***Instructions for Writing a Protocol:***

* *Use this* [*“PROTOCOL TEMPLATE (HRP-503)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/) *to prepare your investigator protocol specifically for IRB review with the information from the following sections.*
* *As you are writing the protocol,* ***remove all instructions*** *in* ***BLUE*** *throughout this document so that they are not contained in your submission to the IRB.*
* ***Some sections may not be applicable to your research*** *depending on the nature of your study. If not applicable, leave the section in (unless otherwise noted) but delete the instructional blue text and mark the entire section as “NA.”*
* ***Keep an electronic copy*** *to ensure you are using the most recent version approved by the IRB. You will need to modify this copy when making changes.*
* ***For versioning control****, include the version number and/or date for your specific protocol (and for subsequent protocol revisions).*

**Study Title**

Include the study title as listed in the IRB application.

**Objectives**

* **Purpose:** Describe the purpose, specific aims, or objectives.
* State the research question (e.g., themes or theories to be explored) or the hypotheses to be tested.
* **Study design:** Describe and explain the study design.
* **Study intervention:** Describe the study intervention (if any) that is being evaluated.
* **Study endpoints (clinical trials):** For clinical trials, describe the primary and secondary study endpoints. (An endpoint is an event or outcome that can be measured objectively to determine the effect of the intervention being studied).

**Background**

* **Significance of research question/purpose:** Describe the relevant prior experience and gaps in current knowledge.
* **Preliminary data:** Describe any relevant preliminary data.
* **Background literature with references:** Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge. Include a list of references in the protocol.

**Study Population**

* **Inclusion and exclusion criteria:** Describe the criteria that define who will be included and excluded in your study (e.g., ages, gender, and racial/ethnic composition, etc.). If only adults are enrolled, describe any relevant local context. (Note: The legal of age of an adult is not 18 years old in all locations such as in Alabama (19), Mississippi (21), and Nebraska (19)).
* **Inclusion of vulnerable populations**: Indicate whether you will specifically target the inclusion of **and/or** obtain information about any of the following special populations (and then provide more details in the “Vulnerable Populations” section later in the document):
	+ UMass Boston students or employees
	+ Children (i.e., individuals who are not yet adults such as infants, children, teenagers)
	+ Prisoners
	+ Pregnant women
	+ Adults unable to consent (i.e., adults with impaired decision-making capacity)
	+ Other (such as economically or educationally disadvantaged or other) – please describe.

**Study Duration**

Describe:

* The duration of an individual participant’s participation in the study.
* The estimated timeframe for the investigators to complete this study.

**Number of Participants**

* Indicate the total number of participants to be accrued.
* If applicable, distinguish between the number of participants who are expected to be enrolled and screened, and the number of participants needed to complete the research procedures (i.e., numbers of participants excluding screen failures.)

**Setting**

Describe the sites or locations where your research team will conduct the research.

* **Sites/locations:**
	+ Identify where your research team will identify and recruit potential participants.
	+ Identify where research procedures will be performed.
* **Prior approvals:** If the research requires ancillary review by other UMass Boston research committees, offices, departments (e.g., [Office of Environmental Health and Safety](https://www.umb.edu/ehs); [Institutional Biosafety Committee (IBC)](https://www.umb.edu/research/orsp/institutional-biosafety-committee-ibc/); Public Safety; [Conflict of Interest review](https://www.umb.edu/research/orsp/research-compliance/conflict-of-interest/); departments or divisions that require approval of the use of their resources, etc.), provide details of the review and the status.
* **External IRB/ethics review:** If external IRB or ethics review committees are reviewing this study, provide details of the review including the name of the institution/organization’s IRB and approval status.
* **Local permissions/local context**: For research conducted outside of UMass Boston and its affiliates describe:
	+ Procedures for gaining local permissions access to the site(s) or location(s) for recruitment and/or to carry out research procedures at the selected site(s) or location(s). Include support letter (or other written correspondence) from site/location if available.
	+ Any local requirements, regulations, or customs affecting the research.
	+ Any local/ethical/IRB review structure or approvals needed from those sites or locations prior to conducting the research.
	+ **For international research**, review any [international research guidelines](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html).

