PLYMOUTH STATE UNIVERSITY

Human Subjects Guidelines and Procedural Manual

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PLYMOUTH STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD

PLYMOUTH STATE UNIVERSITY
HUMAN SUBJECTS GUIDELINES AND PROCEDURAL MANUAL

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INTRODUCTION

The Plymouth State University (PSU) Institutional Review Board (IRB) is charged with protecting the rights and welfare of human subjects and supports Plymouth State University's research mission. The IRB is constituted to be the agency within PSU that reviews and approves research involving humans. Research actions are guided by the principles set forth in the Belmont report.

At PSU, there is one IRB authorized under an assurance approved by the Department of Health and Human Services to review and to approve research involving human participants. The IRB at PSU is a standing committee responsible for protecting the rights and welfare of people who are participants in PSU research activities. Within the IRB Committee, is a group of diverse professionals from various disciplines and individuals with distinct roles including: chairperson, vice chairperson, outside community member(s), prisoner advocate(s), scientist, and at least one non-scientist.

All PSU research activities proposing to involve human participants must be reviewed and receive written, unconditional approval from the IRB before commencing**.** This policy applies to all research activities sponsored by PSU; conducted by or under the direction of any employee, student, or agent of PSU in connection with his or her PSU responsibilities; conducted by or under the direction of any employee, student, or agent of PSU involving the use of any PSU property or facility; or, conducted by or involving any individual or institution working with PSU as part of a collaboration, sub-grant, or sub-contract.

Purpose of this Manual

The purpose of this manual is to provide a comprehensive document indicating the PSU IRB guidelines, ethics, procedures, documents, templates, frequently asked questions, and definitions of terms. The hope is that faculty, students, and research supervisors will find this manual helpful as they conduct research. A committee of individuals, from the standing 2016 IRB committee, created this manual. Committee members included Dr. Stephen Flynn (Committee Chair), Dr. Clarissa Uttley, Dr. Ryanne Carmichael, Dr. Meagan Shedd, and Dr. Jason Swift.

Contact Information

The PSU IRB has a website that includes helpful information and resources. The primary method for contacting the PSU IRB is through emailing the current IRB Chairperson. Information on the current IRB membership can be found on the PSU IRB website. The email address for the IRB chair is psu-irb@plymouth.edu. While the PSU IRB is a standing committee, assistance is provided to the IRB from the Office of Research and Sponsored Programs.

Please note, the IRB application review process is a confidential process and under no circumstances are the identities of reviewers provided to applicants or other interested parties, nor is it allowable to request a particular reviewer.

THE INSTITUTIONAL REVIEW BOARD

An Institutional Review Board (IRB) is a committee established to review and approve research involving human subjects.

Purpose

The purpose of the IRB is to ensure the rights and welfare of research participants are being respected and protected. The IRB is the agency within PSU that reviews and approves research involving humans. This includes research that is taking place under the auspices of Plymouth State University. PSU's IRB has a faculty-governed core that reviews IRB applications, takes part in the CITI Research Training and the CITI Reviewer Training, and remains current about changing rules and protocols.

Roles and Responsibilities

IRB Membership

All PSU IRB appointments are initially for three years. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at PSU. The IRB will consist of individuals who have expertise in the areas of research reviewed and have sufficient expertise and diversity to evaluate ethical issues involved in research. The IRB includes a chairperson, vice chairperson, at least one non-scientist, one prisoner advocate, one scientist, and at least one person who is not affiliated with the university. The committee will not have a member participate in the committee's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. The IRB will invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Chairperson and Vice Chairperson

The IRB Chair and Vice Chair promote a culture consistent with the objectives of Plymouth State University's Research Mission with special emphasis on the protection of individuals participating in research at the University. In promoting such a culture, the Chair and Vice Chair are directly responsible for overseeing the protection of research participants by ensuring the proper review, approval, disapproval, or determination of exemption from further review of research protocol submissions to the IRB.

Responsibilities:

- Chair the IRB Annual Meeting(s)
- Oversee all IRB applications unless a reason exists not to (e.g., conflict of interest)
- Serve as the designated exempt application reviewer
- Participate in all IRB full board reviews
- Facilitate and participate in IRB educational activities
- Keep abreast of regulations and policies governing IRB activities

- Adhere to and administer all determinations made by the IRB
- Serve as an alternate IRB member as needed
- Administer and manage the IRB renewal process

Outside Community Member (non-affiliated)

A community member is someone from outside PSU who serves on the IRB. The community member is usually non-scientific and is not affiliated with the institution. Community members come from a variety of backgrounds and are chosen for particular experience, knowledge, or expertise to the types of studies reviewed by the IRB.

Responsibilities:

- Participate in assigned reviews
- Attend the IRB Annual meeting(s)
- Keep abreast of regulations and policies governing IRB activities
- Participate in IRB educational activities

Prisoner Advocate

A prisoner advocate supports the proper and ethical treatment of prisoner research participants. When the IRB reviews applications proposing to enroll prisoners, the prisoner advocate must be present at the IRB meeting at which the application is discussed. The prisoner advocate serves as a voting member of the IRB when such applications are reviewed.

Responsibilities:

- Participate in assigned reviews
- Attend the IRB Annual meeting(s)
- Take part in reviewing applications that involve prisoners as participants or other individuals related to the prison environment
- Keep abreast of regulations and policies governing IRB activities
- Participate in IRB educational activities

Scientist Member(s)

The PSU IRB includes at least one member whose primary concerns are in scientific areas. This member is normally part of the university community (e.g., faculty, administration). Scientist members are expected to review assigned studies, as well as contribute to the evaluation of a research project on its scientific merits and standards of practice. These members are able to advise the IRB if additional expertise in a scientific area is required to assess if a research project adequately protects the rights and welfare of subjects.

Responsibilities:

- Attend the IRB Annual meeting(s)
- Take part in applications to which he or she is assigned
- Keep abreast of regulations and policies governing IRB activities
- Represent scientific interests such as: the appropriateness of the research method and the purpose of the study
- Participate in IRB educational activities

Nonscientist Member(s)

Nonscientist members are expected to provide input on matters related to their individual knowledge, expertise and experience, professional and otherwise. Nonscientist members advise the IRB if additional expertise in a nonscientific area is required to assess if research project adequately protects the rights and welfare of subjects.

Responsibilities:

- Attend the IRB Annual meeting(s)
- Take part in full board IRB application reviews and other applications to which the individual is assigned
- Participate in IRB educational activities
- Contribute expertise with regulations, policies, and the conduct of human subjects research
- Represent nonscientific interests such as: how well is the research explained in order to comprehend the risk and benefit

Quorum

A quorum is required for full-board reviews. A quorum (a majority of the voting members) is required for study approval, with a majority of those present voting to approve. Per federal regulations, the nonscientific member must be present in order for the IRB to vote on studies [45 CFR 46.108(b)]. Should the quorum fail during a meeting (e.g., those with conflicts being excused, early departures, loss of the nonscientific member), the meeting is terminated from further votes unless the quorum can be restored.

POLICIES, GUIDELINES, REGULATIONS, AND ETHICAL PRINCIPLES

Levels of Review

Exempt Review

A study fits into the exempt category of research if the research involves minimal risk to human subjects. The application will be reviewed as exempt or does not involve human subjects as determined by regulatory guidelines. When an exemption is granted by the IRB committee protocols that are deemed exempt are effectively exempt from continuing review. If the study is not found to be exempt, it will need to go through expedited or full-committee review as determined by the IRB committee. The IRB is required to determine if a research project falls under one of the following six exempt categories listed in the federal regulations (45 CFR 46.101(b)). This level of review is often conducted by 1 or more IRB members.

Common examples of Exempt level research at PSU are:

- Anonymous surveys,
- Interviews of adults about non-sensitive topics,
- Educational tests, or
- Observation of public behavior.

Expedited Review

This type of review is carried out only for studies involving no more than minimal risk to subjects. These reviews are conducted on an ongoing basis where the study is reviewed by a qualified member of the IRB committee who will consult with the Principle Investigator (PI) if necessary to come to a decision about the approval of the study (45 CFR 46.110). This level of review is often conducted by 2 or more IRB members.

Common examples of research that may be reviewed at the Expedited level at PSU are:

- Studies including blood samples taken from healthy volunteers,
- Studies involving moderate exercise by healthy volunteers,
- Collection of data via recordings (such as those taken in the investigation of speech defects),
- Studies of existing data or pathological specimens that include identifying information,
- Linguistic and ethnographic studies, or
- Studies involving focus groups

Full-Board Review

This type of review is conducted by a fully convened IRB committee, which discusses the study and makes an approval decision. The convened meeting must have a quorum of IRB members present. For the research to be approved, it must receive the approval of a majority of those members present. This type of review is carried out for studies with greater than minimal risk to

subjects. Full-board reviews often involve special/vulnerable population(s) and often can involve some level of physical, psychological, social, legal, and/or economic harm to the subject(s) and/or the researcher(s). This level of review is often conducted by 5 or more IRB members. An example of a full board review could be the following:

Common examples of research reviewed at the Full Board level at PSU are studies that include:

- Maximal exercise by healthy volunteers,
- Institutionalized persons (e.g., prisoners, patients in long term care facilities),
- Persons who lack capacity to consent (e.g., persons with severe mental disabilities or developmental delays), or
- Sensitive topics (e.g., criminal behavior, sexuality)

Decision Making Process

The IRB may make the following determinations of a protocol submitted for review:

1. *Approved:* Approval is granted with no revisions necessary.

