Introduction and Determination Checklists

Introduction Statement:

Federal regulations and BYU policies require IRB review of research involving human subjects. If you are unsure whether the proposed activities constitute human subjects research, please indicate below that you wish to view the guidance or contact irb@byu.edu for help in this regard.

Activities that meet the regulatory definitions of 'research' and 'human subjects' constitute human subject research and require IRB approval and oversight.

This section is intended to help you determine if your planned activity meets the definition of "research" under the federal regulations, and if that research involves "human subjects". The questions are formulated to detect if your research must be reviewed by the IRB.

* Determination of Review Needed - Check one

- ○ I know I need IRB review.
- ○ I'm not sure if my activity is human subjects research, walk me through the checklists.

Please save and continue to the next section.

The following checklist is provided to assist you in determining if your activity is "research". The more boxes that are checked, the more likely it is your project will be considered "research". Check all that apply:

- **Definition of Research 45 CFR 46.102(7)(l)**

  Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. The following activities are deemed not to be research:
  1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
  2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
  3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
  4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

- **Student-Conducted Research**

  The IRB reviews human subjects research under federal regulations. As such, research is defined as a systematic investigation designed to contribute to generalizable knowledge. Student-Conducted research related to a class project does not generally qualify as research and therefore, does not require IRB review. For questions of

applicability, contact the IRB Office. Research conducted for master's theses and doctoral dissertations do qualify as research – thus, any human subject involvement in theses or dissertations require confirmation of an exemption or IRB approval prior to being initiated. All students or fellows must obtain the participation of a faculty advisor as the Principal Investigator (PI) on the IRB application.

- [ ] The proposed activities will constitute an investigation (a searching inquiry for ascertaining facts; detailed or careful examinations that generally include activities such as research development, testing and evaluation.)
- [ ] The proposed activities will involve a systematic approach (a 'systematic' approach involves a predetermined method or a plan for studying a specific topic, answering a specific question, testing a specific hypothesis or developing theory. A systematic approach incorporates collection of data, either quantitative or qualitative, or specimens, and analysis.)
- [ ] The proposed activities will contribute to knowledge.
- [ ] The information obtained will be generalizable/scholarly activities designed to draw general conclusions (i.e., knowledge gained from a study may be applied to populations beyond the specific study population), inform policy, or generalize findings.

The following checklist is provided to assist you in determining if your activity involves "Human Subjects". The more boxes that are checked, the more likely it is your project involves "Human Subjects". Check all that apply:

Determination of "Human Subject" 45 CFR 46.102(e)(1)

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:

- **Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or**
- **Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.**

- [ ] The activities will include obtaining information about living individuals.
- [ ] The activities will involve direct or indirect intervention or interaction with the individuals (i.e., prospective collection of data/specimens).
- [ ] The activities will not involve obtaining individually identifiable and private information about living individuals.
- [ ] The activities will involve analysis of existing data/specimens (i.e., data/specimens have been collected and are available for analysis).
- [ ] The data/specimens will be coded such that a link exists that could allow the source of the data/specimens to be re-identified (i.e., key available to decipher the code).
- [ ] There will be a written agreement that prohibits the Principal Investigator and his/her research team from having access to the link.

*** Determination of Research Involving Human Subjects**

Check one below.

- ( ) Ok I'm sure my project is human subjects research.
- ( ) I don't think this is research; or, I don't think it involves human subjects - I need the BYU IRB office to concur with my assessment with a confirmation of "Not Human Subjects Research"

Please save and continue to the next section.

IRB contact: irb@byu.edu.

*** Would you like to submit this information to the IRB for an assessment?**

( ) Yes ( ) No

Principal Investigator General Information

Principal Investigator Name

Department

* Who has performed Scientific Review of the research

- ○ Departmental scientific review (You will attach the scientific review checklist in Section 5 of the submission packet)
- ○ Does not require scientific review (Click the orange ? on the right side for a list of exceptions that do not require scientific review)
- ○ Other
- ○ Previously approved before September 23, 2019

Explain why.

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Please describe:

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Provide your IRB ID#:

*** What type of organization initiated this study?**

- Industry-sponsored trial
- Investigator-initiated
- Other

Please describe:

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Please provide additional information, not already provided in investigators' profiles, about their experience related to this research project.

- PhD in field of research
- Publications in this area of research with this method
- Prior research project with approval using this methodology at BYU

Describe any additional expertise regarding qualifications of the investigator(s).

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*** Do you or any other responsible personnel have a conflicts of interest related to this study?**

Please see the following link: https://policy.byu.edu/view/index.php?p=5

Yes No

*** Have you submitted a conflict of interest management plan to your relevant administrative official?**

Yes No

What are your plans to manage conflict of interest?

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Funding

The IRB will need to know how this research project is funded. Please indicate how you will fund the research activities.

*** Is this research being funded by one or more external sources? For example, grants, clinical trial agreements, private foundation funding, contracts, or any other funding source coming from outside BYU.**

○ * CHECK HERE to affirm that the research is being conducted consistent with the scopes and aims of the grants or other funding sources listed above.

View Details	Sponsor Name	Sponsor Type	Funding Through	Contract Type:	Project Number	Award Number
No Sponsor has been added to this Study						

*** Is this research funded through internal BYU funds?**

○ Yes ○ No

Specify the types of internal funding (university salary is not considered funding):

- ☐ Funded by gift
- ☐ Funded by BYU or BYU program
- ☐ Departmental funding
- ☐ Other internal funding

Describe below:

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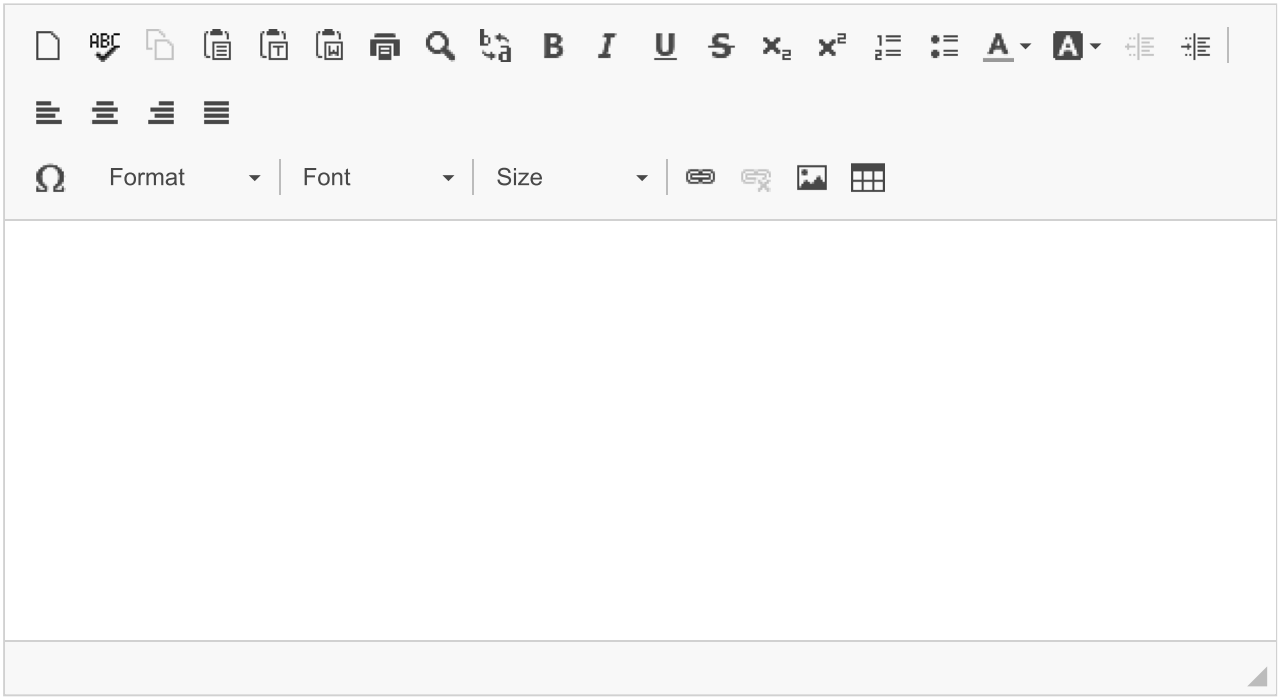
*** Does this research project require financial resources?**

○ Yes ○ No

Please explain how you plan to fund the study.



