**Application for IRB Review of Human Subject Research**

**Instructions:**

Effective July 20, 2020, this form is to be used exclusively for review of Human Subject Research (HSR) as defined in [SD 606](https://prism2.si.edu/SIOrganization/OCFO/OPMB/SD/SD606.pdf). If you are unsure of whether or not you need to submit your project to the Smithsonian Institutional Review Board (IRB) for review and approval, complete HSR-07, Does My Activity Require IRB Review, and consult with the IRB Administrator at [ResearchCompliance@si.edu](mailto:ResearchCompliance@si.edu) or call 202-633-7118 for further guidance.

If you are planning a project (a defined study with a topic of inquiry involving a circumscribed group of people) to conduct research involving living human subjects, you must complete this form **no less than one month** before your desired start date and submit it to the Smithsonian’s IRB by **returning the completed form as an attachment to** [**ResearchCompliance@si.edu**](mailto:ResearchCompliance@si.edu) **or fax to (202) 312-1981.**

**The application consists of three Parts, plus Administrative information. All applicants must complete the Administrative information and Parts 1 and 2 in full. Do not leave any questions blank.**

**Part 3 must be completed when a project will collect personally identifiable information or data considered “sensitive” (see pg.6) or use existing personally identifiable information or sensitive data.**

**Project Investigators** are Smithsonian employees. Affiliated persons**†** who wish to serve as project investigator must secure the significant involvement and approval of a Smithsonian employee (sponsor) to conduct human subject research on Smithsonian premises. Investigators and sponsors must complete certification in human subject protections. Consultants or contractors hired to develop a research protocol and/or conduct a project, who serve as project investigator are included in “affiliated persons,” and also require a Smithsonian employee as “sponsor.”

Projects which have been reviewed, approved or determined exempt by an IRB at another institution must also be reviewed by the Smithsonian IRB if the work will be undertaken by a Smithsonian employee or affiliated person, or on Smithsonian premises. For any project initiated by any **outside person or entity**, intended to be conducted on Smithsonian premises or under Smithsonian auspices, the Smithsonian “sponsor” must provide a statement (see Part 1.1) indicating the project supports the mission of the Smithsonian, what benefit will accrue to the Smithsonian and explain why the project should be accommodated by the Smithsonian on behalf of the outside person or entity.

Projects which collect, use, store, or disseminate personally identifiable information (PII) or enter into a third-party contract that results in the same, are subject to Smithsonian Directive 118, Privacy Policy. Such projects **must be reviewed by the Privacy Office**, regardless of whether they meet the definition of human subject research or have been approved by the IRB.

**The IRB will advise you of its determination or request for additional information as soon as possible. You must not begin your research, including participant recruitment, until you have received an approval or exempt determination from the IRB.**

**†Affiliated persons** refer 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; interns and Fellows; Friends of the National Zoo (FONZ) employees and Smithsonian Early Enrichment Center (SEEC) employees; visiting researchers, scientists, scholars, and students; research associates, regardless of working title; and Federal agency or non-profit employees located at a Smithsonian facility.

**Application for IRB Review of Human Subject Research**

*IRB Use only*: HS\_\_\_\_\_\_\_\_\_\_\_\_

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| **Administrative Information** | | | | | | | | | |
| **Project Investigator (PI)** | | | | | | | | | |
| Last Name | | | | | First Name | | | | |
| Smithsonian Unit: | | | | | | | | | |
| Project Title: | | | | | | | | | |
| Date of Submission Click or tap to enter a date. | | | | | | | | | |
| This Application is:   For a new project  A revision for an application not yet approved  An amendment to an approved project (protocol number HS\_\_\_\_\_\_\_\_\_) | | | | | | | | | |
| PI HS training certification | Which training course taken (e.g., RCO(SI), CITI, NIH): | | | | | | | Date: | |
| Phone: | | | Email: | | | | | | |
| Discipline: | | | Highest Degree: | | | | Year Completed: | | |
| *If you are a Smithsonian affiliated person, rather than SI staff, please provide the following:* | | | | | | | | | |
| Affiliation type: Fellow  Research Assoc.  Visiting Researcher  Contractor  Other: | | | | | | | | | |
| Name of Smithsonian  Sponsor: | | | | Email: | | | | | |
| Phone: | | Sponsor’s HS certification: | | | | Which course? | | | Date |
| **Sponsor justification** for a project initiated by an external person or entity (To be written by SI sponsor: please limit to one to two paragraphs.) | | | | | | | | | |

