Human Subjects Internal Review Board (HSIRB)
PROTECTION OF HUMAN SUBJECTS
Revised: October 2023

Subpart A.--Moravian University and Seminary and Lancaster Seminary Policy for the Protection of Human Research Subjects

Section**:**

Subpart B.--Additional Moravian University and Seminary and Lancaster Seminary Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

Section:

Subpart C.--Additional Moravian University and Seminary and Lancaster Seminary Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

Section:

Subpart D.--Additional Moravian University and Seminary and Lancaster Seminary Protections for Children Involved as Subjects in Research

Section:

Subpart A.--Moravian University and Seminary and Lancaster Seminary Policy for the Protection of Human Research Subjects

Moravian University and Seminary and Lancaster Seminary and Lancaster Theological Seminary follows the Common Rule, established by the U.S. Department of Health and Human Services' Office of Human Research Protections (OHRP). The Common Rule constitutes Subpart A of the OHRP regulations and is available HERE.

Subpart B.--Additional Moravian University and Seminary and Lancaster Seminary Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human In Vitro Fertilization

MU.201 Applicability.

(a) The regulations in this subpart are applicable to all Moravian University and Seminary and Lancaster Seminary projects involving grants and contracts supporting research, development, and related activities involving: (1) the fetus, (2) pregnant women, and (3) human in vitro fertilization.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

MU.202 Purpose.

It is the purpose of this subpart to provide additional safeguards in reviewing activities to which this subpart is applicable to assure that they conform to appropriate ethical standards and relate to important societal needs.

MU.203 Definitions.

As used in this subpart:

(a) "HSIRB" means the Human Subjects Internal Review Board and any other officer or employee of the Moravian University and Seminary and Lancaster Seminary to whom authority has been delegated.

(b) "Pregnancy" encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.

(c) "Fetus" means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.

(d) "Viable" as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary of Health and Human Services may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.

(e) "Nonviable fetus" means a fetus ex utero which, although living, is not viable.

(f) "Dead fetus" means a fetus ex utero which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).

(g) "In vitro fertilization" means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

MU.204 Ethical Advisory Boards.

(a) In the event of Moravian University and Seminary and Lancaster Seminary research necessitating decisions by an Ethical Advisory Board, the Moravian University and Seminary and Lancaster Seminary shall enter negotiations for advice with the St. Luke's Hospital Ethical Advisory Board. Members of these Board(s) are selected so that the Board(s) will be competent to deal with medical, legal, social, ethical, and related issues and may include, for example, research scientists, physicians, psychologists, sociologists, educators, lawyers, and ethicists, as well as representatives of the general public. No Board member may be a regular, full-time employee of the Moravian University and Seminary and Lancaster Seminary.

(b) At the request of the HSIRB chairperson, the St. Luke's Hospital Ethical Advisory Board advice shall be sought consistent with the policies and requirements of this part as to ethical issues, involving activities covered by this subpart, raised by individual applications or proposals. In addition, upon request by the chairperson, the St. Luke's Hospital Ethical

Advisory Board shall render advice as to classes of applications or proposals and general policies, guidelines, and procedures.

(c) The St. Luke's Hospital Ethical Advisory Board may establish, with the approval of the HSIRB, classes of applications or proposals which: (1) must be submitted to the St. Luke's Hospital Ethical Advisory Board, or (2) need not be submitted to the St. Luke's Hospital Ethical Advisory Board. Where the St. Luke's Hospital Ethical Advisory Board so establishes a class of applications or proposals which must be submitted, no application or proposal within the class may be funded by the Moravian University and Seminary and Lancaster Seminary or any component thereof until the application or proposal has been reviewed by the Board and the Board has rendered advice as to its acceptability from an ethical standpoint.

MU.205 Additional duties of the HSIRB in connection with activities involving fetuses, pregnant women, or human in vitro fertilization.

(a) In addition to the responsibilities prescribed for the HSIRB under Subpart A of this part, the HSIRB shall, with respect to activities covered by this subpart, carry out the following additional duties:

(1) determine that all aspects of the activity meet the requirements of this subpart;

(2) determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant or offeror for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the HSIRB or subject advocates in:

(i) assuring an observer to oversee the actual process by which individual consents required by this subpart are secured either by approving induction of each human being into the activity or verifying, perhaps through sampling, that approved procedures for induction of human beings into the activity are being followed, and

(ii) assuring a monitor for the progress of the activity and intervention as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen);

(3) carry out such other responsibilities as may be assigned by the Moravian University and Seminary and Lancaster Seminary Faculty.