2. *Approved subject to required modifications:* If minor changes or clarifications are needed, the IRB Chairperson overseeing the application may approve the research on behalf of the committee once the revisions are completed.

3. *Tabled:* If significant concerns related to the protocol and/or consent forms exist, an application may be tabled pending major revisions by the applicant. The concerns will be specified to the applicant and a revised application may be submitted. In the case of a Full Board review, the IRB may invite the applicant to a meeting if members have any further questions.

4. *Non-approval or disapproval:* When a proposal does not fit the required standards, it will be disapproved. A disapproval occurs when the IRB has determined the protocol has risks that outweigh the benefits of participation and/or the application is significantly deficient in other areas. The application may be re-submitted only after complete revision.

Application Word Limit

The word limit for all IRB Applications (excluding protocols, CITI Training Certificates, etc.) is 12,000 words. Applications that are longer than 12,000 words will be sent back to the applicant without review. Most submitted applications are no longer than 6,000 words.

Authority

Plymouth State University's IRB has been established in accordance with federal regulations. The standing IRB committee is faculty-managed and -controlled. The IRB receives support and empowerment from the Office of Research and Sponsored Programs. The IRB is comprised primarily of faculty members from disciplines that conduct research involving human subjects.

Under Plymouth State University's Assurance Agreement filed with the U.S. Department of Health and Human Services, all research activities involving human subjects, whether federally funded, privately-funded or non-funded, including dissertations, master's theses, pilot studies, class projects, and non-funded faculty-directed research, must be reviewed and approved by the University's IRB prior to conducting the research, if the proposed research meets any of the following conditions:

- the research will be entered into the public domain (i.e. publication, presentation at public conference, etc.), and
- the research is sponsored by the University, *or*
- the research is conducted by or under the direction of any University employee, *or* agent (e.g., faculty member, researcher, or student) in connection with his/her other institutional responsibilities, *or*
- the research is conducted by or under the direction of any University employee or agent (e.g., faculty member, researcher, or student) using any University property or facility, *or*
- the research involves the use of the University's non-public information to identify or contact human research subjects or prospective subjects, *or*
- the research involves the use of the University's students, employees, or facilities. http://www.hhs.gov/ohrp/assurances/

All organizations “engaged in” federally funded human subjects research must have an OHRP-approved Federalwide Assurance (FWA). The FWA is an agreement between the organization and OHRP in which the organization commits itself to certain standards of conduct in research involving human subjects. Before PSU will serve as the IRB for an organization, the organization must have effected an IRB Authorization Agreement (IAA) with PSU and obtained an OHRP-approved FWA on file with OHRP**.** An organization must not submit (or update) its FWA to OHRP before the organization and PSU have signed an IRB Authorization Agreement (IAA).

An organization will need to obtain an OHRP-approved FWA if any of the following apply:

- The organization (through its employee or agents), in the course of non-exempt research activities a) obtains data through intervention or interaction with a living human being or b) obtains identifiable private information about a living human being.
- The organization received a direct federal award to conduct human subjects research, even where all activities involving human subjects are carried out by a subcontractor or collaborator.
- The organization plans to conduct aspects of the research at PSU (regardless of how the research is funded).

Collaboration with other Universities

Extramural investigators desiring to conduct human subject research at Plymouth State University, either by using the University’s facilities or by recruiting members of the University’s community as participants, are expected to demonstrate compliance with all relevant federal and state human subject regulations, including review and approval by their sponsoring or affiliated IRBs. To demonstrate said compliance, extramural researchers should submit a copy of the protocol

submitted to their IRB along with a copy of the IRB's Record of Review indicating that the protocol was approved. Submit these items electronically to the Plymouth State University IRB at this address psu-irb@mail.plymouth.edu. Approval by another IRB does not replace review by Plymouth State University's IRB.

Education and Training for Applicants and Reviewers

The Collaborative Institutional Training Initiative (CITI) Program provides research ethics education to the PSU research community. The CITI program offers both initial and refresher courses covering human subjects research and HIPAA requirements. Additionally, optional Good Clinical Practice (GCP) modules are available for completion, but will not fullfill the requirement for human subjects protection training. All PSU IRB members are required to complete the CITI Reviewer Training.

Plymouth State University requires all individuals involved in the conduct of human subjects research to complete human subjects protection training and to **recertify every 3 years.** IRB approval will be withheld if these training requirements are not met.

These requirements apply to all persons with a significant role in the research, such as those designated as:

- Principal Investigator and Co-investigators,
- Individuals named on a study grant or contract proposal,
- Individuals listed on an FDA form 1572 for the conduct of the research at PSU or at an affiliate institution,
- Individuals named as a contact person in the informed consent document(s) or recruitment materials for research

Eligibility to Serve as Principle Investigator

For the purposes of defining the responsible party, the principal investigator means the individual who is responsible and accountable for conducting the research. The PI assumes full responsibility for the treatment of participants, and for the integrity of the research data and results.

A principal investigator may be a tenure-track faculty, visiting faculty with rank, research faculty with rank, clinical faculty with rank, and permanent staff serving as directors of research studies involving human subjects. Teaching lecturers and graduate and undergraduate students, **must be sponsored** by an individual who qualifies to serve as a principal investigator.

Responsibilities of the Principal Investigator and Faculty Advisor

Principal Investigators are responsible for completing applicable training regarding research involving human subjects including, but not limited to:

- Complying with all applicable provisions of PSU's Assurance, 45 CFR 46, and stipulations of the IRB,

- Gaining familiarity with and adhering to the ethical principles stated in The Belmont Report,
- Keeping co-researchers and all research staff informed about the nature and goals of the study, and the need to adhere to sound ethical practices,
- Acknowledging and accepting responsibility for protecting the rights and welfare of human subjects in their research study,
- Adhering to the approved study and consent process, including providing a copy of the IRB approved and signed informed consent document to each subject at the time of consent, unless the IRB has specifically waived this requirement. All signed consent documents are to be retained by the researcher for at least **3 years** after the end of the study,
- Requesting IRB approval for proposed changes in previously approved human subject research activities before initiating them, except where necessary to eliminate apparent immediate hazards to the subjects,
- Reporting progress of approved research to the IRB no less than once a year from the last review date,
- Reporting all deviations, noncompliance, adverse events, and injuries promptly to the IRB, and
- Promptly reporting to the IRB unanticipated problems involving risks to subjects and others. No researcher obligated by the provisions of the PSU Assurance shall seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without IRB review and approval, to the extent permitted by law (see 45 CFR 46.116[f]). However, such activities cannot be counted as research nor the data used in support of research.

Dissertations, theses (graduate and undergraduate), master's projects, independent research studies, and other research studies involving human subjects undertaken by students should be submitted to the IRB by the student-researcher. All student-researchers must have a faculty or staff member as an advisor of record for a study. In agreeing to be an advisor for a student research study, the faculty or staff member is responsible for, but not limited to, the following:

- Overseeing the design and conduct of the study,
- Protecting the rights and welfare of human subjects in the student research study,
- Informing student-researchers about the ethical principles for the protection of the human subjects of research, the ethical conduct of research involving human subjects, and applicable policies and procedures,
- Ensuring that student-researchers are well-trained and competent,
- Reviewing the application and protocol application prior to signature and submission to the IRB,
- Ensuring that projects are conducted in accordance with PSU's Assurance, 45 CFR 46, and the IRB's stipulations once IRB approval has been issued,
- Ensuring that IRB approval is requested for proposed changes in previously approved human subject research activities before initiating them, except where necessary to eliminate apparent immediate hazards to the subjects,

- Ensuring that progress of approved research is reported to the IRB no less than once a year from the last review date,
- Reporting all deviations, noncompliance, adverse events, and injuries promptly to the IRB, and
- Promptly reporting to the IRB unanticipated problems involving risks to subjects and others.

Responsible Conduct of Research

PSU assumes responsibility for encouraging research activities to benefit the advancement of knowledge of human conditions. At the same time, PSU assumes responsibility for ensuring the conditions for protecting human subjects as required by the National Research Act, public Law 93-348 and implemented by U.S. Department of Health and Human Services (DHHS) Title 45 Code of Federal Regulations Part 46 (45 CFR 46), Protection of Human Subjects, as amended, and by other Federal agencies with appropriate jurisdiction. Additional requirements are imposed by the Food and Drug Administration (FDA) when Investigational New Drugs and Medical Devices are used in research.

