

University of New Hampshire

Template for Cayuse System

Human Subjects

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Study Title
Assign PI

Getting Started

*required

About Cayuse IRB

Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. You do not have to finish the application in one sitting. All information can be saved.

Additional information has been added throughout the form for guidance and clarity. That additional information may be found by clicking the question mark in the top-right corner of a section.

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the Cayuse IRB Procedures Manual: <http://support.cayuse.com/>.

Getting Started

For a complete application submission, you will be required to provide the following (if applicable):

- Detailed Study Protocol
- References (if applicable)
- Proposed Recruitment Materials (if applicable) (e.g., flyer, email announcement, social media post)
- Informed Consent or Assent Documents
- IRB Training Completion Documentation
- Proposed Questionnaires, Guiding Questions, Survey Instruments, Tests, etc.
- Debriefing Information (if applicable)
- Faculty Advisor Letter (for student researchers)
- Letter of Permission from Study Site (if applicable)

General Reminders

- You must not begin recruitment or data collection until you have received a written, unconditional approval letter from the IRB.
- If your study involves any of the following, the IRB is unable to review your application and instead you need to utilize the services of a qualified, accredited external IRB to be the IRB of record for the study:
 - Multi-site clinical trials
 - Studies involving drugs, agents, biologics, devices, or other products regulated by the U.S. Food and Drug Administration (FDA): <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>
 - Industry-initiated or industry-sponsored research.

*I have read the information above and I am ready to begin my submission.

- Yes

USNH Institution

*With which University System of New Hampshire (USNH) institution are you affiliated?

Please note that your application will be routed to the IRB at the institution which you select below. If you are affiliated with more than one USNH institution, choose your affiliation most relevant to this research study.

- University of New Hampshire (UNH)
- Plymouth State University (PSU)
- Keene State College (KSU)

Contact information for each campus for questions.

At UNH, Melissa McGee (603) 862-2005, Susan Jalbert (603) 862-3536, or Julie Simpson (603) 862-2003

At PSU, Clarissa Uttley (603) 535-2915

At KSC, Kim Becker (603) 358-2443, Nan Fey-Yensan (603) 358-2378, or Kim Cassin (603) 358-2780

*What is the Principal Investigator's status at the institution you checked above?

If the Principal Investigator has more than one status at the institution, choose the role in which the Principal Investigator is conducting this study.

- Faculty
- Staff
- Student
- Other

Study Principal Investigator & Primary Contact

Principal Investigator: [**FIND PEOPLE**]

Attach a copy of the PI's certificate of completion of the UNH web-based training on the ethical use and treatment of human subjects in research.

[**ATTACH**]

Primary Contact

This person can make changes to the application (along with the Principal Investigator (PI) and co-PIs) but is not required to certify the initial submission in Cayuse IRB.

NOTE: This defaults to the PI. If you want to add someone else then you have to delete the PI by clicking 'X' in the table and then searching for someone like above.

IRB Process (UNH)

UNH faculty, staff, and students who plan to conduct research involving human subjects must submit applications to the IRB prior to commencing the study. Applicants must receive written, unconditional IRB approval before starting their study. For a flow chart depicting the IRB application review process, please click here: <https://unh.box.com/s/me4v2mdo05m7ls9sqd6y85ymqtsqgb38j>.

The IRB meets twice a month during the academic year and once each month during the summer to review studies qualifying for Full Board review: <https://www.unh.edu/research/irb-review-levels>. Studies requiring Full Board level review must be submitted according to the posted schedule: <https://www.unh.edu/research/irb-meeting-schedule>. Upon receipt by RIS staff, applications are placed on the agenda for the next scheduled IRB meeting. Applications are reviewed on a first come, first served basis; if too many applications are received for review at a specific IRB meeting, the review of those received latest may be postponed until the following IRB meeting. Researchers who plan to conduct studies requiring Full Board review should submit applications to the IRB at least 4 weeks prior to the anticipated start date (allow 8 weeks in the summer).

Studies qualifying for Exempt or Expedited level review: <https://www.unh.edu/research/irb-review-levels> are forwarded upon receipt to IRB members for review. Initial Exempt or Expedited level review generally takes 10 working days during the semester, and 15 working days during the winter break and summer.

Several types of activity, both research and non-research, involving human participants commonly occur at UNH. In order to clarify whether an activity is research or if it involves human subjects, UNH employs the federal government's definition of human subjects and research (see here: <https://unh.app.box.com/s/0dlldovpwf6aup6jer5z72h72nyhvksh> for the IRB's guidance on when IRB approval is needed at UNH.) Activities at UNH involving human participants commonly fall into the following categories:

- Research - the purpose of the activity is to contribute to generalizable knowledge and data gathered may be shared with a research community or the public at large. UNH considers any project conducted for an undergraduate honors thesis, a master's thesis or a dissertation to be research. IRB approval is required at UNH for research that involves human subjects.
- Evaluation/Assessment/Service/Reporting - the purpose of these activities is, upon request, to gather data to measure the current situation in regard to a specific phenomenon or set of factors. UNH IRB approval is not required for these activities, and data gathered may be shared only with the sponsor /client/requesting party and where appropriate, the faculty advisor, or used for internal decision making or informational purposes.
- Classroom Assignments/Educational Inquiry/Practice - the purpose of these activities is the education of an individual student through an inquiry or experiential approach to discover known principles or phenomena. UNH IRB approval is not required for these activities, and data gathered may be shared only with the course instructor or faculty advisor, or in the case of an internship/practicum, the collaborating party.

Individuals gathering data from human subjects as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice abrogate their rights to publish data as research data; if they choose to share observations with others, their actions ought to be governed by the ethical standards of their discipline (e.g., American Psychological Association or American Anthropological Association). Individuals who wish to gather data from human subjects as part of evaluations, assessments, service, reporting, classroom assignments, educational inquiry, or practice AND intend to use the data as research data for the purpose of publishing or sharing with a research community or the public at large (e.g., via the UNH Undergraduate Research Conference [URC] or the Graduate Research Conference [GRC], must obtain IRB approval PRIOR to conducting the activity.

Information from and about the UNH IRB, including guidance, templates, procedures and forms, is available here:

https://www.unh.edu/research/resources/all?combine&resource_type=All&field_resource_category_tid=All&field_resource_topic_tid=88.

