Introduction and Determination Checklists

Introduction Statement:

Federal regulations and BYU policies require IRB review of research involving human subjects. 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. You can also click here to review additional guidance on the IRB website.

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

Determination of Review:

- ◯ 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".

- **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. Research conducted for honors, 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.

  Non-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.
5. Classroom projects that are:
    - Assignments to fulfill course/major requirements which involve interactions with individuals.
    - Typically initiated and completed within a single term.
    - Designed to teach research methods through student interaction with individuals or data about individuals, or designed to help students understand concepts taught in the course.
    - Generally, not intended to create new knowledge or to lead to scholarly publication.

Check all that apply:

- ☐ 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".

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.

Check all that apply:

- ☐ 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).

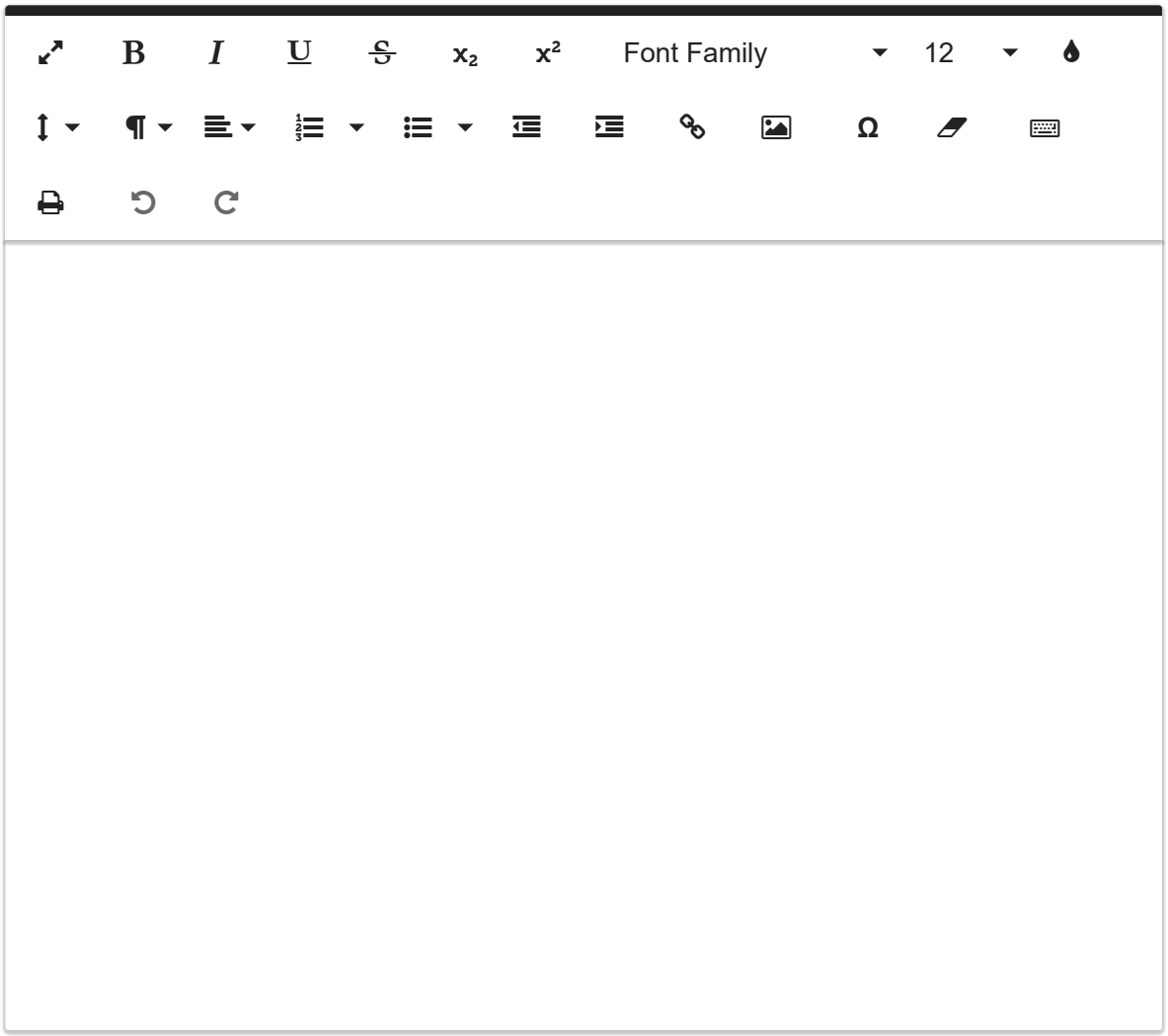
- [ ] The activities will not involve obtaining individually identifiable and private information about living individuals.
- [ ] The activities will involve analysis of existing data/specimens (i.e., data/specimens have been collected and are available for analysis).
- [ ] The data/specimens will be 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

- ◯ 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 add a lay summary of your study. The lay summary must include:

1. **A valid research hypothesis and/or appropriate objectives/research questions to support this project**
2. **Clear, logical, and sufficient support from the scientific literature (e.g., pilot data and citations from current literature) to justify the conduct of the study**
3. **Define the objectives and/or endpoints**



Please save and continue to the next section. You will be taken to the submission packet where you can review your study information before