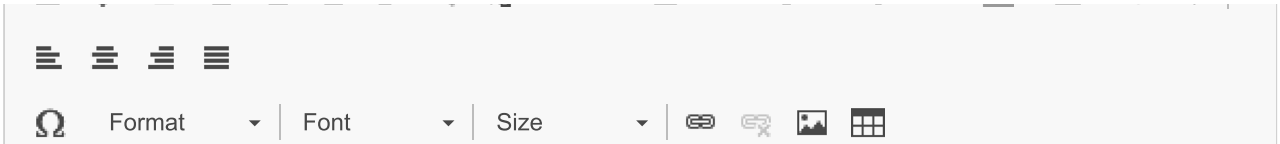
Research Study

This section is intended to identify the objectives, outcomes, research methodologies, type of data collected, and whether this is an interventional study.

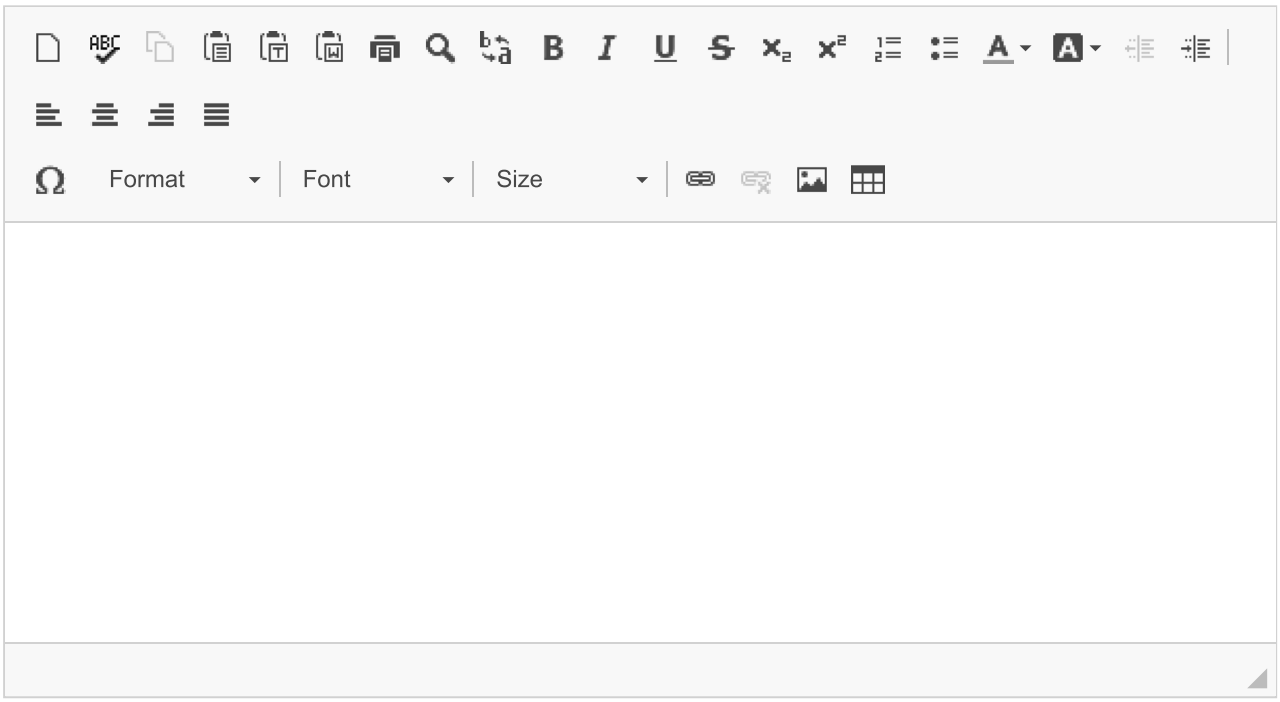
*** Please identify the methods of data collection (check all that apply)**

- [ ] Questionnaire or Survey
- [ ] Interview
- [ ] Observation
- [ ] Educational Tests (e.g., cognitive, aptitude, or achievement)
- [ ] Video recording
- [ ] Audio recording
- [ ] Photographs of human subjects
- [ ] Local computer collected task data (not using internet)
- [ ] Existing databases, Archival Data, Documents
- [ ] Focus Groups
- [ ] Physical Activities
- [ ] Exercise Interventions
- [ ] Physiological Measurements (EEG, Wearable devices, Eye-tracking, body composition, etc.)
- [ ] Internet
- [ ] Data of Public Record
- [ ] Other methods for data collection not described in the options above.

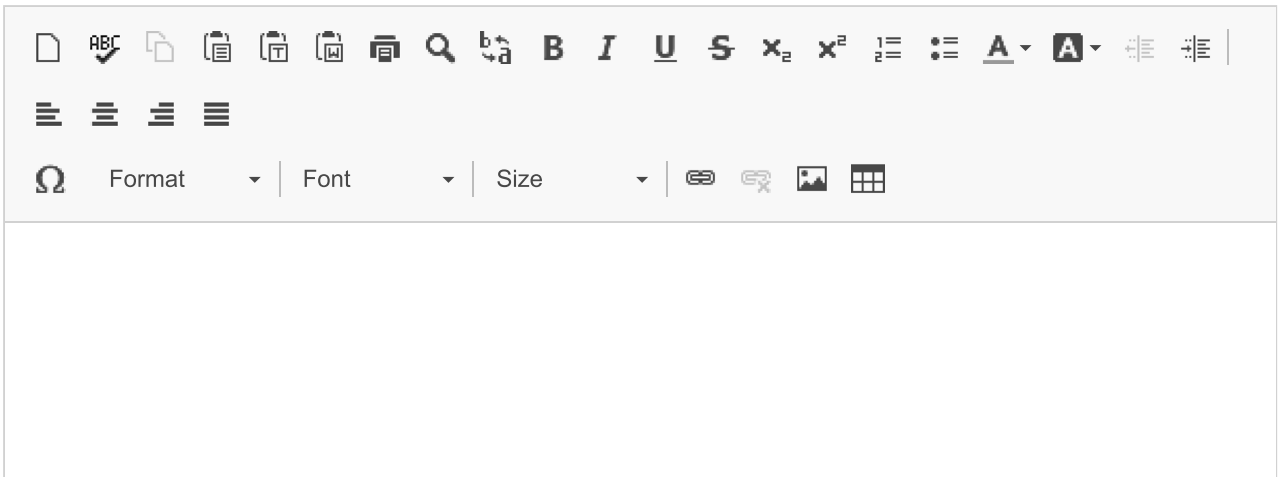
Provide additional details for internet data collection.



Describe data of public record.



Please explain.