Faculty, staff, and students who would like assistance in developing research protocols, or would like to discuss issues related to their research studies, should contact Melissa McGee (603) 862-2005, Susan Jalbert (603) 862-3536, or Julie Simpson (603) 862-2003.

Faculty, staff and students in the psychology department have the option to have their applications reviewed by the psychology Departmental Review Committee (DRC) instead of by the UNH IRB only if the study qualifies for Exempt level review: <https://www.unh.edu/research/irb-review-levels>. For more information about the psychology DRC, contact Professor Robert Ross.

Do you want this study reviewed by the psychology Departmental Review Committee (DRC) instead of by the UNH IRB? If you check yes, the application will be forwarded to the psychology DRC for review as long as it qualifies for Exempt level review. If it does not qualify, the application will be reviewed by the UNH IRB.

- Yes
- No

*I have read the information above and I understand the UNH IRB review process.

- Yes

*Does this study involve multiple institutions?

Include institutions where personnel are "engaged" in research (see here:

<https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html> for an explanation of "engaged").

- No
- Yes

If yes, Is UNH the lead institution for this multi-institution study?

- No
- Yes

If yes....

Is the PI requesting that UNH serve as the IRB of Record for one or more other study sites participating in this study?

- Yes, UNH will serve as the IRB of Record for all institutions involved in this study.

For each site that will rely on the UNH IRB's approval, provide the name of relying IRB/ institution and name of PI for the study at that institution.

This collaborative agreement will be executed via (select one):

- ☐ SMART IRB
 - ☐ IRB Authorization Agreement (IAA)
- No, another site will serve as the IRB of Record for this study.

Outside IRB of Record

Provide the name of the outside IRB of record/institution and the name of the PI for the study at that institution. _____

This collaborative agreement will be executed via (select one):

- ☐ SMART IRB
 - ☐ IRB Authorization Agreement (IAA)
- No, each site's IRB will review the study.

Study Information & Design (UNH)

*Is this submission a continuation/replacement of an existing (legacy) study that was approved by the UNH IRB before May 2021?

- No
- Yes

If yes, please provide the existing (legacy) study UNH IRB approval number (four numbers). ____

Study Dates*

Proposed Start Date:

UNH Policy on the Use of Human Subjects in Research prohibits the start of any research activity (including canvassing and recruiting of subjects) that has not been reviewed by, and received written approval without contingency from, the IRB.

- MM-DD-YYYY

Anticipated End Date

This is the date when you anticipate finishing collecting data from study participants.

- MM-DD-YYYY

Sponsor/Funding Information*

External Sponsor

Has a proposal for funding this study been submitted to an external sponsor (a sponsor external to UNH)?

- Yes
- No

If yes, Select the sponsor(s) for this study.

If the sponsor is not in the list, search for and choose the sponsor "Sponsor Not Found" and provide the information here: FIND SPONSORS (*must hit enter after typing in name to initiate search; once you have the results list click on "name" to sort alphabetically*).

Has the project received funding yet?

- Yes, and the award/contract has been set up at UNH.
- Yes, the study is funded but the award/contract is in the process of being set up by UNH.
- No, it is pending review by the sponsor/client.

Type of Study*

Please select one.

- Research study that involves future data collection only.

If checked:

Please check all that apply.

- Pilot study
- Non-experimental survey
- Experimental research involving control and intervention/treatment group(s)
- Qualitative research study
- Quality improvement project
- Program evaluation also being conducted for research purposes
- Undergraduate Honors thesis
- Master's thesis
- Doctoral dissertation
- Course/class assignment that will also be used for research (e.g., URC or GRC presentation)
- Clinical trial
- Other
- None of the above.

- Research study that involves existing/secondary data only.

If checked:

Please check all that apply.

- Quality improvement project
- Undergraduate Honor's thesis
- Master's thesis
- Doctoral dissertation
- Course/class assignment that will also be used for research (e.g., URC or GRC presentation)
- Other
- None of the above

- Research study that involves both future data collection and existing/secondary data.

If checked:

Please check all that apply.

- Pilot study
- Non-experimental survey
- Experimental research involving control and intervention/treatment group(s)
- Qualitative research study
- Quality improvement project
- Program evaluation also being conducted for research purposes
- Undergraduate Honor's thesis
- Master's thesis
- Doctoral dissertation
- Course/class assignment that will also be used for research (e.g., URC or GRC presentation)
- Clinical trial
- Other

- Other

If checked:

Please explain (open-ended)

- None of the above

Study Site(s)*

Where will data collection take place (check all that apply)?

- UNH
If yes, please select the UNH campus(es) where the study will take place (check all that apply).
 - UNH Durham
 - UNH Manchester
 - UNH Law
- External site (if there are collaborating institutions involved in this study, you will be asked to provide information about them later in this form). Only include sites where data collection will take place.
 - Identify the site(s). [ENTER TEXT]

Attach documentation reflecting permission from each site. **[ATTACH]**

- Online (e.g., via Qualtrics, Zoom)
- Other (e.g., coffee shop, participants' home)
Please explain.

Other Study Personnel

List individuals not listed as the Principal Investigator, Primary Contact or Faculty Advisor who will be working directly with participants or will be working with data from participants.

*Is there a co-Principal Investigator for this study?

This person can make changes to the application in Cayuse IRB and will have to certify the submission to the IRB in Cayuse IRB.

- Yes
Co-Principal Investigator(s)
Note: If you cannot find a person in the people finder, please contact the IRB staff.
[FIND PEOPLE BUTTON]
- No

*Are there additional UNH personnel involved in the study not already identified?

- Yes
Additional UNH personnel (excluding students) who will be involved in the project.
Note: If you cannot find a person in the people finder, please add them in the section immediately below.
[FIND PEOPLE BUTTON]
- No

Additional UNH personnel who will be involved in the project not listed previously or who are students.

For each person you list, provide their name, position (i.e., faculty, staff, student), email address, and role on the project. In the case of students, identify who will supervise them in their work on the study.

DIRECTLY ENTER TEXT INTO BOX

*Are there non-UNH personnel who will be involved in the study?

- Yes
- No

Non-UNH personnel who will be involved in the study.

For each person you list, provide their name, position and organizational affiliation, email address, and role on the project. In the case of students, identify who will supervise them in their work on the study.

