Smithsonian Institution

SMITHSONIAN DIRECTIVE 606,
July 19, 2018

RESEARCH INVOLVING HUMAN SUBJECTS

1. PURPOSE

The purpose of this policy is to ensure that all Smithsonian Institution (SI) research involving human subjects complies with applicable federal laws, regulations and ethical principles, so that the rights and welfare of human subjects involved in research are protected.

2. APPLICABILITY

This directive applies to all Smithsonian research involving human subjects (as defined herein), conducted anywhere in the world, regardless of the funding source used. This includes research conducted by any Smithsonian employee or affiliated person, with respect to his or her Smithsonian activity; research using any Smithsonian resource, property or facility; and research using Smithsonian non-public information to identify or contact prospective human subjects.

Smithsonian Astrophysical Observatory (SAO) staff conducting Smithsonian human subject research activities are subject to this directive and will submit projects to the Smithsonian Institutional Research Board (IRB).

3. POLICY

The Smithsonian acknowledges and accepts responsibility to minimize risks to human research subjects and ensure that their participation is based on informed consent. To fulfill this responsibility, all individuals engaged in research involving human subjects must understand their individual and collective responsibilities for compliance with this policy and any applicable federal, state, or local, laws or regulations, and institutional policies pertaining to human subjects.

To the extent applicable, the Smithsonian Institution will comply with the Federal Policy for the Protection of Human Subjects, also known as the Common Rule (*Code of Federal Regulations* [CFR] Title 45 Part 46 — Protection of Human Subjects), which is available on the Internet at https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html.

The Smithsonian Institution is guided by the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (i.e., the *"Belmont Report"*), which is available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html.

Investigators also should follow the codes of ethics applicable to their particular disciplines. Investigators are responsible for ensuring that the rights and welfare of human subjects participating in Smithsonian activities are protected, whether or not those activities are formally defined as research under this policy directive.

Research with human subjects proposed for Smithsonian premises, or using Smithsonian visitors as potential subjects, may be conducted only by Smithsonian employees or Smithsonian affiliated persons. Research with visitors as potential subjects proposed by Smithsonian affiliated persons may be approved only when the project is found by the sponsoring unit and the IRB to be compatible with the Smithsonian mission and objectives.

4. DEFINITIONS

Human Subject — A living individual about whom an investigator conducting research (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

A living individual is a human subject when an investigator conducting research obtains data, whether identifiable or not, through intervention or interaction, or obtains or uses identifiable data, without interacting with subjects.

4. DEFINITIONS (continued)

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

Research includes such activities as the measuring, taking or testing of a subject's bodily tissue, psychological testing, formal interviews, focus groups, questionnaires, interactive or non-interactive observations of public behavior that obtain personally identifiable information, including the use of either electronic or visual tracking, and related activities that produce a body of study data, with the intent to draw statistically, quantitatively or qualitatively based conclusions.

For the purpose of this directive, research *does not* include:

- interviews used to provide quotes or illustrative statements, such as those used in journalism;
- collections of oral histories and cultural expressions (e.g., stories, songs, customs and traditions and accounts thereof) to document specific historical events or the experience of individuals without intent to draw conclusions or generalizations;
- gathering of information from a person to elucidate a particular item(s) in a museum collection;
- gathering of information from a person to assess suitability for and/or to supplement a public program, publication, exhibition, or cultural performance;
- interview procedures, focus groups, questionnaires, interactive or non-interactive observations of public behavior that obtain personally identifiable information, using either electronic or visual tracking, that are conducted **for Smithsonian internal purposes only**, the results of which will not be published or presented in a public setting (e.g., at conferences or professional meetings).

Assurance of Protection for Human Subjects or Federal Wide Assurance (FWA) — A written agreement, submitted by an institution conducting research involving human subjects, that ensures such research will comply with all federal standards for the protection of human research subjects.