* **Write a complete description of all procedures involving human subjects in the proposed research. This description should include:**

1. **Background and rationale provide sufficient information (e.g., pilot data and citations from current literature) to justify the conduct of the study.**
2. **Valid research hypothesis, research question and/or appropriate objectives,**
3. **Define the objectives and/or endpoints.**
4. **What you are asking subjects to do, when, and for how long.**
5. **A step by step description of each procedure written in chronological order.**
6. **If the study has multiple phases or arms, clearly describe each phase.**
7. **Describe the subjects' experience for each phase/arm will be.**
8. **Use or attach a diagram as 'other study documents' in the submission packet, if necessary**
9. **For data analysis studies with no participant interaction use this section to describe the data collection process.**

The information you provide in this section should align with the information in the consent forms.

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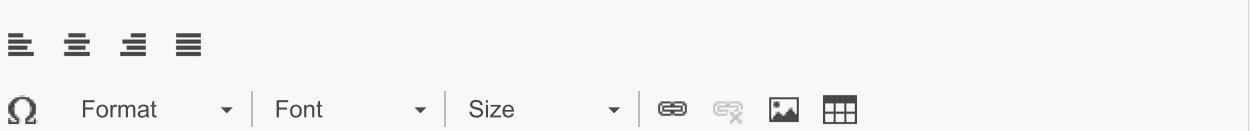
* **Provide details about the data collection instruments you will be using and the rationale for the inclusion of each.**

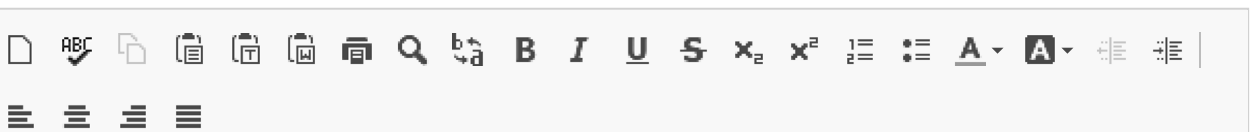


*** Describe your statistical or qualitative analysis plan. How will you know if your research hypothesis or research focus is supported or not?**

*** Will any of the research activities occur at locations outside BYU?**

○ Yes ○ No

Describe in detail the locations of the external sites and what activities will occur at locations outside BYU.



*** Will deception or incomplete disclosure be used in the research design?**

Yes No

Describe in detail how you will use this method, the scientific justification and necessity for using deception and/or incomplete disclosure. Provide a timeline of when the debrief will take place and how it will take place.

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Will you debrief subjects?

Yes No

Provide a timeline of when the debrief will take place and how it will take place.

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Provide a scientific rationale as to why you will not debrief.

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Drugs, Biologics, or Food Supplements

*** Will any FDA regulated drugs, biologics or food supplements be involved or studied in this research? See link https://www.fda.gov/industry/import-basics/regulated-products.**

Note: Drugs include the use of supplements, medical food products, and cosmetics where the intended use is to treat or prevent disease or otherwise affect the structure or functions of the human body.

Yes No

BYU IRB does not currently review FDA regulated studies. Studies subject to FDA regulations will be reviewed by the University of Utah IRB. The following questions will help BYU IRB to determine.

*** Describe how the drugs, biologics, or supplements will be involved.**

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List all drugs or biologics that will be used in this study (contact the IRB office for assistance if needed irb@byu.edu).

View Details	Drug Name	FDA Approved	A new drug or a new use of approved drug:	IND Number
No drugs have been added to this Study				

*** Is this a therapeutic study or intervention (i.e., is this a clinical trial as defined by NIH https://grants.nih.gov/policy/clinical-trials/definition.htm)?**

Note: a therapeutic trial is one where subjects are enrolled and provided a proven treatment for a specific condition and likely to benefit subjects in some way.

Yes No

Answer the three questions below.

Describe the standard of care in the setting where the research will be conducted:

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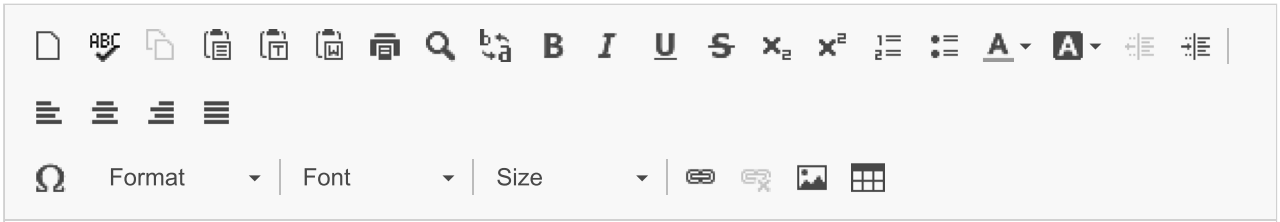
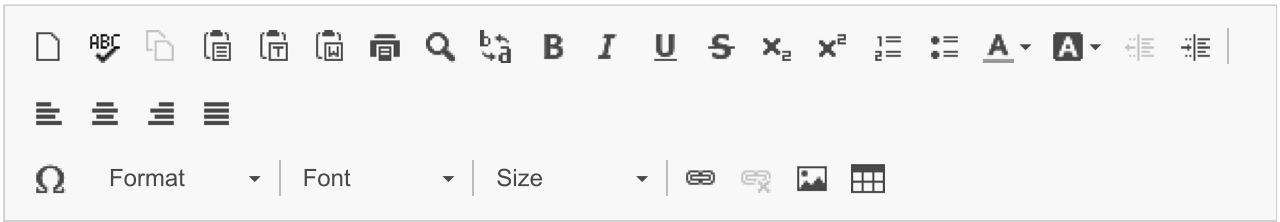
Describe any other alternative treatments or interventions:



Describe any withholding of, delay in, or washout period for standard of care or alternative treatment that participants may be currently using:



*** Devices: Will any devices be involved or studied in this research?**

Please click on the orange help button for additional information.

Note: Investigational devices may include in vitro diagnostic devices, lab developed tests, companion devices, and mobile medical apps.

- ***Device:*** *an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.*
- ***In vitro diagnostic (IVD) products:*** *those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.*

○ Yes ○ No

*** Does this study involve a Humanitarian Use Device (HUD)? https://www.fda.gov/industry/developing-products-rare-diseases-conditions/designating-humanitarian-use-device-hud**

○ Yes ○ No

*** Describe how the device will be involved and provide the approval status of the device.**

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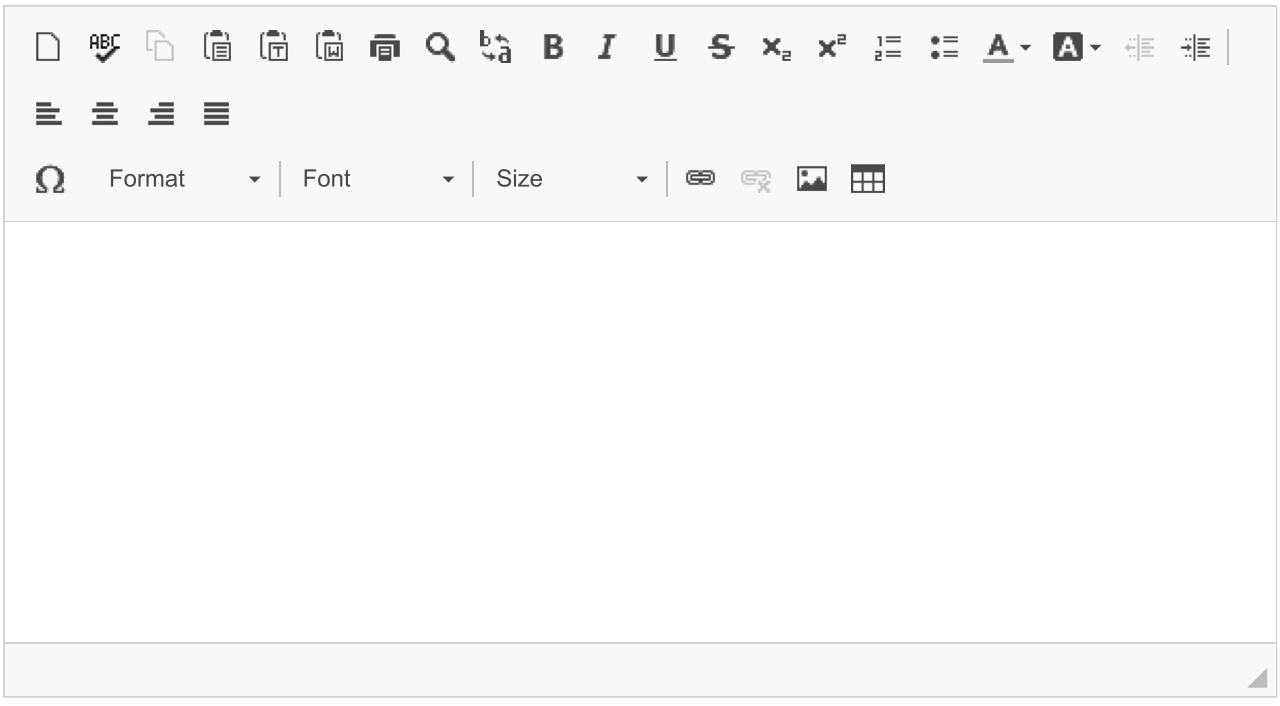
Participants