DIRECTLY ENTER TEXT INTO BOX

Attach copies of the IRB training certificates for personnel listed above.

[ATTACH]

Individual Investigator Agreement

Any non-UNH study personnel who are not affiliated with another institution (or who are affiliated with an institution that does not have an IRB with a [federalwide assurance registration](#)) must sign an [Individual Investigator Agreement](#).

[ATTACH]

***Study Background**

Provide the background, rationale, and significance of the study. *Please be succinct yet provide sufficient detail for the IRB to conduct its review, and write in an active (versus passive) voice.*

DIRECTLY ENTER TEXT INTO BOX

Study Aims*

Provide the study hypothesis(es) or research question(s).

DIRECTLY ENTER TEXT INTO BOX

Participant Info (UNH)

Ages*

Select the age range of participant who will be enrolled in this study. Check all that apply.

- Newborns/infants\
- Children 2-12 years of age
- Adolescents 13 -17 years of age
- Adults (individuals 18 years of age or older)

Note. For each you must:

Enter the approximate number of participants who will be involved in this study. _____

Special Populations*

Please check any special population(s) that will be targeted for enrollment.

- Incarcerated individuals (e.g., prisoners).
- Individuals with impaired decision making (e.g., individuals with mild dementia, active substance abusers).
- Adults with a legal guardian (e.g., individuals with cognitive disabilities, advanced dementia).
- Immigrants (legal or illegal).
- UNH students in courses for which the PI is also the course instructor.
Review the [IRB's Guidelines for Research Involving College Students](#).
- Students in a classroom setting.
Depending on age of the students, review the [IRB's Guidelines for Research Involving College Students](#) or the [IRB's Guidelines for Research Involving Minors/Children](#).
- Adults over 89 years of age.
- Individuals in the European Union if the research involves monitoring a person's behavior in the EU.
Review the IRB's guidance on the [European Union's \(EU\) General Data Protection Regulation \(GDPR\) and Human Subjects Research](#).
- Other special populations.
Please describe. _____
- None of the above.

Inclusion and Exclusion Criteria*

Are there any participant inclusion or exclusion criteria for your study?

- Yes
- No

If yes...

*List and describe the participant inclusion criteria and justification for each criterion.

DIRECTLY ENTER TEXT INTO BOX

*List and describe the participant exclusion criteria and justification for each criterion.

DIRECTLY ENTER TEXT INTO BOX

Recruitment

*Explain who will recruit participants.

Please note that if you recruit UNH students from courses for which you are also the course instructor, you need to make sure that students understand that the research opportunity is not a class assignment and that refusal to participate will not impact their grade. The IRB prefers that individuals other than instructors of courses (e.g., a graduate assistant, another faculty member in the department) present research opportunities to students in courses that they teach to avoid coercion.

DIRECTLY ENTER TEXT INTO BOX

*Describe how, when and where individuals will be first contacted about their interest to participate in the study (e.g., in-person, email, social media, flyers, advertisements, phone call, texts). If you are directly emailing, mailing, texting, or calling individuals, explain how you are obtaining their contact information.

DIRECTLY ENTER TEXT INTO BOX

*Do you plan to use recruitment materials (e.g., emails, social media postings, flyers, advertisements, texts)?

- Yes
- No

If yes...

Select all the types of recruitment materials that you propose to use in this study

- Recruitment scripts (what will be said to potential participants during recruitment)
- Recruitment emails
- Social media postings
- Texts
- Flyers
- Advertisements
- Other

Attach all the types of recruitment materials selected above. Please do not link to recruitment materials as they will not be available for the file if taken down or moved.

Please note: All recruitment materials need to contain the word "research" somewhere in the information.

[ATTACH]

Payments/Incentives to Participants*

- Yes
- No

If yes...

Select all the types of payments/incentives that will be used in this study.

- Non-monetary incentive that is not extra credit

A non-monetary incentive is a reward given to research participants as encouragement to participate in a study (e.g., food, gift, promotional item).

Do you plan to offer the incentive using a drawing?

- No
- Yes

Describe the non-monetary incentive(s) to be used in this study, how they will be awarded, and any criteria for receipt. _____ -

- SONA credit for a study (subject pools)

In any studies where researchers offer SONA credit to students who participate, the researcher must also provide one or more equivalent non-research activities that provide equivalent SONA credit. This is to avoid exerting undue influence on students to participate in research to gain SONA credit.

Describe the amount of SONA credit to be awarded, the equivalent non-research activity to earn the equivalent SONA credit, and the process for reporting the SONA credit to the instructor if not the PI. _____

- Extra credit for a course

In any courses where instructors offer extra credit to students who participate in a research study, the instructor must also provide one or more equivalent non-research activities that provide equivalent extra credit. This is to avoid exerting undue influence on students to participate in research to gain course credit. Instructors must also ensure that students understand that the research activity is not part of the course requirements.

Describe the amount of extra credit to be awarded, the equivalent non-research activity to earn the equivalent extra credit, and the process for reporting the extra credit to the instructor if not the PI. _____

- Monetary incentive

A monetary incentive is a monetary reward given to research participants as encouragement to participate in a study (e.g., cash, gift card).

If you plan to use a drawing to award an incentive, for studies conducted in New Hampshire, you should use the term "drawing" instead of "raffle" as the latter is regulated by the state. Use of the terms "lottery" or "raffle" generally implies participants purchase tickets. For studies conducted in other jurisdictions, you should check the law of the jurisdiction. You should explain the drawing process, including how participants will be entered, the value of the prize(s), when the drawing will take place in the timeframe of the study, and what will happen to participants? contact information submitted after the drawing has taken place.

A friendly reminder/caution regarding monetary incentives or compensation: IRB approval is separate from UNH Purchasing approval of any proposed methods of paying study participants. Before making any payments to study participants, researchers should consult with their BSC or UNH Purchasing to ensure that they are complying with institutional requirements. If such institutional requirements are not consistent with the confidentiality or anonymity assurances in the IRB-approved protocol and consent documents, the researcher may need to request a modification.