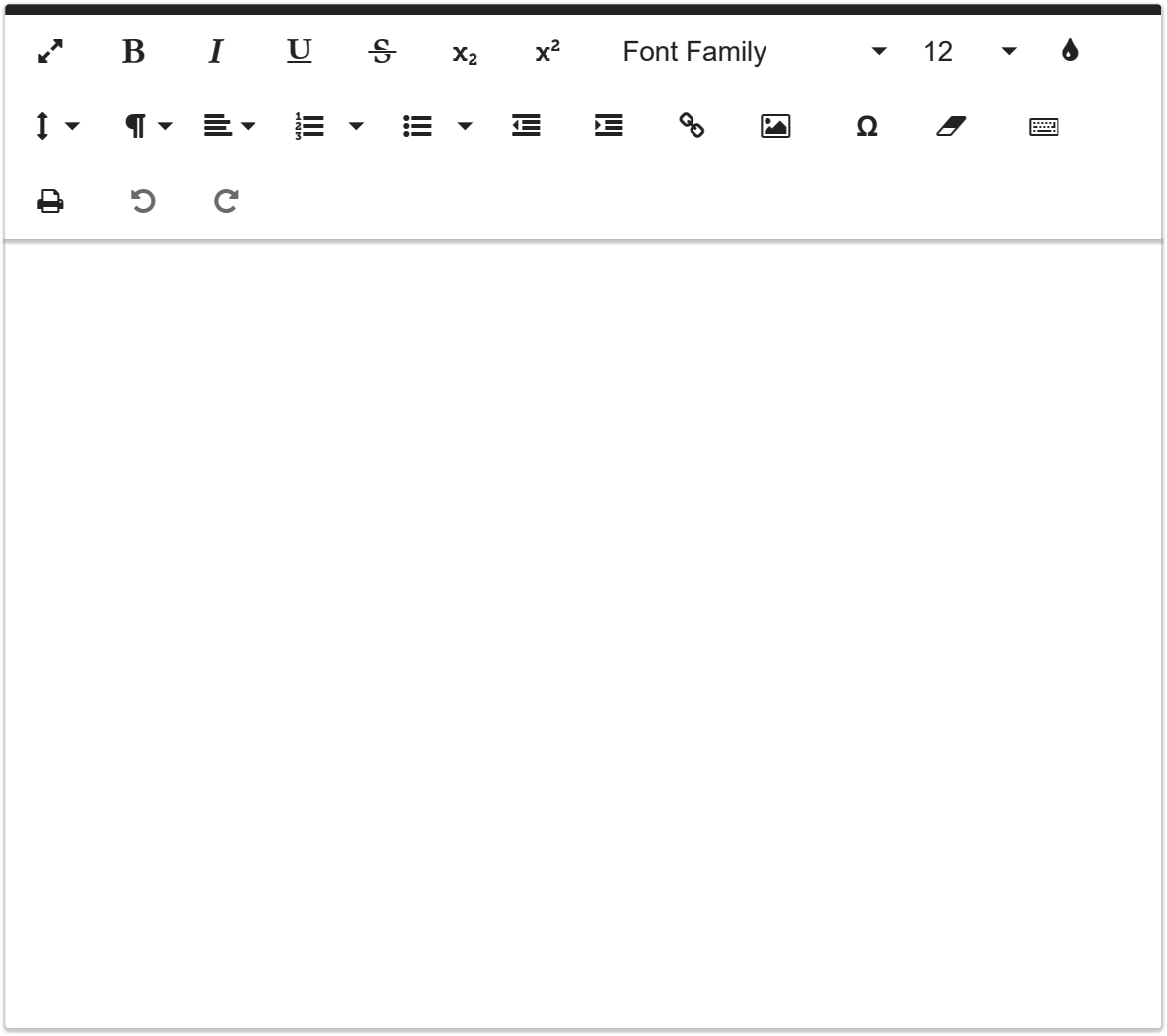
you submit it to the BYU IRB office for processing.

General Information

Lay Summary

Please add a lay summary of your study. The lay summary must include:

1. **A valid research hypothesis and/or appropriate objectives/research questions to support this project**
2. **Clear, logical, and sufficient support from the scientific literature (e.g., pilot data and citations from current literature) to justify the conduct of the study**
3. **Define the objectives and/or endpoints**



Scientific Review

Click here for more information about departmental scientific review and to access the Scientific Review Checklist.

Who has performed scientific review of the research?

