**FSU RESEARCH REPOSITORY PROTOCOL TEMPLATE**

**GENERAL INSTRUCTIONS**:

* + - 1. The purpose of this template is to provide sample text, specific instructions and related guidance for developing a protocol ONLY for the creation and maintenance of a research repository for which individuals’ information will be collected, stored, and used or shared for future research purposes. This template therefore does not require that a description of specific study hypotheses be provided. *For a study to request use or analyses of individuals’ information for a specific research project, and which individuals’ information will be derived from a registry, use instead protocol template HRP-503 or HRP-503a*.

1. Developing and managing a research repository requires an established infrastructure, standardized protocols, and databases. These must be addressed in the research repository protocol.
2. For more information about requirements and expectations that the IRB will apply to its review of your protocol, refer to HRP-337 – CHECKLIST - REPOSITORY.
3. This protocol has two (2) sections. All proposals to develop a repository must complete Part I. After completing Part I, proceed to Part II and answer the question about whether you plan to collect information directly from human research participants by interacting or intervening with them for purposes of collecting and adding their information to the repository. If so, then also complete Part II. Otherwise, the remainder of Part II may be left blank.
4. This template is only for use for repositories that involve no collection, storage, maintenance or use of any biospecimens. *Use HRP-503 – TEMPLATE PROTOCOL for biospecimen repositories*.
5. Complete this template so that it accurately depicts your own repository activity. General instructions are provided in green text boxes followed by sections of the template where you will need to describe or explain the specifics of your study. The [red text in brackets] provide specific instructions; as applicable, you must provide repository specific information or respond as directed. You must use the text box when inserting your own information. Other red text provide options that should be selected where applicable to your study. Do not otherwise modify this template with regard to form or format, or your protocol will be returned to you. Refer to HRP-337-CHECKLIST: REPOSITORY for a list of the required research repository elements that the IRB will evaluate for review and approval purposes.
6. There may be additional information you may need to provide to the OHSP/IRB to explain your study in more detail; the FSU IRB will so inform you pursuant to its review of your study.
7. Ensure consistency between any consent documentation or description and this protocol; if there is substantive inconsistency, both will be returned to you with instructions to render consistent.
8. Keep an electronic copy of your protocol; you will need your originally submitted protocol copy when making changes.

**PROTOCOL TITLE:**

[Include the full protocol title; do not use the short title entered into RAMP IRB]

**PRINCIPAL INVESTIGATOR (PI):**

[First Name Last Name, Credentials]

[Department]

[Telephone Number: Area Code-XXX-XXXX]

[PI’s FSU Email Address]

**FACULTY ADVISOR (If PI is a student):**

**N/A:**

[First Name Last Name, Credentials]

[Department]

[Telephone Number: Area Code-XXX-XXXX]

[Faculty Advisor’s FSU Email Address]

**REVISION HISTORY**

[In the table below list any revisions, to include the version number, date of this version of the protocol and a brief overview of the changes. If additional rows are needed, use the HRP-503r Template Repository Protocol Continuation Page]

|  |  |  |
| --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** (e.g., change to data source; new data source; change in PI; change in study personnel) |
| 1 | Click or tap to enter a date. |  |
| 2 | Click or tap to enter a date. |  |
| 3 | Click or tap to enter a date. |  |
| 4 | Click or tap to enter a date. |  |
| 5 | Click or tap to enter a date. |  |

|  |  |
| --- | --- |
|  | Leave this REVISION HISTORY section blank for the initial submission. The revision history for this protocol should be documented for any subsequent modifications once this Research Repository protocol is approved. Revisions to this protocol should be made in track changes format, with explanatory comments as needed, for quick review reference. Alternatively, if you use the Update feature in RAMP IRB for submitting a revised protocol and upload a “clean” version of the revised protocol, RAMP IRB has a built-in track change feature. |

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| **Abbreviations & Definitions** | |
| Abbreviation or Term | Definition |
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|  | List in this Abbreviations & Definitions section, in alphabetical order, any abbreviations or definitions for key or technical terms that you use in this Research Repository Protocol. IRB members and other reviewers may not always be familiar with the information/data/data source to be included in the repository or the technology and information systems concepts or abbreviations applicable to the proposed repository. |