At PSU, there is one IRB authorized under an Assurance approved by DHHS to review and to approve research involving human subjects. The IRB is a PSU standing committee responsible for protecting the rights and welfare of people who are the subjects of PSU research activities.

PSU's policy regarding the use of human subjects in research states:

All PSU research activities proposing to involve human subjects must be reviewed and receive written, unconditional approval from the IRB before commencing. This policy applies to all research activities sponsored by PSU; conducted by or under the direction of any employee, student, or agent of PSU in connection with his or her PSU responsibilities; conducted by or under the direction of any employee, student, or agent of PSU involving the use of any PSU property or facility; or, conducted by or involving any individual or institution working with PSU as part of a collaboration, subgrant, or subcontract. All research activities involving human subjects must be conducted in accordance with:

- Federal, state, and local laws and regulations applicable to use of human subjects in research. These include, but are not limited to, Federal Policy for the Protection of Human Subjects, 45 CFR 46; FDA human subjects protections regulations, Title 21 Code of Federal Regulations Parts 50 and 56; and, the principles set forth in The Belmont Report.
- PSU Policy for the Use of Human Subjects in Research.
- PSU Assurance.

Failure to submit research involving human subjects to the IRB for review prior to commencing is a violation of PSU policy.

The IRB has the responsibility and authority to:

- Approve, disapprove, or require modifications in studies, based upon consideration of human subjects protections,
- Require progress reports from the researchers and oversee the conduct of the study,
- Suspend or terminate approval of a study, and
- Place restrictions on a study.

- The IRB has authority through PSU's Assurance to interpret and apply federal, state, and local human subjects protections to PSU research studies. The procedures in this Manual are intended to be consistent with the referenced documents.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (http://www.hhs.gov/ohrp/policy/belmont.html) issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979, is the basis for federal regulations.

PSU regards these principles as the foundation for its program to protect the rights and welfare of human subjects in research. The principles in the Belmont Report are:

Respect for Persons

Respect for persons incorporates at least two ethical convictions:
First, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

Beneficence

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In [the Belmont Report], beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.

Justice

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of "fairness in distribution" or "what is deserved." An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally. There are several widely accepted

formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit" (The Belmont Report, April 18, 1979, 2-3.)

Conflict of Interest

A conflict of interest is when professional actions or decisions are determined by personal consideration, financial or otherwise. It is also includes unauthorized use or misuse of PSU resources in the course of an external activity. A conflict of interest exists when it can be reasonably determined that an investigator's personal financial concerns could directly and significantly influence the design, conduct, or reporting of sponsored research activities. Faculty and staff of PSU have an obligation to scrupulously maintain the objectivity of their research so as to avoid any conflict of interest.

Researchers can consider the following points to assess if there is a potential conflict of interest.

- If the investigator or members of the investigator's family have significant financial interest in the study, sponsor of the study or the subjects, technology, site, etc. being investigated.
- If the researcher has an immediate family member including the spouse, dependents, and all members of the employee's household including domestic partners listed as an investigator.
- If the researcher has any conflict that might be perceived to inhibit a fair and unbiased review of the research.
- If the researcher has any interests that may adversely affect the rights and welfare of the subjects.

Research Involving Vulnerable Populations

Specific populations identified and described in Federal regulations (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html) or the "common role" requiring additional protection or consideration prior to inclusion in research studies or "vulnerable" include:

- Pregnant women, human fetuses, and neonates (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartb)
- Prisoners (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartc)
- Children (see http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subpartd)

Research Involving Humans

A human subject is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

Living: means that the subject is alive at the time of the research, according to applicable local and national regulations.

About whom: means the data or information relates to the person. Asking individuals what they think about something is almost always about the person.

Intervention: includes both physical procedures by which data are gathered, and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: includes communication or interpersonal contact between investigator and subject.

Identifiable: the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Private information: includes 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).

Additional Information Regarding Vulnerable Populations:

Federal regulations require that special consideration be given to protecting the welfare of particularly vulnerable study participants, such as children, prisoners, persons with diminished capacity to consent, institutionalized individuals, or economically or educationally disadvantaged persons. Although the regulations allow approval of research involving these populations if it is of minimal risk or if it will benefit the subjects directly, the regulations require special safeguards, particularly with respect to informed consent. The specific requirements for these special populations must be reviewed by the IRB whenever subjects from these populations are proposed to be involved in a study.

Children

The most common special research population at PSU is children. According to federal regulations, "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' [45 CFR 46.402(a)]. In New Hampshire, individuals under the age of 18 are considered children for research purposes. Special considerations that apply to children are:

- Exempt review - Research involving survey or interview procedures or observation of public behavior with children cannot quality for Exempt review, except for research involving observations of public behavior when the researcher(s) do not participate in the activities being observed.

- Consent and Assent - Where children are subjects, the study must provide for obtaining the consent of the child's legal representative (parent or guardian) and the child's assent. Only in very limited circumstances may the IRB waive the requirement for parental/guardian consent or child assent. Per 45 CFR 46.409, additional requirements apply to some research involving children who are wards of the state.

Wards of the State

Federal regulations (45 CFR 46.409) require additional protections for wards of the state who are involved in certain research studies. The IRB recommends that researchers who anticipate involving children in research who are residing at the State of New Hampshire's John H. Sununu Youth Services Center (SYSC) facility in Manchester, at other residential treatment centers, or in foster homes consider them, for research purposes, as wards of the state. When wards of the state are to be involved in a research study, the IRB may require the appointment of an advocate for the wards. This applies particularly to studies that present more than minimal risk. This individual cannot be the child's legal guardian or serving in loco parentis. The advocate also cannot be a member of the research team, although he or she does need to understand the research and must be able to represent the children's interests in terms of the study. The advocate may be one person for an entire group, for example a group of foster children being included in a research project or a group of children at SYSC. Individuals who might be considered for this role are professionals involved in children's lives such as Court Appointed Special Advocate (CASA) volunteers and Guardians ad litem. There may be some circumstances where SYSC residents, youth in residential centers or foster children may not be wards of the state. If the researcher can provide sufficient documentation to the IRB to demonstrate legal guardianship of the child is held by someone other than the state, the appointment of an advocate in these cases is not required.

Prisoners

Prisoner is defined to include any individual involuntarily confined or detained in a penal institution. The term encompasses individuals sentenced to such an institution under a criminal or civil statute; detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; and/or detained pending arraignment, trial, or sentencing [45 CFR 46.303(c)]. Special issues that apply to prisoners are

Composition of IRB - At least one member of the IRB must be a prisoner or prisoner advocate who participates in the review of the study. A majority of the IRB members must have no association with the prison or other facility as defined above.

Review level – All research involving prisoners must be reviewed by the Full Board.

Permissible Research - The IRB must find and document that the research is within a permissible category under 45 CFR 46.306(a)(2) as follows:

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,

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,

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 DHHS has consulted with appropriate experts including experts in penology medicine and ethics, and published notice, in the Federal Register, of its intent to approve such research, or,

Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.

Additional Findings - In reviewing the study, per 45 CFR 46.305 the IRB must make and document in the meeting minutes the following determinations:

- Any possible advantages accruing to the prisoner(s) through her/his participation in the study, 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 her/his ability to weigh the research risks against the value of such advantages in the limited choice environment of the prison is impaired

- The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers,

- Procedures for subject selection within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.

- Unless the principal researcher provides to the IRB 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 study,

- The informed consent information is presented in language understandable to the subject population,

- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making parole decisions, and each prisoner is clearly informed in advance that participation in the research will have no effect on her/his parole, and,

- Where the IRB finds there may be a need for follow-up examination or care of participants after their participation ends, 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.

Persons with Diminished Capacity to Consent

Where research is conducted using human subjects who suffer from conditions, whether temporary or permanent, that may diminish their capacity to consent to participate, additional protections are needed. Considerations include:

- Research studies should not target persons with mental disorders as subjects when such research can be done with other subjects,

- Research studies must include a thorough justification of the research design used, including a description of procedures designed to minimize risks to subjects,

- Studies designed to provoke symptoms, withdraw subjects rapidly from therapies, use placebo controls, or otherwise to expose subjects to risks that may be inappropriate are subject to heightened scrutiny,

- No person who has the capacity to consent may be enrolled in a study without his or her informed consent,

- When potential subjects are capable of making informed decisions about participation, they may accept or decline participation without involvement of third parties,

- Any potential or actual subject's objection to enrollment or continued participation in a research study must be heeded in all circumstances,

- A researcher, acting with a level of care and sensitivity that will avoid the possibility or appearance of coercion, may approach people who previously objected to ascertain whether they have changed their minds,

- For research studies that present greater than minimal risk, the IRB may require that an independent, qualified professional assess the potential subject's capacity to consent. The study should describe who will conduct the assessment and the nature of the assessment. The IRB may permit researchers to use less formal procedures to assess potential subjects' capacity if there are good reasons for doing so,

- A person who has been determined to lack the capacity to consent to participate in a research study must be notified of that determination before permission may be sought from her/his legally authorized representative to enroll that person in the study. If permission is given to enroll the person in the study, she/he must then be notified. Should the person object to participating, this objection must be heeded,

- Persons determined to lack the capacity to consent should not be enrolled in a study which is not likely to result in direct benefit to them, unless the study presents no more than minimal risk, and

- For research studies involving subjects who have fluctuating or limited decision-making capacity or prospective incapacity, researchers should establish and maintain ongoing communication with involved caregivers, consistent with the subjects' autonomy and with medical confidentiality.

