Form 01: IRB Application

Office of Research Integrity

researchintegrity@fau.edu

<https://www.fau.edu/research-admin/research-integrity/human-subjects-irb/>

**INSTRUCTIONS**:

This application must be used for all studies undergoing review by the FAU Institutional Review Board (IRB).

* **Training:** For new projects, continuing reviews, or personnel changes, ensure verification of mandatory training is submitted with submission to the IRB. This means completion of either the Biomedical or Social Behavioral investigators courses via CITI (citiprogram.org). If HIPAA Privacy Rule regarding protected health information (PHI) applies to the project, the Information Privacy & Security (IPS) for Investigators must also be completed.
* **Consenting/Assenting:** If prospectively enrolling participants, upload the applicable consent or assent, accessible via IRBNet.
* **Data Collection:** Upload all supporting materials, including but not limited to recruitment tools, data collection tools (surveys, etc.), letter of support, sponsor protocols, or other documents, as applicable.
* **Signatures:** Obtain all required signatures prior to submission to via IRBNet. For new projects and those requiring continuing review, this is the Principal Investigator (PI), and Department Chair. For amendments, this is the PI only. *Be certain to check with the PI’s college to determine if other signatories such as the Associate Dean for Research or other reviewing official must sign. This requirement varies by college.* *. If PI is also Department Head, obtain electronic signature from the Dean/supervisor (person next in charge ).*

If this project involves any of the following, also complete and submit the Greater than Minimal Risk Protocol.

* Research involving drugs and medical devices that may require FDA review and/or have not the probability and magnitude of harm or discomfort anticipated in the research would be greater than what a participant may encounter during routing daily life or during the performance of routine physical or psychological examinations or tests.

**Amendments:** When amending the application/ protocol, add date of change and write the change in the section that is being amended. Then complete the amendment table at the end of this document.

*Example*:

Original submission on 2/1/2022: Participants will be asked to complete a survey

Amendment on 10/1/2022: Participants will be asked to complete a survey 10/1/2022– and be interviewed

**Notes:**

1Add the respective names in IRBNet, Click “Send project mail” and send email to ask your respective principal investigator and department head to review and provide their signatures *BEFORE* submitting.

2Complete the document sections as they pertain to your study. To facilitate an efficient review, do not copy and paste from a proposal document (funding proposal, dissertation proposal, etc.) into the IRB application. Doing so may result in delays in the review of your research.

**SECTION I: Project Overview – Get Started Panel**

1. Study Title: Click or tap here to enter text.
2. Study Personnel:– **Research Team Panel**

*Principal Investigator (PI) must be fulltime FAU faculty/ employee or otherwise meet PI eligibility criteria. For purposes of the IRB, only one person has responsibility of PI.*

|  |  |
| --- | --- |
| **PI Name:**Click or tap here to enter text. | **PI Email:**Click or tap here to enter text. |
| **PI Phone Number:**Click or tap here to enter text. | **PI College/Area:**Click or tap here to enter text. |
| **PI Department:** Click or tap here to enter text. | **Campus:**Click or tap here to enter text. |
| **Additional Contact (Student, Lab Manager, etc):** Click or tap here to enter text. | **Additional Contact Email:**Click or tap here to enter text. |
| **Additional Contact Phone Number:**Click or tap here to enter text. | **Additional Contact Role:**Click or tap here to enter text. |

1. Other Study Personnel – Research Team Panel

*If other personnel are engaged in the study, complete and submit* *“Appendix 1f\_Personnel Supplement” with this application.*

1. Summary of the study using lay language (**200 words or less**): **– Primary Info Panel**

Click or tap here to enter text.