This section is intended to provide information about the population or records that will be used in this research.

*** Subject contact: Does this study involve ANY contact or interactions with participants?**

- ○ Yes (including phone, mail, digital/electronic, face-to-face)
- ○ No (limited to medical records review, data analysis, and/or biological specimen analysis)

*** How many subjects do you plan to enroll? Provide an explanation and justification for the number of subjects (e.g., power/sample size analysis, citation of comparable studies from literature).**



*** Recruitment: How will participants be identified/recruited, check all that apply**

NOTE: You will be asked to upload the recruiting script, document, advertisement, later in the submission packet)

- [ ] Records review
- [ ] Personal contact, word of mouth
- [ ] Volunteers from undergraduate classes
- [ ] Phone Call (include the script outlining what you will say)
- [ ] Selected using confidential records to screen (medical, school)
- [ ] Postal or University Mail
- [ ] E-mail
- [ ] Social media (e.g. Twitter, Facebook)
- [ ] Newspaper / magazine advertisement
- [ ] Flyers / notices / announcements
- [ ] Handouts to be distributed
- [ ] Professional Research Panel
- [ ] SONA recruitment
- [ ] Other

If you are utilizing recruiting methods other than the options above, please explain. Indicate where any recruitment materials will be posted, distributed or advertised.

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*** Please describe the subjects in terms that are most pertinent to this project. The IRB needs to understand how working with the target population(s) will further your research objectives and what steps need to be taken in order to minimize risks to the subject.**

Describe the population(s) from whom you will collect data. Describe the populations you intend to target and why. Are there subjects you will exclude from the study and if so, why? Where applicable, provide a scientific rationale for the inclusion/exclusion criteria.

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*** Describe the records you intend to review. The IRB needs to understand how accessing these records (existing, archival data) will further your research objectives and what steps need to be taken in order to minimize risks to subjects.**

Consider the following information in your response:

- **From where did you receive the records/data?**
- **How will you access records/data?**
- **Specify the information you will review.**
- **How large is the dataset?**
- **Was the original data gathered under another IRB approval?**
- **Can the data be linked (directly or indirectly) to individuals?**
- **Is the data coded?**
- **Will there be a data use/data transfer agreement?**

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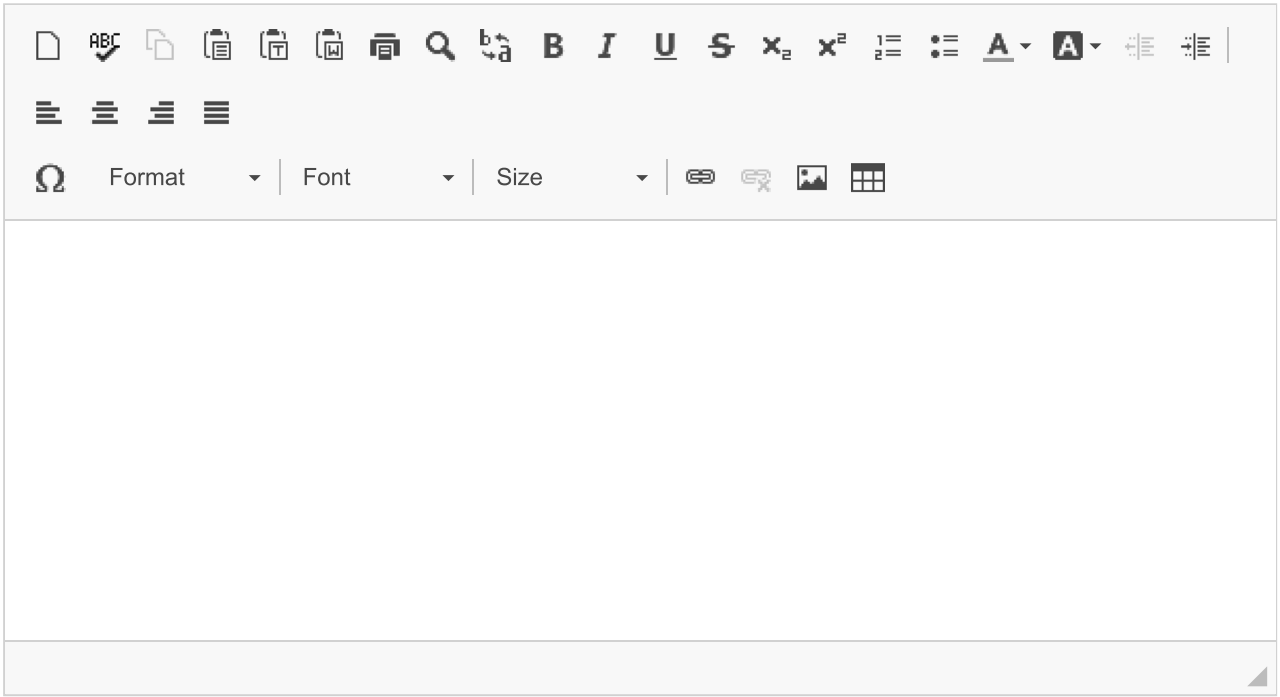
Will this research require special permission to access subjects (e.g., School Districts, Clinics, Employers, State Hospital, data use/transfer agreement, etc.)?

Yes No

Please explain the method to access the contact information. Note that you will be asked to submit documentation of the permission to access subjects later in the submission packet.



Vulnerable Populations

Not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Some persons are in need of extensive protection, even to the point of excluding them from activities that may harm them. Other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. Indeed, some types of research may, in and of themselves, create a vulnerable group – that is, the subjects lose their autonomy or are exposed to unknown risks. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

Please identify any vulnerable populations that you plan to include in this research:

NOTE – if your plans change during the research you must submit a modification to add vulnerable populations later, or enroll someone from a population you did not originally plan to enroll (e.g. adding prisoners).