*Describe the monetary incentive(s) to be used in this study, how they will be awarded, and any criteria for receipt. _____

*What information will you collect from (or record about) the participant to document receipt of the compensation/incentive? (See the IRB Guidance document, Payment of Incentives/Compensation to Research Participants.) _____

■ Compensation

Compensation is remuneration to participants for their time and effort spent in a research study. Researchers should consider a level of compensation earned for unskilled employment involving similar non-research activities in the local area. Compensation should not be calculated using participants' earning potential outside the research context.

A friendly reminder/caution regarding monetary incentives or compensation: IRB approval is separate from UNH Purchasing approval of any proposed methods of paying study participants. Before making any payments to study participants, researchers should consult with their BSC or UNH Purchasing to ensure that they are complying with institutional requirements. If such institutional requirements are not consistent with the confidentiality or anonymity assurances in the IRB-approved protocol and consent documents, the researcher may need to request a modification.

Describe the compensation to be used in this study, how it will be awarded, and any criteria for receipt. _____

What information will you collect from (or record about) the participant to document receipt of the compensation/incentive? (See the IRB Guidance document, Payment of Incentives/Compensation to Research Participants.) _____

■ Reimbursement

Reimbursement is payment to participants for reasonable out-of-pocket expenses by giving them an amount of money equal to what they spent. Such expenses may include travel, parking, accommodation, meals, or childcare.

Describe the reimbursement, how it will be made, and any criteria for receipt.

What information will you collect from (or record about) the participant to document receipt of the compensation/incentive? (See the IRB Guidance document, Payment of Incentives/Compensation to Research Participants.) _____

*Prorating Payments/Incentives:

Will payments/incentives be prorated for partial participation?

- Yes
- No

If yes...

Explain the method of proration. Be sure to include this information in the consent information.

DIRECTLY ENTER TEXT INTO BOX

Study Protocol/Procedures (UNH)

Data Collection Methods*

Please check all that apply.

- Instruments in development and will be submitted to the IRB for review prior to administration.

Type of instrument in development (check all that apply).

- Surveys
- Interview questions
- Focus group questions
- Questionnaires/surveys
 - Web-based (e.g., Qualtrics)
 - Mail
 - Telephone
 - In-person
 - Email

Attach your questionnaire/survey instrument(s); please do not link to the survey as IRB reviewers may not have access to the linked documents or may have to complete the survey to see the questions or the survey will not be available for the file once closed.

[ATTACH]

Please add here any comments or information about your questionnaire/survey instruments that you want the IRB to know. _____

- Interviews
 - Web-based (e.g., via Zoom)
 - Telephone
 - In-person
 - Email

Attach your interview questions; please do not link to the questions as IRB reviewers may not have access to the linked documents or the documents may not be available once the study is finished.

[ATTACH]

Please add here any comments or information about your interview questions that you want the IRB to know. _____

- Focus groups
 - Web-based (e.g., via Zoom)
 - In-person
 - Telephone

Attach your focus group questions; please do not link to the questions as IRB reviewers may not have access to the linked documents or the documents may not be available once the study is finished.

[ATTACH]

Please add here any comments or information about your focus group questions that you want the IRB to know. _____

- Observation
- Recording (including of interviews or focus groups)
 - Audio-recording
 - Video-recording
 - Photography
- Administration of tests, inventories, self-reports, measuring instruments, etc.
 Attach each test/inventory/instrument that will be administered, or a description of the test; please do not link to the instruments as IRB reviewers may not have access to the linked documents or the documents may not be available once the study is finished.
[ATTACH]

Please add here any comments or information about your instruments that you want the IRB to know. _____

- Reviewing medical or education records
 Review information about the Health Insurance Portability and Accountability Act (HIPAA) (medical records) or the Family Education Rights and Privacy Act (FERPA) education records as they may apply to your study.
- Collecting coursework from students
 Review information about the Family Education Rights and Privacy Act (FERPA) as it may apply to your study.
- Physiological testing
 Will study participation involve maximal oxygen uptake?
 - ☐ Yes
 As this study involves maximal oxygen uptake, it will be reviewed by the IRB at the next scheduled IRB meeting (Full Board review).
 - ☐ No
 Does your study involve pregnant women?
 - ☐ Yes
 - ☐ No
 Will you screen participants for health issues?
 - ☐ Yes
 Attach your medical screening questionnaire; please do not link to the questionnaire as IRB reviewers may not have access to the linked documents or they will not be available for the file once the study is closed. **[ATTACH]**
 - ☐ No
 Please explain why not. _____
 Will participants need clearance/permission from a health care provider to participate in this study?
 - ☐ Yes
 Explain the procedure for obtaining health care provider clearance/permission for participants. _____

Attach the proposed documentation for obtaining health care provider clearance for participants; please do not link to them as IRB reviewers may not have access to the linked documents or they will not be available for the file once the study is completed. **[ATTACH]**

- No
Explain why not.
- Medical procedures
 - Blood draw
 - Magnetic Resonance Imaging (MRI) or Functional MRI (fMRI)
 - Electrocardiogram (EKG)
 - Electroencephalogram (EEG)
 - X-ray
 - Body composition testing
 - Other

Does your study involve pregnant women?

- Yes
Attach your medical screening questionnaire; please do not link to the questionnaire as IRB reviewers may not have access to the linked documents or they will not be available for the file once the study is finished. [ATTACH]
- No
Please explain why not.

Will you screen participants for health issues?

- Yes
- No
If yes...

Will participants need clearance/permission from a health care provider to participate in this study?

- Yes
Explain the procedure for obtaining health care provider clearance/permission for participants. _____

Attach the proposed documentation for obtaining health care provider clearance for participants; please do not link to them as IRB reviewers may not have access to the linked documents or they will not be available for the file once the study is completed. [ATTACH]
- No
Explain why not.

- Other
Please describe. _____

Study Attributes*

Please check all that apply.

- This study involves a request for a Title IX Reporting Exception for Research. Visit the Title IX Reporting Exception for Research webpage for the application form and related information about requesting this reporting exception.

Attach the completed Application for a Title IX Reporting Exception for Research. [ATTACH]

- Information subject to the Health Insurance Portability and Accountability Act (HIPAA)
Contact UNH's HIPAA Privacy Officer with questions about HIPAA.
- None of the above.

