IRB Application - IRB Application Form

Drop Image to Up Drag Entry

IRB New Study Application Form

Study Title: (Required)

Requested Start Date: (Required) Date

PI's Name & Personal Number:

Submitted By:

Review - Lead **Email:** michelle@uab.edu

Study Number

123

Current Study Title:

test

What is the nature of the modification / amendment request? (Required)

- Change PI
- Change study title
- Add research personnel
- Change research personnel
- Change study procedures
- Change study documents
- Change study documents (e.g. eligibility criteria, setting or removing subject groups, including or removing study procedures)
- Change in study sites or procedures
- Change in study documents (e.g. consent forms, recruitment materials, setting study location)
- Change in study procedures
- Adding subjects to an ongoing research
- Change study title
- Change study PI
- Other

The root 1 questions will be asked when you select the root 1 amendment, and a new section will appear.

Describe the requested amendment: (Required)

Explain the rationale for the proposed modification/ amendment below. (Required)

Explain how the new information (modifications/ amendment) will be communicated to currently enrolled subjects? (Required)

If currently enrolled participants will be affected by the modification/ amendment or consent is an element from subjects, explain:

- Explain the communication plan to inform participants of the modification/ amendment and how consent will be obtained.
- If consent is required, describe how the study will be conducted with participants who do not consent to the modification/ amendment. Do subjects who do not consent to the modification/ amendment continue in the study? Explain.

Title: (Required)

test

Principal Investigator

PI

PI Name (Required)

Begin typing last name and the system will auto-populate if the user has a Blazerage account

The PI must be a UAB faculty or staff member. Students PIs may not enter here.

If the PI does not have a Blazerage account, the Sponsored Programs Office **can** add the missing name and expiration date of each course that the PI needs to complete. Please contact the Sponsored Programs Office at sponsor@uab.edu for instructions and updates.

You may submit with UTI training pending, but the training will need to be completed before IRB approval can be issued.

PI Department (Required)

Is this a student project? (Required)

Yes
No

If this is for a class or dissertation, or if the research is primarily for educational purposes, enter "Yes".

If this is a student group and is intended for faculty or staff, mark this as "No".

Student PI: (Required)

Begin typing last name and the name will auto-populate if the user has a Blazerage account.

All Student PIs must have current IRB-CITI training on file. The Sponsored Programs Office can add the missing name and expiration date of each course that the PI needs to complete. Please contact the Sponsored Programs Office at sponsor@uab.edu for instructions and updates.

Current study contacts

Name	Role	Primary

Will any other study personnel need access UAB certifications and/or have access to the study in IRBnet?

Most study staff will need access to UAB certifications and/or have access to the study in IRBnet.

Study personnel who do not need access to UAB certifications and/or have access to the study in IRBnet:

- Research Assistants
- Research Associates
- Research Analysts
- Research Coordinators
- Research Scientists
- Research Assistant Professors

List the name of the other IRBs, the date of review, and any other information that would be helpful for the UAB IRB to know. (Optional)

Are you requesting single IRB review? (Required)

Yes
No

When sign off from the other IRB is required? (Required)

Immediately
Prior to enrollment
Prior to study start
Research Analysis Research Intervention

List the name of the other IRB, the date of review, and any other information that would be helpful for the UAB IRB to know. (Optional)

Are you requesting single IRB review? (Required)

Yes
No

If UAB will submit a reliance request to Healthcare and Safety Research Review (HSRR) for review of the study, please provide the name of the other IRB and the date of review. (Optional)

Explain why you are not requesting single IRB review. (Required)

- Investigator is a member of the IRB
- Investigator is a member of the IRB

Explain. (Required)

Upload all crucial submission materials that were submitted to the other IRB. (Required)

Add Attachment

Do you need to collect Protected Health Information (PHI)? (Required)

Yes
No

Personnel to remove (Required)

Action

Save

Describe any potential conflicts of interest for the PI or other research team members, if none, write "none". (Required)

- A conflict of interest can take several forms:
- Financial interests (e.g. stock ownership)
- The **appearance** of a conflict of interest
- Personal relationships (family, friends, acquaintances, or professional)
- Competing interests of research teams that the **potential** exists for the investigator to be influenced in a manner that may, or may appear to, compromise the integrity of research or research subjects.

