# INSTRUCTIONS FOR RESEARCH INVOLVING SURVEYS/INTERVIEWS AND/OR FOCUS GROUPS

1. **Background for Investigator:**

Protocols that involve only interviews, surveys or focus groups by rule are exempt from the requirement for IRB oversight. However, confirmation of exemption at the University of Miami is required by an IRB Designee. Exemption is met per DHHS regulations pursuant to 45 CFR 46.104 if the following apply:

* (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
* (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
* (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).
* Any research involving prisoners is **not** exempt from the requirement of IRB oversight. Other vulnerable populations will be considered on a protocol basis.
1. **How to Use This Template:**
* This template is a suggested format for research that involves surveys, interviews, and focus groups. **If your proposed project involves any activities other than surveys, interviews or focus groups, do not use this form. Do not use this template if you plan on using DECEPTION as a study procedure, even if the deception involves survey, interviews and/ or focus groups.**
* Please take the time to read all italicized instructions and questions.
* **Delete the red italicized instructions before submitting to the IRB.**
* Depending on the nature of what you are doing, **some sections may not be applicable to your research. If so, delete.**
1. **Template (You may remove the first page of instructions- only use content going forward):**
2. Objectives/ Aims

Describe the purpose, specific aims, or objectives. Aims of the study should match proposed studies procedures. State the hypotheses to be tested.

 *Click here to enter text.*

1. Study Background

Do not copy and paste technical pages from proposals. Answer succulently and in ordinary language.

Describe the relevant prior experience and gaps in current knowledge.

Describe any relevant preliminary data.

Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

 *Click here to enter text.*

1. Inclusion and Exclusion Criteria
(*What are your pre-defined characteristics used to identify subjects who will be included in your study? Note if your inclusion targets specifically, minors, cognitively incapacitated, pregnant women and/ or prisoners):*

Inclusion Criteria:

 *Click here to enter text.*

Exclusion Criteria:

 *Click here to enter text.*

Age Range *(Take caution in a college setting on whether students are minors before enrolling):*

 *Click here to enter text.*

1. Vulnerable Populations\*

If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

* If the research is DHHS, DOD, or DHS funded and involves pregnant women, review “CHECKLIST: Pregnant Women (HRP-412)” to ensure that you have provided sufficient information.
* If the research involves neonates of uncertain viability or non-viable neonates, review “CHECKLIST: Non-Viable Neonates (HRP-413)” or “HRP-414 – CHECKLIST: Neonates of Uncertain Viability (HRP-414)” to ensure that you have provided sufficient information.
* If the research involves prisoners, review “CHECKLIST: Prisoners (HRP-415)” to ensure that you have provided sufficient information.
* If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), review the “CHECKLIST: Children (HRP-416)” to ensure that you have provided sufficient information.
* If the research involves cognitively impaired adults, review “CHECKLIST: Cognitively Impaired Adults (HRP-417)” to ensure that you have provided sufficient information.
1. Recruitment Procedures

*Describe how potential participants will be identified. When, where, and how will potential participants be invited to participate in the study:*

 *Click here to enter text.*

 [ ]  A pre-screening process will be used to determine whether potential participants are eligible to participate*. [(Explain how the screening will be performed (telephone interview, online questionnaire, etc)]. Attach a copy of the screening questions/criteria to your eProst application under Recruitment Materials Section (not in this protocol document).*

*Click here to enter text*

 [ ]  I am recruiting from a site that requires special permission. Studies activities will commence upon approval at the site: *Click here to enter text*

*(If you are recruiting at sites that require special permission, such as Miami-Dade County Public Schools, please explain. Study procedures at such sites MAY NOT BE INITIATED until approval has been obtained and documentation of approval provided via eProst).*

**Check all that apply- Attach a copy of each applicable document under Recruitment Materials Section (WORKSHEET LINK FOR GUIDANCE:** [**https://eprost.med.miami.edu/Eprost/sd/Doc/0/SIQ3B6P1S9GKVE0PHKGBG7RI59/HRP-315%20-%20WORKSHEET%20-%20Advertisements.doc**](https://eprost.med.miami.edu/Eprost/sd/Doc/0/SIQ3B6P1S9GKVE0PHKGBG7RI59/HRP-315%20-%20WORKSHEET%20-%20Advertisements.doc)**):**

[ ]  In-Person Plea, Snow-Ball Sampling

[ ]  Flyer/ Postings

[ ]  Email/ Letter

[ ]  Psychology/ School of Communications Research Pool

[ ]  Internet or Social Media (Facebook, website ad, twitter, etc.) (*Creating your own Research-Created Social Media site requires additional consideration by the IRB given the limits of confidentiality and generally not recommended. You may post on EXISTING sites relative to the study topic).*