Institutional Review Board (IRB) — An appropriately constituted group formally designated by the Secretary to review, monitor, and approve any research involving human subjects. This board consists of at least five members with varying backgrounds to evaluate research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

4. DEFINITIONS (continued)

Informed Consent — An agreement to participate in research that is made voluntarily by an individual after disclosure of all material information about the research, including foreseeable risks and benefits. The methods used to obtain informed consent will vary depending on the nature of the research, the risks involved, the research setting, the study participants, and any applicable policies, laws, and regulations. Informed consent is required for all non-exempt research, unless a waiver is granted by the IRB.

Broad Consent — Prospective consent given by the subject for the use of identifiable private information or identifiable biospecimens for unspecified, future, secondary research use, as described in 45 CFR 46.117. Secondary research means research performed by re-using identifiable information or identifiable biospecimens that are collected for some other primary or initial activity.

Exempt Research — Research determined by the IRB to have no more than minimal risk and falling entirely into one or more of eight categories described in the "Process" section beginning on page 8.

Expedited Review Procedure — A review of a research protocol that may be carried out by the IRB chairperson or by one or more experienced reviewers from among the members of the IRB, in accordance with 45 CFR 46.110.

Limited IRB Review — An IRB review of certain categories of exempt research, to determine if these criteria are met, as specified by 45 CFR 46.111(7) and (8):

- adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data

- broad consent is obtained in accordance with 45 CFR 46.116(a)(1)–(4), (a)(6), and (d), and documented in accordance with 45 CFR 46.117.

Limited IRB review may be carried out using an expedited review procedure at the discretion of the IRB chair (see the "Expedited Review" subsection of the "Process" section on pages 10–11 for details).

Intervention — This includes both physical procedures by which data are gathered and manipulations of the subject or the subjects' environment performed for research purposes.

Principal Investigator — A Smithsonian employee or affiliated person who is responsible for proposing and directing a research project covered by this policy. The terms "Principal Investigator," "Responsible Investigator," "Project Director," "Program Director," "Researcher," "Curator," and "Exhibitor" are interchangeable with the term "Principal Investigator" if such individuals are conducting research covered by this policy.

4. DEFINITIONS (continued)

Private Information — Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information provided for specific purposes by an individual and that the individual can reasonably expect not to be made public (e.g., test scores, fiduciary records or medical records). Obtaining private information may constitute "research involving human subjects" if the information is individually identifiable. Information is individually identifiable if the identity of the subject about whom the information pertains is or may be readily ascertained by the researcher or could be associated with the subject by anyone reviewing the research. Note that "private information" is defined more broadly than personally identifiable information (PII) and may be identifiable or not. For more information on PII, see SD 118, Privacy Policy.

Smithsonian Affiliated Persons — This term refers to the following categories of individuals who are not Smithsonian employees but who operate on Smithsonian property:

- Contractors embedded with Smithsonian employees;
- Volunteers, including Regents and advisory board members;
- Academic appointees (Research Associates, regardless of working title, interns and Fellows);
- Friends of the National Zoo (FONZ) employees and Smithsonian Early Enrichment Center (SEEC) employees;
- Visiting researchers, scientists, scholars, and students; and
- Federal agency or non-profit employees located at a Smithsonian facility.

Sponsor — Any organization (e.g., a foundation, corporation, or federal agency) that funds a research, exhibit, or other type of activity.

United States Department of Health and Human Services (DHHS), Office for Human Research Protection (OHRP) — The federal office that provides leadership and oversight on all matters related to the protection of human subjects participating in research conducted or supported by the DHHS.

5. RESPONSIBILITIES

The Secretary of the Smithsonian (or designee) is responsible for:

- serving as the Institution's Signatory Official;

5. RESPONSIBILITIES (continued)

- appointing the IRB members;
- ensuring that all investigators collaborating on research involving human subjects operate under the appropriate FWA;
- ensuring that the review process is both compliant and efficient, so that opportunities for the advancement of knowledge are not unnecessarily impeded; and
- establishing training and oversight mechanisms to ensure that research investigators, IRB members and staff, and other appropriate personnel maintain knowledge of, and comply with, relevant federal regulations, state and local laws, and institutional policies for the protection of human subjects.