Women and Minorities

All research involving human subjects should be designed and conducted to include members of both genders and of minority groups, unless a clear and compelling rationale and justification establishes that such inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Cost is not an acceptable reason for exclusion except when such a study would duplicate data from other sources. Studies should employ a design with gender, racial and/or age representations appropriate to the known incidence/prevalence of the disease or condition being studied. If subjects of a certain gender, race or age group are to be excluded, such exclusion must be clearly explained and justified by the researcher. For example, if inclusion of women is impossible or inappropriate with respect to the purpose of the research, the health of the subjects, or other reasons, or if there is a disproportionate representation of one gender in the only study population available, these reasons for excluding women or men, or for not including either gender in numbers appropriate to the incidence/prevalence of the disease, must be well explained and justified by the researcher. It is not expected that every minority group and subpopulation will be included in each study. However, broad representation and diversity are the goals, even if multiple sites are needed to accomplish it. The Office of Management and Budget (OMB) Directive No. 15 defines the minimum standard of basic minority racial and ethnic categories, and which are used by the National Institutes of Health, (NIH) as

- American Indian or Alaskan Native: a person having origins in any of the original peoples of North America, and who maintain cultural identification through tribal affiliation or community recognition,

- Asian or Pacific Islander: a person having origins in any of the original peoples of the Far East, Southeast Asia, the Indian subcontinent or the Pacific Islands and Samoa,

- Black, not of Hispanic origin: a person having origins in any of the black racial groups of Africa, and

- Hispanic: a person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin regardless of race. Each minority group may contain subpopulations which are delimited by geographic origins, national origins and/or cultural differences. The minority group or subpopulation to which an individual belongs is determined by self-reporting.

FREQUENTLY ASKED QUESTIONS

1. Does my teaching study require IRB approval?

The answer is **yes**, if:

- You will be using the data in your dissertation or thesis.
- The data will be published (including at Lamson library).
- The data will be used to create a presentation that will be given at a peer-reviewed or professional conference.
- Your research poses more than minimal risk to participants.
- You wish to have your research reviewed by IRB for grant review.

The answer is **no**, if:

- You will be collecting the data only to better your teaching skills.
- The data will be shared only on a casual basis with other teachers close to you.
- You will share the data only within the school.
- You will present the data only to the principal.
- You will be presenting the data only to your teacher, class members, and other Plymouth State University students and faculty (not for a thesis or dissertation).
- Your research does not involve vulnerable populations (children, prisoners, pregnant women, or handicapped or mentally disabled persons).
- Your research poses minimal risk to the participants, meaning 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.
- Your research is the analysis of de-identified, publicly available data.

2. When can I begin my research?

Research can only begin once an approval letter is received from the IRB. Therefore, subjects should not be contacted or recruited before the approval letter is obtained.

3. What about secondary data with or without identifiers?

Studies that involve secondary analysis of data generally are not considered human subjects research.

4. What about research at a pilot or feasibility stage?

Pilot studies and feasibility studies, including those involving only one human subject require the same scrutiny as full-scale research projects. Pilot studies should be identified as such in applications to the IRB. Ordinarily, the data collected from subjects in a pilot/feasibility study are not used for study findings. It must be explained to subjects during the consent process that the study is a pilot. When the pilot study becomes a full study, the PI will need to apply for IRB approval again.

5. How do I determine if I have Conflict of Interest (COI) in my study?

- If the investigator or members of the investigator's family have significant financial interest in the study, sponsor of the study or the subjects, technology, site, etc. being investigated
- If you have an immediate family member including the spouse, dependents, and all members of the employee's household including domestic partners listed as an investigator
- If you have any conflict that might be perceived to inhibit a fair and unbiased review of the research
- If you have any interests that may adversely affect the rights and welfare of the subjects

6. Documents researchers should have on file include but are not limited to:

- IRB application
- Consent and/or assent form(s)
- IRB's response or request for additional information or revisions
- Responses to the IRB's requests for additional information or revisions
- Notice of final approval
- Correspondence between the investigator and the IRB
- Continuing Review forms and attachments (if applicable)
- Renewal of Approval (if applicable)
- Amendment forms and attachments (if applicable)
- Amendment approval (if applicable)
- Original letters of collaboration from other institutions and
- All approved research study materials, including IRB validated copies, if applicable (e.g., consent forms, recruitment materials, data collection instruments or forms, etc.)

7. What qualifies as research requiring an IRB review?

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalize knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

8. What is the definition of human participant?

Human participant means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. Private information includes 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). Private information must be individually identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants

9. How long does an IRB review take?

The short answer is that it depends on the nature of the proposed study. Studies involving more than minimal risk to participants and/or protected populations generally take longer than other proposals. Applications that require full Committee review may take as long as two months for Committee review depending on when the application is received and the Committee availability. Exempt or expedited reviews will generally take about 7 to 14 days if all required information and documents are provided and there are no revisions or additional information requested

10. Do I need to have training before being eligible to conduct human participant research?

Currently Plymouth State University requires training on human participant research to be eligible to submit a proposal for research. Some federal agencies also require this training and applicants should check with any funding agency for their requirements. We do strongly recommend, where appropriate, University courses include human participant training within their curriculum. Documentation certifying the completion of this training is required to submit a proposal for IRB review. Training must have taken place in the last 3 years.

11. What do I need to do if I want to change something in my research?

Approval to conduct proposed research is given only on the application and protocol as presented or amended at the time of approval. If there are any changes to the research protocol after this approval has been granted these proposed changes must also be reviewed by the Committee before being implemented. This includes, but is not limited to, any changes in the selection of participants, additional questions or additional survey items, changes in the approved protocol or any deletions or additions in the approved consent forms. This applies to research approved by full Committee review, expedited review, or exempt approval. To notify the Committee of an amendment to a protocol, use the status report form (pdf|doc). If the protocol was originally approved as exempt, you may notify the Committee of changes using a letter detailing the changes, rather than with the status report form. Bear in mind, if the amendment to an exempt project is sufficient to alter its exempt status, an expedited or full review may be required. If you have any additional questions about this, please contact IRB staff prior to any changes in your research

12. What are the deadlines for submitting new IRB applications for human research?

The PSU IRB does not have a cut-off date for material submission. The IRB accepts applications on a regular basis for review.

13. Is there someone I can call if I need assistance or have questions?

Yes. Please do not hesitate to contact IRB if you have questions about any aspects of the application requirements, required forms, or eligibility criteria.

14. Does my study require exempt, expedited, or full-board review?

Exempt Review

A study fits into the exempt category of research if the research involves minimal risk to human subjects. The application will be reviewed as exempt or does not involve human subjects as determined by regulatory guidelines. When an exemption is granted by the IRB committee protocols that are deemed exempt are effectively exempt from continuing review. If the study is not found to be exempt, it will need to go through expedited or full-committee review as determined by the IRB committee. The IRB is required to determine if a research project falls under one of the following six exempt categories listed in the federal regulations (45 CFR 46.101(b)). This level of review is often conducted by 1 or more IRB members.

Common examples of Exempt level research at PSU are:

- Anonymous surveys,
- Interviews of adults about non-sensitive topics,
- Educational tests, or
- Observation of public behavior.

Expedited Review

This type of review is carried out only for studies involving no more than minimal risk to subjects. These reviews are conducted on an ongoing basis where the study is reviewed by a qualified member of the IRB committee who will consult with the Principle Investigator (PI) if necessary to come to a decision about the approval of the study (45 CFR 46.110). This level of review is often conducted by 2 or more IRB members.