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| **Project/ Study Information** | | | | | | |
| Anticipated Funding Source (internal funds, external sponsored project, name of sponsor): | | | |  | | |
| If externally sponsored project, provide Designated Code, Proposal ID or Award # | | | |  | | |
| Grant Title (if different than Project Title above): | | | | | | |
| Anticipated HSR Start Date: | | | | Anticipated HSR End Date: | | |
| Will others conduct or assist with the research project *(recruiting, interviewing, answering questions, or distributing surveys or have access to personal information contained in the collected data*:    NO  YES If yes, list below: | | | | | | |
| Name | Email | Role | | | Training date | Training provider |
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| ***Attach certification of human subjects training****, the training date, and provider (e.g., RCO, NIH, CITI) completed within the last 24 months for each individual.* | | | | | | |
| Describe where the study will be conducted. | | | | | | |
| Is the approval or determination of other research compliance committees or another Institutional Review Board required?  No  Yes. If Yes, what review board(s)? Please append the protocol application, and if approval/determination has been obtained, include documentation. | | | | | | |
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| What, if any, is the institutional affiliation(s) of the participants? If permission has been obtained from cooperating institutions (school, hospital, corporation, prisons, U.S. or non-U.S. government agency, etc.), append documentation of the approval (letter, email, etc.). | | | | | | |
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| **PART 1** | | | | | | |
| * 1. **Describe** what you will do with your results. | | | | | | |
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| * 1. Documents included (\* indicates required)   Short project description\*  Recruitment script or advertisement to be used in inviting participants to participate\*  Consent document, information sheet or script\*  Assent script for minor participants (if participants will be under age 18)  Surveys, questionnaires or tests (if participant will provide responses in writing or online)  Interview script (if participant will provide responses orally)  Certificate(s) evidencing completion of training in human subject research for all persons interacting with participants or having data access to personally identifying information of participants. \*  Other: specify below | | | Procedures you will be using (check all that apply)  Physical interventions (injection, pills)  Taking, testing, measuring human tissue  Inducement of psychological stress  Deception of human subjects  Seeking embarrassing/sensitive information  Survey  Interview  Focus group  Still photo, moving images, voice recording  Analysis of existing identifiable data  Other: specify below | | | |
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| 1.3 Will participants under 18 years of age be studied:  No  Yes  If Yes, will minors participate in **surveys, interviews or focus groups** (with or without personally identifiable information, or PII), or **benign behavioral interventions**?  No  Yes  Please describe the activities below, and how parents or guardians will be informed or involved in this project. | | | | | | |
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| 1.4 Will information be recorded about the participants in such a manner that the identity of the participants can be ascertained by the researcher, directly or through identifiers (code) linked to the participants? Note that email address, audio, video and still image recording of persons constitutes PII, even if names are not known.  No  Yes  **If you check Yes, you must complete Part 3**, andyou must also submit the project to [SmithsonianPrivacyReview@si.edu](mailto:SmithsonianPrivacyReview@si.edu) for Privacy Review under [SD 118](http://prism2.si.edu/SIOrganization/OCFO/OPMB/SD/SD118.pdf). | | | | | | |
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| * 1. Is the level of risk more than the risk encountered in activities of normal daily living? Will participants will be exposed to physical or psychological risk? Would disclosure of participant responses outside the research reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, educational advancement or reputation?   NO to all of the above  YES.  If your answer is YES to any of these, **describe below** if in your research methods or techniques, any of the following might result due to participation in the study:  providing personally embarrassing or sensitive\* information  persecution  psychological distress  social censure  criminal prosecution  bodily harm  disease  deception of human subjects  other potential harm, **specify below**  **\*If you will collect information that is considered sensitive, because it could cause embarrassment or other harm to the participant should it become known by others outside the research, you must complete Part 3.** | | | | | | |