Example:

- A personal interest in the outcome of the study, or the potential for a personal gain from research, including the outcome of the study or the use of research results in a manner that benefits the investigator or a relative or associate of the investigator.
- A research project with a sponsor or a pharmaceutical manufacturer.
- A research project with research assistants who are also employed by the investigator's department or research team.

Study Details Information

Your IRB approval of study: (Required)

Approval Letter
Approval Memo

No activities may begin before IRB approval.

Upload your approval letter or approval memo. Upload one file at a time. Upload multiple files if needed. Only upload the final approval letter or approval memo (not initial review and amendment requests).

Other start date: (Required)

Date

Take into account data collection, analysis, and publication.

What is the risk level of this study? (Required)

Minimal Risk
Greater than Minimal Risk

"Minimal Risk" means the probability and magnitude of harm or discomfort anticipated in the research are not greater in itself than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Example:

- A study is a pure survey or survey with a physical component. Participants are not being asked to do anything that is not routine.
- Risk surveys, interviews, focus groups, and program evaluations are considered minimal risk if the information being collected is not sensitive and participants are not being asked to do something that is not routine.
- Review of existing medical records is considered minimal risk.
- Review involving only kind of analysis or testing non-IRB approved device is considered minimal risk if the device is safe.

Greater than minimal risk is a flexible category. We create rules that minimal risk for some experiences such as children, individuals with mental illnesses, individuals with disabilities, and others.

What aspects of the study involve more than minimal risk? (Required)

What is the funding source for this study? (Required)

Federal Funding (e.g. NIH, NSF, DoD, VA, etc.)
State Funding (e.g. Alabama Department of Mental Health)
Industry Funding (e.g. Pfizer, Novartis, etc.)
Not Funded

List the funding source. (Required)

List the grant or award number(s). (Optional)

Determination of Clinical Trial (Please select all that apply. (Required)

The study involves human participants.
Biomedical and behavioral research of an intervention.
Prospectively assign human participants to a single or parallel or crossover intervention.
Measure biomedical or behavioral outcomes in the participants.

Is this study a Clinical Trial as defined by the NIH? (Required)

The NIH defines a clinical trial as a research study in which biomedical or behavioral research participants are prospectively assigned to an intervention. The intervention may be a drug, biologic, a medical device, a behavioral intervention, or a change in a participant's diet or exercise regimen. The study is used to evaluate the effect of the intervention on the participants.

Not Applicable

Is a clinical trial required to be registered with ClinicalTrials.gov? (Required)

Yes
No

Not applicable

Is a clinical trial required to be registered in the NIH Scientific Management Review Board (SMRB) Protocol Registration System? (Required)

Yes
No

Not applicable

Are you a Principal Investigator or Co-Principal Investigator on a clinical trial? (Required)

Yes
No

Study Design

Provide a brief overview of your study in non-technical language. Explain what you plan to study and the basic study design. (Required)

Describe what you will do with the study data. Describe what you will do with the study results. Describe how the study will be conducted.

Do not include technical terms. Be sure to define or explain them.

What is the purpose / hypothesis / significance of the research? Describe in non-technical language or explain technical terms. (Required)

The study involves the following (check all that apply) (Required)

- Secondary Data/Chart Review
- Prospective Data Collection
- Interviews
- Questionnaires/Surveys
- Focus Groups
- Clinical Research
- Behavioral Intervention
- Medical Intervention
- Site Visits / Video, etc. etc.
- Phone Calls
- Review grants and educational records
- Review medical records
- Review Medical Records
- Review Medical Records
- Review Medical Records
- Review Medical Records

What is the source of the data? (Required)

Describe how you have / will receive access to the data.

Does the data owner require any special data protections, data use agreements, etc.? (Required)

Please describe. (Required)

Are the subjects given permission for their data to be used in the study? (Required)

Is this the same, or very similar, to the consent form and/or assent form in the original (parent) Protocol? (Required)

Explain. (Required)

Upload the consent form template that was used in the previous study, if possible.

Add Attachment

List the variables you will collect / analyze, or you may attach a separate file below.