1. Is this a student Project? **– Primary Info Panel** [ ]  Yes [ ]  No
2. Type of project: Choose an item. **– Primary Info Panel**

*Please review Policy 10.3.3, "Defining Human Subjects Research" to ensure your project requires IRB review.*

1. Is the study externally funded? **– Primary Info Panel** [ ]  Yes [ ]  No

7a. If yes, provide the following information for the funding source: **– Primary Info Panel**

|  |  |
| --- | --- |
| Sponsor NameClick or tap here to enter text. | Sponsor Type (Federal, Foundation, Nonprofit, Other institution)Click or tap here to enter text. |
| Grant/ Contract Number in NovelutionClick or tap here to enter text. | Is FAU the primary funding recipient: [ ]  Yes [ ]  No |
| Sponsored Project Title (if different from IRB)Click or tap here to enter text. |

1. Is this a multi-site Study (i.e. clinics, other universities, hospitals, K-12 schools, etc.)? **– Review Type Panel (appears when “No” is selected to the first question**  [ ]  Yes [ ]  No

8a. If yes, list the collaborating sites: **– Review Type Panel**

Click or tap here to enter text.

*The 2018 Common Rule requires use of a Single IRB (sIRB) for all cooperative research that is subject to the Common Rule. These requirements apply to any studies approved by the IRB on or after January 20, 2020 and so it is possible that your study may require the use of a Single IRB unless:*

*i. The study is NOT federally funded*

*ii. The study is federally funded AND solely involves international sites besides FAU*

*iii. The collaborating site is the VA, or another national IRB required by law (such as a tribal IRB)*

1. Is FAU *only* acting as the data coordinating site for this study? [ ] Yes [ ] No [ ] N/A
2. FAU’s Role in the Project: **– Review Type Panel**

*If seeking a collaborative Institutional Authorization Agreement (IAA or IRB reliance) with an external IRB, complete and submit Form 15\_IRB Reliance Request Form.* *\*Note\* Exempt projects are not eligible for IRB Reliance.*

[ ]  Sole Site (FAU is the only IRB involved in this study)

[ ]  FAU is the Lead Site (and the other site(s) will be relying on FAU)

[ ]  FAU is the Lead Site (and each site is doing their own review)

[ ]  FAU is a Participating Site (and will rely on another IRB for review)

[ ]  FAU is a Participating site (and each site is doing their own review)

**SECTION II: Objectives and Justification**

1. Objective(s) **– Protocol Description Panel: Purpose, Goals, and Research Question**

and justification of the study including the purpose, **– Protocol Description Panel: Background Information & Justification**

research question(s), **– Protocol Description Panel: Purpose, Goals, and Research Question**

hypothesis, and relevant background information. **– Protocol Description Panel: Background Information & Justification**

1. Describe how the research results will be used and will contribute to generalizable knowledge. **–**

Click or tap here to enter text.

1. ~~Please choose yes for at least one of the following: Your study may be Social/Behavioral/Educational and/or Biomedical. If you are unsure, default to the PI’s discipline.~~

~~13a. Are you conducting a social, behavioral or educational research study?~~ [ ]  ~~Yes~~ [ ]  ~~No~~

~~13b. Are you conducting a biomedical research study?~~ [ ]  ~~Yes~~ [ ]  ~~No~~

1. Are you conducting secondary use research*?* Meaning data that was collected for non-research purposes related to medical care, school grades, employment records, public health data? **– Protocol Description Panel: Secondary use of data & Secondary Research Panel**

[ ]  Yes [ ]  No

1. Are you conducting secondary research? Meaning analyzing data that was previously collected for research purposes **– Protocol Description Panel: Secondary use of data & Secondary Research Panel**

[ ]  Yes [ ]  No

*If yes, provide a copy of the approved consent document and any other study related documents such approvals, etc.*

1. Anticipated study period
2. Proposed dates for data collection and/or data analysis **– Protocol Description Panel: Anticipated Start date of the research**

Click or tap here to enter date range of anticipated start and end dates

b. Retrospective data analysis only: Provide the exact date range (MM/DD/YYYY- MM/DD/YYYY) from which data will be accessed. All data accessed for this research must be in existence at the time of the initial IRB submission in order to meet the definition of “retrospective.” **– Protocol Description Panel: Anticipated Start date of the research**

