**Protocol Title:**

**Principal Investigator:**

**Department:**

**Funding Source** (if no external funding for the project, enter "University")**:**

 **If externally funded, Coeus Institute Proposal # for the project:**

**Is this an undergraduate student project? Yes**       **No**       **If yes, name of student:**

**(1**) Attach to this form the information required for a complete protocol, as outlined beginning on page 3 of this form, Instructions & Information. Additional information about preparing a protocol can be found [here](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/preparing-complete-irb-protocol).

**(2)** Select the appropriate type and category number of review. See descriptions of [Expedited](#Expedited) categories. If no expedited categories completely describe the proposed research, select “Full Board.”) **[ ]  Expedited #** **[ ]  Full Board**

**(3) Investigator Conflict of Interest Statement:**

 [The *Brown University Conflict of Interest Policy for Officers of Instruction and Research*](https://www.brown.edu/research/COIpolicy) *(“COI Policy”)* defines the term “Investigator” as “the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research.” Using this definition of “Investigator,” please ensure that all Investigators on this protocol answer questions 3(a) and 3(b) below [attach additional sheets for any Investigators who are not the PI; they only need to answer 3(a) and 3(b)]:

 *(a)* Have you completed a conflict of interest disclosure (i.e. *Annual COI Assurance Form* **or** *COI Reporting Form*) within the past 12 months and is it accurate and up-to-date as of the time of this submission, as required by the [COI Policy](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/ori-staff-directory/coi-policy)? (You may access the system [here](https://infoed.brown.edu/EnableWeb/Portal/Home) to confirm.)

 **[ ] YES** **[ ] NO**

*(b)* Do you have a [significant financial interest](https://www.brown.edu/research/COIFAQ#interest) (SFI) that is related to this research protocol? “Related” could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI and/or that the SFI could be affected by the proposed research or its results. **[ ] YES** **[ ] NO**

**Principal Investigator certifies to the following: *(1)*** The rights and welfare of the participants are adequately protected. ***(2)*** The risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained. ***(3)*** This protocol is accurate and complete; if the project scope or design is later changed, the PI will resubmit for review. ***(4)*** All research personnel, including the PI, has been, or will be, adequately educated in human research protections prior to beginning work on the project.

**Principal Investigator signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_

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(Advisor’s signature is required for all graduate/medical student projects.)

**Advisor certifies to the following:** Advisor has read the protocol and approves of the project.

Advisor’ name:

**Advisor's signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date:**  \_\_\_\_\_\_\_\_\_\_\_\_\_

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***For IRB Use Only***

**Signature of the Authorized Official of the IRB: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Date of IRB approval*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

**Protocol Checklist and Submission Procedures**

**This page must be COMPLETED and INCLUDED as page #2 of your submission**

To ensure the quickest turnaround time possible, please prepare your protocol for IRB review (full board or expedited) with all the following information that is applicable to your project, number the pages and note the page numbers of each item on the checklist. Refer to the following instructional pages for more information about the required elements of an IRB protocol.

|  |  |  |
| --- | --- | --- |
| Protocol component | Included? | Page number(s): |
| 1. IRB Form #1
 | Yes |  |
| 1. Lay Summary
 | Yes |  |
| 1. Protocol Narrative:
 |  |  |
|  Aims & Methodology | Yes |  |
|  Informed consent procedure | Yes |  |
|  Consent/Assent documents/scripts | Yes  N/A |  |
|  Risks and Benefits | Yes |  |
| 1. Attachments (if applicable):
 |  |  |
| 1. Interview/survey/focus grp instruments
 | Yes  N/A |  |
| 1. Letters/e-mails to participants
 | Yes  N/A |  |
| 1. Recruitment materials
 | Yes  N/A |  |
| 1. Letters of support/permission
 | Yes  N/A |  |
| 1. Other IRB approvals
 | Yes  N/A |  |
| 1. Data Use Agreements
 | Yes  N/A |  |
| 1. Protocol addenda/appendices (as needed)
 | Yes  N/A |  |
| 1. Funding application
 | Yes  N/A |  |

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**Protocol Submission Procedures**

**Full Board Protocols:** Submit the complete protocol (as identified above) to the Human Research Protection Program (HRPP), by e-mail in ONE PDF file to IRB@brown.edu in sufficient time to meet the agenda deadline (see [the HRPP Meetings and Deadlines page](https://www.brown.edu/research/conducting-research-brown/preparing-proposal/research-integrity/hrppirb-home-page/irb-meetings-deadlines) for upcoming full board meeting dates and submission deadlines).

**Expedited Protocols:** There is no specified deadline for submission of Expedited Protocols. Review time varies depending upon the project. The average review time is approximately 4 weeks. Please submit the complete (as identified above) protocol to the Human Research Protection Program (HRPP), by e-mail in ONE PDF file to IRB@brown.edu, with sufficient time to allow for review and revisions, if necessary.