- [ ] Children (individuals under the age of 18)
- [ ] Pregnant women and/or fetuses
- [ ] Students enrolled in your class(es)
- [ ] Prisoners
- [ ] Cognitively impaired individuals
- [ ] Other (e.g. socially disadvantaged, economically disadvantaged, educationally disadvantaged, undocumented persons, etc.)
- [ ] None – No vulnerable populations

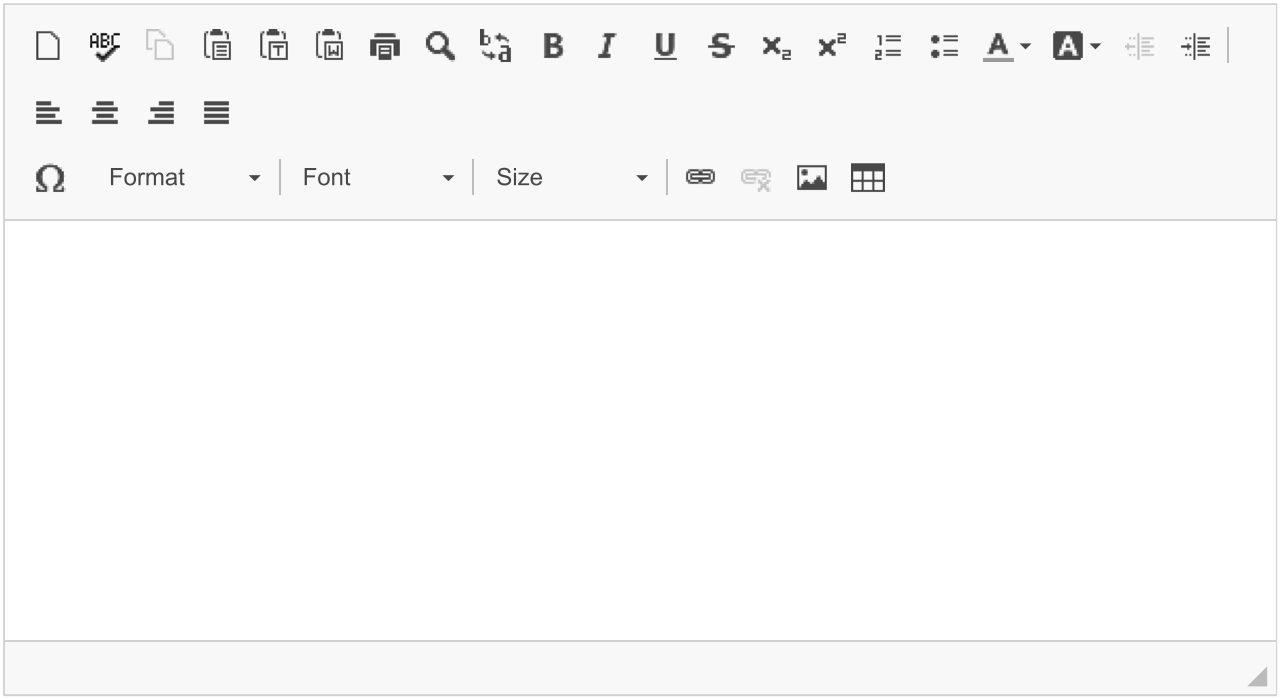
Children

Research involving children requires that the IRB carefully consider consent, beneficence, and justice. The determination of risk (possible harms) and possible benefit to the child is at the core of the concept of beneficence when considering research involving children. Therefore, the IRB must consider the degree of risk and discomfort involved in the research in relation to the direct benefits it offers to the child before it can determine whether or not the IRB has the authority to approve the study.

Note: the following parent permissions requirements for the categories identified above are set out per federal regulations and BYU standard operating procedures (Vulnerable Populations – Children):

- Category 1: The IRB can find permission from one parent is sufficient.
- Category 2: The IRB may find that the permission of one parent is sufficient for research, but must determine whether permission from one or both parents is required.
- Categories 3 or 4: Permission must be obtained from both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

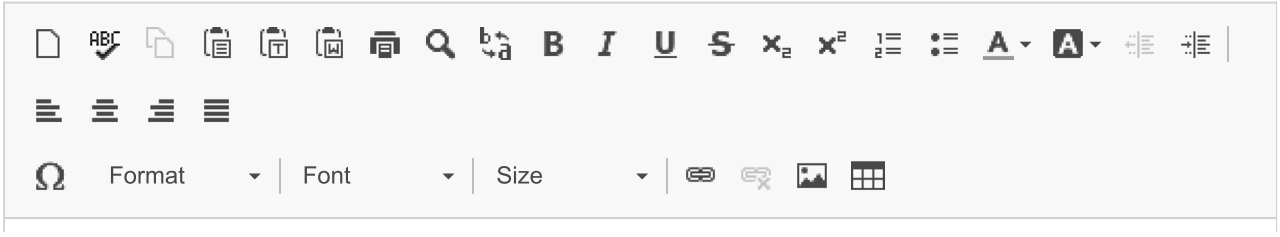
*** Describe how children will be involved in the research. If there is more than one participant group in the research (e.g., two interview groups, a control arm, etc.), describe each participant group involving children.**



Please choose the category relevant to your research for each participant group that involves children (e.g., a participant group receiving intervention vs. participant group receiving none), and provide protocol specific justification for the category.

☐ (45 CFR 46.404)—Research not involving greater than minimal risk. Minimal risk means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

* **Please provide justification for category 45 CFR 46.404.**



(45 CFR 46.405)—Research involving greater than minimal risk but of possible direct benefit to the child, in which the risk is at least as favorable to the subject as that presented by available alternative approaches.

* **Please provide justification for category 45 CFR 46.405.**

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(45 CFR 46.406)—Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding.

* **Please provide justification for category 45 CFR 46.406.**

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(45 CFR 46.407)—Research not meeting the specifications above, but which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health and welfare of children. This category is considered so serious that it must be submitted to a ruling by the Secretary of DHHS following consultation with an appropriate panel of experts.

* **Please provide justification for category 45 CFR 46.407.**

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*** What are the ages of children participants in the research (check all that apply)**

- Ages 0-6: The IRB generally does not require written assent from younger children in this age group. The IRB still expects researchers to explain what is happening to the child to the degree possible.
- Ages 7-17: The IRB generally requires the use of a written assent form.
- Wards of the state

*** Will assent be obtained from all participants?**

Yes No

Describe the population who will not provide assent and explain why assent will not be obtained.

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Please describe the assent process, including if assent will be verbal and/or written.

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Is it possible that child participants will turn 18 during the course of the research?

Yes No

Will you re-approach the participant when they turn 18 to obtain informed consent and/or HIPAA authorization?

Yes No

* **Please explain why participants will not be re-approached to obtain informed consent when they turn 18.**

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Will Ward of the State or foster children be enrolled in this study?

Yes No

Obtaining informed assent and valid parental permission

All investigators conducting studies involving wards of the state should address the following issues related to the consent process and documenting parental permission and assent:

1. Documentation should be obtained from all persons who provide "parental permission" for the ward. This means the guardian is required to provide a signature on the parental permission document.
2. The investigator should maintain documentation in their research files of guardian's official designation by the state as the person who may make medical and legal decisions for the ward.
3. The investigator must provide the IRB with a specific description of how the consent process will be handled for wards of the state. The description should include a contingency for re-consenting participants/their parents in cases where guardianship is returned to the former ward's biological parent(s) while they are participating in the study, as applicable.

*** Describe how the consent process will be handled for wards of the state. How will the investigator ensure the guardian who signs the parental permission document is legally appointed to make decisions for the ward? The investigator should indicate their agreement to maintain documentation in their research files of guardian's official.**

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Pregnant Women or fetuses

* To approve research that involves pregnant women or fetuses, the IRB must determine that the research meets the following conditions (Please click on the orange help button to your right to look at these conditions):

☐ I affirm that all of the above conditions apply;

If any exceptions to the conditions will occur, please describe below.