Click or tap here to enter date range of start and end dates

**SECTION III: Study Details**

1. Provide a step-by-step description of the research procedures, study schedule, and interactions with human participants. If multi-visit study, also include a schedule of research activities. [Click to see a sample for reference](https://drive.google.com/file/d/1qA4Ck2d6WR6Z9zm9iPrbeWDnj5yyNKcU/view?usp=sharing). **– Protocol Description Panel: Describe in detail your research design and methodology. Use nontechnical language to describe what participants will do and/or what information will be collected about them*. Note: Study population details are in a separate question***

*Note: If using standard practice vs research, clearly detail which activities would happen*

*independent of the research (standard) and which are research.*

* *What will participants be asked to do*
* *Where will the research take place*
* *When will the research take place and for how long*

Click or tap here to enter text.

1. Will participants be audio-recorded, video recorded, or photographed? Check all that apply. **– Privacy & Confidentiality Panel: Will any personally identifiable information (PII) be collected from or about participants? Select “Yes” > Select ALL PII that will be obtained (Audio, Video, there is no option for photo but for “Full face and comparable image”)**

[ ]  Audio-recorded [ ]  Video-recorded [ ]  Photographed [ ] N/A

18a. If yes, Describe in detail the transcription process of the recordings **– Privacy & Confidentiality Panel: Will any personally identifiable information (PII) be collected from or about participants? Select “Yes” > Describe the coding system (link) that will be used to protect against disclosure of PII. (Answer only if applicable, otherwise indicate N/A)\***

along with the final disposal of the recordings. **– Privacy & Confidentiality Panel: When will identifiers be removed from the dataset and/or the records? State for how long research records will be maintained**

Describe if, how, and when recording or photographs will be destroyed. **– Privacy & Confidentiality Panel: When will identifiers be removed from the dataset and/or the records? State for how long research records will be maintained**

Click or tap here to enter text.

1. Explain inclusion of recordings in presentations or for any reason other than data analysis. If you wish to use recordings or photographs for presentation purposes, please justify. If yes, please be certain to include an audio-visual and/or photo release with your package. If obtaining signed consent as part of this study, including the release statement in the consent form is an option. **– Privacy & Confidentiality Panel: Why is it necessary to maintain PII?**

Click or tap here to enter text.

**SECTION IV: Study Population**

1. General description of the study population. **– Protocol Description Panel: Describe the sampling plan, the sample size or study group(s)**

Click or tap here to enter text.

1. Describe the inclusion criteria. Include all criteria that every potential participant must satisfy, to qualify for study entry. Provide a statement that individuals must meet all of the inclusion criteria in order to be eligible to participate in the study and then list each criterion and how it will be verified. **– Recruitment panel**

Click or tap here to enter text.

1. Describe exclusion criteria. If specific populations are excluded (e.g., elderly or pediatric populations, women or minorities, those with limited English proficiency), provide a clear and compelling rationale and justification, to establish that inclusion is inappropriate with respect to the health/safety of the participants or the purpose of the research. **– Recruitment panel**

Click or tap here to enter text.

1. Locations where participants will engage in FAU IRB supervised research activities, and/or from which data are retrieved: **– Protocol Description Panel: Specify where the research will be conducted.**

|  |  |
| --- | --- |
| Organization/ Facility/ Location | Research Activities Performed (recruitment, consenting, data collection, etc) |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Click or tap here to enter text. | Click or tap here to enter text. |
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| Click or tap here to enter text. | Click or tap here to enter text. |
|  |  |

1. If your study involves research activities (i.e. recruiting, obtaining records from) at an external site (non-FAU), do you need permission to perform the activities at the site(s)? *NOTE: This is not informed consent from participants, but rather administrative permission for involvement of the site in the research study.*

 [ ]  Yes (If yes, upload a site permission letter, or letter of cooperation)

 [ ]  No

 [ ]  NA (does not involve non-FAU site)