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**PART I: RESEARCH REPOSITORY**

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|  | Part I must be completed if the proposed research repository will be used to create and maintain a research repository for which individuals’ information will be collected, stored, and used or shared for future research purposes. This applies whether or not data were or will be collected for a separate research or non-research purpose. |

**1.0 Purpose and Significance**

* 1. Purpose [describe the purpose, specific aims or objectives for creating this repository]:
  2. Significance [provide any relevant background, evidence, or information that supports the importance or justification and scientific value of creating this repository]:
  3. Scope of research focus [indicate the possible scope of research interests (e.g., human conditions or development, social phenomena, educational or vocational improvement, health care/health services delivery) that use of repository information is intended to or may support]:

|  |  |
| --- | --- |
|  | For this Purpose and Significance section, the IRB will consider whether sufficient justification for the need to develop a research repository has been provided. The IRB will weigh the risks of the research repository in relation to the importance of the knowledge that may reasonably be expected to result from use of repository information for future research purposes. |

**2.0 Governance and Oversight**

* 1. Resourcing [describe the key personnel positions that will be in place to ensure proper oversight and function of activities necessary to create and maintain the repository]:
  2. Continuing Operations [describe the plan for continuing operations in the absence or departure of the PI; or anticipated/unanticipated loss of data or damage to or corruption of repository data; or loss of data privacy or security]:
  3. Quality Assurance Oversight [indicate who or what position will be responsible for assuring the quality and integrity of the data in the repository, as well as the person/positions related experience and credentials. Also describe how the quality and integrity of the data will be evaluated]:
  4. Honest Broker of Identifiable Information [indicate the specific individual(s) within the institution that will have the authority and responsibility to act on behalf of the repository to remove links to identifiers in order to provide data to researchers without revealing the identity of human research participants/individuals about whom the data pertain. The honest broker shall not be a member of a research team that plans to request research use of the repository. Outline the policies and procedures that enable the honest broker to perform his/her function]:
  5. Custodian of Data [identify the individual who will serve as the Custodian of repository data and who will be responsible for the management of repository data and repository resources. Describe how the Custodian will work with other key repository stakeholders in the management of the resource including the tracking of all relevant documentation for the repository data and resources, and for ensuring that policies regarding access to the repository and repository data are in place and implemented according to appropriate guidelines]:

**3.0 Data Collection**

* 1. Types or Classes of Information [indicate in the table below the types or classes of information that will be collected; select all that apply]

|  |  |
| --- | --- |
| Information | Select Yes, No or Not Sure |
| Government records (e.g., Social Security (including Social Security numbers), military service, Medicare, Medicaid, Veterans, SNAP, disability, immigration, taxpayer, naturalization) |  |
| Health records (e.g., hospitalization, clinic, outpatient, medical treatment, pharmacy, counseling, immunization) |  |
| Vital records (e.g., birth, death, fetal death, marriage, divorce or dissolution of marriage) |  |
| School records (e.g., tests or assessments, grades, transcripts, student health, financial, admission, classes, courses, graduation, disciplinary, awards) |  |
| Employment records (e.g., hire, discharge, performance evaluation, payroll, tax, references, retirement, disciplinary, classification and title, accommodations) |  |
| Insurance records (e.g., workers compensation, disability, life, automobile, unemployment, health, payment, beneficiary) |  |
| License, registration and permit records (e.g., drivers, motor vehicle registration, voter, professional, occupational, business, vocational, gun) |  |
| Legal records (e.g., property, business, lawsuits, judgement, liens, court, bankruptcy, custody, guardianship, estate) |  |
| Law Enforcement records (e.g., arrest, warrant, criminal, police reports, jail, prison) |  |
| Research records collected or to be collected from other studies (describe other types or classes of information that will be collected): |  |
| Other (describe other types or classes of information that will be collected): |  |