Study Procedures*

Describe what your participants will do in this study. Ensure that you explain the duration of study participation, the length, type and number of each activity/procedure that participants will undergo and a step-by-step description of the activity/procedure, and the timeline for completing the activities. If your study involves treatment and control groups, explain clearly what each will be doing. Please be succinct yet provide sufficient detail for the IRB to conduct its review, and write in an active (versus passive) voice. Please do not include information in this section about the process of obtaining informed consent or working with the data as you will provide that information in subsequent sections.

DIRECTLY ENTER TEXT INTO BOX

Please attach (not link) here any documentation (photographs, images, flow charts, etc.) that will help explain your study.

[ATTACH]

*Will the data collection method record any information that can identify participants either directly or indirectly, or that can be linked to them (e.g., via a code)?

- Yes
- No

If yes...

Please justify why the data collection method needs to record identifiable information.

Recording

Describe the type of recording(s) that will be made, the recording protocol, and the procedure for transferring digital recordings/images from the recording device to UNH IT secure cloud storage (e.g., UNH Box, UNH OneDrive/SharePoint).

Will the recordings be transcribed?

- No
- Yes

Explain who will transcribe the recordings (e.g., the researcher, a third party). If a third party, explain whether you will use an individual or a service, and if a service, whether it is online and if so, which one(s). Explain the measures in place with the transcriptionist/transcription service regarding confidentiality.

Debriefing*

Do you plan to provide your participants debriefing information?

- ☐ Yes
- ☐ No

If yes....

Attach your debriefing script/information; please do not link to the debriefing as IRB reviewers may not have access to the linked documents or may have to complete the survey to see the debriefing or the debriefing may not be available for the file once the study is finished.

[ATTACH]

Informed Consent (UNH)

Informed consent (or assent for those under age 18 or adults who have a legal guardian) is a process, not simply a document. Researchers and their staff must devote adequate time to explain the research to potential study participants and answer questions or concerns before an individual signs the consent/assent document. The informed consent/assent process begins when the researcher initially approaches the participant/family and it continues throughout the study.

Unless otherwise requested, the IRB expects researchers to obtain informed consent from participants before involving them in a study. A written consent document using the IRB's template in and of itself embodies all of the required elements of informed consent, as required in the federal human subjects protections regulations.

The researcher (or research personnel) may read the informed consent form to the participant or the participant's legally authorized representative to facilitate comprehension, but the researcher must still give either the participant or the representative adequate opportunity to read the form before signing it. When the full form is used, the participant or representative signs the full form, and receives a copy of the signed form from the researcher.

Special Considerations for Confidentiality Language in Informed Consent Documents

Please check all that apply.

- This study may involve/elicit responses that trigger mandatory reporting:
<https://unh.box.com/s/5t238wgsobftbw8zpsjr9nodh9lf8f50> (e.g., suspected child abuse or neglect, student hazing, sexual violence). The sections below include questions about potential mandatory reporting requirements relative to the populations(s) involved in the study.
- A Certificate of Confidentiality applies to this study.
<https://grants.nih.gov/policy/humansubjects/coc.htm>
 You must include in your consent document information about the protections that a Certificate of Confidentiality provides and any limits to that protection (see here for sample text).
- A National Institutes of Justice (NIJ) Privacy Certificate applies to this study:
<https://nij.ojp.gov/funding/privacy-certificate-guidance>
 You must include in your consent document information about the protections that a Privacy Certificate provides and any limits to those protections.

 * Attach (not link) the Privacy Certificate for this study.
[ATTACH]
- This study involves deliberately recruiting individuals located in the European Union and collecting identifiable information about them:
<https://unh.box.com/s/j0wwus0r62oxwv9435quqkgl0ksdxbam>.
- Other
 Please explain. _____

Informed Consent for Adults (individuals 18 years of age or older)

*Does your study involve adult participants 18 years of age or older?

- Yes
- No

If yes....

*Delivery of informed consent information to participants.

Please check all that apply.

- Cover letter mailed with survey.
- Cover letter posted on a survey website and where participants click on a button to give or refuse to give consent.
- Written form which will be signed.
- Written form which will not be signed.

*I request a waiver of documentation of informed consent (i.e., waiving a participant's signature on a consent document) for the following reason:

Please check one.

- Research participation involves only completing one or more surveys and generally, the IRB does not require participants' signatures on consent forms for surveys as it considers completion of surveys as indicating consent.
- The signed consent document is the only study record of the participant's name and a breach of confidentiality would present risk to the participant.
- It is culturally inappropriate to ask participants to sign documents.
- Script for oral presentation to participants.
- Use of translated documents for individuals who do not read or speak English.
The IRB must review and approve translated consent documents prior to use.
- Submission of an English version of informed consent information for oral presentation by a translator to participants in their native language which is not written.
- Involvement of individuals with language or learning difficulty.
In your description of the consent process, you need to address how you will ensure participants understand the informed consent/assent information, especially that participation is voluntary.
- I request an alteration of informed consent information (not including all required elements of informed consent or deliberately misleading individuals [incomplete disclosure or deception]).

Incomplete Disclosure or Deception

Deception or incomplete disclosure may interfere with the ability of research participants to make a fully informed decision about whether to participate in the study. Deception is when a researcher gives false information to subjects or intentionally misleads them about some key aspect of the research. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

Either must be justified and the IRB must find the following in order to approve a consent procedure that involves either:

- The research involves no more than minimal risk to the participants;

- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever possible, the subjects will be provided with additional pertinent information after participation (a complete debriefing).

Will your study involve incomplete disclosure?

- ☐ No
- ☐ Yes

Describe the information about the study that will not be shared with participants via the informed consent process and the rationale for doing so.

Will your study involve deception?

- ☐ No
- ☐ Yes

Describe the manner in which participants will be deceived, how the deception will take place, the rationale for employing deception, whether the deception results in increased risk, alternatives to deception that were considered and why they were not employed, and whether deception may impact a participant's willing to participate in the study.

- I request a waiver of the informed consent process (participants will not receive any consent information).

Explain why you do not want to obtain informed consent from your participants.

- Other

Please explain. _____

*Describe the process of obtaining informed consent from participants. Do not answer, "see the attached consent form" as this does not describe the process of obtaining informed consent. Describe who will obtain informed consent, how, when, and where.

DIRECTLY ENTER TEXT INTO BOX

*Attach the informed consent document(s) for this study; please do not link to the document(s) as IRB reviewers may not have access to the linked documents or they will not be available for the file once the study is completed.

