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| **Document:** | Human Subjects Policy and Procedures |
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It is the intent of the National Youth Science Foundation (NYSF) to protect the rights of its students, faculty, staff, and visitors and their data. Furthermore, the NYSF commits to ensure the appropriate implementation of all applicable regulations for the protection of human subjects participating in research programs conducted or supported by the NYSF. This policy applies to all NYSF activities that involve human participants or data that contains identifiable private information for research conducted or supported by the NYSF. This policy also applies to activities conducted by members of the NYSF staff and guest presenters. The basis of this policy is the United States Department of Health and Human Services' Policies and Procedure for the Protection of Human Subjects Participating in Research Program Conducted or Supported by HRSA[i].

**Definitions:**

1. **Research**
    a. The NYSF defines "research" as a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." In the context of this policy, all activities meeting this definition constitute research 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.
    b. For the purposes of this policy, "research" should include all NYSF-conducted or supported epidemiological and service utilization studies, surveys, and evaluations involving a systematized collection and analysis of information for the purpose of developing or contributing to generalizable knowledge (i.e., new information that has relevance beyond the population or program from which it was collected). If a NYSF-conducted or supported program includes at least one component that is designed to develop or contribute to generalizable knowledge, then that component must be considered "research" even if the program is not generally considered "research." The ultimate classification of an activity as "research" depends on the intent of the activity. "Research" would not ordinarily include public or personal health service programs that collect information *solely* to establish eligibility for public health services or benefits, or *solely* to record or evaluate the delivery of such services for internal program purposes. A program would also not be considered "research" if the purpose is to prevent/control disease, improve health, improve a service or program, where the study would primarily benefit only program participants and any knowledge generated would not extend beyond the scope of the program, or where cooperation with local/state government is required by law. However, if the intent of a program (or component of a program) is to produce generalizable knowledge that benefits individuals beyond the program participants, then it would be considered "research."
2. **Human Subject**
    a. 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. For example, human subjects in NYSF-conducted or supported research may include students, clients, or beneficiaries who receive services, and the providers who deliver services.
3. **Intervention or Interaction**

a. An intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulation of the subject or the subject's environment that are performed for research purposes. An interaction includes communication or interpersonal contact between investigator and subject.

4. **Private Information**

   a. Private information includes information about a behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that 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 subject 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 subjects.

**Background:**

The NYSF is committed to the protection of human subjects and their data by subjecting its research programs to the ethical principles defined in the Belmont Report[ii]. The Belmont Report sets forth the following three basic ethical principles underlying the acceptable conduct of research involving human subjects:

1. **Respect for persons**

   a. Involves a recognition of the personal dignity and autonomy of individuals, and special protections for those persons with diminished autonomy and underlies the need to obtain informed consent. Potential subjects should be treated as individuals capable of deliberate judgment; they must be given the opportunity to be fully informed about, and to choose voluntarily and without coercion, what will or will not happen to them. At the same time, appropriate protection must be offered to persons with diminished capacity for self-determination.

2. **Beneficence**

   a. Entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. The principle of beneficence underlies the need to engage in a risk/benefit analysis and to minimize risks.

3. **Justice**

   a. Requires that the benefits and burdens of research be distributed fairly. Participants should be treated fairly. Selection of participants should be equitable so that benefits and burdens are shared fairly at both the individual and societal level.

**Protection of Human Subjects:**

All human subjects research activities conducted or supported by the NYSF will provide appropriate protections for human subjects, including, among other things, adequate provisions for minimizing risks to subjects, obtaining and documenting the legally effective informed consent of the subjects or the subjects' legally authorized representative, protecting the privacy of subjects, and maintaining the confidentiality of data. All intramural and extramural human subjects research activities conducted or supported by the NYSF will provide all basic research participant protections, including those outlined in the Family Educational Rights Protection Act (FERPA) and its Protection of Pupil Rights Amendment (PPRA), and comply with all applicable ethical guidelines and regulations. The NYSF will identify and comply with all regulatory responsibilities related to the protection of human subjects.

**Informed Consent:**

Participation in any research activity must be voluntary. Informed consent must be obtained before individually identifiable private data are to be collected for study purposes, unless informed consent is waived by an institutional review board (IRB). The informed consent must be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative, unless the IRB waives documentation of consent.

**NYSF Policy:**

The NYSF will not support or conduct any activity:

1. that places any student, faculty member, staff member, or visitor at more than minimal risk (including risk of disclosure of identifiable information);
2. that involves any significant physical invasion or intrusion on the privacy of its students, faculty members, staff members, or visitors;
3. that uses any experimental procedures or investigative drugs or devices; or

4. that requires or withholds any accepted treatment for study purposes.

The NYSF allows:

1. the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
    a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
    b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
2. research involving the collection or study of existing documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available, or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly, or through identifiers linked to the subjects.
3. research and demonstration projects which are designed to study, evaluate, or otherwise examine:
    a. public benefit or service programs;
    b. procedures for obtaining benefits or services under those programs;
    c. possible changes in or alternatives to those programs or procedures; or
    d. possible changes in methods or levels of payment for benefits or services under those programs.

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[i] https://www.hrsa.gov/sites/default/files/publichealth/clinical/HumanSubjects/humansubjectspolicyoct2015.pdf
[ii] https://en.wikipedia.org/wiki/Belmont_Report