◯ Departmental scientific review

Does not require scientific review

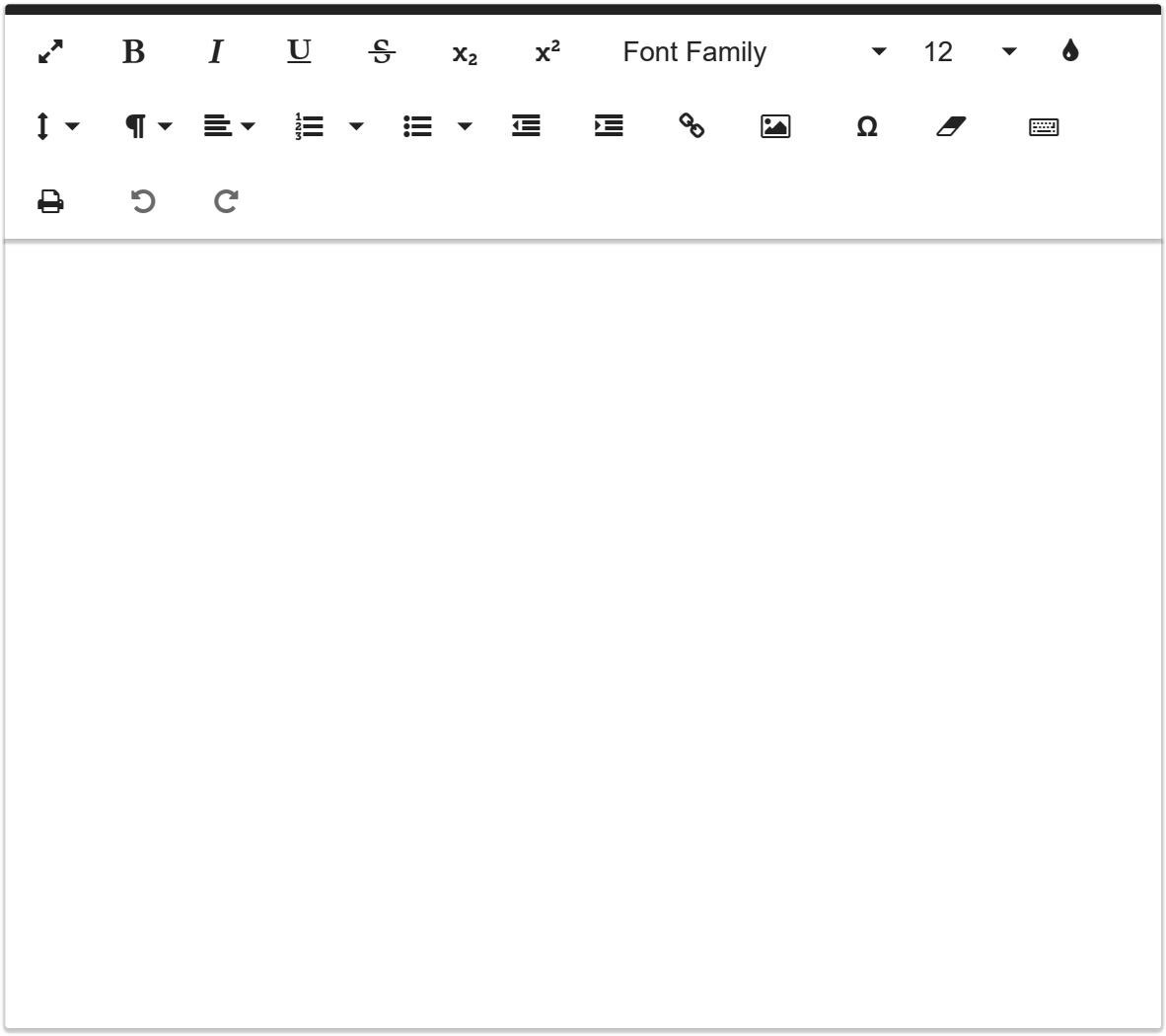
- ◯
- ◯ Other

Please indicate which exemption your protocol meets

- ◯ Already peer reviewed by a federal-funding agency (e.g., NIH, NSF, DOD) or a national foundation
- ◯ No direct involvement of human subjects, such as existing data or archival research
- ◯ Theses/dissertations (including Honors theses) approved by their academic committees PRIOR to IRB submission
- ◯ Research categorized as exempt (Section 16 of the application will walk you through the exempt categories)

Clear

You marked "Other". Please describe:



You will attach the completed scientific review checklist later in the submission packet.

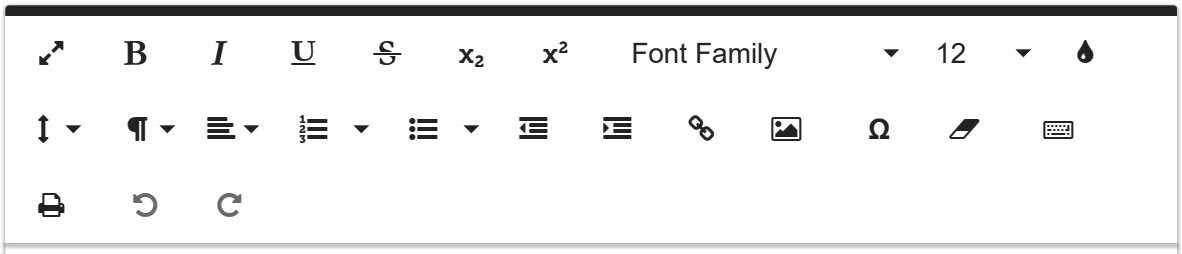
Later in the submission packet, you will attach a screenshot of your approval from the Grad Progress System.

What type of organization initiated this study?

- ◯ Industry-sponsored trial

- ◯ Investigator-initiated
- ◯ Other

You marked "Other". Please describe:



Are there any external (non-BYU) researchers?

◯ Yes ◯ No

Click here for information on how to add an external researcher to iRIS.

Please complete the following table with information for each external (non-BYU) researcher. Note: You must list researchers in Section 3 in order for them to appear in this table. It's just the way iRIS works. If you don't see a person you were expecting, check to confirm they are listed in Section 3 as key study personnel.

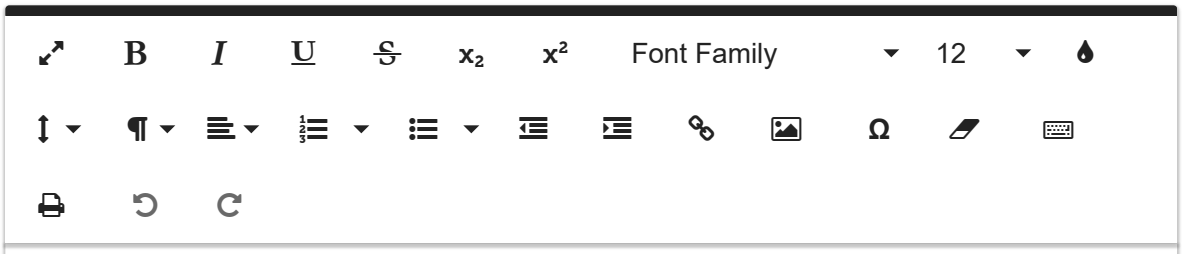
External (non-BYU) Researcher	Home Institution	Study Role	Study Role
No records have been added			

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

Check all that apply

- ☐ 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).