(b) No award may be issued until the applicant or offeror has certified to the granting institution that it has made the determinations required under paragraph (a) of this section and the HSIRB has approved these determinations, as provided in MU.120 of Subpart A of this part.

(c) Applicants or offerors seeking outside support for activities covered by this subpart must provide for the designation of a Human Subjects Institutional Review Board, subject to approval by the institution, where no such Board has been established under Subpart A of this part.

MU.206 General limitations.

(a) No activity to which this subpart is applicable may be undertaken unless:

(1) appropriate studies on animals and non-pregnant human beings have been completed;

(2) except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity; human beings engaged in the activity will have no part in:

(i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and

(ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

(b) No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

MU.207 Activities directed toward pregnant women as subjects.

(a) No pregnant woman may be involved as a subject in an activity covered by this subpart unless:
  (1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or
  (2) the risk to the fetus is minimal.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:
  (1) the purpose of the activity is to meet the health needs of the mother;
  (2) his identity or whereabouts cannot reasonably be ascertained;
  (3) he is not reasonably available; or
  (4) the pregnancy resulted from rape.

MU.208 Activities directed toward fetuses in utero as subjects.

(a) No fetus in utero may be involved as a subject in any activity covered by this subpart unless:
  (1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or
  (2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(b) An activity permitted under paragraph (a) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if:
  (1) his identity or whereabouts cannot reasonably be ascertained,
  (2) he is not reasonably available, or
  (3) the pregnancy resulted from rape.

MU.209 Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects.

(a) Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless:
  (1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or
  (2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

(b) No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:
  (1) vital functions of the fetus will not be artificially maintained,
  (2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and
  (3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

(c) In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.

(d) An activity permitted under paragraph (a) or (b) of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if:
  (1) his identity or whereabouts cannot reasonably be ascertained,
  (2) he is not reasonably available, or
  (3) the pregnancy resulted from rape.

(4)

MU.210 Activities involving the dead fetus, fetal material, or the placenta.
Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

MU.211 Modification or waiver of specific requirements.
Upon the request of an applicant or offeror (with the approval of another Institutional Review Board), the HSIRB may modify or waive specific requirements of this subpart, with the approval of the St. Luke's Hospital Ethical Advisory Board after such opportunity for public comment as the St. Luke's Hospital Ethical Advisory Board considers appropriate in the particular instance. In making such decisions, the HSIRB will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant such modification or waiver and that such benefits cannot be gained except through a modification or waiver. Any such modifications or waivers will be published as notices to the Moravian University and Seminary and Lancaster Seminary Faculty.

Subpart C.--Additional Moravian University and Seminary and Lancaster Seminary Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects

MU.301 Applicability.

(a) The regulations in this subpart are applicable to all biomedical and behavioral research conducted or supported by the Moravian University and Seminary and Lancaster Seminary Departments and Organizations involving prisoners as subjects.

(b) Nothing in this subpart shall be construed as indicating that compliance with the procedure set forth herein will authorize research involving prisoners as subjects, to the extent such research is limited or barred by applicable State or local law.

(c) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

MU.302 Purpose.

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

MU.303 Definitions.

As used in this subpart:

(a) "HSIRB" means the Moravian University and Seminary and Lancaster Seminary Human Subjects Institutional Review Board and any other officer or employee of the Moravian University and Seminary and Lancaster Seminary to whom authority has been delegated.

(b) "HSIRB" replaced the Human Subjects Committee in Spring 1999.

(c) "Prisoner" means any human being involuntarily confined or detained in a penal institution. The term is intended to encompass human beings sentenced to such an institution under a criminal or civil statute, human beings detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and human beings detained pending arraignment, trial, or sentencing.

(d) "Minimal risk" is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

MU.304 Composition of HSIRB where prisoners are involved.

In addition to satisfying the requirements in MU.107 of this part, the HSIRB, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

(a) A majority of the HSIRB (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the HSIRB.

(b) At least one member of the HSIRB shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

MU.305 Additional duties of the HSIRB where prisoners are involved.

(a) In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the HSIRB shall review research covered by this subpart and approve such research only if it finds that:

(1) the research under review represents one of the categories of research permissible under MU.306(a)(2);

(2) any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his

or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;

(3) the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers;

(4) procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the HSIRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;

(5) the information is presented in language which is understandable to the subject population;

(6) adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

(7) where the HSIRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

(b) The HSIRB shall carry out such other duties as may be assigned by the Moravian University and Seminary and Lancaster Seminary Faculty.

MU.306 Permitted research involving prisoners.