Upload a separate variable list

Add Attachment

Where will the research take place? Check all that apply. (Required)

- At UAB's campus
- At UAB's clinics
- At a school
- At a private residence
- At a community center
- At a hospital
- At a nursing home
- Other

You selected "Other." Please describe. (Required)

Will any research be conducted outside the US? (Required)

Yes
No

Will you be conducting research in any locations subject to American Indian tribal oversight? (Required)

Examples: Reservations, tribal lands, tribal schools or other institutions

Explain how you are including input from tribal leadership and members of the tribe(s) when designing your research. (Required)

Research should be conducted with guidance of the elders and written permission from the tribal leadership and members of the tribe(s) involved in tribal lands and schools.

Will you access or use any Protected Health Information (PHI), governed by HIPAA regulations? (Required)

Choose Yes if:

- You are accessing or receiving medical record data from a skilled nursing facility, hospital, or other medical facility, or from a health care provider.
- Your research involves the creation of a new HIPAA Compliant database or repository for future research purposes or UAB IT is a vendor for your research project.

Choose No if:

- You are using de-identified or PHI that is provided to you for research purposes, and do research in no part of a HIPAA covered entity.

Do the main page, you will be asked to provide more details about the use of HIPAA in your research.

Will you be collecting, analyzing, and/or accessing HIPAA protected data in your research? (Required)

Yes
No

- Student educational records
- Employee records
- Medical, employment, or other law need

Choose Yes if you are an employee and have access to these records as part of your job duties.

Choose No if you are not an employee and have access to these records as part of your job duties.

Choose Other if you are a student, employee, or other person who is conducting research using student or employee records, medical records, or other protected records, and the research is not part of a HIPAA covered entity.

Does your research involve any biological samples or Deliverables-controlled items, drugs, tissue, etc.? (Required)

Yes
No

You will need to be submitted separately to the IBC.

Use of Human materials require biosafety review. Click here to post a Biosafety application. If you have not already done so, please complete the application.

Will you use radiation in your research? (Required)

Yes
No

This includes x-rays, CAT scans, etc.

You will be asked to provide more details about the use of radiation in a following page.

Click the main journey background that informed your study design. You can provide other's selection bibliography or a descriptive rationale of existing literature. (Required)

HIPAA

UP Researchers working with HIPAA protected data must familiarize themselves with HIPAA regulations and complete HIPAA training.

Link to UAB HIPAA education

Link to Covered UAB HIPAA training

Contact UAB HIPAA Security for assistance with determining relevant protections for HIPAA-covered data.

Contact UAB HIPAA Security for assistance with creating a HIPAA Compliant database through UAB's Star Group Services. Research personnel must complete HIPAA training before being granted access and required to complete UAB's HIPAA training.

Recommended training requirements for all personnel involved in the study or data.

Describe why the Protected Health Information (PHI) is necessary in your research. (Required)

Specify the PHI that will be gathered, accessed, or used. (Required)

Which of the following identifiers are connected with the data? (Check all that apply. (Required)

- Names
- Geographic subdivisions smaller than state, including street address, city, county, and zip code
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and exact age if over 89
- Telephone numbers
- Vehicle identifiers and serial numbers, including license plate numbers
- Email addresses
- Medical record numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Account numbers
- Certificate/license numbers
- Social security numbers
- Health plan beneficiary numbers
- Biometric identifiers, including finger and voice prints
- Full face photographs and any comparable images

List the source of the PHI. (Required)

Who will have access to PHI? (Required)

List the roles or titles of all research team members who will have access to protected health information.

Will the PHI leave the Covered Entity? (Required)

Yes
No

Explain. (Required)

Describe your plan for maintaining identifiers. Specify which identifiers will be destroyed and when.

If you are not able to destroy identifiers, provide justification for the need for a permanent retention and describe the security safeguards that will be used to protect the identifiers.

(Required)

Will participants give written permission for you to use their protected health information? (Required)

Yes
No

If you will use a cloud-share HIPAA collaboration tools (such as Box.com), please describe how. (Optional)

Remember, the cloud share must be included in a HIPAA authorization form and/or consent form.