Students

The Family Educational Rights and Privacy Act (FERPA) is a Federal law administered by the U.S. Department of Education; 34 CFR Part 99. FERPA applies to all educational agencies and institutions that receive federal funding like BYU.

FERPA aims to protect the privacy of Student Education Records. Education records include any record containing personally identifiable information (PII) directly related to the student. PII is not limited to name, but may include indirect identifiers as well.

(For the Overview and Training on FERPA, please click on the orange help button on your right)

☐ * I affirm I will comply with all University and federal FERPA requirements.

If any exceptions to the conditions will occur, please describe below.

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Prisoners

"Prisoner" is defined as any person involuntarily confined or detained in a penal institution. The term also includes persons detained in other facilities (e.g., group homes, work release centers) by statute or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, as well as persons detained pending arraignment, trial, or sentencing.

If a subject in an ongoing research study subsequently becomes a prisoner, the researcher must report this to the IRB immediately so that the IRB can review the protocol again with a prisoner representative present, to adequately assess the special conditions that the prisoner will face with respect to continued participation in the study while incarcerated. (To look at what research involving prisoners the IRB will approve, please click on the orange help button to your right).

☐ * I affirm that all of the above conditions apply

If any exceptions to the conditions will occur, please describe below.

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NOTE - The IRB must submit a Certification Letter to OHRP following review of DHHS-supported research involving prisoners. The purpose of this letter is to certify to the Secretary that the IRB approved the research under 45 CFR 46.305.

Cognitively Impaired Individuals

Studies involving subjects who are decisionally-impaired may take place over extended periods.The IRB will need to consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary.The IRB may require that Investigators re-consent subjects after taking into account the study's anticipated length and the condition of the individuals to be included (e.g., subjects with progressive neurological disorders).Additionally, the IRB will want to consider whether, and when, it should require a reassessment of decision-making capacity.

* Please provide rationale for including adults with diminished capacity and the precautions taken to ensure the participants' safety.

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* Please describe the consenting process for these individuals including how you will determine whom can serve as the legally authorized representative who will give consent for the diminished capacity individual to be enrolled.

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Other Vulnerable Populations

* Please describe any other "vulnerable" populations will be enrolled, e.g., socially disadvantage, educationally, economically disadvantaged, cognitively impaired, migrants.

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Compensation

Research subjects may be offered compensation to offset the time and inconvenience involved in participating in research. Within bounds, it may also serve as an incentive for participation. It is not, however, to be considered a benefit of participation in the research.

There are no specific regulations on compensation other than it may not constitute undue influence or coercion. Investigators and IRB are both responsible to ensure that any compensation provided to subjects is fully disclosed and does not constitute either undue influence or coercion.

*** Will compensation or extra credit be provided to the subjects for participation in your research project?**

Yes No

Indicate the type of compensation and the maximum value a subject may receive during the course of participation.

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*** Describe procedures to distribute compensation. Include distribution schedule, when it will be done and how it will be done.**

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*** Who will receive the compensation (i.e., research subject, parent, school, legally authorized guardian, non-profit organization, etc.)?**

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Benefits of Participation

In evaluating the benefits, the IRB will consider only those benefits that may result directly from the research (as distinguished from benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research benefits. In this section, please describe the possible benefits of participation.

*** What are the benefits of participating in this research study? Benefits help to outweigh the risks to the participants, though not every study will have direct benefits to the participants. In this section, use the following questions as a guide for your response:**

- **Will there be any benefits to the participants in your study? If so, what are they?**
- **What is the general importance of the knowledge you expect to gain?**

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Risks

In evaluating risks, the IRB will consider only those risks that may result from the research (as distinguished from risks of therapies that subjects would receive even if not participating in the research). In this section, please describe the possible risks to participation.

*** Is this research limited only to the analysis of existing information or biospecimens where the only risk of the research is loss of confidentiality?**

○ Yes ○ No

*** List the known risks for participants as a result of participation in the research. As a guide, please estimate the frequency, severity, and reversibility of each risk.**

NOTE: Risks included here should be included in the consent form or cover letter, as applicable.

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Describe how you will minimize risks listed in the previous question.

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*** Do you foresee that you might become aware of the need for medical or psychological services as a result of the research procedures/interventions (e.g., suicidal ideations, PTSD, injuries)?**

Yes No

*** Describe the provisions that have been made to make these resources available.**

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*** The IRB must determine the risks of participation are not disproportionate to the benefits. In your opinion, do the benefits or knowledge to be gained outweigh the risks to participants?**

Yes No

*** Provide justification for performing the research:**

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Data Safety Monitoring Plan

A criterion for IRB approval is that the research provides adequate provisions for monitoring data to ensure safety of subjects and research integrity. The data and safety monitoring should be commensurate with risks.

Does this study include an intervention that is more than minimal risk?

Yes No

* Describe who will monitor the study for the safety of the participants (investigators, sponsor, independent monitor, etc). Provide a plan (monitoring provisions) which may include information on: the type of data or events to be captured, who is responsible for monitoring data related to unanticipated problems and adverse events, time frames for reporting adverse events and unanticipated problems.

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Consent

* Please select all that apply

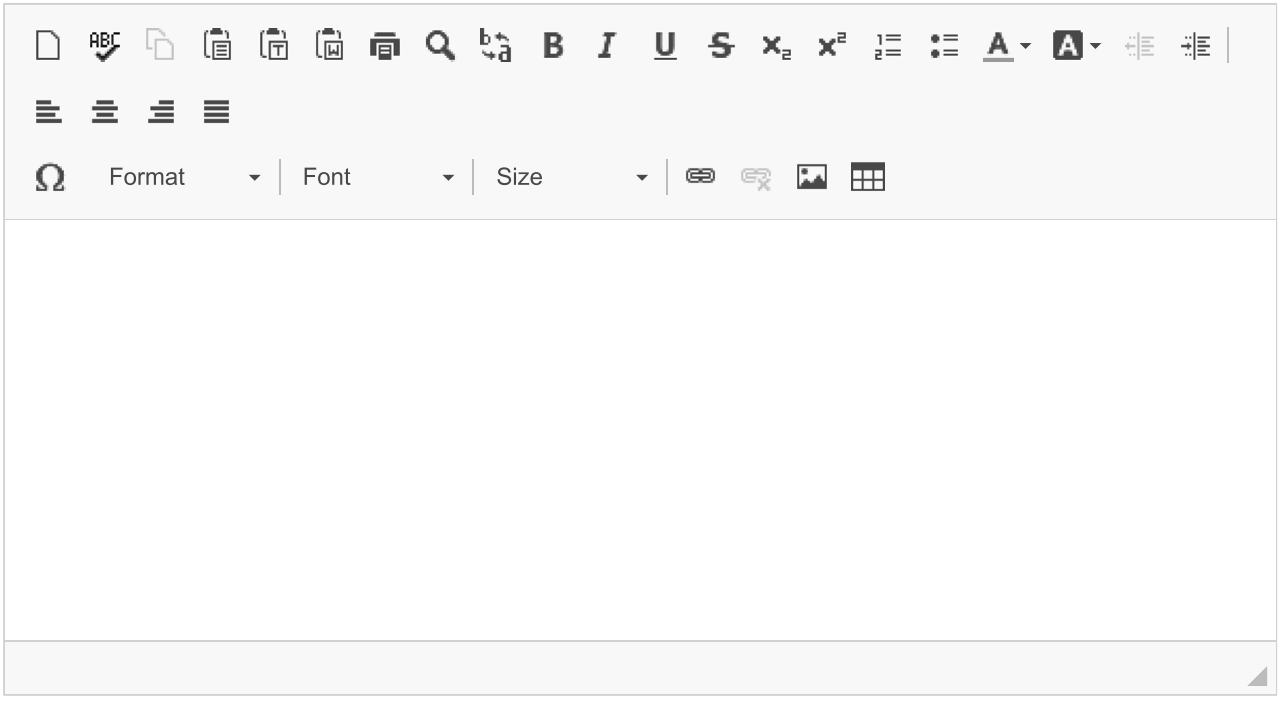
NOTE: You will be asked to attach consent documents (e.g., information sheet, cover letter, verbal script, consent form) as part of the submission packet.