The Institutional Review Board (IRB) is responsible for:

- conducting reviews and approving, requiring modifications in (to secure approval), or disapproving all proposals for human subject research;
- conducting reviews of research and determining whether research is exempt, or requires limited IRB review of certain exempt categories, as described at 45 CFR 46.104;
- determining approval of and granting waivers of informed consent;
- determining when continuing review is required for research that was approved under expedited review;
- reporting to the Secretary and to the Office of Sponsored Projects (OSP) any suspension or termination of IRB approval, or any serious or continuing noncompliance with the regulations or determinations made by the IRB, or any other unanticipated problems involving risks to human subjects or others; and
- developing IRB procedures and maintaining all documentation of IRB activities.

Unit Directors are responsible for:

- ensuring that employees, volunteers, and other affiliated persons comply with this directive; and
- ensuring that any unit staff proposing, conducting, assisting with, or overseeing affiliated persons conducting research involving human subjects, as defined by this directive, have met training requirements in the ethical treatment of human subjects in

5. RESPONSIBILITIES (continued)

research (see www.citiprogram.org or http://phrp.nihtraining.com/users/login.php for online training).

Principal Investigators (PIs) are responsible for:

- completing training in the protection of human subjects in research, prior to engaging in research that meets the definitions of this directive (see www.citiprogram.org or http://phrp.nihtraining.com/users/login.php for online training);
- submitting proposals for all research involving human subjects to the IRB for approval or exempt determination prior to recruiting subjects or commencing research;
- informing the IRB of the unique local laws, if any, applicable to the research that the PI will conduct;
- seeking approval from the Privacy Office, under SD 118, prior to initiating research that collects personally identifiable information;
- supervising activities related to the use of human subjects in their projects, including obtaining the appropriate informed consent;
- submitting progress reports on ongoing approved research if required by the IRB;
- ensuring that their project staff complete required training in the protection of human subjects in research, as defined by this directive;
- obtaining from independent or collaborating investigators (who are not otherwise affiliated with the Smithsonian) a written agreement regarding their commitment to relevant human subject protection policies and IRB review, either by their own institution or by the Smithsonian. The decision about which IRB reviews the project will be made on a case-by-case basis in consultation with the Smithsonian IRB chair;
- submitting in advance proposed changes in the design of a research activity; and
- reporting unanticipated problems with a research activity involving risks to humans and/or non-compliance to the IRB.

The Under Secretary for Museums and Research/Provost, or designee, is responsible for:

- serving as Institutional Signatory Officer on behalf of the Secretary of the Institution;

5. RESPONSIBILITIES (continued)

- collecting relevant information from the IRB and reporting, as needed, to the DHHS OHRP;
- guaranteeing that IRB approval has been obtained prior to acceptance of a grant or contract;
- ensuring that prepared reports are distributed to the DHHS or other federal agencies, as required;
- developing, maintaining, and submitting the FWA;
- providing a copy of IRB procedures to the DHHS OHRP or any department or agency upon request; and
- ensuring that the Secretary and the IRB are updated on changes made to applicable human subject research laws and regulations.

Smithsonian employees and affiliated persons are responsible for reporting incidents involving the unethical treatment of human subjects and any noncompliance with this policy or the requirements or determinations of the IRB to the Smithsonian IRB.

6. PROCESS

Exemptions

Listed below are the eight categories of human subject research activity, as defined in 45 CFR 46.104, which may be determined by the IRB to be exempt from further review or requirements. Subparts B (Pregnant Women, Fetuses and Neonates), C (Prisoners) and D (Children) of 45 CFR 46 contain additional protections for these vulnerable subject populations, which may alter some of these categories of exemption. See 45 CFR 46.104(b) or contact the IRB administrator in OSP for additional guidance on whether a particular project may be determined to be exempt.

1. Research in established or accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or assessment of educators who provide instruction, as specified in 45 CFR 46.104(d)(1).
2. Research that only includes interactions involving educational tests (e.g., cognitive, diagnostic, aptitude or achievement), survey procedures, interview procedures, or

6. PROCESS (continued)

observation of public behavior (including visual or auditory recording), if at least one of these criteria, as specified in 45 CFR 46.104(d)(2), is met:

a. The information is recorded with no identifiers, direct or indirect;
b. Any disclosure of responses outside the research would result in no risk of civil or criminal liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
c. The information is recorded with identifiers, direct or indirect, and the IRB conducts a limited IRB review to ensure adequate provisions for protection of privacy and confidentiality of data.