{Note that the IRB (not the investigator) makes the final determination of whether a protocol is full board or expedited. Thus, full board review may be necessary even if you suggest expedited review in your protocol.}

**What Makes a Complete Protocol:**

1. ***IRB Form #1*** (completed and signed by PI and faculty advisor if PI is a graduate student)

1. ***Lay-person summary.*** A brief (1-3 paragraph) description of the proposed project written in lay language. (Note: This summary will also be required for future related submissions such as progress reports and modification requests.)

1. ***Protocol Narrative – to include the following components:***

***Project aims and methodology*** (what, why, how, and who). Describe the specific aims of this project and the methodologies to be used. Including:

* + - A detailed description of the project (purpose, all procedures to be conducted with human subjects)
		- participant population (criteria for inclusion/exclusion including the attempts made to include women and members of minority groups)
		- recruitment procedures (how potential participants will be identified, approached and selected/screened)
		- how confidentiality of data will be maintained (where data is kept, who has access to it, and how it is kept secure).

***Informed Consent***. Describe the methods to be used in securing the informed consent of participants. If involving minors, describe how assent and parental permission will be obtained. If an informed consent/assent document is to be used, attach it. Written documentation of consent is strongly recommended. If the PI feels that a verbal consent procedure is more appropriate for the population and circumstances, a rationale for the alternate procedure is required along with a written version of the consent script/information sheet.

Whether written or verbal, the basic elements of informed consent must be present as outlined on the following page.

***Risks and Benefits***. This section includes a description of the potential risks to participants and how the project is designed to minimize those risks, as well as a description of the anticipated benefits, whether to the individual or to the body of science. If no direct benefits to participants are expected, this should be stated.

1. ***Attachments*** – attach the following to your protocol application, if applicable.
2. ***Interview/Survey Instruments/Focus group topics***. A copy of all interview or survey instruments must be attached. If no formal instruments will be utilized, as may be the case in semi-structured/qualitative interviews, provide a list of sample questions/topics that encompass the scope of the activity.
3. ***Anticipated letters/emails to participants*** (invitations, reminders, etc.)
4. ***Recruitment materials*** (fliers, brochures, scripts for radio/tv, web pages, Craig’s List ads, etc.)
5. ***Letters of support/permission*** (If approval is needed from any collaborating agencies/institutions/groups prior to the conduct of some or all of the research project, provide documentation of such approvals in writing. This includes entities such as schools, community organizations, clinics, doctors' offices, and other private organizations, with the exception of local hospitals affiliated with Brown University.)
6. ***Other IRB approvals*** (If other IRBs need to review the project, provide copies of those IRB approvals or determinations (if available or applicable.)
7. ***Data use agreements*** – for secondary data analysis studies that require a DUA, submit a draft or final document with the protocol.
8. ***Protocol addenda/appendices*** – provide any completed addendum/appendix documents, as appropriate for study procedures. These could include the Prisoner Checklist for research with prisoners or the Medication Management Addendum for research that includes the administration of drugs to participants. See the [HRPP Forms page](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies) for a complete list of required addenda and appendices.
9. ***Application/proposal for funding/support*** (if an application/proposal of any kind was/will be submitted to an *external* sponsor in order to obtain funding/support of the project, attach a copy of the full application/proposal, including ALL budget pages).

**The following are the basic elements of informed consent:**

1. A statement that the study involves Brown University research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

2. A description of any reasonably foreseeable risks or discomforts to the subject;

3. A description of any benefits to the subject or to others which may reasonably be expected from the research;

4. A statement of appropriate alternative procedures (or courses of treatment), if any, that might be advantageous to the subject;

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs during the conduct of the study; and, if so, what they consist of, or where further information may be obtained;

7. An explanation of whom to contact for answers to pertinent questions about the research (PI and advisor if applicable) and research participants' rights (HRPP), and whom to contact in the event of a research-related injury to the subject; and

8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled; and s/he may discontinue participation at any time without penalty or loss of benefits to which s/he is otherwise entitled.

(See OHRP regulations at 45CFR46, section 46.116 for additional elements of information that may be provided to participants in the consent procedure, when appropriate.)

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either that the:

1. Only record linking the participant and the research would be the consent document and the principle risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA-regulated. Participants will be asked whether they want documentation linking them with the research, and their wishes must govern. (Example: domestic violence research where the primary risk is discovery by the abuser that the participant is talking to researchers.);

OR

1. The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB requires the investigator to provide in the application materials a written summary of the information to be communicated to the participant, and the IRB will consider whether to require the investigator to provide participants with a written statement regarding the research.

**EXPEDITED REVIEW1 – applicability and categories of review**

*Applicability*

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by [45 CFR 46.110](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.110) and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

*Expedited Categories of Review*

(1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.); or

(b) Research on medical devices for which

(i) an investigational device exemption application (21 CFR Part 812) is not required; or

(ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children2, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

*Expedited Categories of Review (continued)*

(3) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human research participants. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human research participants. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(8) Continuing review of research previously approved by the convened IRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or (b) where no participants have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1 An expedited review procedure consists of a review of research involving human research participants by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

2 Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a).