Common examples of research that may be reviewed at the Expedited level at PSU are:

- Studies including blood samples taken from healthy volunteers,
- Studies involving moderate exercise by healthy volunteers,
- Collection of data via recordings (such as those taken in the investigation of speech defects),
- Studies of existing data or pathological specimens that include identifying information,
- Linguistic and ethnographic studies, or
- Studies involving focus groups

Full-Board Review

This type of review is conducted by a fully convened IRB committee, which discusses the study and makes an approval decision. The convened meeting must have a quorum of IRB members

present. For the research to be approved, it must receive the approval of a majority of those members present. This type of review is carried out for studies with greater than minimal risk to subjects. Full-board reviews often involve special/vulnerable population(s) and often can involve some level of physical, psychological, social, legal, and/or economic harm to the subject(s) and/or the researcher(s). This level of review is often conducted by 5 or more IRB members. An example of a full board review could be the following:

Common examples of research reviewed at the Full Board level at PSU are studies that include:

- Maximal exercise by healthy volunteers,
- Institutionalized persons (e.g., prisoners, patients in long term care facilities),
- Persons who lack capacity to consent (e.g., persons with severe mental disabilities or developmental delays), or
- Sensitive topics (e.g., criminal behavior, sexuality)

Appendix A

Plymouth State University
Institutional Review Board

Institutional Review Board – Full Board Review

Meeting Date and Time:	
Location:	
Application Title:	
Present:	
Non-Scientist Present:	
Vulnerable Population:	
In favor of approving the application:	
In favor of denying the application:	
In favor of approving the application subject to required modifications	
In favor of tabling the application	

Dear Dr. XXXX

In compliance with the state and federal law, the Plymouth State University Institutional Review Board (IRB) convened for a full board review of your application entitled, XXXXXXXXXX.

Feedback

Appendix B

Institutional Review Board

Date

Dear

Study:
Approval Date:

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study as Exempt as described in Title 45, Code of Federal Regulations (CFR), Part 46, Subsection 101(b). Approval is granted to conduct your study as described in your protocol. Be sure to complete the Final Report Form when your research is finished.

If, during the course of your project you intend to make changes that may significantly affect the human subjects involved (particularly methodological changes), you must obtain IRB approval prior to implementing these changes. Any unanticipated problems related to your use of human subjects must be promptly reported to the IRB. The IRB may be contacted through XXXXX, Chair of the IRB. This is required so that the IRB can update or revise protective measures for human subjects as may be necessary.

You are expected to maintain as an essential part of your project records, any records pertaining to the use of humans as subjects in your research. This includes any information or materials conveyed to and received from the subjects as well as any executed forms, data and analysis results. If this is a funded project (federal, state, private, other organization), you should be aware that these records are subject to inspection and review by authorized representatives of the University, State of New Hampshire, and/or the federal government.

Please note that IRB approval cannot exceed one year. If you expect your project to continue beyond this approval period, you must submit a request for continuance to the IRB for renewal of IRB approval. IRB approval must be obtained and maintained for the entire term of your project or award.

Please notify the IRB in writing when the project is completed. We may ask that you provide information regarding your experiences with human subjects and with the IRB review process. Upon notification, we will close our files pertaining to your project. Any subsequent reactivation of the project will require a new IRB application. I have attached the Project Completion Form for your convenience.

Please do not hesitate to contact the IRB if you have any questions or require assistance. We will be happy to assist you in any way we can. Thank you for your cooperation and efforts throughout this review process. We wish you success in this endeavor.

Sincerely,

Institutional Review Board

Appendix C

Institutional Review Board

Date

Dear

Study:
Approval Date:

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study as Expedited as described in Title 45, Code of Federal Regulations (CFR), Part 46, Subsection 1101(b). Approval is granted to conduct your study as described in your protocol. Be sure to complete the Final Report Form when your research is finished.

If, during the course of your project you intend to make changes that may significantly affect the human subjects involved (particularly methodological changes), you must obtain IRB approval prior to implementing these changes. Any unanticipated problems related to your use of human subjects must be promptly reported to the IRB. The IRB may be contacted through XXXX, Chair of the IRB. This is required so that the IRB can update or revise protective measures for human subjects as may be necessary.

You are expected to maintain as an essential part of your project records, any records pertaining to the use of humans as subjects in your research. This includes any information or materials conveyed to and received from the subjects as well as any executed forms, data and analysis results. If this is a funded project (federal, state, private, other organization), you should be aware that these records are subject to inspection and review by authorized representatives of the University, State of New Hampshire, and/or the federal government.

Please note that IRB approval cannot exceed one year. If you expect your project to continue beyond this approval period, you must submit a request for continuance to the IRB for renewal of IRB approval. IRB approval must be obtained and maintained for the entire term of your project or award.

Please notify the IRB in writing when the project is completed. We may ask that you provide information regarding your experiences with human subjects and with the IRB review process. Upon notification, we will close our files pertaining to your project. Any subsequent reactivation of the project will require a new IRB application. I have attached the Project Completion Form for your convenience.

Please do not hesitate to contact the IRB if you have any questions or require assistance. We will be happy to assist you in any way we can. Thank you for your cooperation and efforts throughout this review process. We wish you success in this endeavor.

Sincerely,

Institutional Review Board

Appendix D

Institutional Review Board

Date

Dear

Study:
Approval Date:

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study as Expedited as described in Title 45, Code of Federal Regulations (CFR), Part 46, Subsection 110. **Approval is granted to conduct your study as described in your protocol for one year from the approval date above.** Be sure to complete the Final Report Form when your research is finished.

If, during the course of your project you intend to make changes that may significantly affect the human subjects involved (particularly methodological changes), you must obtain IRB approval prior to implementing these changes. Any unanticipated problems related to your use of human subjects must be promptly reported to the IRB. The IRB may be contacted through XXXX, Chair of the IRB. This is required so that the IRB can update or revise protective measures for human subjects as may be necessary.

You are expected to maintain as an essential part of your project records, any records pertaining to the use of humans as subjects in your research. This includes any information or materials conveyed to and received from the subjects as well as any executed forms, data and analysis results. If this is a funded project (federal, state, private, other organization), you should be aware that these records are subject to inspection and review by authorized representatives of the University, State of New Hampshire, and/or the federal government.

Please note that IRB approval cannot exceed one year. If you expect your project to continue beyond this approval period, you must submit a request for continuance to the IRB for renewal of IRB approval. IRB approval must be obtained and maintained for the entire term of your project or award.

Please notify the IRB in writing when the project is completed. We may ask that you provide information regarding your experiences with human subjects and with the IRB review process. Upon notification, we will close our files pertaining to your project. Any subsequent reactivation of the project will require a new IRB application. I have attached the Project Completion Form for your convenience.

Please do not hesitate to contact the IRB if you have any questions or require assistance. We will be happy to assist you in any way we can. Thank you for your cooperation and efforts throughout this review process. We wish you success in this endeavor.

Sincerely,

Institutional Review Board

Appendix E

Institutional Review Board

Date

Dear

Study:
Approval Date:

The Institutional Review Board for the Protection of Human Subjects in Research (IRB) has reviewed and approved the protocol for your study. **Approval is granted to conduct your study as described in your protocol for one year from the approval date above.** Be sure to complete the Final Report Form when your research is finished.

If, during the course of your project you intend to make changes that may significantly affect the human subjects involved (particularly methodological changes), you must obtain IRB approval prior to implementing these changes. Any unanticipated problems related to your use of human subjects must be promptly reported to the IRB. The IRB may be contacted through XXXX, Chair of the IRB. This is required so that the IRB can update or revise protective measures for human subjects as may be necessary.

You are expected to maintain as an essential part of your project records, any records pertaining to the use of humans as subjects in your research. This includes any information or materials conveyed to and received from the subjects as well as any executed forms, data and analysis results. If this is a funded project (federal, state, private, other organization), you should be aware that these records are subject to inspection and review by authorized representatives of the University, State of New Hampshire, and/or the federal government.

Please note that IRB approval cannot exceed one year. If you expect your project to continue beyond this approval period, you must submit a request for continuance to the IRB for renewal of IRB approval. IRB approval must be obtained and maintained for the entire term of your project or award.

Please notify the IRB in writing when the project is completed. We may ask that you provide information regarding your experiences with human subjects and with the IRB review process. Upon notification, we will close our files pertaining to your project. Any subsequent reactivation of the project will require a new IRB application. I have attached the Project Completion Form for your convenience.

Please do not hesitate to contact the IRB if you have any questions or require assistance. We will be happy to assist you in any way we can. Thank you for your cooperation and efforts throughout this review process. We wish you success in this endeavor.

Sincerely,

Institutional Review Board

Appendix F

Institutional Review Board

Human Subjects Research Final Report

INSERT DATE

Study Title: **PLEASE INSERT RESEARCH TITLE HERE**

Upon completion of your study, please provide the information requested below and submit to the Institutional Review Board (IRB) along with a report of findings for this study, for audit purposes. Copies of abstracts, articles, and/or publications specific to the project are acceptable. Send the report to the IRB at psu-irb@plymouth.edu.

1. Please give termination date of study's intervention or interaction with participant data

_____

2. How many people were studied in your research? _____

3. Did you conduct the research in accordance with the procedures reviewed and approved by the IRB? (Yes or No) (If NO, please describe on a separate sheet)

4. Did any problems emerge or were any serious unexpected adverse subject experiences observed? Yes or No (If YES, please describe on a separate sheet)

Principal Investigator or Advisor Signature:_____

Please send electronically to the IRB at psu-irb@plymouth.edu.