**Recruitment Methods**

* **Recruitment process:** Describe when, where, and how potential participants will be identified and recruited.
	+ Describe the source of subjects.
	+ If applicable, describe procedures for oral or written communication with the prospective subject or legally authorized representative that will be done for purposes of screening, recruiting, or determining eligibility.
	+ If applicable, describe procedures for accessing records or stored identifiable biospecimens for purposes of screening, recruiting, or determining eligibility.
* If using **SONA**,review [*“IRB SONA Guidance”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies)for guidelines to ensure you are following the appropriate steps.
* ﻿If requesting to use **RESEARCH MATCH**, review the [*"Research Match guidelines"*](https://www.umb.edu/research/orsp/research-match/) to ensure you are following the appropriate steps.
* **Recruitment materials:** Describe materials that will be used to recruit participants. Review [*“Advertisements WORKSHEET (HRP-315)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies)for guidelines. Attach copies of these printed, audio, video, screening scripts with the application. (Final copies of advertisements including any images, audio, and video, must be first reviewed and approved by the IRB prior to use. You may submit the draft for IRB review prior to submitting the final for IRB review.)
* If using the **UMass Boston student broadcast recruitment email**, please state this in the protocol, and then attach the recruitment email in Study Attachments. You must follow the format below (copy the following 3 sections into your attachment).
1. Subject line for UMass Boston student broadcast email:
2. Email content (please be brief and simple – no graphics) (Max 500 characters):
3. Please identify target population (e.g., graduate students; undergraduate students; graduate and undergraduate students):
* **Screening for eligibility:** Describe how individuals will be screened for eligibility. For individuals who are determined ineligible or who decline to participate, how will any identifiable information collected in the screening be securely destroyed?

**Procedures Involved**

* **Study procedures:**
	+ Describe all research procedures being performed and the order in which they are performed and the amount of time to complete the different procedures (e.g., survey, interview, focus group). If needed, include a table or flow chart.
	+ Describe what data (or biospecimens) will be collected during the study and how the data (or biospecimens) will be obtained. (Attach surveys, instruments, interview scripts, data collection forms.)
	+ Describe any randomization process and the probability for random assignment to each group.
	+ For **secondary research**:
		- Explain the source of the existing data (or biospecimens). Include names of datasets you will access and links to data sources.
		- Describe what information are included in the dataset (or biospecimens) along with any identifiers (or if they are coded or fully de-identified). Indicate whether the data (or biospecimens) can be directly linked to individuals, (e.g., the dataset includes names), indirectly linked through a code (e.g., the dataset includes a code and you have the key to the code), or not linked at all to individuals (e.g., the dataset includes a code, but no one other than the person giving you the data or specimens has the key to the code).
		- Explain how you are gaining access to the dataset (or biospecimens). (Are you obtaining them from another researcher? Are you pulling data directly from a medical record? Are you pulling leftover samples from a lab?)
		- Explain whether or not you have the ability to re-identify the data (or biospecimens) and if you will not re-contact the participants.
		- Indicate if there is a data agreement in place to access and/or use the data (attach template) and what that entails.
		- Upload any other documentation related to any IRB requirements by the provider of the data (or biospecimens).
* **Follow-up:** If there are plans for long-term follow-up of participants (once all research related procedures are complete), what data will be collected during this period.
* **Payment/incentives:** If paying participants (or providing other incentives for participation), describe the amount, method, and timing of disbursement. Review [*“Payments WORKSHEET (HRP-316)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) for guidelines.

**Data Analysis**

* **Data analysis:** Describe the data analysis plan (including any statistical procedures and/or power analysis if applicable).
* **Data integrity:**
	+ Describe any procedures that will be used for quality control of collected data.
	+ Review the [**Online Survey Protection References**](https://www.qualtrics.com/support/survey-platform/survey-module/survey-options/survey-protection/) if you are creating an online survey to incorporate adequate protection against bots and other unwanted responses.

**Risks to Participants**

* **Risks:** List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the participants related the participants’ participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.
* If identifiers are obtained and can be directly or indirectly linked to data by the investigator(s), a breach of confidentiality should be addressed.
* Describe any procedures performed to lessen the probability or magnitude of risks or to monitor participants for safety.
* If applicable, indicate the following:
	+ Which procedures may have risks to the participants that are currently unforeseeable.
	+ Describe any risks to others who are not participants.
	+ Which procedures may have risks to an embryo or fetus should the participant be or become pregnant.

**Potential Benefits to Participants**

* Indicate if there is no direct benefit to participants.
* Or, describe any direct benefits of the research individual participants may experience. (Do NOT list payment or other participant incentives as a benefit of participation.)