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| * 1. Will the living human subjects, from whom data will be collected, be any of the following? Include all participants, including those from previously identified communities, such as existing mailing lists, classrooms, etc.   adult museum visitors  participants in Smithsonian educational program (specify below)  Smithsonian employees  patientspersons potentially under duress or coercion  prisonerspersons with mental disabilities  persons unable to give informed consent  other potentially vulnerable persons, **describe below**. (Consider vulnerability in two senses: vulnerability to coercion in the recruitment process [e.g., your own students, your own employees], and vulnerability to greater risk of harm versus participants drawn from the general population.)  If none of the above, **describe who the participants will be below**: | | | | | | |
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| 1.7 Will you be interacting with non-English speaking participants?  No  Yes  If Yes, are you fluent in the language they understand?  No  Yes If you are not fluent in their language, indicate how you will communicate with participants (e.g., via interpreter), and if so, who will serve in this role. | | | | | | |
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| 1.8 **Describe below** any payment in cash or in kind, compensation of expenses or any other incentive offered, such as a small token or gift card.  Is receipt of the payment, compensation or incentive contingent on participant completion of activities in their entirety?  Yes  Or will the participant receive these even if he/she withdraws?  Yes Is the arrangement made clear in information presented to the participant?  Yes  No  If providing a gift card as incentive, did you indicate in Item 1.4 that you will collect an email address?  Yes  No | | | | | | |
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| **Exemption Categories 45 CFR 46.104(d)** |
| 1.9 Do all the activities in the project fall into one or more of the following exemption categories? Please check the category(ies) the research involves, **if any**: |
| * 1. Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact student’s opportunity to learn required educational content or the assessment of educators who provide instruction. *[this refers to regular classrooms, not informal museum education programs]*   2. Research that only includes educational tests, surveys, interviews, observation of public behavior (including visual or auditory recording) with **adult participants only. Choose one:**   (a) Information obtained will be recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the participants*. [the researcher will not obtain any identifiers from participants]*  (b) Any disclosure of the human subjects’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement or reputation*. [the researcher may or may not obtain identifiers, but the content of responses is not sensitive or likely to cause harm.]*  (c) Information obtained will be recorded in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the participants. *[the researcher will obtain identifiers, and the IRB must determine if proposed protections will mitigate any risk*]  *Readily ascertained means the researcher has the identifiers or has access to a code linking responses to identifiers. If PII or sensitive data will be collected, complete Part 3.*   * 1. Research involving benign behavioral interventions (e.g., online games, solving puzzles, data entry) with **adult participants only**, with collection of verbal, written or audiovisual recording of responses, with the participant prospectively agreeing to the intervention. **Choose one [*conditions same as above]****:*   (a) Information obtained will be recorded in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the participants.  (b) Any disclosure of the human subjects’ responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ financial standing, employability, educational advancement or reputation  (c) Information obtained will be recorded in such a manner that the identity of the human subjects can readily be ascertained directly or through identifiers linked to the participants.  *If PII or sensitive data will be collected, complete Part 3.*   * 1. Secondary research use of identifiable private information or identifiable biospecimens, previously collected, either by you or by another party, for some other primary or initial use, and for which consent is not required, because (**choose one**):  (a) The identifiable private information or identifiable biospecimens are publicly available *[the information was collected in a private setting, but is now made publicly available by the collector]*   (b) The information, which may include information about biospecimens, will be recorded in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants and the investigator will not re-identify participants. |
| If your project activities do not fit completely into one of the categories above, the IRB will initially review this application under expedited review. |
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| 1.10 How will you invite (recruit) participants to participate in the research? Specify the recruitment wording and indicate where participants will be recruited. Be sure to attach copies of any flyers or advertisements. |
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| 1.11 How many participants will be invited to participate in the research? If your study includes multiple categories of participant (e.g., teachers, parents, visitors), please provide figures for each. |
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| 1.12 How often will participants be contacted and why that frequency |