[ ]  Online Survey Platform (*Amazon MTurk may be used for recruitment, but Qualtrics is recommended for online research procedures)*

*Click here to enter text.*

[ ]  CTSI Consent to Contact Registry *(Cannot be used for HIPAA additional authorization categories: HIV, STD, Mental Health, substance abuse and sexual assault-targeted studies. You must provide a script under Recruitment Materials Section)*

[ ]  Existing Research Data Registry: *Click here to enter text.*

[ ]  Other: *Click here to enter text.*

1. Check the procedures that you will use to collect data *(include estimated time for each participant to complete all study activities)*.

[ ]  Surveys – Attach all surveys, including Demographic Forms, in Other Attachments Section.

*Describe the survey process. Click here to enter text.*

[ ]  Interviews – Attach an interview script in Other Attachments Section.

*Describe the Interview Process Click here to enter text.*

[ ]  Focus groups – Attach a summary of the focus group outline in Other Attachments Section.

*Describe the focus group process. Click here to enter text.*

 [ ]  Audiotaped: *Click here to enter text.*

 [ ]  Videotaped: *Click here to enter text.*

Are you planning on transcribing the tapes and destroying the recordings when transcription is complete? [ ]  Yes [ ]  No

*\*If recording is mandatory for participation, a rationale must be provided and the consent form must include this detail.
Click here to enter text.*

1. Compensation (WORKSHEET LINK FOR GUIDANCE: <https://eprost.med.miami.edu/Eprost/sd/Doc/0/55SUR0F62PP4B9HCS6OF797I5B/HRP-316%20-%20WORKSHEET%20-%20Payments.docx>)

[ ]  Participants will not be compensated.

[ ]  Participants will be compensated – *Describe timing, amount and type. This also includes Research Credit:* *Click here to enter text.*

*\** *Raffles and lotteries are not allowed at the University of Miami as a method of compensation for taking part in research*.

1. Consent Process

*A complete waiver of the Informed Consent Process is not appropriate for surveys, interviews and focus group studies. Consent may be obtained in some manner without the requirement for a signed document: Consent is a PROCESS. Attach a copy of the consent content in the Informed Consent Section in eProst. Sample templates may be found here:* [*https://hsro.uresearch.miami.edu/researchers/forms-and-templates/templates/index.html#*](https://hsro.uresearch.miami.edu/researchers/forms-and-templates/templates/index.html)

The consent process will be initiated with study participants prior to starting any research procedures. Participants will be given ample time to consider their agreement. The study team will be available to answer any question in the method the participant prefers to communicate. No one in a perceived coercive position in relation to the participant will engage in the consenting process. Consent will be obtained voluntarily prior to initiating any study procedures:

[ ]  Verbally – Describe the Consent Process: *Click here to enter text.*

[ ]  Online – Describe the Consent Process: *Click here to enter text.*

[ ]  Other – Describe (*Include details if (1) consent will be obtained in a language other than English (2) For longitudinal studies: If enrolling minors that turn 18, whether re-consent will be obtained (3) If members of the research team have roles that can rise to concerns about undue influence (such as physician-patient, teacher-student), please explain the steps will take to minimize undue influence/ coercion*): *Click here to enter text.*

* Minors – Describe how parental consent and child assent will be obtained, if relevant: **Click here to enter text.**
1. Risks to Subjects *(check those that apply)*

 Minimal, if any, risks are expected for study procedures given:

[ ]  Identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects and/ or

 [ ]  The topic addressed would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.

*Explain: Click here to enter text.*

<*If focus group >* By nature of the study design of focus groups, participants will overhear others’ responses on the topic discussed. The study team will inform participants of this confidentiality limitation. Participants will be reminded to respect the privacy of the group participants and not disclose the discussion outside the group.

Will the survey, interview, focus group questions address any issues that require mandatory reporting laws (e.g., mandatory reporting of child/ elderly abuse and neglect, harm to self or others?) ***If yes, explain the reporting process:***

<*If illegal immigrants >* Will the survey, interview, focus group questions be conducted, potentially, with undocumented immigrants? ***If yes, are there any foreseeable risks (such as detention by ICE) entailed by their participation in this study?***

Other – Describe the risks and procedures in place to mitigate the acknowledged risks: *Click here to enter text.*

1. Potential Benefits to Subjects

The participants who complete surveys or participate in interviews, focus groups are not likely to receive any direct benefit from the proposed research but others may benefit from the knowledge obtained.