Appendix G

Plymouth State University
Institutional Review Board

RENEWAL / PROTOCOL AMENDMENT FORM
Plymouth State University
Institutional Review Board

1. Date: _____

2. Principle Investigator: _____

3. Email: _____

4. Telephone: _____

5. Supervising Professor (for Student Projects): _____

   5a. Email: _____

   5b. Phone: _____

6. Project Title: _____

7. Sponsoring Agency (if applicable): _____

8. Initial IRB Approval Date: _____

9. Action requested (check one):
[ ]One year renewal without changes
[ ] One year renewal with changes (please describe in item *#15*)
[ ]Changes within current approval period (please describe in #15)

10. Does this project involve oversight from another Institutional Review Board? Check one:
[ ] No
[ ] Yes, (please specify institution): _____

11. Give a brief description of the project: _____

12. What is the current status of the project?
[ ] Currently open to new participant enrollment
[ ] Currently closed to new participant enrollment, but with participants still undergoing intervention or study
[ ] Currently closed to new participant enrollment, with intervention over, but ongoing participant monitoring

[ ] Currently closed to new enrollment, but continuing with data analysis using identifiable information
[ ] Other (explain) _____

13. How many participants or patients have been studied to date? _____

14. Did any problems emerge or were any serious, unexpected, adverse subject experiences observed?
[ ] No
[ ] Yes, (Please explain) _____

15. Please describe any changes, however minor, to the research protocol. Please include an electronic copy of the consent form(s) or protocols if amended.
[ ] No changes to previously approved application
[ ] Changes: (please detail): _____

16. Please sign below and return to the chair of the Institutional Review Board.

SIGNED: _____
Principal Investigator (electronic signature)

Appendix H

Plymouth State University
Institutional Review Board

Plymouth State University Assent Form

Application approval date:

Study Title:

1. **What will happen to me in this study?**
   Description of the study:
   Explain the reason for the research.
   Describe what the child will be expected to do.
   Describe all procedures using simple terms and explain any technical terms.

2. **Can anything bad happen to me?**
   Risks or Discomforts of Participating:
   Explain any possible risks to the child, using simple terms.
   If something might be painful, state this in the assent.
   Explain that the child should inform his/her parents if they are uncomfortable with the study

3. **Can anything good happen to me?**
   Benefits of Participating:
   Only describe known benefits to the child.
   You may include any possible future benefits to others.
   If there are no known benefits, state so.
4. **Do I have other choices?**
   Appropriate Alternatives:
   Describe any alternative procedures that might be available to the child other than this study.
   If none, this section can be omitted.

5. **Will anyone know I am in the study?**
   Confidentiality:
   Explain in simple terms that the child's participation in the study will be kept secret, but information about him/her will be given to xy and z.
   Note: This information may not be applicable in assent forms for very young children.

6. **What happens if I get hurt?**
   Compensation for Participation/Medical Treatment:
   Describe that the child's parents/legal guardians have been given information on what to do if the child is injured during the study.

7. **Who can I talk to about the study?**
   Contact Information:
   List people the child can contact if he/she has any questions or problems related to the study:

   If you have any questions about the study or any problems to do with the study you can contact the Protocol Director (name of Protocol Director). You can call him/her at (Protocol Director's phone number). You can also call (name) at (phone number).

   Keep the following sentence in exactly as written:
   If you have questions about the study but want to talk to someone else who is not a part of the study, you can call the Plymouth State University Institutional Review Board (IRB) at (603)-535-XXXX.

8. **What if I do not want to do this?**
   Voluntary Participation:

   LET THE CHILD KNOW THAT THEY CAN STOP BEING IN THE STUDY AT ANY TIME WITHOUT GETTING IN TROUBLE.

SIGNATURE

If you agree to be in this study, please sign below.

_____ _____
Signature of Child Date

_____
Printed name of Child

Appendix I

Plymouth State University
Institutional Review Board

SAMPLE INFORMED PARENTAL CONSENT LETTER

Instructions: Replace red type with appropriate information and print letter on department or personal letterhead.

Date:

Dear Parent,

I am (insert your position at the University, e.g., a faculty member in the "x" department at PSU) and I am conducting a research project to find out (insert purpose of the research). I am writing to invite your child to participate in this project. I plan to work with approximately (insert anticipated number of participants) children in this study.

If you allow your child to participate in this study, your child will be asked to (insert description of what participants will be expected to do and anticipated time commitment. If audio or video recording, explain the purpose of the recordings and how they will be used). Neither you nor your child will receive any compensation to participate in this project (if there is compensation, modify this sentence stating the type and amount of compensation, and any conditions that need to be met to receive the compensation).

The potential risks of your child participating in this study are (insert any potential risks; if risks are anticipated to be minimal, state this). Although your child is not expected to receive any direct benefits from participating in this study (if direct benefits to participants are anticipated, modify this part of the sentence accordingly), the benefits of the knowledge gained are expected to be (state the benefits of the study at the community and/or societal levels).

Participation is strictly voluntary. If you refuse to allow your child to participate, neither you nor your child will experience any penalty or negative consequences. Your child may refuse to answer any question. If you allow your child to participate in this project and your child wants to, and then either you change your mind or your child changes his/her mind, you may withdraw your child, or your child may withdraw, at any time during the study without penalty (modify the latter sentence if there are conditions to receive compensation).

I seek to maintain the confidentiality of all data and records associated with your child's participation in this research. (If your study involves personally-identifiable information, include the following two sentences.) You should understand, however, there are rare instances when I am required to share personally-identifiable information (e.g., according to policy, contract, regulation). For example, in response to a complaint about the research, officials at the Plymouth

State University, designees of the sponsor(s), and/or regulatory and oversight government agencies may access research data. (If your study may lead to disclosure of information covered by New Hampshire mandatory reporting laws, such as suspected child abuse and/or neglect, include the following sentence). You also should understand that I am required by law to report certain information to government and/or law enforcement officials (e.g., child abuse, threatened violence against self or others, communicable diseases). (If your study involves transmitting data via email or the Web [e.g., Web-based survey], include the following sentence.) Further, any communication via the Internet poses minimal risk of a breach of confidentiality. (If your study involves focus groups, include the following sentence.) While I plan to maintain confidentiality of your child's responses, other focus group participants may repeat responses outside the focus group setting. I will keep data on a password protected computer; only I will have access to the data modify these sentences to reflect actual situation; identify everyone named in the application with access to the data; if applicant is a student, the faculty advisor must have access to data; explain if deidentified data may be shared with other researchers). (If audio and/or video recording, explain how and where recordings will be stored, and what will happen to them during and after the study [e.g., transcribed and then destroyed].) I will report the data (explain how data will be reported [e.g., in aggregate, using pseudonyms]). The results may be used in reports, presentations, and publications (modify this sentence to reflect how the results may be used).

If you have any questions about this research project or would like more information before, during, or after the study, you may contact **(insert name of contact person, phone number and/or email address).** If you have questions about your child's rights as a research subject, you may contact XXXX in PSU IRB Chair at 603-535-XXXX or XXXX@plymouth.edu to discuss them.

I have enclosed two copies of this letter. Please sign one indicating your choice and return in the enclosed envelope. The other copy is for your records. Thank you for your consideration.

Sincerely,

Researcher's name
Researcher's title/position

Yes, I,_____consent/allow my child_____to participate in this research project.

No, I,_____do not consent/allow my child_____to participate in this research project.

_____ _____
Signature of Parent Date

Appendix J

INFORMED CONSENT FORM

CONSENT TO PARTICIPATE

VOLUNTARILY IN A RESEARCH INVESTIGATION

PLYMOUTH STATE UNIVERSITY

Instructions: Replace red type with appropriate information and remove sections/information not relevant to the study.

INVESTIGATOR(S) NAME: (Insert name and credentials of the Principle Investigator.)

STUDY TITLE: (Insert study title.)

PURPOSE OF THE STUDY
The purpose of this research study is to **(Describe the purpose of the study in one or two sentences in lay terms.)**. You are being asked to be a participant in the study because **(In lay terms, clearly describe why the participant is asked to be in the study.)**.

DESCRIPTION OF THE STUDY
(Describe the study in language that is easily understandable. In this section, clearly describe what will be expected of the participant. DO NOT CUT AND PASTE TEXT FROM THE PROTOCOL DESCRIBED IN THE APPLICATION.)
The amount of time required to participate in the study is **(Indicate the amount of time that participation in the study will require. Describe any anticipated costs associated with being in study such as travel to be a participant in the study. If there are no known costs, clearly indicate.)**.

RISKS AND DISCOMFORTS
As a participant in this study, you may experience **(Describe any risks or anticipated discomforts. If there is no risk, clearly indicate.)**.

BENEFITS
There may be no direct benefits of participating in this study; however, the knowledge received may be of value to **(Indicate any benefits for the participants and the larger society.)**.

OR

(If there is a benefit to participating in the study, please describe.)