- [ ] I'm obtaining informed consent, guardian/parental permission, minor assent
- [ ] I need a waiver or alteration of informed consent
- [ ] I need a waiver of documentation of informed consent (e.g. I plan on getting verbal consent only)

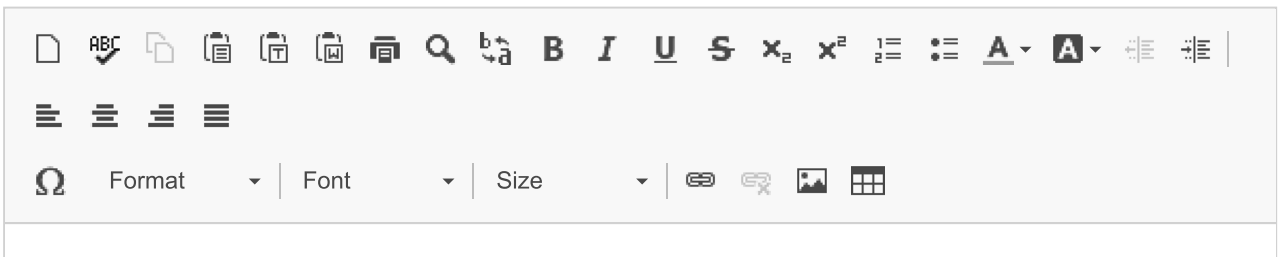
Consent Process

* Consent is an on-going process that starts when you first inform your participant about the study through your recruitment/advertising efforts and ends when the participant's data are no longer needed. Please consider the following questions when you describe the consent process. (Text box must be completed)

- Who will present the consent information and how will it be presented?
- How will you assess if the participant, or their legally authorized representative, understood the information?
- How will you document consent?
- Are your participants able to sign a form, and if not, how will you document consent?
- Will you use more than one form (if you use more than one version of the consent form)?
- When and where will participants receive the consent form?
- Who will give them the consent form?



* Who are the persons who will provide consent, permission, and/or assent?



*** What steps will be taken to minimize the possibility of coercion or undue influence?**

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*** What language will the prospective participants and/or the legally authorized representative understand?**

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*** What language(s) will be used to obtain consent?**

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*** If any protocol-specific instruments will be used in the consenting process, such as supplemental handouts, videos, or websites, describe these here and provide a copy of each later, in the submission packet.**

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*** How long will participants have between the time they are told about the protocol and the time they must decide whether to enroll (weeks, days, hours, minutes, etc.)?**

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Are you requesting to alter or waive Informed Consent?

Yes No

Please select all that apply.

- The research involves no more than minimal risk to the subjects.
- The research could not practicably be carried out without the requested waiver or alteration.
- The research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.
- The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Please explain why this study is no more than minimal risk.

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Please explain why it is impracticable to obtain informed consent.

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Please explain why it is impracticable to use deidentified information or biospecimens.

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Please explain why the waiver will not adversely affect subjects.

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Please decribe how pertinent information will be shared.

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Are you requesting to waive documentation of informed Consent (e.g., you are getting consent and telling the participant all about the research, but you are not getting a signed consent document.)?

An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

- That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;
- That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or
- If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

○ Yes ○ No

Provide a justification to waive documentation of informed consent.

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Confidentiality of Data and Privacy

The IRB must determine there are adequate provisions to maintain the privacy interests of participants and the confidentiality of data.

Confidentiality of data - data gathered for this research will include the following:

* Please check all that apply.

- [ ] Name
- [ ] Date of Birth
- [ ] Mailing Address
- [ ] Email Address
- [ ] Phone or Fax number
- [ ] Social Security Number
- [ ] Medical Records
- [ ] License, certificate, or Vehicle ID
- [ ] IP Address
- [ ] Biometric identifiers ((Physical and behavioral)
- [ ] Photos/images recordings
- [ ] Audio-only recordings
- [ ] Audio/Video recordings
- [ ] Signatures, or handwriting samples (other than signatures on consent forms)
- [ ] Participants and their responses cannot be identified
- [ ] MRI Scans
- [ ] Third party/Professional Research Panels

* **Please provide additional details: If you use audio recordings, photographs, video recordings or other similar data recording devices, justify why it is necessary to use these devices, how you will use them, and what you will do with the data after they are collected.**

Provisions used to maintain confidentiality:

What methods will you use to maintain subject confidentiality during the lifecycle of the research, including data collection, analysis, long-term storage, data sharing (when applicable). Check all that apply:

- [ ] Data will only be made available to Principal Investigator and immediate study personnel
- [ ] Data collection will be anonymous (no identifiers that can link to specific subject)
- [ ] Data collection will be confidential and de-identified (collected with identifiers, but identifiers removed)
- [ ] Data collection will be intentionally identified (linked to subject by personal identifiers)
- [ ] Data will be rendered anonymous for reporting
- [ ] Data will be stored in a locked office
- [ ] Data will be stored in a locked cabinet
- [ ] Data will be coded to a master list
- [ ] Data will be stored on a restricted computer
- [ ] Data will be password protected
- [ ] Data will be stored in a locked private office
- [ ] Data will be encrypted
- [ ] Data will be stored behind a firewall system
- [ ] Data will be stored in the cloud (e.g., Box, Google Drive, etc.)
- [ ] Data will be stored in a shared file with limited access to research personnel only
- [ ] Data sharing by data use/data transfer agreement
- [ ] Other

*** Please describe Other:**

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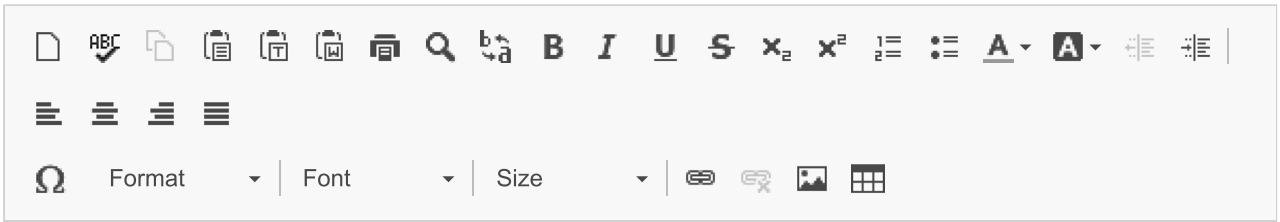
How will you store the data? Discuss both how you plan to store data during collection, analysis, and your long-term plan for maintaining the data when the active research phase is complete.

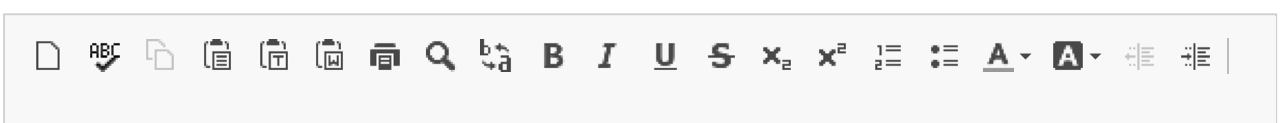


Disposition of data at completion of the study

* Please check all that apply:

- [ ] Data will be de-identified and kept for future PI analysis
- [ ] Audio/Video tapes will be destroyed and files deleted after transcription
- [ ] Data will be retained indefinitely after de-identification for meta-analytic purposes, as a requirement for publication, and/or for longitudinal comparisons with future datasets.
- [ ] Data will be de-identified and then made available as a public data set for secondary analysis. (This use must be specified in the consent document.)
- [ ] Other

* If the disposition of data at completion of the study does not match any of the above options, please explain:



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Protecting Privacy: Indicate how subject privacy will be protected.