- Ensure that you use one of the IRB's informed consent document templates.
- If you indicated above that your study may involve mandatory reporting, ensure you include in the document the requisite information about exceptions to confidentiality applicable to your study.

- If you requested a Title IX Reporting Exception for Research, ensure that you use the informed consent document template for studies that have received a Title IX Reporting Exception for Research.
[ATTACH]

Informed Consent for Adults (individuals 18 years of age or older) who have a Legal Guardian

In this section, "wards" refers to the adult participants in the study who have a legal guardian and therefore cannot legally consent for their own participation in the study.

*Does your study involve adults with legal guardians?

No

Yes

Delivery of informed consent information to guardians.

Please check all that apply.

- Cover letter mailed with survey.
- Cover letter posted on a survey website and where guardians click on a button to give or refuse to give consent for their ward to participate.
- Written form which will be signed.
- Script for oral presentation to guardians.
- Use of translated documents for individuals who do not read or speak English.
The IRB must review and approve translated consent documents prior to use.
- Submission of an English version of informed consent information for oral presentation by a translator to participants in their native language which is not written.
- Involvement of individuals with language or learning difficulty.
In your description of the guardian consent process, you need to address how you will ensure participants understand the informed consent/assent information, especially that participation is voluntary.
- I request a passive guardian consent/opt out procedure (where guardians only return the guardian consent form if they do not want their ward to participate)?
- I request an alteration of informed consent information (not including all required elements of informed consent or deliberately misleading guardians [incomplete disclosure or deception]) as to their ward's participation in the study.

Incomplete Disclosure or Deception

Deception or incomplete disclosure may interfere with the ability of research participants to make a fully informed decision about whether to participate in the study. Deception is when a researcher gives false information to subjects or intentionally misleads them about some key aspect of the research. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

Either must be justified and the IRB must find the following in order to approve a consent procedure that involves either:

- The research involves no more than minimal risk to the participants;

- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever possible, the subjects will be provided with additional pertinent information after participation (a complete debriefing).

Will your study involve incomplete disclosure to guardians?

No

Yes

Will your study involve deception of guardians?

No

Yes

- I request a waiver of the informed consent process (guardians will not receive any consent information about their ward's participation in the study).

Explain why you do not want to obtain informed consent from guardians.

- Other

Please explain.

Describe the process of obtaining informed consent from guardians. Do not answer, "see the attached guardian consent form" as this does not describe the process of obtaining guardian consent. Describe who will obtain guardian consent, how, when, and where.

DIRECTLY ENTER TEXT INTO BOX

Delivery of informed consent information to wards.

- Cover letter mailed with survey.
- Cover letter posted on a survey website and where wards click on a button to give or refuse to give assent.
- Script for oral presentation to wards.
The IRB must review and approve translated assent documents prior to use.
- Use of translated documents for individuals who do not read or speak English.
The IRB must review and approve translated assent documents prior to use.
- Submission of an English version of informed assent information for oral presentation by a translator to participants in their native language which is not written.
- Individuals with a learning or language difficulty.
In your description of the ward assent process, you need to address how you will ensure participants understand the informed consent/assent information, especially that participation is voluntary.
- Written form which will be signed.
- Written form which will not be signed.

I request a waiver of documentation of informed assent (i.e., waiving a participant's signature on a assent document) for the following reason:

Please check one.

- Research participation involves only completing one or more surveys and generally, the IRB does not require participants' signatures on consent forms for surveys as it considers completion of surveys as indicating consent.
- The signed consent document is the only study record of the participant's name and a breach of confidentiality would present risk to the participant.
- It is culturally inappropriate to ask participants to sign documents.
- I request an alteration of informed assent information (not including all required elements of informed consent or deliberately misleading wards [incomplete disclosure or deception]) as to their participation in the study.

Deception or incomplete disclosure may interfere with the ability of research participants to make a fully informed decision about whether to participate in the study. Deception is when a researcher gives false information to subjects or intentionally misleads them about some key aspect of the research. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

Either must be justified and the IRB must find the following in order to approve a consent procedure that involves either:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever possible, the subjects will be provided with additional pertinent information after participation (a complete debriefing).

Will your study involve incomplete disclosure to wards?

No

Yes

Will this study involve deception of wards?

No

Yes

- I request a waiver of the informed assent process (wards will not receive any consent information about their participation in the study).
Explain why you do not want to obtain informed consent from your participants.

- Other
Please explain. _____

Describe the process of obtaining ward assent. Do not answer, "see the attached assent form" as this does not describe the process of obtaining assent. Describe who will obtain ward assent, how, when, and where.

DIRECTLY ENTER TEXT INTO BOX

Parental Consent and Child Assent (for children under 18 years of age)

Please refer to the IRB's Guidelines for Conducting Research Involving Children/Minors:

<https://unh.box.com/s/2j9i8a34we2xm7fy3a0udmher8vyaggs>

*Does your study involve minors (children under 18 years of age)?

No

Yes

If yes...

This study may involve collecting information from participants subject to mandatory reporting requirements (review the IRB guidance on Information Individuals in New Hampshire are Legally Required to Report: <https://unh.box.com/s/5t238wgsobftbw8zpsjr9nodh9lf8f50>).

- Suspected abuse or neglect of a child.
- Direct knowledge of any student hazing at an educational institution in New Hampshire.

Delivery of informed consent information to parents.

- Cover letter mailed with survey.
- Cover letter posted on a survey website and where parents click on a button to give or refuse to give consent for their child to participate.
- Script for oral presentation to parents.
- Use of translated documents for individuals who do not read or speak English.
The IRB must review and approve translated consent documents prior to use.
- Submission of an English version of informed consent information for oral presentation by a translator to participants in their native language which is not written.
- Involvement of individuals with language or learning difficulty.
In your description of the parental consent process, you need to address how you will ensure participants understand the informed consent/assent information, especially that participation is voluntary.
- Written form which will be signed.
- I request a passive parental consent/opt out procedure (where parents only return the parental consent form if they do not want their child to participate)?

Please note the following:

1. New Hampshire RSA 186:11, IX-d requires written parental consent for any non-academic survey or questionnaire administered to students in public K-12 schools.