Do you or any other key study personnel listed in Section 3 have a conflict of interest related to this study?

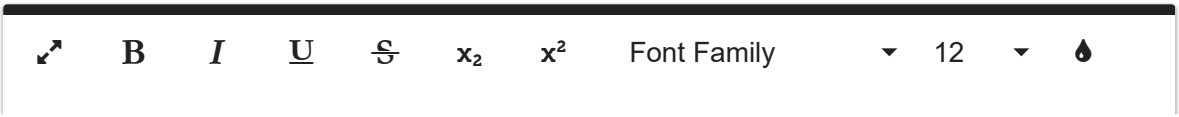
Click here to read BYU's policy on Conflict of Interest.

○ 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?



Funding

The IRB will need to know how this research project is funded.

Does this project require financial resources?

○ Yes ○ No

How will this research be funded? Check all that apply

- ☐ External source(s), for example, grants, clinical trial agreements, private foundation funding, contracts, or any other funding source coming from outside BYU
- ☐ Internal BYU fund(s)
- ☐ Other source(s)

Please complete the following table for all external sources that will fund this research

View Details	Sponsor Name	Sponsor Type	Funding Through:	Contract Type:	Project Number	Award Number

No Sponsor has been added to this Study

Specify the types of internal funding (university salary is not considered funding). Check all that apply

- ☐ Funded by gift

- [ ] Funded by BYU or BYU program
- [ ] Departmental funding
- [ ] Other internal funding

You marked "Other internal funding". Please describe:

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You marked "Other source(s)". Please describe:

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Research Study

This section is intended to identify the research methodologies and type of data collected.

Please identify the methods of data collection (check all that apply). Click here for examples on the IRB website.

- ☐ Questionnaire or survey (online and hard-copy)
- ☐ Interview (online and in-person)
- ☐ Observation (no interaction)
- ☐ Educational tests (e.g., cognitive, aptitude, or achievement)
- ☐ Video recording
- ☐ Audio recording
- ☐ Photographs of human subjects
- ☐ Local computer collected task data (not using internet)
- ☐ Focus groups (online and in-person)
- ☐ Physical activities
- ☐ Exercise interventions
- ☐ Physiological measurements (EEG, wearable devices, eye-tracking, body composition, etc.)
- ☐ Internet usability or human factor study
- ☐ Data of public record
- ☐ Ethnographic methods
- ☐ Other methods for data collection not described in the options above.

You will attach the data collection instruments/forms later in the submission packet. Some common examples are:

- **Screening questionnaires**
- **Survey(s), including online surveys**
- **Demographic questionnaire(s)**
- **Interview guide(s), e.g., questions or interview guides for semi-structured interviews**
- **Focus group guide(s)**
- **Any other documents used to collect data**

For focus groups, you will need to use special language in the consent forms. Click here for more information.

You marked "Questionnaire or survey". Will you distribute the instruments online or hard-copy?

- [ ] Online
- [ ] Hard-copy

You marked "Questionnaire or survey". Please describe. For online instruments, specify the platform you will use (i.e., Qualtrics, SurveyMonkey).

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You marked "Interview". Will the interviews happen online or in-person? For online interviews, specify the platform you will use (i.e., Zoom, Skype).

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You marked "Observation". What will you observe and how will you record the data?

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You marked "Educational tests". Please describe:

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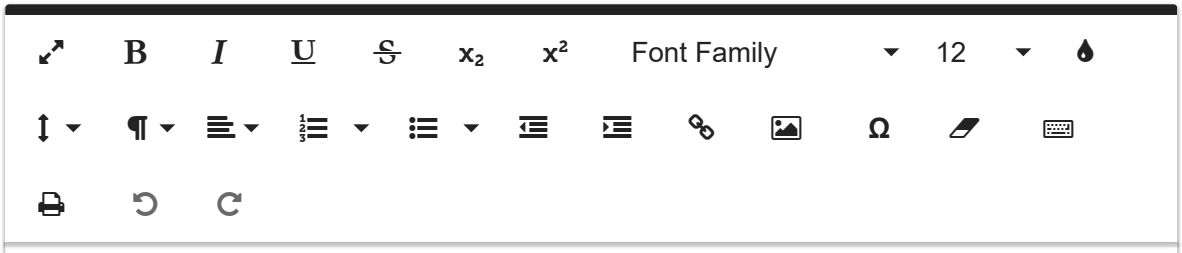
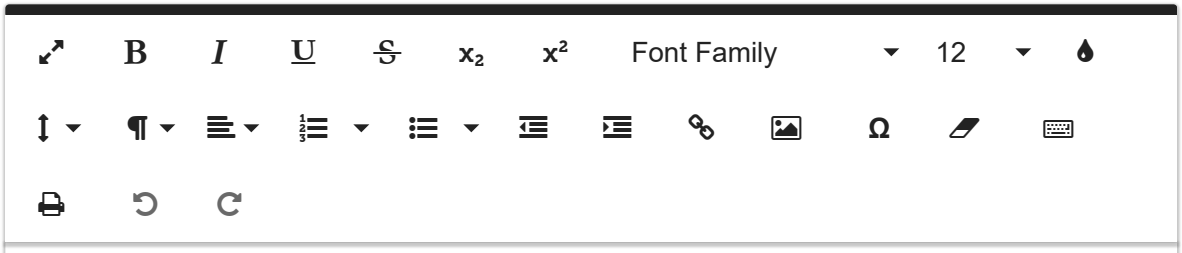
You marked "Video recording". What kind of devices will you use to record the data and who will be transcribing the recordings?

You marked "Audio recording". What kind of devices will you use to record the data and who will be transcribing the recordings?



You marked "Photographs". Please describe the images you will gather for this study, for example, headshots, a specific part of the body, etc.