Sample cloud-share HIPAA collaboration template

Explain why you cannot obtain written authorization. (Required)

UAB is never allowed the proposal process as outlined the waiver.

Attestation

Investigator that involves survey collection with human subjects. Minimum Requirement of Health Services requires the following information in accordance with Health 000-1017, Appendix B of the Minimum Internal Control Standards.

Investigator that involves survey collection with human subjects. Minimum Requirement of Health Services requires the following information in accordance with Health 000-1017, Appendix B of the Minimum Internal Control Standards. Any data collection with human subjects, and the time-stamped consent form, the URL either with notify the Radiation Safety Committee of the proposed research study.

Any new activities and activities involving radiation until you have received the reference from the state. The process can take some time. Please plan accordingly.

For more information, please see the Radiation Safety website.

PI name and address where the research will take place. (Required)

Describe the proposed to be used in selecting the individuals screened and their present medical conditions of the results of the screening procedure and any further medical needs indicated. (Required)

Describe the procedures for the referral or disposition of the subjects, therapy, program and other records pertaining to the x-ray examination. (Required)

Indicate the frequency of the screening and the duration of the entire screening program. (Required)

Research Location

Research Location

In what country are you conducting research? (Required)

What region / province / state / town / city? (as applicable) (Required)

List the country of the researchers(s) who will be traveling to the country in conduct research. (Required)

Why was this location chosen? (Required)

If you have previous universities or experience in this location, please include a description in your answer.

Have you been invited by local residents to do research here? Explain. (Required)

Have your local relatives been involved in the research design and planning? Explain. (Required)

Language

Sample

What language(s) do your potential research participants speak, and in what language will the research be conducted? *(Required)*

Do you speak the language(s) listed above? *(Required)*

- Yes
- No

Describe your proficiency level and experience with the language. *(Required)*

Who will interpret / translate? What qualifications does this person have? *(Required)*

Other Ethical / Regulatory Oversight

Who oversees research in this location? *(Required)*

This may be an IRB, local ethics committee, ministry of health, etc.

What is the process for obtaining approval from this entity or organization? *(Required)*

Do you have approval from this entity or organization? *(Required)*

- Yes
- No

Please upload a copy of the approval. *(Required)*

Add Attachment

Where are you in the process of obtaining this approval? *(Required)*

Cultural / Political / Economic Considerations

What is the age of consent in this location? *(Required)*

Age of consent is the age at which individuals are legally considered adults.

In many countries this is age 18, but some places have different ages or other criteria, such as marriage, that qualify younger individuals as legal adults.

To help the IRB understand your subject population, please rate the following for your participants: *(Required)*

Rate as best you can. We understand that these are difficult to describe or quantify in many cases, but they are used to give the IRB a general idea of the population you're recruiting and any additional protections that might be needed.

What other relevant cultural factors affect the conduct of your study, or the well-being of participants? How have these influenced your study design? What additional measures are in place to protect participants? *(Required)*

Subject Population

Will you enroll any participants who are part of a vulnerable population? Check all that apply. *(Required)*

- Students recruited in the educational setting
- Prisoners
- Minors (under 18 years old)
- Pregnant women or neonates
- Institutionalized individuals / Nursing home residents
- Decisionally or cognitively impaired
- Economically or educationally disadvantaged
- Non-English speaking
- Terminally ill
- Other
- None of the above

You checked Other. Please describe: *(Required)*

List subject group(s) and how many you expect to enroll from each group. *(Required)*

Overestimate your enrollment. Take into account potential withdrawals in your total.

For secondary data analysis studies, use this and the next section to describe the dataset and the population from whom data was collected.

Click Save at the end of each row before moving to the next.

Subject groups*	Anticipated enrollment*	Action
E.g. students, teachers,		Save

List your eligibility criteria for each group. *(Required)*

List the subject groups from the question above, or if the criterion applies to all groups, list "all groups" in the first column. In the Rationale box, explain why you have chosen these eligibility criteria.

For secondary data analysis studies, use this section to describe the population from whom data was collected.

Click Save at the end of each row before moving to the next.