* 1. Identifiable Data Elements [Indicate below which of the following data will be collected for the repository]

|  |  |
| --- | --- |
| Data Element: are ANY of the following elements associated with individual about whom data are collected, including elements associated with relatives, employers or household members of the individual? | Select Yes or No  (If not sure, select Yes) |
| Names |  |
| Any geographic subdivision smaller than a State (i.e. street address, city, county, zip code or equivalent geocode) |  |
| Any date element (except for year) |  |
| Telephone or fax numbers |  |
| Email addresses |  |
| Social Security numbers |  |
| Medical record numbers |  |
| Health plan beneficiary numbers |  |
| Account numbers |  |
| Certificate of license numbers |  |
| Vehicle identifiers and serial numbers including registration or license plate numbers |  |
| Device identifiers and serial numbers |  |
| Web URLs (Universal Resource Locators) or web addresses |  |
| Internet Protocol (IP) addresses |  |
| Biometric identifiers (i.e. retinal scan, fingerprints, voice scans) |  |
| Full face photographic, video or comparable facial images |  |
| Any other unique identifying number, characteristic or code (except for codes that are not derived from or related to an individual’s information and which are not otherwise capable of being translated so as to identify the individual) |  |
| Could any individual whose information is maintained in the repository be identified by anyone, whether using only repository information or in combination with repository information? |  |

* 1. This repository will collect and store information from one or more of the following sources (select all that apply):
     + - 1. Directly from human research participants through interaction (e.g., surveys, visits, assessments) or intervention (e.g., results from tests or assessments, activity logs) with them
         2. Data from a federal agency [list each federal agency from which data will be obtained]:
         3. Data from state or local government agencies [list each state or local government agency from which data will be obtained]:
         4. Data from a health care provider (FSU or non-FSU) that is subject to the “HIPAA Privacy Rule” [list by name each health system, organization, institution, hospital or practice from which data will be obtained]:

For any health care provider that you do not know or if you are certain is not subject to the HIPAA Privacy Rule, check one of the following and list the health care provider:

I do not know if the following health care provider(s) is subject to the HIPAA Privacy Rule:

I am certain that following health care provider(s) is not subject to the HIPAA Privacy Rule:

* + - * 1. Data from other non-government sources [list each other sources from which data will be obtained]:
  1. Medical and other Health Information: If you will be collecting data from a health care provider (FSU or non-FSU) or other institution or organization that is subject to the HIPAA Privacy Rule, select and/or describe each of the following:
     1. Medical and other health information will be in the future (prospectively) collected from patients. [if this section is checked, describe here how you will verify that patients will be asked to provide their consent or authorization for use or disclosure of their information in the repository (and include a copy of the IRB-approved consent and approved authorization template with the protocol]:
     2. Patients’ medical and other health information already (retrospectively) collected will be obtained. [if this section is checked, describe here how you will verify that that patients have consented or authorized use of their information in the repository (and include a copy of the IRB-approved consent and approved authorization template with the protocol]:
  2. Transfer of Existing Research Information/Data [if an existing dataset(s) will be transferred/added to the repository, describe where the pre-existing data are currently stored and how those data will be transferred to the repository]:
  3. If as indicated above existing research information will be transferred/added to the repository, indicate in the table below the title and IRB identification number of each study from which existing research information will be transferred/added to the repository.

|  |  |  |
| --- | --- | --- |
| Study Title | IRB Study ID | Indicate below whether original informed consent or authorization permits use of existing research data for repository purposes |
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[If additional rows are needed, use the HRP-503r Template Repository Protocol Continuation Page]

* 1. Follow-Up Data [if you will collect any follow-up data that will be added to the repository, describe how this data will be collected (i.e., through additional cohorts of data/datasets; follow-up surveys, or questionnaires)]:
  2. Non-U.S. Information Sources [if information will be collected from individuals living outside the U.S., provide a justification for their inclusion and outline the international laws that permit such a transfer of information to the repository. Review the FSU IT General Data Protection Regulation [(GDPR) FAQs](https://its.fsu.edu/ispo/GDPR-FAQ) (or <https://its.fsu.edu/ispo/GDPR-FAQ>) for more information]:

**4.0 Data Storage and Retention**

* 1. Storage [describe how and where data and/or specimens will be stored and maintained. Reference any relevant storage standard operating procedures developed for the database, registry, or repository. Indicate whether the database will be maintained in, e.g., HBD, Redcap, Qualtrics, FSU Dropbox]:
  2. Withdrawal [indicate whether human research participants will be able to have their data withdrawn from the repository. If so, describe the withdrawal process]:
  3. Destruction [indicate whether the data will be destroyed at any time point and how that will be done]:

**5.0 Data Access and Release**

* 1. Describe researchers that may be granted access or to whom repository information may be released [indicate whether only researchers who are employees or agents (e.g., students, faculty) of the FSU will have access or whether external (i.e., non-FSU) researchers will also be able to request access]:
  2. Identifiable data release [describe the process for requesting and associating FSU or other institutions’ IRB approval documentation with all such releases; if only de-identified data will ever be releases, so state]:
  3. Prohibitions on uses of accessed or released data [describe any prohibited use (e.g., access to linking key or cyphers to de-identified data; attempts to re-contact individuals about whom repository data pertain; re-disclosures of repository information to others not identified in the request for access or release) you will communicate to all investigators who request and receive data from the repository; describe how these prohibitions will be communicated or documented]:
  4. Release/Sharing [describe the procedures to request and release repository data, including: the process to request a release, approvals required for release and who will check for those approvals before release; who can obtain data; and the data elements to be provided]:
  5. Preparation for Release/Sharing [explain how data will be prepared for sharing; if data will be de-identified, coded, or anonymized provide specific information about how those processes will be conducted]:

1. **Confidentiality and Data Security**
   * 1. Information collected for the repository may be covered by federal Health Information Portability and Accountability Act (HIPAA), Privacy Act of 1974, and Family Educational Rights and Privacy Act (FERPA) and other federal, state and local laws. The collection of such information must conform to these laws’ specific confidentiality and security requirements. You must contact your data sources that are agencies, institutions or other organizations to confirm whether obtaining their information is subject to these laws and if so ensure compliance with these laws. Documentation of compliance with applicable laws should be provided with this protocol; this includes data use and confidentiality agreements, and waivers of authorization or exceptions issued by the data source.
     2. Data Security [describe in detail all the steps that will be taken to secure the data (e.g., explain implementation of training of repository protocol staff; compliance with applicable regulations and standards for data security; use of secure FSU servers for data storage; using only trusted programs, applications and/or platforms for all repository activities; adoption of established, recommended or required data security best practices; following procedures to authorize and limit repository access and use; password protection and authentication; encryption of data during transmission, at rest and during use; redundancy or backup of repository data; procedures for reporting data breaches; physical controls; use of federal Certificates of Confidentiality for identifiable and sensitive information; separation of identifiers and data; controls on cyphers or linking keys; and use of Honest Brokers to de-identify information)]:

**7.0 Risks**

7.1 Risks [describe any potential risks related to the information transmitted to or collected for the repository, stored or maintained in the repository, or disclosed from the repository. For example, explain the risk of interference or tampering with transmission and collection of information for the repository; unauthorized access to, breach or theft/removal of repository information; loss of repository information; or failure or interruption of data security procedures. If information was unintentionally released or accessed with authorization, describe whether individuals about whom the data pertain may be at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing]:

**8.0 Population Characteristics**

* 1. Inclusion Criteria [describe the inclusion criteria for data to be added to/included in the repository. For example, will data be about or collected from individuals of a specific age, background, status, affiliation, education, profession, credential, and/or experience, and/or will data be about or collected from individuals with a particular condition, characteristic, disease or other attribute? Data collected should be appropriate to the scientific goals of the repository]:
  2. Exclusion Criteria [describe if applicable any criteria that will be used to exclude data from the repository]:
  3. Age Range [describe the specific age range, if any, of the individuals about whom data will be collected for the repository. If the age range is undefined or broad, indicate whether both children and adult information will be collected]:

**PART II: PROSPECTIVE COLLECTION**

|  |  |
| --- | --- |
|  | Part II must be completed if the proposed research repository will be used to prospectively collect information through *interactions*[[1]](#endnote-1) or *interventions*[[2]](#endnote-2) with individuals for the sole purposes of the research repository (i.e., the data were not already previously collected for a separate research or non-research purpose).  Indicate here whether you will prospectively collect information by interacting or intervening with individuals to collect their information for the repository:  If you answered No to the question above, leave the remainder of this Part II section blank. |

**9.0 Special Populations**

* 1. Special Populations: [Review the table below and for each of the listed populations, use the drop-down menu to indicate whether information from any individual in those population groups will be prospectively collected]

|  |  |
| --- | --- |
| Population | Select Yes, No or Not Sure |
| Pregnant women, human fetuses or neonates |  |
| Prisoners or inmates |  |
| Children (any persons under the age of majority in their state of residence) |  |
| Decisionally impaired |  |
| Economically disadvantaged |  |
| Educationally disadvantaged |  |
| Students or employees under the supervisory or evaluative authority of the researcher |  |
| Institutionalized individuals |  |
| Non-English speaking |  |

* 1. If the research involves one or more individuals from the populations below which federal law specifically identifies as likely to be vulnerable to coercion or undue influence, additional protections to protect their rights and welfare must be implemented. For each population below from which you plan to prospectively collect an individual’s information, review the linked checklist to see what the IRB will consider for purposes of determining whether these individuals will be sufficiently protected from coercion or undue influence when they are asked to provide you with their information.
     + 1. Pregnant women, human fetuses or neonates: review [HRP-412-CHECKLIST-Pregnant Women](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/N9LJ0T9UCT4KR90G3JT58M3EF8/HRP-412%20-%20CHECKLIST%20-%20Pregnant%20Women.docx) to prepare your description of the additional protections to ensure that you have provided sufficient information.
       2. Prisoners or inmates: review [HRP-415-CHECKLIST-Prisoners](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/1RAG99HOLRB4TF2050ALLEQB8C/HRP-415%20-%20CHECKLIST%20-%20Prisoners.docx) to prepare your description of the additional protections to ensure that you have provided sufficient information.
       3. Children (any persons under the age of majority in their state of residence): review [HRP-416-CHECKLIST-Children](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/B9HM9AK8BMTK1FLB4QAO8QR97B/HRP-416%20-%20CHECKLIST%20-%20Children.docx) to ensure that you have provided sufficient information.
       4. Decisionally impaired: review [HRP-417-CHECKLIST-Cognitively Impaired Adults](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/F151R3ECRG34J12F8S6Q9MKPF9/HRP-417%20-%20CHECKLIST%20-%20Cognitively%20Impaired%20Adults.docx) to ensure that you have provided sufficient information. You should also provide justification for the inclusion of this population and describe the importance of the knowledge to be gained; explain how including this population represents the least degree of impairment compatible with the aims of this study; and specify how risks are minimized and/or whether the risks or discomforts are greater for this population.

**10.0 Recruitment and Compensation Methods**

Provide the following information about recruiting individuals for the purpose of prospectively collecting their information.

* 1. Recruitment Process [describe when, where, and how potential participants will be recruited. For example, will recruitment advertisements be sent to potential participants? Will advertisements be posted publicly? If recruitment will involve a non-FSU site, describe whether site approval for recruitment is required, and attach documentation of site approval]:
  2. Identification of Potential Participants [describe the methods that will be used to identify potential participants. Describe whether participants will self-identify in response to posters, mailings, emails, or other outreach or communications, or whether participants will be recruited based on information contained in other records (e.g., health, service, student, program, work, government, law enforcement/criminal justice, civic or other records that may contain individuals’ contact information, including records already held by the PI)]:
     1. For information contained in any records, explain how the researcher has authorized access to these records:
     2. Identify who will make initial contact with potential participants for recruitment purposes:
     3. Identify whether the records will contain individuals’ health information, and how the PI will document that these individuals have authorized use or disclosure of their health information for the repository, or that the entity whose records will be used or disclosed for the repository has approved of a waiver or alteration of the individuals’ authorization:
  3. Recruitment Materials [describe the materials that will be used to recruit participants; submit final copies of these materials. If advertisements are recorded for broadcast, submit the audio/video recording. Alternatively you may submit drafts; however, when any draft is finalized, you must submit the final materials as a study modification]:
  4. Compensation or Payments
     1. Indicate whether participants will be paid, reimbursed, receive any other item of monetary or nominal value or (for students) receive extra credit:
     2. Describe the type of compensation and the maximum value participants may receive:
     3. Describe when compensation will be provided, including a schedule, and whether payments will be prorated for multiple visits/sessions:
     4. Describe who will receive payments, if not the participants themselves:

**11.0 Consent Process**

* 1. General Consent Procedures: Describe the consent process, including:
     1. Location where the consent process will take place (be specific and describe the location, i.e., in person at the participants’ home, work, school or other specified location; telephone; email; through the repository web site; other web site or internet):
     2. What if any waiting period is there between informing the prospective participants or their legally authorized representative[[3]](#endnote-3) and obtaining the consent:
     3. By whom and how will it be determined that a potential participant or their legally authorized representative understands the information about the repository (provide name and position, affiliation and process to determine participants’ understanding):
     4. What if any process will be implemented to ensure a participant’s or legally authorized representative’s ongoing (after their initial) consent:
     5. If you will document consent in writing (participants or their legally authorized representative will be provided with a print-on-paper or electronic version of the consent form) be sure to submit the appropriate and separate (i.e., not embedded in the IRB application or data collection instrument) consent document for IRB review.
     6. Indicate whether you will ask participants or their legally authorized representative if they wish to be re-contacted for future research studies for which they might be eligible (Note that this must align with the consent form, as applicable):
  2. Waiver or Alteration of Consent Process (i.e., when consent will not be obtained, or when required consent elements will be altered) [indicate whether you are requesting a consent alteration or waiver; if so, respond to the item below]: 
     1. Review [HRP-410 - Checklist - Waiver or Alteration of Consent Process](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/2I87GMSRBLPKDAAO9REABQD411/HRP-410%20-%20CHECKLIST%20-%20Waiver%20or%20Alteration%20of%20Consent%20Process.docx) to ensure that you have provided sufficient information in this protocol for the IRB to make this determination. Do not fill out the checklist. [describe below how your protocol meets the requirements noted in HRP-410]:
  3. Waiver of Written (print-on-paper or electronic, and signed, including electronically) Documentation of Consent (i.e., when written and signed consent will not be obtained) [indicate whether you are requesting a waiver of written consent; if so, respond to the item below]:
     1. Review [HRP-411 – Checklist – Waiver of Written Documentation of Consent](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/ANHTPT6TV0V4756ON1J7TIDT2B/HRP-411%20-%20CHECKLIST%20-%20Waiver%20of%20Written%20Documentation%20of%20Consent.docx) to ensure that you have provided sufficient information in this protocol for the IRB to make this determination. Do not fill out the checklist. [describe below how your protocol meets the requirements noted in HRP-411]:
     2. If you will not obtain written consent, but instead provide verbal consent, then be sure to submit the appropriate verbal consent script.
  4. Non-English Speaking Participants [if you are not planning to invite non-English speaking participants to provide their information for the repository, provide a scientific rationale for their exclusion; otherwise, complete the items below]:
     1. Describe the process to ensure that the oral or written information provided to non-English speaking participants will be in their own language. Indicate the language that will be used by those obtaining consent:
     2. If you will be using an interpreter during recruitment, consent, data collection, or data analysis, specify how you will identify an appropriate interpreter and, for an outside interpreter, what the provisions will be for protecting the confidentiality of participants:
     3. A Short Form of informed consent (also requiring signature of the participant as well as a witness, unless waived) may only be used for participants with limited English language proficiency, but the Short Form must be used in conjunction with a written summary (a version of the standard Informed Consent form but not requiring a signature). The Short Form consent document or script must be translated into the language for non-English speaking participants who will be asked to provide their information for the repository, and both the English and translated forms must be provided to the IRB. Once approved by the IRB, the translation be certified by a reputable translation service. Once certified, submit the translated consent document and the certification must be submitted as a modification to the IRB for review and approval.
  5. Participants Who Are Not Yet Adults or Emancipated (e.g., minor children who have not reached the age of majority, which in Florida is 18 years of age):
     1. Indicate whether you will recruit individuals who are not yet adults or emancipated; if you indicate No, proceed to section 11.6:
     2. Determining whether an individual may consent [describe the procedure that the study team will use to confirm that an individual who is asked to provide information for the repository is of legal age to provide consent in every jurisdiction from which individuals will be recruited. As state laws may vary on age of consent, the age of consent must be examined for every state from which individuals will be recruited]:
        1. In Florida: [for research conducted in Florida, review [HRP-013 – SOP – LARs, Children, and Guardians](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/UJTJH6BT3CD45DLD4EAE89VS73/HRP-013%20-%20SOP%20-%20LARs%2C%20Children%2C%20and%20Guardians.pdf) to be aware of which individuals in the state meet the definition of “children”]
        2. Outside of Florida: [review information about the age of consent in any jurisdiction other than Florida and in which research will be conducted, and be prepared to provide this information if requested by the IRB; indicate below whether research with children will be conducted outside of Florida]:
     3. Indicate below how parental permission will be obtained:
        1. Permission will be obtained from both parents (unless you are certain and are able to provide documentation that one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child):
        2. Permission will be obtained from only one or neither parent (even if the one or both parents are alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child):
        3. If you will not obtain parental permission, be sure to review [HRP-416 – Checklist - Children](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/B9HM9AK8BMTK1FLB4QAO8QR97B/HRP-416%20-%20CHECKLIST%20-%20Children.docx) to ensure that you have provided sufficient information in this protocol for the IRB to make a determination that waiver of parental permission and waiver of documentation of parental permission is justified. Do not fill out the checklist [describe below how your protocol meets the requirements noted in HRP-410 and HRP-411 for waiving parental permission and waiver of documentation of parental permission]:
        4. Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to or provide permission on behalf of the child:
     4. Assent. Assent means an affirmative agreement by individuals who are not yet adults or emancipated (e.g., minor children who have not reached the age of majority) to decide to provide their information for the repository. Assent is in addition to parental permission.
     5. Indicate whether assent will be obtained from all, some, or none of the children:
     6. If assent will be obtained from some children, indicate for which children assent will be obtained (e.g., 7-13 year-old children only; 14-17 year-old children only:
     7. When assent is obtained, describe whether and how assent will be documented:
     8. If you will document assent in writing (participants and/or their parent(s) will be provided with a print-on-paper or electronic version of the assent form) be sure to submit the appropriate and separate (i.e., not embedded in the IRB application or data collection instrument) assent document for IRB review.
     9. If you will not obtain written assent, but instead obtain verbal assent, then be sure to submit the appropriate verbal assent script.
  6. Adults Unable to Consent. Generally all adults should be presumed capable of providing informed consent to participate in research unless there is specific evidence that an individual’s condition or disability would impair reasoning or judgment, or other indication that the individual is unable to understand and choose whether to participate in research. For adults that are not able to provide legally effective consent, their legally authorized representative may provide consent (refer to the Consent Process section above). However, an adult that is not able to provide informed consent may be able to assent to participation. The IRB will determine whether the assent of some or all such adults is required, taking into account the condition and psychological/ or emotional states of the adults involved.
     1. Indicate whether you will recruit adult individuals who are unable to provide consent; if you indicate No, proceed to section 11.7:
     2. Permission, for research conducted in Florida: [review [HRP-013 – SOP – LARs, Children, and Guardians](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/UJTJH6BT3CD45DLD4EAE89VS73/HRP-013%20-%20SOP%20-%20LARs%2C%20Children%2C%20and%20Guardians.pdf) to be aware of which individuals in the state may, in order of priority, provide permission on behalf of adults who are unable to provide consent, then list the individuals from whom permission will be obtained (e.g., health care surrogate; durable power of attorney; judicially appointed guardian; participant’s spouse)]:
     3. Permission, for research conducted outside of Florida: [review other jurisdictions’ authoritative information about individuals that may provide permission on behalf of adults who are unable to provide consent, and be prepared to provide this information if requested by the IRB; then, list the individuals from whom permission will be obtained. Legal counsel’s review may be required in advance of IRB review and approval]:
     4. Assent: Assent means an affirmative agreement by individuals that are unable to provide consent, to decide to provide their information for the repository. Assent is in addition to permission of legally authorized representatives. Regardless of a legally authorized representative’s permission, the dissent or refusal of an individual to have their information provided for the registry must be honored.
        1. Indicate whether assent will be obtained from all, some, or none of the participants who are unable to provide consent :
        2. If assent will only be obtained from some of the participants who are unable to provide consent, indicate which participants will be asked to provide assent and which will not:
        3. If assent will not be obtained from some or all participants who are unable to provide consent, explain why not:
        4. Describe how assent of the participants will be documented, and the process to document assent:
     5. If you will document assent in writing (participants and/or their legally authorized representative will be provided with a print-on-paper or electronic version of the assent form) be sure to submit the appropriate and separate (i.e., not embedded in the IRB application or data collection instrument) assent document for IRB review.
     6. If you will not obtain written assent, but instead obtain verbal assent, then be sure to submit the appropriate verbal assent script.
  7. Re-contact:
     1. Indicate whether participants may be re-contacted regarding their information in the repository; if you indicate No, proceed to section 11.8:
     2. If you may re-contact participants, describe the purposes for re-contact (e.g., obtain new or updated information, confirm continuing interest and/or consent); how and by whom participants will be re-contacted; and how re-contact and participants’ responses will be documented. Make certain that the consent form adequately informs participants of the intention for future contact and includes a statement to opt in to future contact:

**12.0 Sharing Repository Information with Participants**

* 1. Indicate whether any individual or aggregate results or outcomes derived from interactions or interventions with repository participants may be shared with participants or their legally authorized representatives:
  2. Make certain that the consent form adequately informs participants of the intention to share or not to share individual or aggregate results or outcomes with repository participants.
  3. If either individual or aggregate results may be shared with repository participants, describe what and how results will be shared:

**ENDNOTES**

1. *Interactions* include communications or interpersonal contacts between an investigator (researcher) and a human subject. Examples of interactions include, for example, interviews, focus groups, surveys or similar interpersonal contacts and communications with human subjects. Interactions may involve the collection and use of information for research purposes. Studies may include both interactions and *interventions* (see *interventions* description below). [↑](#endnote-ref-1)
2. *Interventions* include both physical procedures by which information or biospecimens are gathered from human subjects, and manipulations of human subjects’ environment. Examples of interventions include, for example (a) actions and activities such as exercises, body movements, stress tests and human factor measures; (b) medical, psychological and behavioral examinations, use of and tests involving medicinal or nutritional supplements, and implantation or application of medical devices or other sensors; (c) taking biological specimens such as blood, sputum and any other body tissue or fluids; and (d) manipulating human subjects or their environments such as having human subjects watch a video, look at images, read materials or take notes, alter or test a human subject’s lived, learning or occupational environment, complete computer tasks, and undergo training. Interventions will generally involve *interactions* with human subjects (see *interactions* description above). [↑](#endnote-ref-2)
3. A *legally authorized representative* is an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures(s) involved in the research. If there is no applicable law addressing this issue, then this individual is recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject’s participation in the procedure(s) involved in the research. See [HRP-013 – SOP – LARs, Children, and Guardians](https://myrampirb.research.fsu.edu/IRB/sd/Doc/0/UJTJH6BT3CD45DLD4EAE89VS73/HRP-013%20-%20SOP%20-%20LARs%2C%20Children%2C%20and%20Guardians.pdf) for who may serve as a legally authorized representative at this institution. [↑](#endnote-ref-3)