You marked "Local computer collected task data". Please describe:

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You marked "Focus groups". Please describe how groups will be organized and the amount of people per group.

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You marked "Physical activities". Please describe:

You marked "Exercise interventions". Please describe:

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You marked "Physiological measurements". Please describe what you will use to collect the data and the measurements you will collect.

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You marked "Internet usability or human factor study". Please describe:

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You marked "Data of public record". Please describe the data you plan to access, including the data format, permissions to access, etc.

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You marked "Ethnographic methods". Please describe:

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You marked "Other methods". Please describe:

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Write a complete description of all procedures involving human subjects in the proposed research.

Click here for more guidance from the IRB website on how to complete this section of the application.

Please copy and paste numbers 1a-c below into the textbox to use as headers.

1. **A step by step description of each procedure written in chronological order, explaining:**
   a. **What you are asking subjects to do**
   b. **When they are going to do it, and**
   c. **For how long**

The next question will ask you to describe the data collection instruments. You do not have to include that description in this section.

If necessary, you can attach a diagram, image, video, etc. later in the submission packet.

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

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Does the study have multiple phases or arms?

○ Yes ○ No

Clearly describe each phase or arm of the study.

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Describe the data collection instruments (checked in section 7.1) you will be using. [This information will be reviewed by the Scientific Review Committee.]

Instrument: A tool used to collect, measure, and analyze data related to your subject (e.g., tests, surveys, scales, questionnaires, checklists).

Click "Add a new row" to add a row for each instrument you will use in the study. DO NOT copy and paste the text of the instruments in this section.

List the title for each instrument.	What is the rationale for the inclusion of each instrument?	If available, provide validation and reliability information for each instrument. If not available, respond "N/A".
No records have been added		

Describe your proposed statistical or qualitative analysis plan. [This information will be reviewed by the Scientific Review Committee.]

Where will data collection occur? Check all that apply

This question is specifically asking about where research subjects will complete research activities and submit their data. If the study is online (such as an online survey or online interview) and will be completed outside of the US, you should mark "International sites" because international regulations still apply to online studies.

- ☐ BYU campus
- ☐ Off-campus, within the US
- ☐ International sites

Click "Add a new row" to add a row for each location where data collection will occur.

1. **Describe the location. Provide as much detail as currently available about the location(s): state, city and address if possible. For example, residence of the subjects in Dallas and Fort Worth, TX; private hospital at 801 Braxton Place, Madison, WI; public elementary school at 1001 E Montgomery Ave, Spokane, WA.**
2. **What research activities will occur at this location?**

Describe the location:	What research activities will occur at each location?
No records have been added	

In addition to IRB requirements, you are responsible for understanding and complying with BYU's Surveys Policy (**click here to review on policy.byu.edu**).

International Research

1. **Describe the international sites or locations where your research team will collect the data. Provide as much detail as currently available: country and province/city and description, etc. For example, "residence of the subjects in and around Copenhagen, Denmark; Stockholm, Sweden; Oslo, Norway; and Helsinki, Finland"; "refugee camps near the village of Moria, as well as the nearby city of Mytilene in Greece"; "public elementary schools throughout Samoa and American Samoa".**
2. **Describe the site-specific regulations or customs affecting the research at those locations. For example, "Cultural norms dictate that males cannot be alone with females in the same room", or "In this country, the school principal has legal authority to sign parental permission forms", or "Historical events make this society suspicious of signing documents".**

Click here to view the compilation of human research standards for international locations provided by the Office for Human Research Protections. Please review the information for the location(s) where you will collect data before answering the following questions for international research.

What experience does the research team have with conducting research in that country?

Describe the local laws/regulations governing research.

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Is there a formal review body, such as IRB, ethics committee, or government entity that is reviewing the study in the host country?

○ Yes ○ No

Provide the name and contact information/website of the IRB, ethics committee, or government entity.

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Provide information about the status of the local review. If the study has been approved, you will attach the approval letter later in the submission packet.

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Provide a letter of support from a local expert or authority. You will attach the letter of support later in the submission packet.

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Please provide the name and contact information of a person not affiliated with the research who has expertise on the local context of the country or community where the research will be conducted, or explain why you don't have an individual with that expertise.

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Deception or Incomplete Disclosure

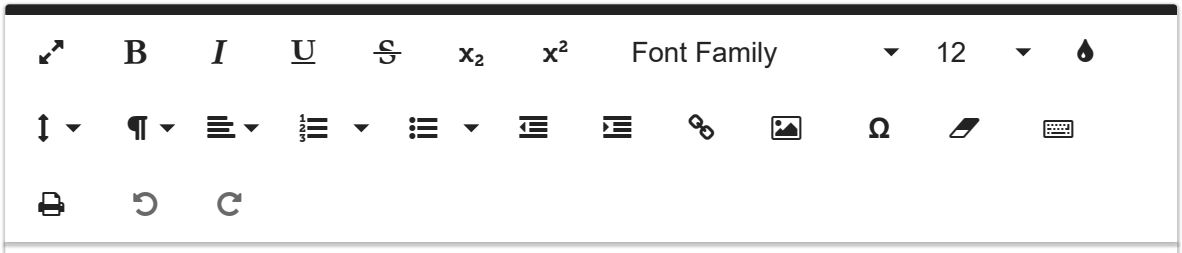
- **Deception:** Providing false information to subjects or intentionally misleading them about some aspect of the research
- **Incomplete Disclosure:** Withholding material or information about the specific purpose of nature of the research

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

○ Yes ○ No

Please describe:

1. **How you will use deception and/or incomplete disclosure**
2. **The scientific justification and necessity for using deception and/or incomplete disclosure**



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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You will attach the debriefing statement later in the submission packet.