Subject group(s)*	Inclusion/Exclusion*	Criteria*	Rationale*	Action
				Save

How will you verify that participants meet your eligibility criteria? *(Required)*

If you will ask any screening questions, you can either list them in this box or attach a separate form below.

Will eligibility be verified before or after you obtain informed consent? *(Required)*

- Before consent
- At the time of or after consent
- Other

You selected "Other". Please explain. *(Required)*

Upload a separate screening form here (optional)

Add Attachment

Recruitment, Consent, Deception and Compensation

Recruitment: Describe how, when, and where potential participants will first learn of your study. *(Required)*

If you will be emailing or calling potential participants, explain how you will obtain their contact information.

List all methods of recruitment (e.g. social media, in-person, flyers/ads, emails, phone calls, etc.) and provide details of how this initial contact will occur.

Who will recruit potential participants? *(Required)*

You can list either by name or by role (e.g. "PI", "SPI", "doctoral research assistants")

What recruitment strategies are you using to ensure you have a diverse sample? If none, explain why not. *(Required)*

Within the research ethics community, increasing focus is being placed on ensuring diverse representation in study subjects. This promotes the Belmont principle of justice and produces better scientific results.

"Diverse representation" includes race, culture, gender, sexual orientation, age, socio-economic status, disabilities, etc.

Unless your protocol specifically requires studying a homogenous group, you should be including methods that ensure representation of minorities and other underrepresented groups in your study sample.

Attach all recruitment materials here (verbal or email scripts, social media posts, flyers, ads, etc).

Add Attachment

Submit the final, fully formatted versions.

For verbal and email recruitment, submit a script so we can see how you will present the study information to potential participants.

Recruitment materials should NOT have compensation as the main focus.

If you will be using a video, please also upload a transcript.

Who will obtain informed consent (or parental permission, if you are enrolling minors)? *(Required)*

You can list either by name or by role (e.g. "PI", "SPI", "doctoral research assistants")

Explain how and when participants will provide informed consent, or, if you are enrolling minors, explain how and when parents/guardians will provide parental permission. *(Required)*

Explain how and when you will obtain assent from participants who are minors or otherwise not able to consent for themselves. If you do not plan to obtain their assent, explain why. *(Required)*

Explain how you will ensure that potential participants don't feel coerced or pressured into participating. *(Required)*

Examples:

Instructors recruiting their own students could have someone else recruit on their behalf when they aren't present, or not learn who consented until after grades are finalized for the course.

When employees are recruited in the workplace, employers should not know who participates or not whenever possible, and the decision whether or not to participate should have no bearing on any performance reviews, promotions, or disciplinary actions.

How will you obtain informed consent? Check all that apply. *(Required)*

- Signed consent
- Verbal or online consent, no signature (waiver of documentation/signature)
- Altered consent (certain information is withheld)
- Requesting a full waiver of consent or parental opt-out (not frequently permitted)

If you are using an "opt-out" parental permission procedure, answer "Requesting a full waiver of consent".

Please note: Waiving parental permission / opt-out procedures for non-educational research is not recommended. Written parental consent should be obtained whenever possible. If the opt-out method is requested, full board review will be required.

Waiver / Alteration Details

You have indicated that you are requesting a waiver of documentation of consent. Which of the following applies to your study? *(Required)*

A waiver of documentation of consent means you still provide all the same consent information, but accept an electronic or verbal affirmation instead of a written signature (e.g. verbal or online consent).

If none of these apply to your study, then you must obtain written signatures.

- The consent document would be the only record linking the subject and the research, and the principal risk is harm from a breach of confidentiality. Participants will be asked whether they want documentation linking them to the research, and their wishes will govern.
- The research is minimal risk and does not include any procedures that require written consent outside the research context.
- Participants are members of a cultural group or community in which signing forms is not the norm, the research is minimal risk, and there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- None of the above.

Explain which required elements of consent you want to alter or waive. *(Required)*

Explain why you are requesting the waiver or alteration. *(Required)*

Attach the consent and assent form(s) for your study. *(Required)*

Add Attachment

Be sure you carefully proofread for spelling and grammar before submitting.

If you will be using an opt-out letter, attach it here.