**Resources Available**

* Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.
* Describe the qualifications of the PI to serve in this research role as well as qualifications required of other study team members (e.g., training, including training by the PI; experience; oversight). When applicable, describe knowledge of the local study sites, culture, and society to demonstrate cultural understanding and sensitivity.
* If applicable, describe the availability of resources (e.g., psychological, medical, counseling, etc.) that participants might need because of anticipated consequences of the human research.

**Consent Process**

If you will be obtaining consent:

* Describe:
	+ Where will the consent process take place.
	+ The role of the individuals listed in the application as being involved in the consent process.
	+ Any provisions such that participants have enough time to consider whether to participate.
	+ Steps that will be taken to minimize the possibility of coercion or undue influence.
	+ Steps that will be taken to ensure the participants’ understanding.
	+ Any process to ensure ongoing consent throughout participation.
	+ Describe if and how consent will be documented in writing (i.e., obtaining signed consent). Or, explain if signed consent will not be documented (e.g., by verbal agreement; by presentation of consent form online before taking survey). Review [*“Waiver of Written Documentation of Consent CHECKLIST (HRP-411)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) to ensure that you have provided sufficient information. (In general, signed consent is not required for minimal risk research procedures which do not normally require consent outside of the research context.)
	+ Attach the consent form(s) or script(s) with your submission. You may use [*Consent template*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/) to create the consent document or script.
* If you will enroll **non-English speaking participants:**
	+ Indicate what language(s) other than English are understood by prospective participants or representatives. Indicate the language that will be used by those obtaining consent.
	+ If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language.
		- Confirm that translations will be an accurate translation of the English-approved version.
		- Confirm that translations are conducted by an individual fluent in the language.

If your study involves **incomplete disclosure or deception**:

* Explain how the study meets a Waiver or Alteration of Consent Process. Review the [*“Waiver or Alteration of Consent Process CHECKLIST (HRP-410)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) to ensure you have provided sufficient information (e.g., rationale; any debriefing process) for the IRB to make these determinations.

If you will NOT have any consent process with participants:

* Explain how the study meets a **Waiver or Alteration of Consent Process.** Review the [*“Waiver or Alteration of Consent Process CHECKLIST (HRP-410)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) to ensure you have provided sufficient information for the IRB to make these determinations.

**Vulnerable Populations**

If the research specifically seeks involvement of **and/or** obtain information about individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare (e.g., permission process; assent process; provision of accessible formats of research consent and materials; etc.). For example:

* **UMass Boston students or employees**:
	+ If enrolling members of these groups, does anyone on the study team teach, supervise, or have the ability to influence a participant’s grades, academic success, or professional advancement? If yes, what additional protections are in place to ensure that participants do not feel unduly influenced to participate?
	+ If students are offered course credit for research participation, will another comparable method of obtaining course credit be available besides research participation?
	+ If using **SONA**,review [“IRB SONA Guidance”](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies)for guidelines to ensure you are following the appropriate steps.
* **Children**: Review the [*“Children CHECKLIST (HRP-416)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) to ensure that you have provided sufficient information.
	+ Indicate the process to obtain parental permission.
	+ If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent.
	+ Describe the assent process:
		- How will you explain the research so that the children understand what they are being asked to do?
		- How will you obtain the child’s overt agreement to participate?
		- Confirm you will not enroll a child if there is any sign of unwillingness.
		- Are there children you will not ask to assent? If yes, which ones and why?
		- If you obtain assent from children, will it be documented, and if so, how?
	+ Describe the criteria that will be used to determine whether a prospective participant has 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.
		- For research conducted in the state, review [*“Legally Authorized Representatives, Children, and Guardians SOP (HRP-013)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) to be aware of which individuals in the state meet the definition of “children.”
		- For research conducted outside of the state or in a foreign country, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted.
* **Prisoners**: Review [*“Prisoners CHECKLIST (HRP-415)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies)to ensure that you have provided sufficient information.
* **Pregnant women**: Review [*“Pregnant Women CHECKLIST (HRP-412)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies) to ensure that you have provided sufficient information.
* **Adults unable to consent**: Review [*“Adults with Impaired Decision-Making Capacity CHECKLIST (HRP-417)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies)to ensure that you have provided sufficient information.
	+ How will you determine when an adult has the capacity to consent?
	+ Who will provide permission for the participant to participate?
	+ Describe the assent process:
		- How will you explain the research so that individuals understand what they are being asked to do?
		- How will you obtain the individual’s overt agreement to participate?
		- Will you not enroll an individual if there is any sign of unwillingness?
		- Are there individuals you will not ask to assent? If yes, which ones and why?
		- If you obtain assent, will it be documented, and if so, how?