ALTERNATIVE PROCEDURES
(Indicate any alternatives to participation in the study. If the study does not involve an intervention, the alternative would be to not participate.)

CONFIDENTIALITY
All documents and information pertaining to this research study will be kept confidential in accordance with all applicable federal, state, and local laws and regulations. The data generated by the study may be reviewed by Plymouth State University's Institutional Review Board, which is the committee responsible for ensuring your welfare and rights as a research participant, to assure proper conduct of the study and compliance with university regulations. If any presentations or publication result from this research, you will not be identified by name. As per federal guidelines, the information collected during your participation in this study will be kept for a minimum of three years.

I plan to maintain the confidentiality of all data and records associated with your participation in this research. **(If your study involves individually identifiable information, include the following sentence and bullets.)** There are, however, rare instances when I may be required to share individually identifiable information with the following:

- Officials at Plymouth State University (PSU),
- Regulatory and oversight government agencies, or
- The sponsor(s). **(Include this last bullet only if your study is being sponsored by an external entity.)**

(If your study may lead to disclosure of information covered by New Hampshire mandatory reporting laws, such as suspected child abuse or neglect, or hazing, or Federal laws relating to sexual harassment and violence include the following sentence and applicable bulleted language.)
I also may be required by law to report certain information:

- To government and/or law enforcement officials (for example, child abuse, threatened violence against self or others, or hazing). If I believe that such a report is required, I will follow the guidance of the PSU Institutional Review Board for the Protection of Human Subjects in Research (and of the University's General Counsel) in making any such report, in order to provide as much protection for your privacy as possible while still complying with the law.
- To appropriate PSU authorities (e.g., disclosures involving Sexual Violence - which includes sexual harassment, sexual assault, unwanted sexual contact, sexual misconduct, domestic violence, relationship abuse, stalking [including cyber-stalking] and dating violence - must be reported to the PSU Title IX Coordinator or PSU Police).

(If your study involves transmitting data via email or the web [e.g., web-based survey], include the following sentence.) Further, any communication via the internet poses minimal risk of a breach of confidentiality. **(If your study involves focus groups, include the following sentence.)** While I plan to maintain confidentiality of your responses, other focus group participants may repeat responses outside the focus group setting.

To help protect the confidentiality of your information, **(Address the following: (1) explain procedures in place to protect confidentiality of study data; (2) identify everyone named in the application with access to the data; (3) explain whether identifiable information may be shared with a third-party data processor (e.g., transcription service); (4) [select as appropriate] explain if data, once de-identified, may be used for future studies or may be shared with other researchers OR if data, even if de-identified, will not be used for future studies; (5) if audio and/or videorecording, explain how and where recordings will be stored, and what will happen to them during and after the study [e.g., transcribed and then destroyed].)**. I will report the data **(Explain how data will be reported [e.g., in aggregate, using pseudonyms].)**. The results may be used in reports, presentations, and publications **(Modify this sentence to reflect how the results may be used.)**.

TERMINATION OF PARTICIPATION
You may choose to withdraw from this study at any time and for any reason. If you choose to drop out of the study, you may contact the investigator and your research records will be destroyed. **(If this is an anonymous survey, explain that research records cannot be destroyed following submission of the survey. If indicated by exclusion criteria, describe any reasons the principle investigator may terminate the participation of the subject.)**

COMPENSATION
You will not receive payment for being in this study. Participation in this study is strictly voluntary. There will be no cost to you for participating in this research.

OR

You will receive the following compensation for being in this study **(Clearly describe the compensation and requirements to receive compensation.)**. There will be no cost to you for participating in this research.

INJURY COMPENSATION
Neither Plymouth State University nor any government or other agency funding this research project will provide special services, free care, or compensation for any injuries resulting from this research. The treatment for such injuries will be at your expense and/or paid through your medical plan.

QUESTIONS
If you have further questions about this study, you may contact **(Insert name of the Principle Investigator and faculty supervisor if a student.)**, at **(Provide a phone and/or email contact.)**. If you have any questions about the rights of research participants, you may call the Chairperson of the Plymouth State University's Institutional Review Board at 603-535-XXXX (Valid until XXXX).

VOLUNTARY PARTICIPATION
You understand that your participation in this study is entirely voluntary, and that refusal to participate will involve no penalty or loss of benefits. You are free to withdraw or refuse consent, or to discontinue your participation in this study at any time without penalty or consequence.

You voluntarily give your consent **(to participate/for my child to participate)** in this research study. You will be given a copy of this consent form.

Signatures:

_____
Participant's Name (Print)

_____ _____
Participant 's Signature Date

I, the undersigned, certify that to the best of my knowledge, the subject signing this consent form has had the study fully and carefully explained by me and have been given an opportunity to ask any questions regarding the nature, risks, and benefits of participation in this research study.

(Print Principle Investigator's name)
Investigator's Name (Print)

_____ _____
Investigator's Signature Date

Plymouth State University's IRB has approved the solicitation of participants for the study until **(Leave blank, a date will be assigned.)**.

Appendix K

PLYMOUTH STATE UNIVERSITY

Institutional Review Board

Application for Approval for Research Involving Human Subjects

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Full Review ☐ Expedited Review ☐ Exempt Review ☐

Proposed Start Date Click here to enter text.

Is research being funded? Yes ☐ No ☐ Source of funding: Click here to enter text.

Title of Study Click here to enter text.

Investigator:

Name Click here to enter text.

Position Click here to enter text.

Phone Number Click here to enter text.

Email Click here to enter text.

Faculty Advisor Name (if applicable) Click here to enter text.

Qualifications to Conduct this Research Click here to enter text.

Additional Research Staff and Qualifications to Conduct Research

Click here to enter text.

1. Purpose of the Study and Brief Background and Review of Literature

Describe your research question and the background for the study. Include a brief literature review with supportive references.

Click here to enter text.

2. Recruitment Procedures and Participant Population

A. List the expected number of participants Click here to enter text.

B. Does the research involve special populations specifically, children, prisoners, or individuals who are cognitively impaired? Yes ☐ No ☐

C. Describe who is going to participate in the research (i.e. age, demographic characteristics, etc.).
Click here to enter text.

D. Indicate whether anyone might be *excluded* from the research and why.
Click here to enter text

E. Discuss how and by whom participants will be recruited, selected, and assigned to groups. Attach flyers, posters, oral or written communication, or other recruitment materials used to contact potential subjects as an appendix.
Click here to enter text.

3. Procedures and Methodology

A. Materials: Describe the apparatus, stimuli, questionnaires, or any type of measures to be used in the study. Attach questionnaires, interview guidelines, and measures to be used as an appendix.
Click here to enter text.

B. Describe each step of the procedure or study protocol, including the instructions participants will be given and any experimental manipulations that will be administered. Indicate where the research be conducted.
Click here to enter text.

Continues to next page

C. State the specific dates/timeframe in which you plan to conduct your research.

Click here to enter text

4. Informed Consent Process

A. How and when will you explain the study and the informed consent?

Click here to enter text

B. If there are subjects under the age of 18, how will the study be explained to them? How will parental consent and child assent be handled?

Click here to enter text.

C. Indicate the primary language(s) of the participants. If not English, explain how you will ensure the participants understand the informed consent and procedures of the study. Discuss the need for foreign language translations, if applicable.

Click here to enter text.

5. Participant Debriefing

Will participants be exposed to deception? Yes ☐ No ☐

If yes, how will the participants be debriefed?

Click here to enter text.

6. Risks and Safeguard Procedures to Minimize Risk

A. What kind of risks, if any, will the participants be exposed to? (*Enter response on next page*)

The risks you describe here should match the risks you list in the informed consent form.

Guidelines for Determining Risk.

Risk relates to the probability of harm or injury (physical, psychological, social, economic, legal) occurring as a result of participation in a research study. Risks also include invasion of privacy and loss of confidentiality. Types of risk include: (1) physical, (2) psychological, (3) social, (4) legal and (5) economic harm. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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.

Click here to enter text.

B. What efforts will be made to minimize the risks?

Click here to enter text.

C. Discuss how participants' rights to privacy and confidentiality will be protected. Discuss how and where data will be stored and how long the data will be kept. Who will have access to the data and how will access be limited?

Click here to enter text.

D. Alternative Therapies or Procedures: Indicate if there are any alternatives. If there are none, indicate the alternative is not to participate in the study.

Click here to enter text.

7. Benefits

Discuss the potential benefits to participants and society, science, and/or knowledge development.

Click here to enter text.

8. References

List supportive references used in the application.

Click here to enter text.

9. Assurances

Investigator's Assurances:

I certify that the information contained herein is complete and accurate. I agree to conform to the procedures as described and to conduct the research with the highest respect and regard for the participants' right to be protected from undue risk or invasion of privacy. If changes to the procedure become necessary, I agree to seek prior approval from the IRB.

In the case that a student is the principal investigator, if changes to the procedure become necessary, I agree to seek prior approval from the IRB as well as to inform my research supervisor and the Director of my program. Finally, I agree to keep my research supervisor informed of my progress and of any complications that may arise.