FDA Regulated Drugs, Biologics, or Food Supplements

Click here for more information from the FDA. 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.

Will any FDA regulated drugs, biologics, or food supplements be involved or studied in this research?

○ 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 appropriate oversight.

List all drugs or biologics that will be used in this study.

View Details	Drug Name	FDA Approved	A new drug or a new use of an already approved drug:	IND Number

No drugs have been added to this Study

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

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Therapeutic Study or Intervention

Click here for more information from NIH. 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.

Is this a therapeutic study or invention?

○ Yes ○ No

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.

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

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Devices

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.

Will any devices be involved or studied in this research?

○ Yes ○ No

Does this study involve a Humanitarian Use Devise (HUD)? Click here for more information from the FDA.

○ Yes ○ No

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

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Subject Enrollment

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

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

[This information will be reviewed by the Scientific Review Committee.]

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Please list each recruitment method that you will use to recruit subjects.

Select all the tools you will use to recruit subjects	What permissions, if any, do you need to recruit using this method? For example, will you need a group administrator to approve recruiting methods for a social media support group? Will you need to seek approval before you distribute flyers? If none, mark N/A.
No records have been added	

You will attach the recruitment materials later in the submission packet. Click here for guidance about recruiting materials.

- **Name the document using the following format: "Type of recruitment"_"group"_"version date", i.e., Email_Control group_10.20.2021, Flyer_10.20.2021**
- **For visual recruiting materials (i.e., flyers, social media, etc.) attach the final wording and graphics to be used**
- **For verbal recruiting materials (i.e., personal contact, phone call, etc.) attach the script outlining what you will say**
- **For emails, please include the subject line**

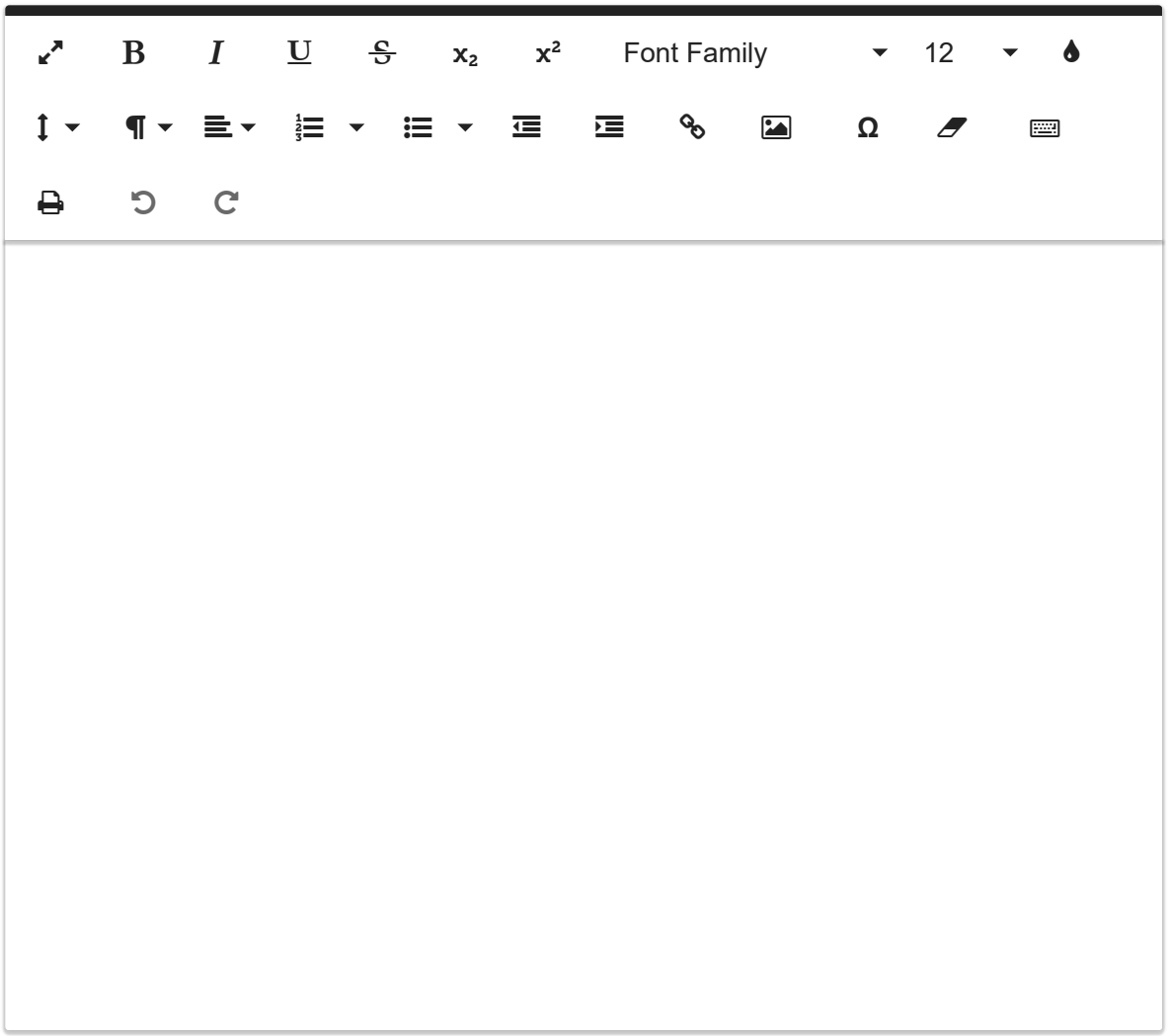
Inclusion/Exclusion Criteria

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 objects and what steps need to be taken in order to minimize risks to the subject.