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| 1.13 Attach a brief summary, in layman’s terms, describing your hypotheses or research goals. Will the results be shared outside of the Smithsonian, and with whom? Describe the design of your research and planned use of human subjects. Include a brief description for each method of data collection (survey, focus group, observation, etc.) mentioned in 1.5 above. (Please limit to two pages.)? |
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| **PART 2 Participant Information and Agreement** |
| **All applicants complete Part 2** |
| 2.1 Will you provide information to participants regarding the project (disclosure) prior to their participation?  Yes  No.  N/A – all data is pre-existing How will this information be provided?  in written form  by oral presentation   both written and oral.  For data that is not pre-existing, **provide below** (or attach) the introductory/recruitment, consent language or other information script, whether delivered as a flyer, email, letter, or orally (**note:** you may not begin recruitment until you have received determination/approval,) or written consent form. If you answered NO, you may need to also complete OSP-HS-05, Waiver Requested for Informed Consent. Consult with the IRB administrator for assistance. |
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| 2.2 Will you ask human subjects for agreement to participate (consent) in the research?  (a) Written Adult Participant Consent (participant will sign form and return)  (b) Written Parental/Guardian Consent for minor participants (minors are unable to provide consent)  (c) Information sheet only, no signature  (d) Click Consent for Online Survey  (e) Oral agreement/consent only  (f) I will not obtain agreement/consent  (g) N/A - data is pre-existing *If you check box (c) through (f), you may also need to complete* ***HSR-05, Waiver of Informed Consent****. Consult with the IRB administrator for assistance*. |
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| 2.3 If your participant population includes children/minors, do you intend to obtain assent from the child as well as parental permission? |
| This question does not apply: there will be no minor participants.  Yes, assent will be obtained in writing. (Please attach a copy of the assent form.)  Yes, assent will be obtained orally. (Please attach a copy of the assent script.)  No If No, please explain why assent will not be sought: |
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| 2.4 If participants are vulnerable due to their legal status, economic status, illiteracy or other circumstances, describe steps to minimize the risk of coercion or undue influence. Include in your description how you ensure participants understand that their participation is voluntary. |
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| **PART 3 Collection and Care of  Personally Identifiable Information (PII) or Sensitive Data** |
| Answer Part 3 Questions only if you will have access to or will collect PII, or data which is considered “sensitive” because it could cause embarrassment or other harm to the participant should it become known by others outside the research |
| 3.1 Check all of these that are true regarding personally identifiable participant information (PII) or sensitive data in this study:  I will collect PII or sensitive data directly from participants in this study  PII or sensitive data has been collected from participants in existing data and I will record it for my project  There is PII or sensitive data in existing data, but I will not collect any of the PII for this project, nor attempt to contact the participants, nor re-identify the participants  There is PII or sensitive data in existing data, and I will record it, contact participants or re-identify them |
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| 3.2 **Describe below** **and justify** any sensitive information you will collect that could damage participants’ reputation or employability, financial standing, or place them at risk for criminal or civil liability. |
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| 3.3 **Describe below** what types of PII, including name, email, **photo, video or voice recording**, or highly specific demographic information will be or have been gathered from participants. See SD 118 for full definition of PII: <http://prism2.si.edu/SIOrganization/OCFO/OPMB/SD/SD118.pdf> . Will any participant data be gathered through photographic, video or voice recording devices?   Yes  No. If Yes, **describe below** what recording(s) will be made and when. |
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| 3.4 Have you submitted the project to the [Privacy Office](mailto:SmithsonianPrivacyOffice@si.edu) for review and approval?  Yes  No If Yes, describe when and explain disposition below: |
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| 3.5 Concerning existing PII or sensitive data, for which this study is a secondary use of the data,  data is Smithsonian data, collected by Smithsonian persons or in Smithsonian possession - **specify** **below** which collection and name of responsible curator/archivist.  data was collected elsewhere – **describe below** where the data came from originally  N/A, this project does not use existing data containing PII or sensitive data |