Name: Click here to enter text.

Signature: Click here to enter text. Date: Click here to enter text.

Assurances of Faculty Research Supervisor:

I certify that the information contained herein accurately represents the student's complete and final research study and that it has been reviewed and approved by all responsible for the supervision of the work. I agree to periodically review the student's progress and make sure that the procedures are being carried out as approved.

Name: Click here to enter text.

Signature: Click here to enter text. Date: Click here to enter text.

INSTITUTIONAL REVIEW BOARD (IRB)
Conflict of Interest Disclosure Statement

Name:Click here to enter text. Department/Unit: Click here to enter text.

Phone: Click here to enter text. E-mail:Click here to enter text.

An investigator has a **Conflict of Interest** in a research study when she/he or any member of his/her immediate family (spouse/spousal equivalent, parents, and children) has interests in the design, conduct, or reporting of the research that might compromise the integrity of the research. Conflicts of interest can be financial, personal, supervisory, academic, or professional. For further guidance, the University's general Conflict of Interest Policy is set forth on the back of this Statement. The investigator has an ethical responsibility to disclose a potential conflict of interest or a possible appearance of a conflict of interest to the IRB and to potential research subjects as part of the informed consent process. If an investigator or his/her immediate family member is directly involved in potential subjects' health care, professional or academic supervision/evaluation, precautions must be undertaken to avoid the appearance of coercion or conflict of interest in the recruitment process. Please check all applicable boxes.

☐ 1. I and no member of my immediate family have any **financial conflict of interest** (a) that is related to or would reasonably appear to be affected by the proposed research; or (b) in external entities whose financial interests would reasonably appear to be affected by such activities.

☐ 2. I am disclosing the following **financial conflict(s) of interest**:

- ☐ Salary, consulting fees, or other payments for services
- ☐ Equity or ownership (stock, stock options, partnership interests or other ownership)
- ☐ Intellectual property rights (patents, trademarks, copyrights, licensing rights, etc.)
- ☐ Honoraria, royalties for books, publications or lectures, gifts or other payments
- ☐ Positions in entity related to research (board member, officer, etc.)
- ☐ Other financial interests that could affect or be perceived to affect the results of research or educational activities proposed for funding

☐ 3. I and no member of my immediate family have a **personal/professional dual role conflict of interest** related to this proposed research.

☐ **4.** I am disclosing the following **personal/professional dual role conflict(s) of interest:**

- ☐ Supervisory role as faculty/teacher, direct supervisor/manager
- ☐ Healthcare provider
- ☐ Family/friend relationships
- ☐ Other

If you have identified any conflict of interest (numbers 2 and/or 4), please provide additional details below. Describe how the investigator plans to manage, reduce, or eliminate the conflict. Describe how any identified conflicts of interest will be managed
Click here to enter text.

I certify, as an investigator of this research, that I am in compliance with and will continue to comply with Plymouth State University's policy and procedures pertaining to financial and/or

personal/professional CONFLICT OF INTEREST. I further certify that I will comply with any conditions or restrictions imposed by the University IRB to manage, reduce, or eliminate actual or potential conflicts of interest.

I attest to the accuracy of these answers and, should circumstances change in the future, I will contact the Plymouth State University IRB to update this disclosure statement.
Name: Click here to enter text.

Signature: Click here to enter text.

Date: Click here to enter text.

***All investigators listed on IRB application must complete and sign a conflict of interest form.**

IRB APPLICATION CHECKLIST

Before submitting the application to the IRB, complete the following checklist:

If any item below is not applicable, please mark the item N/A and provide a brief rationale describing why the item does not apply or should not be required in the application.

APPLICATION:

1. ☐ CITI Training certificate for each researcher, research assistants, and faculty advisor.
2. ☐ Recruitment materials (i.e. fliers, advertisements, etc.).
3. ☐ Appendices related to support for the project (approval for use of Institutional equipment, approval by appropriate person at site for collaboration with letter of support.
4. ☐ Surveys, questionnaires, or interview questions.
5. ☐ Consent and/or child assent forms.
6. ☐ Conflict of Interest Disclosure has been completed and signed.
7. ☐ Investigator and/or Faculty assurances have been signed.

INFORMED CONSENT:

1. Identify the **Flesh-Kincaid** grade level of the language used in the consent form and rationale for identified reading level: Click here to enter text.

2. ☐ A foreign language translation must be included if the study will include participants whose first language of choice is not English.

Introduction/Background

3. ☐ A statement that the study involves research, and an explanation of the purpose and a description of the procedures to be followed.
4. ☐ A statement of expected duration of the participant's participation (e.g., one hour).

Benefits and Risks

5. ☐ A description of all reasonably discomforts or foreseeable risks to the participant, as identified in the study and any additional, known and unknown. ***This should match the risks described on the application.***
6. ☐ A description of any benefits (indirect or direct) to the participant or others that may reasonably be expected from the research; if there is no benefits to the participant this should be stated.
7. ☐ A statement of risk to human participants including availability of treatment if physical or psychological injury occurs and a statement regarding liability for any injury arising out of study participation.

Alternatives

8. ☐ Disclosure of appropriate alternative procedures or treatment, if any, available to the participant whether or not the participant elects to participate in the study. If the study is a treatment study, what alternatives to participation are available to participants and at what costs (i.e., free or not).

Confidentiality

9. ☐ A statement related to confidentiality of records, any exceptions to confidentiality.

Termination of Participation

10. ☐ A statement to the effect that participation is voluntary, refusal to participate will result in no penalty or loss of benefits to which the participant is otherwise entitled; the participant may discontinue participation at any time without penalty.

Compensation

11. ☐ A description of compensation or incentive (e.g., monetary, course credit, treatment) for participation and any criteria for receipt.

Questions

12. ☐ The name of the contact person for information related to questions about the research (the Principal Investigator), the rights of human participants (the IRB Chairperson), and whom to contact in the event of a research-related injury (the PI).
13. ☐ A statement that the investigator has answered and will answer all questions posed by the participant now and in the future to the best of his/her ability.

Other

14. ☐ A statement regarding injury compensation and institutional or PI liability for any injuries that might occur.
15. ☐ A statement indicating voluntary consent has been obtained, including signature lines for participant and investigator, and date.
16. ☐ A statement that the participant will receive a copy of the consent form (when an oral summary is read, and short consent form is used, the statement should read that a complete copy of the consent form will be provided to the participant).
17. ☐ A statement that the IRB has approved the solicitation of participants for the study; this appears after the signatures.

Terms and Definitions

45 Code of Federal Regulations Part 46

The federal policy that provides regulations for the involvement of human subjects in research. The Policy applies to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency that takes appropriate administrative action to make the Policy applicable to such research. Also referred to as **45 CFR 46.**

Assent

Affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research.

Autonomy

Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

Confidentiality

Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

DHHS

Department of Health and Human Services. An agency of the federal government; formerly the Department of Health, Education and Welfare (DHEW).

FDA

Food and Drug Administration; an agency of the federal government established by Congress in 1912 and presently part of the Department of Health and Human Services. More information

FWA (Federalwide Assurance)

A written document submitted by an institution (not by an IRB) that is engaged in non-exempt human subjects research conducted or supported by DHHS. Through the assurance, an institution commits to DHHS that it will comply with the requirements set forth in as well as the Terms of Assurance.

Guardian

An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)].

Human Subject

Living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.

Identifier

The term "Identifier" refers to any information that could be used to match the data with the individual subject. Some examples are the subject's full or partial name, initials, social security number, student ID, and phone number.

Individually Identifiable

The identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Informed Consent

A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].

Investigator

Any individual who is engaged in conducting human subjects research studies. Such engagement would include: obtaining information about living individuals by intervening or interacting with them for research purposes; obtaining identifiable private information about living individuals for research purposes; obtaining the voluntary informed consent of individuals to be subjects in research; and studying, interpreting, or analyzing identifiable private information or data for research purposes.

IRB (Institutional Review Board)

A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or social/behavioral research.

Minimal Risk

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults – Risk of physical or psychological harm that is no greater in probability and severity than that ordinarily encountered in the daily lives, or in the routine medical, dental, or psychological examinations of healthy persons.

OHRP (Office for Human Research Protections)

An administrative unit within the Department of Health and Human Services (DHHS). The OHRP's functions include implementation of the DHHS Regulations for the Protection of Human Subjects (45 CFR 46), and the guidance on ethical issues in biomedical or social/behavioral research.

Parent

A child's biological or adoptive parent.

Principal Investigator

The scientist or scholar with primary responsibility for the design and conduct of a research project.

Prisoner

An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statue; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

Private Information

Includes 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).

Protocol

The formal design or plan of an experiment or research activity, specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes but not limited to a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Research

A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Respect for Persons

An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

Risk

The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (See also: Minimal Risk.)

Voluntary

Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.