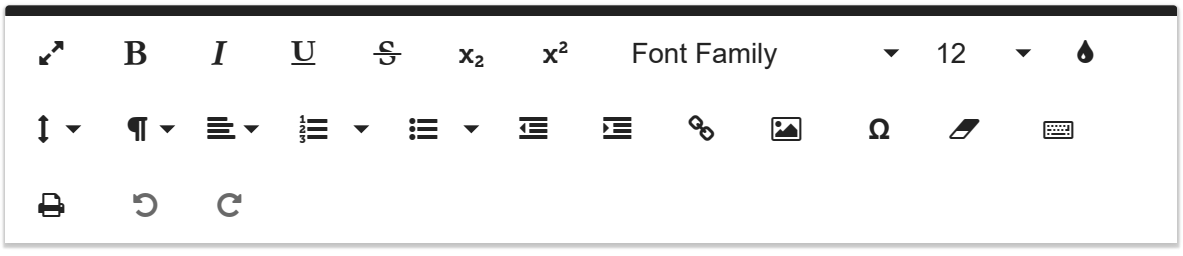
1. **Identify the population you intend to study. Your study should include those who are able to participate and those who represent**

the population where your study is relevant.

2. **Include any applicable information that would make someone eligible for this study.**
    - **Include any geographic criteria (e.g., BYU undergraduate students, a national sample of adults with engineering degrees, minors aged 8-12 in the Provo School District, university faculty in Utah and the UK)**
    - **Include information about age/age range, health status, sex, ethnicity, education status, etc.**



1. **Are there research subjects you will specifically exclude from the study beyond the inclusion criteria listed above, and if so, why?**
2. **Where applicable, provide a scientific rationale for the exclusion criteria.**



Screening

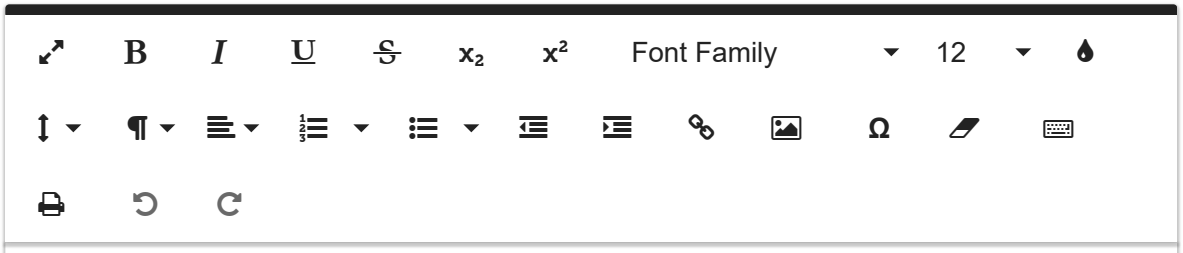
Will you screen participants?

○ Yes ○ No

Describe how you will screen individuals for eligibility:

1. **When will screening occur?**
2. **What procedures will you use?**

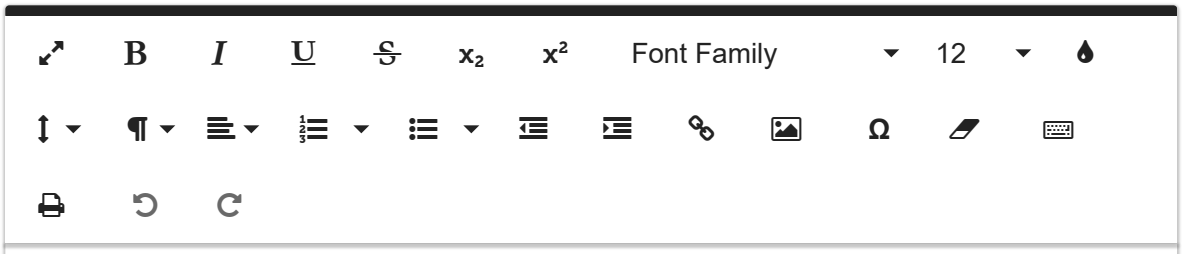
You will attach any screening scripts or surveys later in the submission packet.



Will this research require special permission to access subjects (e.g., school districts, clinics, employers, state hospital, etc.)?