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| 3.6 Will you share the PII or sensitive data with other researchers or other institutions? Name/describe the recipients, and explain/justify the sharing below. Has a Data Sharing Agreement been executed with the collaborating institution?  Yes  No If Yes, please provide a copy of the agreement. |
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| 3.7 Indicate what procedures you will use to safeguard participant PII or sensitive data (indicate all that apply). Describe location, storage and encryption methods below, if applicable.  identifiers in existing data will not be recorded in any way by investigators  identifying information about human subjects will be retained in the possession of the researcher and/or Smithsonian with appropriate restrictions, such as (describe below):  physical controls (guards, locks, ID cards, key cards, CCTV, etc.)  technical controls (encryption, password, etc.)  other, **specify below**  identifying information about human subjects will be retained by investigator, but will be removed from the data, given a code, and the code key kept separately from the data (**describe below** at what point identifiers will be removed)  project results containing PII or sensitive data will be accessioned into a Smithsonian collection according to standard unit oral history and SD 600 procedures, **specify** **below** to which collection and name of responsible curator/archivist.  all data is already in the public domain  no safeguards will be used (**justify below**) |
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| 3.8 **Describe below** what will be done with any photos, video, or audio recordings of participants (i.e., used in publications, presentations, transcribed, etc.) How will you protect the confidentiality of recorded materials (photos, video or audio recordings) produced (if so promised)? |
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| * 1. Please indicate the procedures to be used to safeguard participant privacy in **research publications** (indicate all that apply).   no personally identifiable private information or sensitive data will be published (pseudonyms or camouflage of identify will be used where necessary)  identifiable private information is already in the public domain  for public figures and cultural exemplars, as well as for sources, the information to be revealed   conforms to the generally accepted standards of the research discipline  other, **specify below**:  no safeguards will be used  If you plan no safeguards for preserving the confidentiality of private information in publications, **justify below***.* |
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| 3.10 How will the desire of some participants to remain anonymous and the desire of other to be cited in publication be handled? |
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| **CERTIFICATION** |
| Smithsonian Institution policy requires formal training in human subject research. Before determination or approval will be granted by the IRB, all Smithsonian employees, sponsors, and affiliated persons proposing, conducting or assisting with the research project must have completed training (typically on-line) offered by the CITI Program in the Protection of Human Subjects (available at <http://www.citiprogram.org/>), or equivalent program within the past 24 months and obtained a certificate of completion. ***Please provide certificate(s) with your application*** |
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| All Smithsonian employees and affiliated persons participating in this project, **listed on page 1**, have completed human subject research training within the past 24 months.  YES  NO |
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| Neither I nor any of my associates in this research project, to my knowledge, has a real or apparent conflict of interest that would lead me or my associates to misrepresent the research, the treatment of human subjects, and the facts contained in this application.  This is correct  This is not correct (please explain below) |
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| By submitting this application, I certify that the research has been adequately designed to protect human subjects in accordance with [SD 606](http://prism2.si.edu/SIOrganization/OCFO/OPMB/SD/SD606.pdf) and all of the information contained in this application is accurate and complete.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator - sign and date |
| *If the applicant is a Smithsonian “affiliated person”.*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Smithsonian HS Sponsor – sign and date. *Note:* ***Sponsor must provide written justification for SI involvement in Administrative section, p. 1****.* |
| *Approval of Unit Director (for all applicants):*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Museum/Unit Director – sign and date.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (***Please provide printed name of Director***)  *Director’s signature indicates approval of the proposed activity to be undertaken on your premises and/or in the name of the Smithsonian and your unit/center.* |

**The IRB will advise you of its determination/approval or request for additional information as soon as possible. You must not begin your research (including recruiting participants) until you have received IRB approval or an Exempt determination.**