1. Number of participants

*For a multi-center study, both local and total accrual numbers must be provided if FAU is acting as the IRB of Record. If this study does not involve multiple sites or the number of participants at other sites is unknown, complete only the “Locally” row. Participants are considered to be enrolled and count towards your total number of participants once they begin study procedures, which excludes screening procedures. A list of participants who sign the informed consent document but did not meet inclusion criteria should be kept for your files.*

25a. MAXIMUM NUMBER of participants to be enrolled: **– Recruitment panel**

|  |  |  |
| --- | --- | --- |
|  | Annually | Entire Study |
| Locally (by FAU researchers) |  # |  # |
| Study-wide (Multi center) |  # |  # |

25b. If existing data or records will be accessed, maximum number of records:

|  |  |  |
| --- | --- | --- |
|  | Annually | Entire Study |
| Locally (by FAU researchers) |  # |  # |

1. Age range of participants # - # **– Recruitment panel**
2. Special Populations to be involved in the research. **– Review Type Determination panel**

*For any population selected, please provide a justification why the population is necessary and explain additional steps that will be taken to protect the participants*

[ ]  Impaired decision making capacity (See policy 10.3.2)

[ ]  Developmentally Disabled persons

[ ]  Employees directly supervised by PI or sub-investigator Employees of research site or sponsor

[ ]  Limited literacy or non-readers

[ ]  Low income or uninsured persons

[ ]  Military personnel to be recruited by military personnel

[ ]  Minors (underage of majority in jurisdiction where research will be performed) (See policy 10.3.6)

[ ]  Nursing home residents recruited in the nursing home (See policy 10.3.2 )

[ ]  Persons in treatment for a physical, mental, or emotional condition

[ ]  Pregnant women/fetuses/ neonates of undetermined viability

[ ]  Prisoners or persons with court sanctioned limited freedoms (including juvenile justice system)

[ ]  Students of PI or study staff (See policy 10.3.7 and /or policy 10.3.8)

[ ]  Students to be recruited in their educational setting (i.e. in class or at school) (See policy 10.3.8)

[ ]  Wards of the state (e.g. foster children, juveniles in detention) (See policy 10.3.6)

[ ]  Others vulnerable to coercion (Specify): Click or tap here to enter text.

**SECTION V: Recruitment**

1. Does any member of the research team have an existing relationship with any potential **participants**? **– Recruitment panel**

[ ]  Yes [ ]  No

28a. If yes, explain the relationship and describe steps that will be taken to minimize risks to participants and reduce potential for bias. Address any conflict of role that this relationship poses:

Click or tap here to enter text.

1. Step by step recruitment process. **– Recruitment panel**

*This section is only asking about recruitment procedures – how you will find and approach potential participants. The next section asks more detailed information about the informed consent process which should not be described here. Provide copies of all recruitment materials.*

*Consider including the following information when describing recruitment process:*

* *How will potential participants be identified?*
* *Who will approach potential participants to take part in the research study? Where participants will be approached?*
* *How will potential participants be asked to participate in the study? What will be done to protect individuals' privacy in this process?*
* *Describe all of the recruitment techniques that will be used, if any (e.g., email, flyers, other print media, social media, verbal announcements, snowball sampling).*
* *Explain if participants will be recruited through the research team accessing existing records? Such as medical, student, employment, prisoner, health and human services, financial, etc.*

Click or tap here to enter text.

**SECTION VI: Informed Consent Process**

1. Consent method being requested for the study **– Informed Consent Panel: Will all participants provide informed consent for themselves? When no is selected, questions below will appear**

[ ]  Written consent document with signature (obtaining participant or Legally Authorized Representative Signature)

[ ]  Waiver of documentation of consent (electronic or verbal consent)

[ ]  Waiver of consent process

[ ]  Waiver or alteration of some of the required elements of consent

1. Describe the informed consent process, assent process, and parental permission process. **– Informed Consent Panel**

*Consider the following:*

* *Who will conduct consent?*
* *Where will consent occur?*
* *When will consent occur?*
* *If obtaining signed consent documents, where will they be maintained and by whom?*

Click or tap here to enter text.