Add Attachment

Will you share the study results with participants once the study is complete? *(Required)*

- Yes
- No

When and how? *(Required)*

Why not? *(Required)*

Will your study involve any deception? *(Required)*

- Yes
- No

Explain why deception is necessary to your study. *(Required)*

Will participants know when they give consent that certain information about the study is being withheld (authorized deception)? *(Required)*

- Yes
- No

Authorized deception is considered more ethically acceptable and studies have shown it actually results in higher satisfaction than traditional deception, without negatively impacting recruitment or introducing study bias.

Authorized deception is recommended whenever possible.

Explain when and how you will debrief participants about the deception. Include a debriefing script. *(Required)*

You may attach your debriefing script as a separate file here, if you prefer.

Add Attachment

Are you offering any kind of compensation or recruitment incentive to participants? *(Required)*

- Yes
- No

This can be monetary, extra credit, small gifts/items, etc.

What form of compensation will you offer? Check all that apply. *(Required)*

- Cash or check
- Gift cards
- Extra Credit
- Items, tokens, or gifts
- Raffle or Prize drawing
- Other

If a participant will receive an electronic device to use during the study that they will be permitted to keep, that should be considered an "Item" for the purposes of this section.

You marked "other". Please describe. *(Required)*

Raffles and prize drawings must comply with Wisconsin state gambling laws. See UWM Legal Affairs guidance for more information.

How much compensation are you offering? *(Required)*

If participants may receive different amounts (either prorated or different groups receiving different compensation), explain.

If you are offering items or small gifts, provide the approximate value.

For international studies:

- *Indicate the equivalent amount in US dollars.*
- *Provide context for the amount in terms of a typical hourly or daily wage for your participant population.*

When extra credit is offered, the researcher must also provide a non-research alternative. Please describe the alternate activity students may do in lieu of research participation. *(Required)*

The alternate activity must:

- *Require the same amount of time and effort as research participation*
- *Be worth the same amount of extra credit*
- *Be clearly communicated in recruitment and consent materials*

What Level of Confidentiality of Payments are you requesting? *(Required)*

Level 1: Confidentiality is not a serious issue. Providing a social security number or other identifying information for payment would not pose a serious risk to subjects.

- *For payments over $50, the researcher must collect and maintain a record of the payee's name, address, social security number, amount paid, and the payee's signature indicating receipt of payment.*
- *Payment information will be retained in the extramural account folder at UWM Research Services and will be attached to the voucher in Accounts Payable. These are public documents, potentially open to public review.*

Level 2: Confidentiality is an issue, but is not paramount to the study.

- *For payments over $50, the researcher must collect and maintain a record of the payee's name, address, social security number, amount paid, and the payee's signature indicating receipt of payment.*
- *The IRB will issue a formal notice that Level 2 Confidentiality of Payments has been granted.*
- *Payment information will be attached to the PIR and become part of the voucher in Accounts Payable. These are not considered public record.*

Level 3: Confidentiality must be guaranteed. Collecting identifying information such as a social security number would put subjects at increased risk.

- *The researcher must maintain a record of the research subject's name and corresponding coded identification. This will be the only record of payee names, and it will stay in control of the researcher.*
- *If payment is via cash or gift card, the researcher must obtain signatures indicating receipt.*
- *The IRB will issue a formal notice that Level 3 Confidentiality of Payments has been granted.*
- *Note: Level 3 CANNOT be selected if the total payment to an individual subject is $600 or more within one calendar year.*

- Level 1
- Level 2
- Level 3

Explain the reason for selecting Confidentiality Level 2 or 3. *(Required)*

Consent waiver

For a consent waiver to be approved, your study must fall under one of the following scenarios.

If you are conducting research on Public Benefit or Service Programs (uncommon), answer questions for Scenario A.

All other studies, answer questions for Scenario B.

If you're not sure, choose Scenario B.

Scenario A: Public Benefit or Service Program Research Only

A.1 The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

A.2 Explain why the research could not practicably be carried out without the waiver or alteration.

A.3 Has any participant already refused consent for their data or biospecimens to be used in this way?

Scenario B: All other types of research

B.1 Research is minimal risk.

B.2 Explain why the research could not practicably be carried out without the waiver or alteration.

