Review will be responded to by the IRB Chair, or a designee, within two weeks. Research requiring a Full Board Review will be reviewed and responded to by the IRB Chair, or a designee, within four to six weeks.

VI. Informed Consent Procedures

Unless exempt or specifically waived by the IRB or its agents, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. The prospective subject or the representative must be given sufficient opportunity to consider whether or not to participate under circumstances that minimize the possibility of coercion or undue influence and in understandable language. The waiving or appearance of waiving any of the subject's legal rights, and/or the release or appearance of release from liability of the investigator, the sponsor, the institution or its agents for negligence, are not permissible.

The following basic elements of informed consent information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following additional elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

A consent procedure may be acceptable which excludes or alters some or all of the above elements of informed consent, or waives the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   a. public benefit of service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs
2. The research involves no more than minimal risk to the subjects;
3. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
4. The research could not practicably be carried out without the waiver or alteration; and
5. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Documentation of informed consent

Unless specifically waived, informed consent shall be documented by the use of an IRB-approved written consent form and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. A written consent form should include those standard elements listed above, and contain signature and date lines. This form may be read to the subject or the subject's legally authorized representative, but in any event, the researcher shall give either the subject or the representative adequate opportunity to read the form before signing it.

A short written consent document stating that the above required elements of informed consent have been presented orally to the subject or the subject's legally authorized representative can also be used. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the

person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Video/Audio taping Procedures

Projects involving the use of videotaping or audio taping must make specific mention of these in the consent documents. The subject must have the choice of whether to participate in the video or audio taping procedures. This consent is separate and distinct from consent to participate in the project, requiring separate signature and date lines.

Requests for a full or partial waiver of informed consent procedures must be accompanied by sufficient justification. Requests should be submitted along with the Application for Institutional Review of Research.

Researchers are responsible for retaining the consent documents signed by human research subjects in a repository approved by the IRB Chair for three years.

VII. Additional Protections for Children and Other Special Populations

The IRB, in compliance with federal regulations, gives special consideration to proposed research involving: prisoners, children, persons with physical or mental handicaps, fetuses, pregnant women, and other potentially vulnerable groups. The additional regulations pertaining to these protected groups are located in Subpart B of the regulations (45 CFR 46, as amended).

Of particular concern is research conducted involving children as subjects. Parental consent (as well as IRB approval) must be obtained prior to beginning any research project which alters a child's routine or behavior. This includes research conducted in classroom settings such as educational tests, surveys, and so forth. Parental consent may be waived only when the child is legally designated an emancipated minor or when it is determined by the IRB that parental permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children). For research conducted in settings in which general blanket participation forms have been signed by guardians, (i.e., schools, classrooms, and so forth.), specific consent of the guardian and assent of the child must still be obtained for each project conducted with these subjects unless there will be no manipulation of the subject's behavior or disruption of the normal routine of the individuals in these settings. Furthermore, verbal assent must be obtained from the minor unless the IRB determines that the capability of some or all of the minors is so limited that they cannot reasonably give assent. Information on the requirements for assent is available from the IRB and the Office of Institutional Research.

The mostly minor-level students at IMSA similarly are members of this protected group. However their role as voluntary participants in a laboratory environment is inherent in their selection of IMSA as their place of matriculation. Furthermore, their parents sign a blanket statement of approval of their involvement as subjects of a research study (see attached IMSA Research Consent Form, Appendix D). Nevertheless, a research project-specific parental consent form can be required if deemed appropriate by the IRB.

VIII. Procedures for Approval of Cooperative Research and Grant Proposals

Cooperative Research: The human and animal subjects regulations cover not only research conducted at IMSA, but also projects conducted at or in cooperation with another entity by IMSA administrators, faculty, staff, or students. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR 46.

Grant Proposals: Researchers should obtain IRB approval prior to submitting a proposal to an external granting agency to avoid possible delays in the review of the grant application. Some granting agencies require approval prior to submitting the grant application; for other agencies, the IRB may submit a "pending" letter to the agency should IRB approval not be obtained by the application due date. In such cases, certification of approval must then be submitted within sixty days after the application due date.

IX. IRB Membership

The IRB is made up of five individuals, one of whom must not be affiliated with IMSA and who is not part of the immediate family of a person affiliated with IMSA. The members must be of varied backgrounds, including consideration of the gender, racial, and cultural backgrounds of members as well as sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human and animal subjects. The IRB members must also possess sufficient expertise to address issues pertinent to research involving the use of human and animal subjects. The IRB shall include at least one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas. All appointees are expected to remain on the board for a minimum of three years. Should a member resign, another individual with comparable expertise is selected as a replacement to serve the remainder of the term.

In light of the above, the President of IMSA shall appoint the members of the IRB. The committee shall be comprised of the following members:

- One member from the Office of Institutional Research (Chair)
- One member whose primary interest is scientific
- One member whose primary interest is nonscientific
- One member who has expertise with minor populations
- One member who is not an IMSA faculty/staff member

Selection of new or replacement IRB committee members: At least two months prior to the resignation or completion of a term of one of the IRB committee members, the IRB will solicit nominations for new members and present a list to the President of IMSA for selection. The President will appoint the members who will serve a term of at least three years. Current IRB members will have the option of renewing their terms.

X. Additional Responsibilities of the IRB

The IRB reports directly to the Executive Director of Institutional Research.

The IRB will follow IMSA's governance and operations policy, as that policy relates to subcommittees of the Board of Trustees. The IRB will also follow IMSA's policies, and state and federal laws, related to the disclosure of student records.

Convened meetings of the IRB shall occur: 1) semi-annually in September and February; or 2) at the call of the chair when the chair judges the meeting to be necessary or advantageous.

The IRB is subject to the Illinois Open Meetings Act, and therefore shall be open to the public except for the discussion of security, safety, personnel, and proprietary issues.

The IRB shall prepare and maintain adequate documentation of IRB activities (in the Office of Institutional Research), including the following:

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by researchers and reports of injuries to subjects.

- Minutes of IRB meetings which shall be in sufficient detail to show the names of attendees at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution. If a member in attendance has a conflicting interest regarding any project, minutes shall show that this member did not participate in the review, except to provide information requested by the IRB. Minutes of the open sessions of the IRB meetings are to be made available to the public ten days after their approval

- Records of continuing review activities.

- Copies of all correspondence between the IRB and the researchers.

- A list of IRB members as required by 45 CFR 46.103(b)(3).

- Written procedures for the IRB as required by 45 CFR 46.103(b)(4).

- Statements of significant new findings provided to subjects, as required by 45 CFR 46.1 1 6(b)(5)

The IRB shall maintain records relating to research conducted for a minimum of three years after completion. IRB records shall be accessible for inspection and copying by authorized representatives of DHHS at reasonable times and in a reasonable manner, or shall be copied and forwarded to DHHS when requested by authorized DHHS representatives. Researchers are encouraged to retain personal copies of their applications, correspondence, etc. as well.

The IRB chair shall be responsible for promptly reporting information to the IRB and/or appropriate administrative entity 1) any instances of injuries to subjects and unanticipated problems involving risks to subjects or others, and 2) information concerning the IRB's reasons for the termination or suspension of IRB approval.

To the extent that any of the above records created by the IRB are determined to be public records under the Freedom of Information Act," the IRB will be subject to IMSA's "Freedom of Information Act" policy as well.

Amendment of policy and procedures may be recommended at any time by the IRB and members of the IMSA community. Proposed amendments shall be submitted to the full board for review, and must be approved by a majority of a convened meeting. Approved amendments will be made public on the IRB website in a timely fashion.