2. The IRB rarely approves a passive parental consent procedure for minors to be involved in a study where participation involves activities other than surveys, such as interviews, focus groups, behavioral interventions, or non-invasive procedures. The IRB believes that parents have to actively provide consent for their children to engage in such face-to-face activities with researchers, regardless of where they take place, unless there are extenuating circumstances and where the IRB can make required findings. Please read Section B of the IRB's Guidelines for Research Involving Minors regarding "passive" parental consent for more information.

- I request an alteration of informed consent information (not including all required elements of informed consent or deliberately misleading parents [incomplete disclosure or deception]) as to their child's participation in the study.

Incomplete Disclosure or Deception

Deception or incomplete disclosure may interfere with the ability of research participants to make a fully informed decision about whether to participate in the study. Deception is when a researcher gives false information to subjects or intentionally misleads them about some key aspect of the research. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

Either must be justified and the IRB must find the following in order to approve a consent procedure that involves either:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever possible, the subjects will be provided with additional pertinent information after participation (a complete debriefing).

Will your study involve incomplete disclosure to parents?

No

Yes

If yes...

Describe the information about the study that will not be shared with participants via the informed consent process and the rationale for doing so. _____

Does this study involve deception of parents?

No

Yes

If yes....

Describe the manner in which parents will be deceived, how the deception will take place, the rationale for employing deception, whether the deception results in increased risk, alternatives to deception that were considered and why they were not employed, and whether deception may impact a participant's willing to participate in the study. _____

- I request a waiver of the parent consent process (parents will not receive any consent information about their child's participation in the study).

Explain why you do not want to obtain informed consent from parents.

- Other _____

Please explain. _____

Describe the process of obtaining informed consent from parents/guardians. Do not answer, "see the attached parental consent form" as this does not describe the process of obtaining parental/guardian consent. Describe who will obtain parental/guardian consent, how, when, and where.

DIRECTLY ENTER TEXT INTO BOX

Delivery of informed assent information to children.

- Cover letter mailed with survey.
- Cover letter posted on a survey website and where children click on a button to give or refuse to give assent.
- Written form which will be signed.
- Written form which will not be signed.

I request a waiver of documentation of informed consent (i.e., waiving a participant's signature on a consent document) for the following reason:

Please check one.

- Research participation involves only completing one or more surveys and generally, the IRB does not require participants' signatures on consent forms for surveys as it considers completion of surveys as indicating consent.
- The signed consent document is the only study record of the participant's name and a breach of confidentiality would present risk to the participant.
- It is culturally inappropriate to ask participants to sign documents.
- Script for oral presentation to children.
- Use of translated documents for individuals who do not read or speak English.
The IRB must review and approve translated consent documents prior to use.
- Submission of an English version of informed consent information for oral presentation by a translator to participants in their native language which is not written.

- Involvement of individuals with language or learning difficulty.
In your description of the assent process, you need to address how you will ensure participants understand the informed consent/assent information, especially that participation is voluntary.
- I request an alteration of informed consent information (not including all required elements of informed consent or deliberately misleading children [incomplete disclosure or deception]) as to their participation in the study.
Incomplete Disclosure or Deception

Deception or incomplete disclosure may interfere with the ability of research participants to make a fully informed decision about whether to participate in the study. Deception is when a researcher gives false information to subjects or intentionally misleads them about some key aspect of the research. Incomplete disclosure is a type of deception that involves withholding some information about the real purpose of the study, or the nature of the research procedures.

Either must be justified and the IRB must find the following in order to approve a consent procedure that involves either:

- The research involves no more than minimal risk to the participants;
- The waiver or alteration will not adversely affect the rights and welfare of the participants;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever possible, the subjects will be provided with additional pertinent information after participation (a complete debriefing).

Will your study involve incomplete disclosure?

No

Yes

If yes...

Describe the information about the study that will not be shared with participants via the informed consent process and the rationale for doing so. _____

Will this study involve deception of children?

No

Yes

If yes...

Describe the manner in which children will be deceived, how the deception will take place, the rationale for employing deception, whether the deception results in increased risk, alternatives to deception that were considered and why they were not employed, and whether deception may impact a participant's willing to participate in the study. _____

- I request a waiver of the informed consent process (children will not receive any consent information).
Explain why you do not want to obtain informed consent from your participants
- Other
Please explain.

Describe the process of obtaining child assent. Do not answer, "see the attached assent form" as this does not describe the process of obtaining assent. Describe who will obtain child assent, how, when, and where.

DIRECTLY ENTER TEXT INTO BOX

Data (UNH)

Keeping participants' information secure is a fundamental responsibility of researchers who involve human subjects in research. When participating in research studies, participants entrust researchers with the information they provide, some of which may be sensitive. Accordingly, researchers must ensure that they have in place adequate measures to protect the security of participants' data, regardless of its form (e.g., paper, electronic).

Before completing this section, please read the UNH IRB's Guidance on Privacy, Confidentiality and Anonymity in Human Subjects Research: <https://unh.box.com/s/ek7j9iiy08qju46shypzeipd39kuyr91>.

Data Management Plan

If you have developed a data management plan for this study as part of an application to a sponsor, please attach it here.

[ATTACH]

Data Analysis and Interpretation

*Describe how data will be analyzed or studied (using quantitative or qualitative methodologies).

DIRECTLY ENTER TEXT INTO BOX

*Describe how the interpretation will address the research question(s)/aim(s).

DIRECTLY ENTER TEXT INTO BOX

Data Reporting, Access and Use

*Describe how data will be reported (e.g., aggregated, pseudonyms for participants). If your study involves collecting a combination of demographic information that may identify unique individuals, or individuals from small limited samples, explain how you will protect their identity in reporting your results. If you plan to use direct quotes from individuals, explain how you mask the identity of the participants quoted (unless they agreed to be identified with their quotes).

DIRECTLY ENTER TEXT INTO BOX

*Describe who will have access to identifiable data (put N/A if none collected).

DIRECTLY ENTER TEXT INTO BOX

*Describe how data will be used (e.g., in presentations, thesis, publications).

DIRECTLY ENTER TEXT INTO BOX

Data Security and Storage

For security purposes, the UNH IRB strongly encourages researchers to store research data on UNH IT secure cloud storage (e.g., UNH Box, UNH OneDrive/SharePoint). If storage on UNH IT cloud storage is not appropriate for this study, please state that and explain why.