Other – Describe *Click here to enter text.* *(Compensation for participation is not a benefit to research)*

1. Data Management and Confidentiality

An identifier is any data that can either directly (such as name, address, SSN) identify an individual or link an individual to their identity. An anonymous study is a study where identifiers are not collected and/or not linked to participants’ identity. Indirect identifiers include information that can be combined with other information to identify specific individuals. If participant identifiers are collected, it is important that the data and identifiers are kept confidential, are appropriately stored, and are destroyed when no longer needed. <http://privacy.med.miami.edu/data-broker-services/data-handling-faq>

Indicate how you will protect the information, including tapings, you obtain and record while conducting this study from disclosure to any individual who does not have a right or a need to access the information (check all that apply)

[ ]  Individual’s responses/statements will not be linked to their identity. (No identifying information will be included on the documents/recordings and the documents/recordings will not be coded and linked to the individual’s identity.)

[ ]  Individual’s responses/statements will not be linked to their identity. Identifying information will be collected for logistic purposes such as paying participants but will not be associated with or linked to the study data.

[ ]  Individual’s responses/statements will not include any information that identifies the individual, but the responses/statements will be coded and linked to their identity on a separate document or in a separate database. *If yes, provide justification for recording identifiers. In other words, why do you need to record the identifiers? It is generally recommended that for one-time research procedures, no identifiers should be recorded.* Click here to enter text.

 [ ]  All identifiable electronic data will be maintained on an encrypted device requiring a password for access. Passwords will not be shared and will be protected from access.

 [ ]  All paper records will be stored in a locked room/file-cabinet with access limited to only individuals who have a right and need for access.

 [ ]  Other – (e.g. how will you manage the confidentiality for visual images and/or audio/video tapes?) Describe Click here to enter text.

Are there any mandatory reporting laws that apply to your research (e.g., mandatory reporting of child abuse and neglect?)

*Click here to enter text.*

1. Data Storage

Will data be stored for future use **for other than research** described in this protocol? [ ]  Yes [ ]  No

Future use means that the data obtained from THIS study will be used for research yet to be determined at this time. A definitive time frame on when in the future does not need to be specified.

 If data will be stored for future use, (a) the aims of the study must justify the retention of the data, (b)you will need to address the additional questions below and (c) the consent form must indicate that data will be stored for future use.

If yes, will the data that are stored be identifiable?

 [ ]  Yes, the data will be identifiable

 [ ]  No, the data will be completely anonymous.

[ ]  No, the data will be stripped of identifiers and will be coded. A separate link from data to identifiers will be maintained, but the link to the individual’s identity will not be made available to those requesting data from the data bank and will be maintained separately from the data bank.

Where will the data be stored (eProst Application: Additional Study Information Q#2b: the first ten selections refer to the acceptable UM Data Storage Options instances of these system)?

Click here to enter text.

How long will the data be stored?

Click here to enter text.

Who will have access to the data?

Click here to enter text.

Describe the procedures to release data, including: the process to request a release, approvals required for release and who can obtain data.

Click here to enter text.

1. International Research (where data collection will occur outside the United States and U.S. territories)

Will your research will take place outside the United States, please outline sites:

[ ] Will you obtain review by an IRB/research ethics committee located in the country where you will be doing research? *Some countries do not have IRBs/research ethics committees, and in some countries the IRBs review only biomedical research – we understand that IRB review in another country is not always possible, but expect that review by an IRB/research ethics committee be obtained whenever possible in the country where research will take place – it is your responsibility to determine whether there is an IRB/research ethics committee that can review your research in the countries where you plan to collect data.*

*Click here to enter text.*

[ ] What sociocultural factors could affect the consent process in the countries/regions where you will do research? (*For example, are there low rates of literacy, are there cultural customs that require consent from a community or family leader? Are there risks to subjects that would be greater than if the research were conducted in the US, etc?)*

*Click here to enter text.*

NOTE: If you plan to collect data **from individuals located in the European Economic Area**, you must take into consideration the General Data Protection Regulations (GDPR) (see [GDPR guidance](https://irb.northwestern.edu/policies/human-research-policies-guidance-oversight)).

*Click here to enter text.*

NOTE: If you will be collecting data that are sensitive, you must use good **data security practices** to collect, store, and transport your data. Keep in mind that officials in other countries, as well as U.S. Customs and Border Protection, could potentially try to access data stored on a phone, laptop, or other device.