**SECTION VII: Waiver of Documentation of Consent or Waiver of Consent**

*Note: If requesting a waiver of documentation of consent, the IRB requires the investigator to provide subjects with an information sheet regarding the research. Submit the information sheet (or waiver of documentation of consent template) with your application in the Initial Review Submission Packet. Please be specific in explaining why either statement is true for your research. If not requesting a waiver for consent process, you may proceed to the next section.*

1. To request a **waiver of documentation** of informed consent (you will obtain informed consent but not have the participant sign), please select at least one of the following statements: **– Informed Consent Panel: Are you requesting to waive the signature requirement for informed consent?**

[ ]  The only record linking the participant and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. If you answer this question and the IRB grants the waiver of written consent request, each participant must be asked whether the participant wants documentation linking the participant with the research and the subject’ s wishes will govern.

[ ]  The research presents no more than a minimal risk of harm to participants and involves no procedures for which written consent is normally required outside the research context. (e.g., asking individuals on the street about eating habits).

Please justify.

Click or tap here to enter text.

1. To request a **waiver of consent**, ***all of*** the following must be true: **– Informed Consent Panel: When yes is selected to: Are you requesting a waiver and/or alternation of informed consent**
* The research involves no more than minimal risk
* The research could not practicably be carried out without the waiver or alteration
* If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format
* The waiver or alteration will not adversely affect the rights and welfare of the subjects
* Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Please justify.

Click or tap here to enter text.

**SECTION VIII: Risks and Benefits**

1. Risks to participants. **– Risks & Benefits Panel**

*All research studies have some risk, such as possible loss of confidentiality. You may not answer this question "N/A" or "no risk". All must be included. Risks may be cognitive, affective, biological/physical, legal, economic, or social.*

Click or tap here to enter text.

1. Benefits of this research to the participant and/ or society. *Note that compensation is not considered a benefit of research. Compensation is addressed in question #46.* **– Risks & Benefits Panel**

Click or tap here to enter text.

1. Is there any deception or incomplete disclosure (withholding of complete information) required for the validity of this study? **– Risks & Benefits Panel**

 [ ]  Yes [ ]  No

36a. If yes, describe and provide justification for the incomplete disclosure. Include a disclosure statement for participants to receive upon conclusion of the need for deception and describe how you will debrief them.

Click or tap here to enter text.

1. If obtaining, viewing, or collecting records or data from school, employment, or medical or clinical settings to support subject selection, will any potential subjects currently be under supervision or treatment by a member of the research study team? [ ]  Yes [ ]  No

37a. If yes, describe how you will mitigate undue influence.

Click or tap here to enter text.

**SECTION IX: Privacy and Confidentiality – Privacy & Confidentiality Panel**

1. Which personal or demographic data will be collected? Check all that apply:

|  |  |
| --- | --- |
| [ ]  Name | [ ]  Phone number |
| [ ]  SSN | [ ]  Home address |
| [ ]  Medical record number (MRN) | [ ]  City |
| [ ]  Date of Birth | [ ]  State/ other |
| [ ]  Age | [ ]  Zip code |
| [ ]  Race or Ethnicity | [ ]  Department/ division |
| [ ]  Gender or sex | [ ]  Disease status |
| [ ]  Email | [ ]  Biological samples |
| [ ]  Date of service or medical procedure | [ ]  Other unique identifier (describe below)Click or tap here to enter text. |
| [ ]  Employer or school name |  |
|  |  |

1. Describe how the information selected will be collected. **– Privacy & Confidentiality Panel: In what format will the data originate?**

*Consider the following:*

* *Will any of it be obtained from the medical record or other existing record?*
* *Will it be obtained via self-report?*

Click or tap here to enter text.

1. Will you retain a link between study code number (such as participant #1, #2, #3) and direct identifiers (such as name, birth date, etc.)? [ ]  Yes [ ]  No

40a. If yes, justify the need for the link as well as the appropriate safeguards regarding data management. i.e. where it will be stored, who will have access, and when it will be destroyed. **– Privacy & Confidentiality Panel: Describe the coding system (link)…**

Click or tap here to enter text.