**Provisions to Protect the Privacy Interests of Participants**

**“Privacy” interest pertains to the** **person** and refers to a person’s desire to place limits on whom they interact or whom they provide personal information.

* **Protection of privacy:**
	+ Describe the steps that will be taken to protect participants’ privacy interests.
	+ Describe what steps you will take to make the participants feel at ease with the research situation in terms of the questions being asked and the procedures being performed. “At ease” does not refer to physical discomfort, but the sense of intrusiveness a participant might experience in response to questions, examinations, and procedures. For example, will procedures be conducted in a private setting and without third party monitoring or surveillance? Is the collection of sensitive information about participants limited to the information that is necessary to conduct the research? Will participants be told that they can skip any question they wish?

If using **Zoom**, confirm you will follow the [Zoom guidelines set forth by UMass Boston IT](https://www.umb.edu/it/training-classroom-support/avsct/secure-your-zoom-meeting/). Contact [IT](https://www.umb.edu/it/help) for questions about how to run a secure Zoom.

Inform participants of steps they can take to protect privacy (e.g., closing their web browser after survey completion, avoid using shared devices, finding a private location to complete interviews, etc.).

When conducting interviews via Zoom or other videoconferencing – take precautions to protect participant privacy (e.g., do not conduct a video interview in a publicly occupied space or a common room where roommates/family members may overhear).

Likewise, ensure the researcher is in a private area (use headphones in a location where other people are not able to see or overhear the interviews).

* **Access to private information:**
* Indicate how the research team is permitted to access any sources of information about the participants. (Note: Data Use Agreements are negotiated through the [Office of Research and Sponsored Programs](https://www.umb.edu/research/orsp/contact-us/by-dept/). Contact the [UMass Boston Research Computing Group and the IT Security Group](https://www.umb.edu/rc/services/data-security/) for assistance with structuring the associated data security plan and local computing environment to ensure compliance with Data Use Agreements.)
	+ If the research team will access protected health information for research purposes, address compliance with **HIPAA** regulations.
	+ If the research team will access student education records for research purposes, address compliance with **FERPA** regulations. Review [*“FERPA Compliance WORKSHEET (HRP-331)”*](https://www.umb.edu/research/orsp/institutional-review-board-irb/applying-to-the-irb/#Policies)to ensure that you have provided sufficient information. Contact the [Registrar’s Office](https://www.umb.edu/registrar/policies/ferpa) with any FERPA questions and for FERPA Guidelines for Staff and Faculty.

**Data Confidentiality**

**“Data confidentiality” pertains to the data/documents** and the steps in place to protect data and documents.

* Describe what, if any, personally identifying information (e.g., direct identifiers such as name, address, phone number, IP address) will be collected from participants.
* If personally identifying information will be collected from participants, indicate whether or not the investigator will keep a link between the individual participant’s data and the participant’s identity (e.g., in a master list with access to the key limited to investigator).
* Or, clarify if and how identifying information be collected but never linked to the data (e.g., contact information is collected only for purposes of paying participants who completed online survey).
* For **international travel**, the data confidentiality plan should take into consideration any restrictions for [Data Protection and Export Control Laws](https://www.umb.edu/academics/global-programs/data-protection--export-control-laws/).
* Recordings:
	+ If recording interviews or focus groups, are you only recording the audio and not video (generally, video should not be recorded unless it is necessary to meet the study objectives).
	+ Are recordings saved to a secure drive (e.g., [UMass Boston OneDrive](https://www.umb.edu/it/admin_systems/onedrive)) and not to a location that could be backed up to a commercial cloud or with third party access?
* Describe the steps that will be taken to secure the data during storage, use, and transmission such as:
	+ Separation of direct identifiers and data (e.g., will data be labeled with pseudonyms or ID code numbers instead of direct participant identifiers)
	+ Password protection
	+ Encryption (e.g., if using portable devices like laptops, are they encrypted?)
	+ Physical controls (e.g., locked cabinets)
	+ Training, authorization of access
	+ [Certificates of confidentiality](https://grants.nih.gov/policy/humansubjects/coc.htm)
* Describe how data or specimens will be handled study-wide:
	+ What information will be included in that data or associated with the specimens?
	+ Where and how data or specimens will be stored?
	+ How long the data or specimens will be stored?
	+ Who will have access to the data or specimens?
	+ Who is responsible for receipt or transmission of the data or specimens?
	+ How data or specimens will be transported?
	+ How soon identifying information will be destroyed?
	+ If the research uses audio or video recording, please also state how long the recordings will be kept after transcription and when they are destroyed.