(a) Biomedical or behavioral research conducted or supported by Moravian University and Seminary and Lancaster Seminary may involve prisoners as subjects only if:

(1) the HSIRB has approved the research under MU.305 of this subpart; and

(2) in the judgment of the HSIRB the proposed research involves solely the following:

(A) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(B) study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

(C) research on conditions particularly affecting prisoners as a class for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the HSIRB has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice to the Moravian University and Seminary and Lancaster Seminary Faculty of the intent to approve such research; or

(D) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the HSIRB to control groups which may not benefit from the research, the study may proceed only after the HSIRB has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

(b) Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by Moravian University and Seminary and Lancaster Seminary shall not involve prisoners as subjects.

Subpart D.--Additional Moravian University and Seminary and Lancaster Seminary Protections for Children Involved as Subjects in Research

MU.401 To what do these regulations apply?

(a) This subpart applies to all research involving children as subjects, conducted or supported by the Moravian University and Seminary and Lancaster Seminary.

(1) This includes research conducted by Department employees, except that each head of an Operating Division of the Department may adopt such non-substantive, procedural modifications as may be appropriate from an administrative standpoint.

(2) It also includes research conducted or supported by the Moravian University and Seminary and Lancaster Seminary outside the United States, but in appropriate circumstances, the HSIRB may, under paragraph (i) of MU.101 of Subpart A, waive the applicability of some or all of the requirements of these regulations for research of this type.

(b) Exemptions at MU.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at MU.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at MU.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in paragraphs (c) through (i) of MU.101 of Subpart A are applicable to this subpart.

MU.402 Definitions.

The definitions in MU.102 of Subpart A shall be applicable to this subpart as well. In addition, as used in this subpart:

(a) "Children" are 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.

(b) "Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) "Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) "Parent" means a child's biological or adoptive parent.

(e) "Guardian" means a human being who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

MU.403 HSIRB duties.

In addition to other responsibilities assigned to the HSIRB under this part, the HSIRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

MU.404 Research not involving greater than minimal risk.

The Moravian University and Seminary and Lancaster Seminary will conduct or fund research in which the HSIRB finds that no greater than minimal risk to children is presented, only if the HSIRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in MU.408.

MU.405 Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

The Moravian University and Seminary and Lancaster Seminary will conduct or fund research in which the HSIRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the HSIRB finds that:

(a) the risk is justified by the anticipated benefit to the subjects;

(b) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
(c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in MU.408.

MU.406 Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
The Moravian University and Seminary and Lancaster Seminary will conduct or fund research in which the HSIRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the HSIRB finds that:
(a) the risk represents a minor increase over minimal risk;
(b) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
(c) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
(d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408.

MU.407 Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.
The Moravian University and Seminary and Lancaster Seminary will conduct or fund research that the HSIRB does not believe meets the requirements of MU.404, MU.405, or MU.406 only if:
(a) the HSIRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
(b) the HSIRB, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
(1) that the research in fact satisfies the conditions of MU.404, MU.405, or MU.406, as applicable, or
(2) the following:
(i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
(ii) the research will be conducted in accordance with sound ethical principles;
(iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in MU.408.

MU.408 Requirements for permission by parents or guardians and for assent by children.
(a) In addition to the determinations required under other applicable sections of this subpart, the HSIRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the HSIRB the children are capable of providing assent. In determining whether children are capable of assenting, the HSIRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the HSIRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the HSIRB determines that the subjects are capable of assenting, the HSIRB may still waive the

assent requirement under circumstances in which consent may be waived in accord with MU.116 of Subpart A.

(b) In addition to the determinations required under other applicable sections of this subpart, the HSIRB shall determine, in accordance with and to the extent that consent is required by MU.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the HSIRB may find that the permission of one parent is sufficient for research to be conducted under MU.404 or MU.405. Where research is covered by MU.406 and MU.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in MU.116 of Subpart A, if the HSIRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of inappropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by MU.117 of Subpart A.

(e) When the HSIRB determines that assent is required, it shall also determine whether and how assent must be documented.

MU.409 Wards.

(a) Children who are wards of the State or any other agency, institution, or entity can be included in research approved under MU.406 or MU.407 only if such research is:

(1) related to their status as wards; or

(2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

(b) If the research is approved under paragraph (a) of this section, the HSIRB shall require appointment of an advocate for each child who is a ward, in addition to any other human being acting on behalf of the child as guardian or in loco parentis. One human being may serve as advocate for more than one child. The advocate shall be a human being who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the HSIRB) with the research, the investigator(s), or the guardian organization.

END