*As applicable, please describe:

- How you will protect data while on-site and during travel (e.g., from data collection site back to the office). When traveling, particularly overseas, or when using portable devices, address the measures you will use to protect data storage and security of electronic data as well as physical data (e.g., paper surveys).
- Where data will be stored and for how long.
- How you will maintain confidentiality of data while being stored, accessed, used, or shared, including measures to protect the identity of participants and their responses (e.g., data deidentified, limited access to identifiable data).

DIRECTLY ENTER TEXT INTO BOX

*Describe what will happen to any audio or videorecordings (if collected), including details of transcription and disposition of the recordings after transcription or at the end of the study (put N/A if none collected).

DIRECTLY ENTER TEXT INTO BOX

Data Sharing*

Describe how data will be shared beyond the personnel named in this application, and if so, with whom, in what state (e.g., deidentified, aggregated), and how (e.g., deposited in a repository).

DIRECTLY ENTER TEXT INTO BOX

Risks & Benefits (UNH)

All research carries some degree of risk, even if minimal (the risk of everyday life). Studies involving risk of physical injury, civil, financial or criminal liability, risk to a participant's employment, or where the research involves sensitive aspects of participant's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol or tobacco (if underage), have the potential of involving more than minimal risk.

Level of Risk*

What is the level of risk that participation in your study is anticipated to present to participants? Select one.

- This study is anticipated to present no more than minimal risk to participants.
Please explain. _____
- This study is anticipated to present greater than minimal risk to participants.

Potential Risks

Select the type(s) of risk that participating in this study may present to participants (check all that apply).

- Psychological
- Physical
- Legal
- Social
- Economic
- Other

Describe the possible risks to participants as indicated above and explain measures in place to minimize them. _____

Describe any potential legal, financial, social, or personal effects on participants due to a breach of confidentiality (e.g., accidental data disclosure). _____

Safeguarding Participants' Identity

*What precautions will be taken to safeguard identifiable records or individuals' identity during the use of the data as indicated in the previous section?

DIRECTLY ENTER TEXT INTO BOX

Anticipated Benefits

*Describe anticipated direct benefits for participants, if any. Please note that the IRB does not consider compensation or incentives to participate a benefit.

DIRECTLY ENTER TEXT INTO BOX

*Describe anticipated benefits of the knowledge gained via the study at the community level, and in general.

DIRECTLY ENTER TEXT INTO BOX

References

If you have cited any literature in the application, please attach a list of the references.

[**ATTACH**]

Note. It's useful to use APA or some other reference style that does not include numbers. If you have to go back and make changes to your application, the use of numbered references (e.g., AMA style) can be difficult for tracking using this separate reference upload feature.

Outside Interests (UNH)**

** ~ Shows if checked externally funded study

*Do you or any investigator(s) participating in this study have any outside interests related to this research project?

An "outside interest" means involvement with any person, trust, organization, enterprise, government agency, or other entity not a part of USNH.

This includes both unpaid/uncompensated activities, as well as activities that constitute a financial interest for the investigator or their immediate family, such as salary/wages, other payment for services (e.g., expert testimony, board service, editing, lecture, authorship, etc.) consulting, honoraria, stocks, options, gifts, gratuities, IP income, paid travel, or any ownership interest (including sole proprietorship, partnership, LLC membership, or other ownership).

It does not include activities assigned by UNH, such as appointment to an external board or committee, or professional license maintenance requirements.

- Yes
- No

If yes...

Provide the name(s) of the person(s) with external interests.

Note: If you do not find the person you are looking for, please contact the IRB Office immediately.

[FIND PEOPLE BUTTON]

Has the individual(s) named above made all required disclosures to UNH (or their institution if not employed by UNH) and the research sponsor (if applicable)?

If funding for this research is or will be provided by a non-USNH entity, then UNH personnel must submit or update disclosures under their Profile in Cayuse.

- Yes, all investigators on this research study have submitted all required external activity disclosures.
- No, some required disclosures are pending submission.

If yes...

If any such disclosures have been made, has the applicable investigator reached an agreement with UNH (or their institution if not employed by UNH) that provides for conditions or restrictions necessary to manage, reduce, or eliminate any potential or actual financial conflicts of interest?

Such an agreement may be called a "management plan." If a management plan is attached to this IRB application, confidential information in the plan can be redacted

(e.g., details about the value of the financial interest), but the plan should address any restrictions applicable to the recruitment, enrollment or consenting of human subjects. See the UNH Conflicts of Interest and Commitment page for a template plan.

- Yes. A copy of the management plan is attached.
- No, but a management plan is pending.
- N/A - no management plan was required by the cognizant COI review committee.

Attachments

This section includes placeholders for all possible attachments, not just required attachments. Please do not link to files as IRB members may not be able to access them or once the study is completed the documents may not be available for the file. At the end is a place for any miscellaneous attachments that do not appear to fit into any of the other listed categories/purpose.

Note. If you uploaded any of these files earlier they will appear in this section.

Personnel

Faculty Advisor Letter

[ATTACH]

Study Information

Site Permission Letters

[ATTACH]

IAA

[ATTACH]

IIA

[ATTACH]

Study Protocol/Procedures

Survey Instruments

[ATTACH]

Interview Questions

[ATTACH]

Focus Group Questions

[ATTACH]

Medical Screening Questionnaire

[ATTACH]

Health Care Provider Clearance Documentation

[ATTACH]

Title IX Reporting Exception Request

[ATTACH]

Study Documentation

[ATTACH]

Debriefing Information

[ATTACH]

Participant Information

Recruitment Materials

[ATTACH]

Informed Consent

Privacy Certificate

[ATTACH]

Informed Consent Documents

[ATTACH]

Parental Consent Documents

[ATTACH]

Child Assent Documents

[ATTACH]

Guardian Consent Documents

[ATTACH]

Ward Assent Documents

[ATTACH]

Data

Data Management Plan

[ATTACH]

References

[ATTACH]

Existing Data

Data Use Agreement

[ATTACH]

Business Associate Agreement

[ATTACH]

Miscellaneous

Miscellaneous attachments that do not appear to fit into any of the other listed categories/purposes.

[ATTACH]