**Data (and Specimen) Banking for Use in Future Studies**

This section is not applicable (“NA”) unless you will bank data and/or specimens that maintain direct or indirect (i.e., coded with link to) participant ***identifiers*** for use in future studies.

* **Storage and access:** If data (or specimens) will be banked for future use, describe where they will be stored, how long they will be stored, how they will be accessed, and who will have access to the data (or specimens).
* **Data elements:** List the data elements to be stored or associated with each specimen and banked for future use.
* **Data release/sharing:** Describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

**Sharing of Results with Participants**

* Describe whether or not results (study results or individual participant results) will be shared with participants. If so, describe how the results will be shared.

**Economic Burden to Participants**

* Describe any costs that participants may be responsible for because of participation in the research.

**Withdrawal of Participants**

This section is not applicable (“NA”) unless you may withdraw participants from the research without their consent.

* **Withdrawal circumstances:** Describe any anticipated circumstances under which participants will be withdrawn from the research without their consent.
* **Withdrawal steps:** Describe any procedures that will be followed (such as for safety reasons) when participants withdraw from the research, including partial withdrawal from procedures with continued data collection, and any procedures for orderly early termination.

**Community-Based Participatory Research**

*Community-Based Participatory Research* is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. *Community-Based Participatory Research* begins with a research topic of importance to the community, and aims to combine knowledge with action and to achieve social change to improve health outcomes and eliminate health disparities or work towards beneficial outcomes for all participants, including communities.

* Describe how community partners will participate in various stages of the research.
* Describe the plan for educating community partners about human research protections.
* Describe the agreement with the community partner organization. If appropriate, provide a letter or memorandum of understanding.

**Compensation for Research-Related Injury**

* If the research involves more than Minimal Risk to participants, this section is required. In general, UMass Boston has not set aside funds for research-related injury.

**Provisions to Monitor the Data to Ensure the Safety of Participants**

This section is required for NIH-funded clinical trials OR when research involves more than Minimal Risk to participants.

Describe:

* The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe. (The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.)
* What data are reviewed, including safety data, untoward events, and efficacy data.
* How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).
* The frequency of data collection, including when safety data collection starts.
* Who will review the data.
* The frequency or periodicity of review of cumulative data.
* The statistical tests for analyzing the safety data to determine whether harm is occurring.
* Any conditions that trigger an immediate suspension of the research.

**Multi-Site Research**

Delete this section unless you are part of a multi-site study. A multi-site study is a study in which PIs from two or more sites are conducting the same protocol.

Describe:

* Study-Wide Number of Participants
	+ Indicate the total number of participants to be accrued across all sites.
* Study-Wide Recruitment Methods
	+ If participants will be recruited by methods not under the control of the local site (e.g., call centers, national advertisements), describe those methods.
	+ Describe study-wide materials that will be used to recruit participants.
* Indicate if you are the lead investigator of all sites.

If you are the **lead investigator** of a multi-site study (delete this section if you are not the lead investigator):

* Describe the processes to ensure communication among sites for the following:
	+ All sites have the most current IRB-approved version of the protocol, consent/assent document, subject/recruitment materials, HIPAA authorization, and other study documents.
	+ All required approvals (initial, continuing review and modifications) have been obtained at each site (including approval by the site’s IRB of record).
	+ All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.
	+ All engaged participating sites will safeguard data, including secure transmission of data, as required by local information security policies.
	+ All local site investigators conduct the study in accordance with applicable federal regulations and local laws.
	+ All Relying Institutions and/or local site investigators are responsible for ensuring that its investigators and research personnel meet the Relying Institution’s standards for eligibility to conduct research. This includes, but is not limited to, having appropriate qualifications, human research training, appointments, credentials, privileges, insurance, and background checks.
	+ All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.
* Describe the method for communicating to engaged participating sites:
	+ Problems (inclusive of reportable events).
	+ Interim results.
	+ The closure of a study