B.3 If the research involves identifiable or coded data or biospecimens, explain why the research could not practicably be carried out unless the data/biospecimens were identifiable/coded.

B.4 Explain how the waiver or alteration will not adversely affect the subjects' rights and welfare.

B.5 Explain whether the subjects will be given additional pertinent information after participation. If not, explain why not.

B.6 Has any participant has already refused consent for their data or biospecimens to be used in this way?

Procedures, Risks, and Benefits

Describe in detail each intervention or activity the participants will be asked to perform. *(Required)*

List each activity individually and provide details, including how long each activity will take.

For surveys, interviews, and focus groups, provide an overview of the questions (you'll attach the specific questions separately).

For focus groups, explain how many people per group and how many groups total there will be.

B I U Format

Does your research involve the use or testing of any specialized devices or equipment? *(Required)*

"Specialized devices or equipment" means any specialized equipment that is part of the research intervention being tested and/or will gather data, either from a distance or directly applied to participants' bodies. Examples include eye-tracking cameras, motion sensors, pulse oximeters, etc.

This includes both novel devices being tested as part of the research as well as approved devices being used to collect data.

This does NOT include phones, audio recorders, or computers used solely for recording interviews or data analysis.

- Yes
- No

Devices or specialized equipment used in this research study *(Required)*

Click Save at the end of each row before moving to the next.

Action
Save

Attach any device-related documents that might be important for the IRB to review.

Add Attachment

Examples:

- *User manual / instructions for use*
- *Diagram or design parameters*
- *FDA IDE letter, or determination that the device is a Non-Significant Risk device*

Explain who will be collecting the data and their qualifications for performing this role in the research. *(Required)*

List either by name or by role (e.g. PI, graduate research assistant, etc.)

Qualifications:
For many low-risk studies, qualifications are often simple, such as CITI training and going over the protocol with the PI.

For more sensitive data, such as collecting data about traumatic experiences, the IRB generally expects to see some sort of psychology counseling, social work, or other specialized training that enables the researcher to address any emotional risks of the study.

For physical interventions, describe any training the researcher will have received with regards to using the equipment.

B I U Format

Explain where data collection will occur. *(Required)*

Generic descriptions are fine; specific addresses are not needed.

Examples:
"In the PI's lab on UWM's main campus"
"In participants' homes"
"In meeting rooms at community libraries"

Describe any steps taken to maintain subjects' privacy during data collection. *(Required)*

B I U Format

If your subject population is likely to include individuals with a disability (e.g. hearing, vision, mobility, etc.), describe what accommodations you have built into your study design to make your research procedures accessible. *(Required)*

B I U Format

Describe all potential risks associated with your study activities, and explain how you are minimizing these risks. *(Required)*

Risks may be:

- *physical*
- *emotional*
- *social*
- *financial*
- *legal*
- *negative impacts to reputation or employment*

Include risks related to any devices used in this study.

"Minimizing risk" means either steps taken to prevent a risk from happening, or to minimize any negative impact if it does occur.

Click Save at the end of each row before moving to the next.

Risk*	How you are minimizing this risk*	Action
		Save

Will you collect any data about illegal activities? *(Required)*

- Yes
- No

Be sure to list the illegal activities above in the Risks question, and what potential harm could occur if there were a breach in confidentiality.

Are there any direct potential benefits to participants? If yes, describe. *(Required)*

Do NOT include compensation, which is an enrollment incentive rather than a benefit.

Benefits include potential improvement to a participant's life or wellbeing as a direct result of participation in this research.

Describe the potential benefits to society or to advancing knowledge within your field. *(Required)*

Cannot be "none".

The potential benefits must outweigh the potential risks.

If there are no benefits, the research is not ethical and can't be approved.

Attach all data collection tools and documents you will use. *(Required)*

Include the full version of all forms, surveys, interview questions, focus group questions, etc.

If you are using a Qualtrics or other electronic survey, do not paste the link to the online survey. Convert to pdf or Word and attach as a separate document.

For semi-structured interviews, list the specific questions you plan to ask and provide a note indicating the type of follow-up questions that may be asked.