1. Describe in detail the protections that will be implemented to maintain the confidentiality of data, and/or specimens.

Contact your college’s IT for assistance in determining the need for/developing a data management plan (DMP).

[Contact the IBC](https://www.fau.edu/research-admin/research-integrity/institutional-biosafety-committee/ibc-contacts/) for more information regarding use of biospecimens. **– Privacy & Confidentiality Panel**

 *Consider the following when describing data management:*

* *Where and how will data and specimens be stored? How long will the data and specimens be stored?*
* *Who will have access to all study materials?*
* *How will study materials be destroyed?*
* *How will data and specimens be transported and who is responsible for receipt or transmission of the data or specimens?*
* *Will data or specimens be used for future research?*
* *Where will data analysis take place and how will data security be maintained during analysis?*

Click or tap here to enter text.

1. Data Reporting: Describe whether data will be aggregated/summarized in publications and presentations and/or individual results (e.g., de-identified quotes) will be communicated. If individual results are to be communicated, this should be clearly described to the subject in the consent document. **– Privacy & Confidentiality Panel: Indicate ALL proposed forms of dissemination**

Click or tap here to enter text.

1. If the project is NIH funded, please detail your data sharing plan.

Click or tap here to enter text.

1. If not federally funded, and the study will collect information that, if disclosed, could have significant negative consequences to the subjects such as damage to their financial standing, employability, insurability or reputation (e.g. STDs; use of alcohol, drugs, or other addictive products, illegal behaviors, etc.), will a Federal Certificate of Confidentiality (CoC) be obtained for this research? **– Privacy & Confidentiality Panel**

*Note: NIH automatically provides CoC for NIH funded projects.*

[ ]  Yes

[ ]  No

[ ]  N/A (no sensitive information is being collected)

**SECTION X: Use of Protected Health Information (PHI): HIPAA Requirements**

*Under the HIPAA Privacy Rule, covered entities may use or disclose protected health information from existing databases or repositories for research purposes either with individual authorization as required at 45 CFR 164.508, or with a waiver of individual authorization as permitted at 45 CFR 164.512(i).*

1. Will this study involve access to, use, or disclosure of any subjects’ 18 identifiable pieces of protected health information (PHI) defined under HIPAA (45 CFR 164.514(A)(2)) from a covered entity? **– Privacy & Confidentiality Panel**

[ ]  Yes

[ ]  No

* *If yes and obtaining written consent, include appropriate HIPAA authorization language in your consent document;*
* *If yes and requesting a waiver of consent, include a request for HIPAA waiver;*
* *If yes but only to identify participants for contact, include a partial HIPAA waiver or preparatory to research waiver.*

**SECTION XI: Compensation and Cost**

1. Will subjects be given payments/compensation, gift cards, travel expense reimbursement, gifts, incentives, or raffles? **– Recruitment Panel: Will incentives be offered for the research?**

*Please note, per Florida statute (*849.09*), raffles, drawing, or lotteries may* ***not*** *be used.*

[ ]  Yes

[ ]  No

1. Describe the payment schedule, amount, and what will happen if subjects withdraw from the study prior to completion.

Click or tap here to enter text.

**~~SECTION XII: Amendment History~~**

~~The table below is intended to capture changes of IRB-approved versions of the project, including a description of the change and rationale.~~

|  |  |  |  |
| --- | --- | --- | --- |
| **~~IRB Submission Date~~** | **~~Description of Change~~** | **~~Brief Rationale~~** | **~~IRB Approval Date~~** |
| ~~Date~~ | ~~Click or tap here to enter text.~~ | ~~Click or tap here to enter text.~~ | ~~Date~~ |
| ~~Date~~ | ~~Click or tap here to enter text.~~ | ~~Click or tap here to enter text.~~ | ~~Date~~ |
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**SECTION XIII: References**

List citations for the most significant studies that support your rationale.

Click or tap here to enter text.