3. Research involving benign behavioral interventions (e.g., online games, solving puzzles, data entry) with collection of verbal, written or audiovisual recording of responses, if the subject prospectively agrees to intervention, and at least one of these criteria are met, as specified in 45 CFR 46.104(d)(3):
    a. The information is recorded with no identifiers, direct or indirect;
    b. Any disclosure of responses outside the research would result in no risk of civil or criminal liability or other damage to the subject; or
    c. The information is recorded with identifiers, direct or indirect, and the IRB conducts a limited IRB review to ensure adequate provisions for protection of privacy and confidentiality of data.

4. Secondary research uses of identifiable private information or identifiable biospecimens, for which consent is not required, if at least one of these criteria is met, as specified in 45 CFR 46.104(d)(4):
    a. The identifiable private information or identifiable biospecimens are publicly available;
    b. Information, which may include information about biospecimens, is recorded without identifiers, direct or indirect. The investigator does not re-identify or contact the subjects;
    c. The research involves only Health Insurance Portability and Accountability Act (HIPAA)-protected health information, as specified in 45 CFR 164, Privacy of Individually Identifiable Health Information; or
    d. The research is conducted on behalf of a federal department or agency using Government-generated or Government-collected information obtained for nonresearch activities, and the research generates identifiable private information that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 *United States Code* (USC) 3501 note, if all of the identifiable private information collected, used, or generated as part of the

6. PROCESS (continued)

activity will be maintained in systems subject to the Privacy Act of 1974, 5 USC 552a, and if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 USC 3501 et seq.

5. Research to study public benefit or service programs, as specified in 45 CFR 46.104(d)(5).

6. Taste and food quality evaluation and consumer acceptance studies, as specified in 45 CFR 46.104(d)(6).

7. Storage or maintenance of individually identifiable private information or individually identifiable biospecimens for potential future secondary research for which broad consent is required, if the IRB conducts a limited IRB review to ensure adequate provisions for protection of privacy and confidentiality of data, as specified in 45 CFR 46.104(d)(7).

8. Secondary research involving the use of identifiable private information or identifiable biospecimens for which broad consent is required, if all these criteria, as specified in 45 CFR 46.104(d)(8), are met:
    a. Broad consent was obtained from the subject;
    b. Documentation of informed consent or waiver of documentation of consent was obtained;
    c. The IRB conducts a limited IRB review to ensure adequate provisions for protection of privacy and confidentiality of data; and
    d. The investigator does not include returning individual research results to subjects as part of the study plan.

Expedited Review

The Secretary of DHHS has established a list of categories of research, found in Appendix A, which may be reviewed by the IRB through an expedited review procedure. The IRB may use the expedited review procedure to review the following:

a. Some or all of the research appearing on the list (Appendix A) unless the reviewer determines that the study involves more than minimal risk;
b. Minor changes to previously approved research during the period for which approval is authorized; or

6. PROCESS (continued)

c. Research for which limited IRB review is a condition of exemption under categories 2c, 3c, and 7 and 8 above.

7. ADDITIONAL GUIDELINES

Additional guidance to supplement this policy can be found in the following documents:

- *OSP Compliance Policies,* available on Prism at http://prism2.si.edu/SIOrganization/OSP/Compliance/Pages/Compliance.aspx;
- SD 604, Misconduct in Research;
- SD 321, Review and Submission of Proposals for Sponsored Projects
- SD 205, Smithsonian Institution Research Associates;
- SD 701, Smithsonian Institution Fellows;
- SD 118, Privacy Policy;
- SD 119, Privacy Breach Notification Policy;
- 45 *Code of Federal Regulations* (CFR) 46; and
- *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (also known as the Belmont Report), which is available at http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm.

SUPERSEDES: SD 606, March 31, 2015
INQUIRIES: Office of Sponsored Projects (OSP)
RETENTION: Indefinite. Subject to review for currency 36 months from date of issue.