Gender demographics: *When collecting demographics about participants' gender, you should at a minimum include the options "man", "woman", and "another gender identity not listed here". Questions about biological sex should only be asked if they are directly relevant to the research aims, and should be paired with questions asking about gender identity. For more details about collecting data on gender, sex, and sexual orientation, please see our guidance page for Research with LGBTQ+ individuals.*

Add Attachment

Data analysis and storage

How will data be analyzed or studied? *(Required)*

Be sure to describe whether data is quantitative or qualitative.

How will data be reported? *(Required)*

Will it be aggregated? Reported anonymously? Pseudonyms used for participant names? etc.

Identifiability of collected and stored data. Data will be: *(Required)*

Check all that apply.

Consider different types of data as well as the same data at different timepoints. If the data won't be handled the exact same way at every stage, multiple boxes should be checked here (example: data is initially identifiable, but then later de-identified).

Please read the IRB Guidance Document on Data Storage for recommendations about data security and confidentiality.

Anonymous	No identifiers are collected at any point and it would be impossible to identify specific individuals from the data.
De-identified	The identity of who participated in the study is or was previously collected, but this information is completely separate from the data. There is no possible way to connect participants' identity with their data.
Indirectly identifiable	The data does not have any direct identifiers or a link to identifiers, but it could be possible for a combination of data to pinpoint a specific individual (e.g. a combination of certain demographic characteristics).
Coded / Pseudonym	Data is linked to a participant's identity indirectly through use of a study ID or pseudonym. The linking key/file is stored in a separate, secure location.
Identifiable but Confidential	Data is stored with direct identifiers, but participants' true identity will not be disclosed to anyone outside the research team.
Identifiable and Disclosed	Data is stored with direct identifiers, and participants' identity will be revealed with their consent.
Participant choice	Participants may choose whether their identity is disclosed or confidential.
Other	

Describe other: *(Required)*

You have selected more than one option. Explain which method is used for which data. *(Required)*

Will any recordings (audio/video/photos) be done as part of the study? *(Required)*

- Yes
- No

Explain what activities will be recorded and the recording method(s). *(Required)*

Will the recordings be used in publications or presentations? If yes, explain. *(Required)*

Describe how data will be stored and the security measures in place to prevent a breach of confidentiality. *(Required)*

Type of data examples: screening data, paper questionnaires, online survey responses, EMG data, audio recordings, interview transcripts, subject contact information, key linking Study ID to subject identifiers, etc.

Storage location examples: file cabinet in PI's office, OneDrive, a laptop computer, desktop computer in shared lab space, Qualtrics servers, etc. (Listing specific room numbers is not necessary).

Security measures: Describe the measures for each storage location to protect against a breach of confidentiality. Examples: locked office, encrypted devices, coded data, non-networked computer with password protection, etc.

Who will have access: List either the role (e.g. PI, SPI) or specific names of anyone who would be able to access the data.

Estimated date of disposal: May be a specific date or an event (e.g. recordings deleted as soon as they are transcribed). If a given type of data will not be discarded, state "none".

To add a new row, click "Save" under the Action heading on the right end of the table.

Type of Data*	Storage Location*	Security Measures*	Who will have access*	Estimated date of disposal*	Action
					Save

Will data be retained for uses beyond this study? *(Required)*

- Yes
- No

Describe the potential future use(s) of this data. *(Required)*

nsent form as well.

Other relevant information

Is there any other information the IRB should know when reviewing this study? (optional)

Attach any other documents that might be important for the IRB to review. (optional)

Add Attachment

Signature for submission

By signing this form, I attest that:

- **I accept responsibility for complying with Federal and State regulations and UWM polices relative to the protection of human research subjects.**
- **I will not initiate this study until I receive written approval from the IRB.**
- **I will promptly report to the IRB any unanticipated problems and adverse events, as well as any findings during the course of the study that may affect the risks and benefits to subjects.**
- **I will obtain prior written approval for any changes to this protocol.**
- **I will provide status updates to the IRB upon request.**

(Required)

Sign...

After you enter your signature, click Next and then Submit on the following page.

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2021.7.5861.0/Release/cd7273c | GCWAWS1 | 2021-08-08 20:55:26Z | 0.623s
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