- [ ] Conduct conversation about the research in a private room
- [ ] Ask the subject how they would like to be communicated with – what phone number can be used, can messages be left, can they receive mail about the study at home, etc.
- [ ] Take special measures to ensure that data collected about sensitive issues do not get added to their medical records or shared with others without the subject's permission.
- [ ] Other methods
- [ ] We will not interact directly with subjects
- [ ] We will not collect sensitive data

* Describe other methods:

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*** Sensitive data: Do any of the instruments or interview questions ask about illegal or stigmatized, emotionally sensitive behavior?**

○ Yes ○ No

*** Describe the instruments and the precautions taken to secure access to the instruments.**

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*** Consequences of a loss of privacy or confidentiality - Could a breach of privacy or confidentiality result in any significant consequences to participants, such as criminal or civil liability, loss of state or federal benefits, or be damaging to the participant's financial standing, employability, or reputation?**

Yes No

*** Describe any extra steps that will be taken to assure confidentiality and protect identifiable information from improper use and disclosure.**

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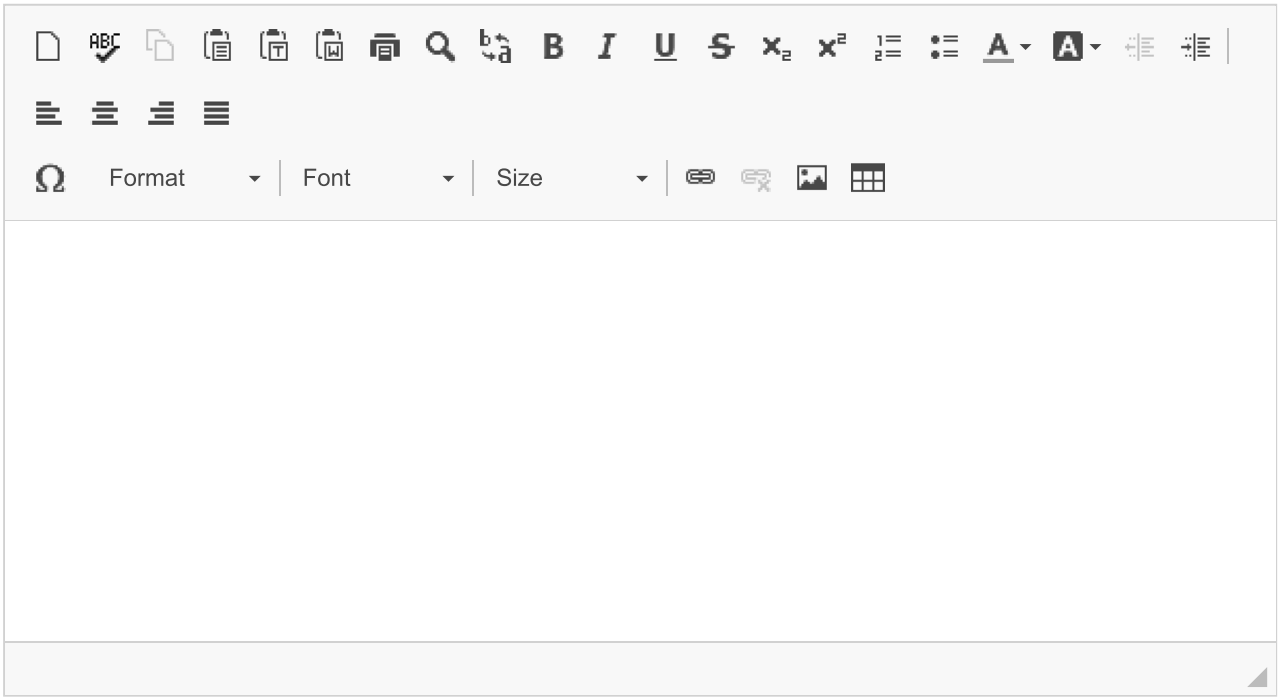
*** Do you anticípate that this study may collect information that state or federal law require to be**

reported to other officials, such as elder abuse, child abuse, or threat to self or others?

○ Yes ○ No

*** Describe the types of reportable information the study may encounter and provide the details of the reporting plan.**



Review Determination

Would you like information about how your study will likely be categorized?

○ Yes ○ No

* Please select the anticipated IRB category of review. Clicking on the category and select save and continue to see more information about the category.

- ○ Exempt
- ○ Expedited
- ◉ Full Board

Exempt review

Studies that are not more than minimal risk and all of the research procedures fit within one or more of the exemption categories 1 to 6. There are no deadlines for exempt studies.

The research must involve no more than minimal risk and fit in one of the categories listed below. "Minimal risk" means that the person participating in your study would experience no more risk that he or she would throughout the course of a normal day or during routine physical exams or psychological tests.

Please select all that apply:

- ☐ Research conducted in established or commonly accepted educational settings

Note: Studies involving possible "adverse effects" on student learning of the required educational content and/or the assessment of educators do not qualify for this exemption.

☐ Research using tests, surveys, or observations

Note: The scope is expanded to include collection of sensitive and identifiable data, including visual and auditory recordings. This exemption still does not allow for the following: interventions, collection of biospecimens, linking to additional personally-identifiable data, and research with minors (except for educational tests or some public observation). Limited IRB review is required for certain Category 2 studies.

☐ Research utilizing painless, brief behavioral interventions subjects would not find offensive or embarrassing

Note: This category permits data collection via a benign interaction (e.g., survey, interview, audio/visual recording) from adult subjects with prospective agreement. "Benign intervention" is defined as one that is brief in duration, harmless, not physically invasive, painless, not embarrassing or offensive, and not likely to have a lasting impact. This exemption cannot be used for the following: research with minors, deception (unless prior agreement is obtained), physiological data collection methods (e.g., EEGs, wearable devices, blood pressure monitors), or linking to additional personally-identifiable data. Limited IRB review is required for certain Category 3 studies.

☐ Secondary research uses of identifiable private information or identifiable biospecimens for which consent is not required

Note: The scope is expanded to include the following: prospective data review; maintenance of identifiers, if all study data is protected health information (PHI); and research that is conducted by, or on behalf of, a Federal department/agency or using government-generated or government-collected information obtained for non-research activities.

☐ Research involving public benefit or service programs

Note: In order for this exemption to be applied, the project must be published on a federal website.

☐ Taste and food quality evaluation and consumer acceptance studies

Expedited Review

Research can be approved as "expedited" if it is no more than "minimal risk" and fits in one of the federally designated expedited review categories. There are no deadlines for expedited studies.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. Select all categories that apply.

☐ Category 1: (Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

a. Research on drugs for which an investigational new drug application (21 CFR 312) is not required. Research involving food or color additives that are regulated by the FDA for which a marketing permit has not yet been issued would fall into this category. (Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (i) an investigational device exemption application (21 CFR 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling. (May not be allowed if randomization is involved in study.)

☐ Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

b. from other adults and children, considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

☐ Category 3: Prospective collection of biological specimens for research purposes by noninvasive means.

a. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

☐ Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x rays or microwaves.

a. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ Category 5: Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

☐ Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Full-Board Review

Research that does not qualify for expedited or exempt review (presents more than minimal risks to subjects) will receive review at a fully convened IRB committee meeting.