○ Yes ○ No

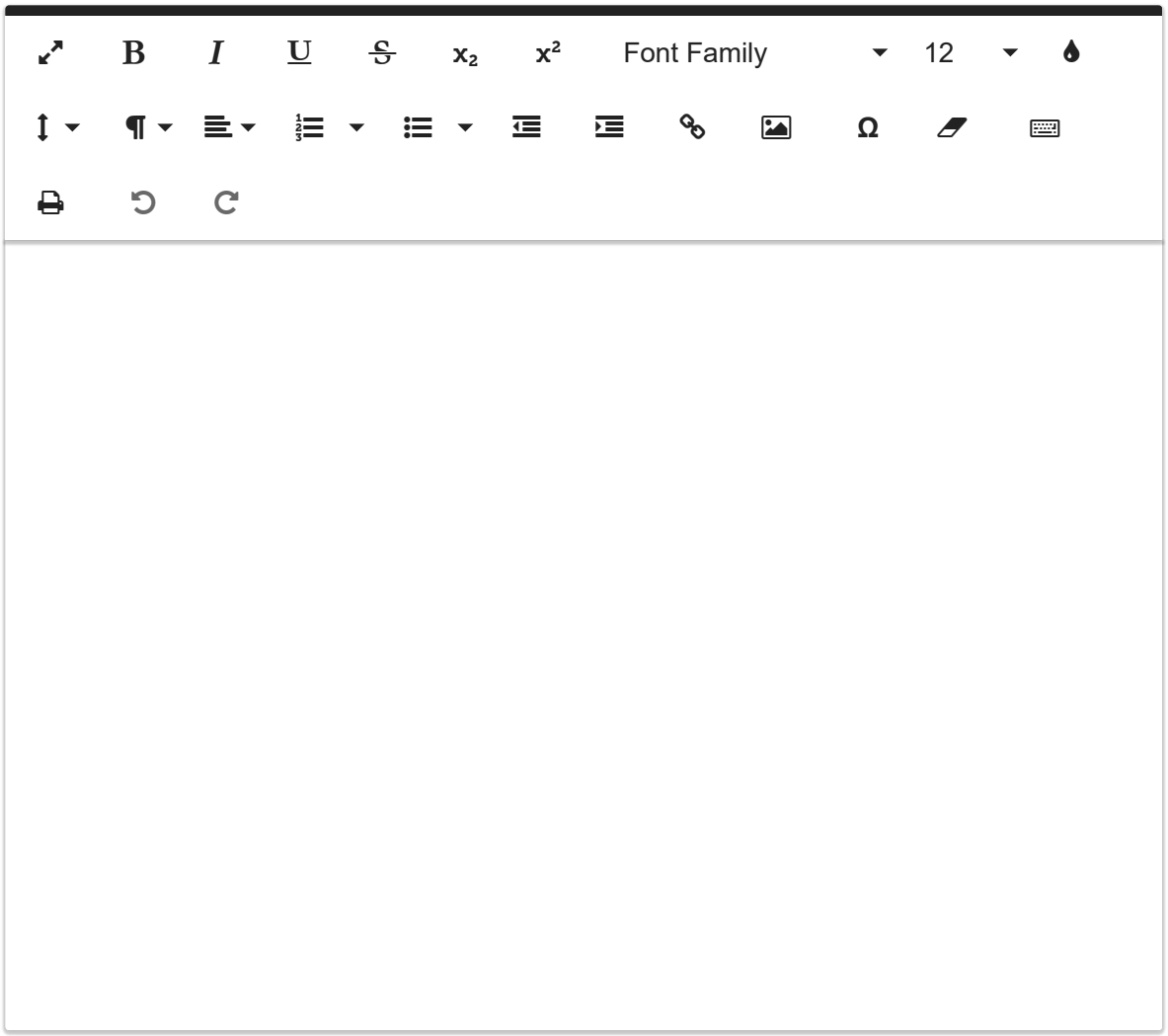
Please explain the approval process to access the study population, e.g., IRB approval is required before school district approval; MRI director's approval required before IRB submission. You will attach permission documentation later in the submission packet.



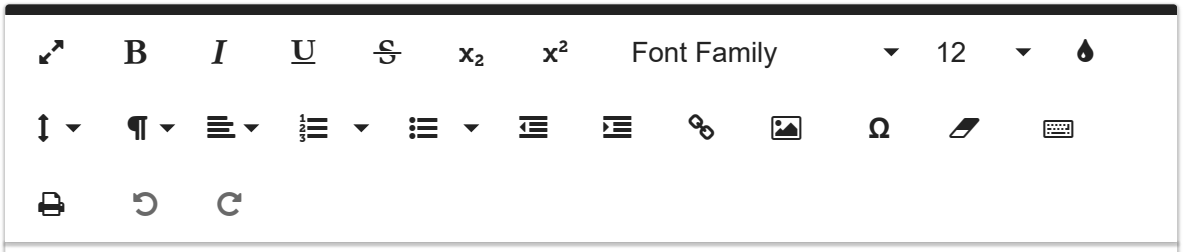
Existing Records

Describe the existing 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.

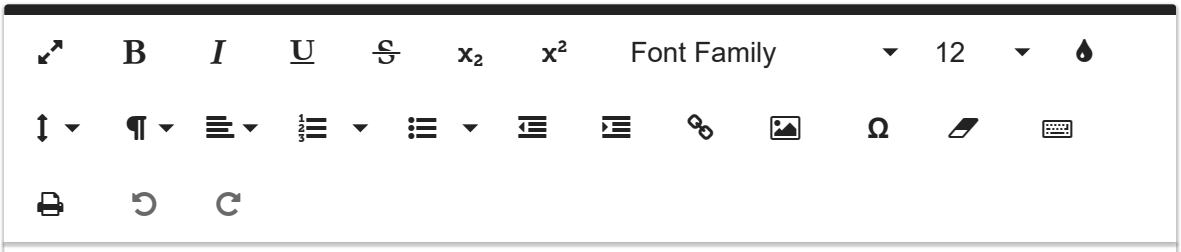
1. **Where did you receive the records/data?**
2. **How will you access the records/data?**
3. **Specify the information you will review.**
4. **How large is the dataset?**
5. **Was the original data gathered under another IRB approval?**



1. **Can the data be linked (directly or indirectly) to individuals?**
2. **Is the data coded?**



Will there be a data use/data transfer agreement? Please describe.



Vulnerable Populations

Researchers who are targeting vulnerable populations must provide additional information about their research methods, for example, recruiting minors in the Provo School District. However, sometimes research subjects within a vulnerable population are incidental to the study, for example, recruiting a national sample of adults which may include pregnant individuals, students in your classes, etc.

Please identify any vulnerable populations that you are targeting to include in this research.

- ☐ Children (individuals under the age of 18)
- ☐ Pregnant women and/or fetuses
- ☐ Students enrolled in your class(es)
- ☐ Prisoners
- ☐ Cognitively impaired individuals
- ☐ Other vulnerable populations (e.g. socially disadvantaged, economically disadvantaged, educationally disadvantaged, undocumented persons, etc.)
- ☐ No vulnerable populations will be involved 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).

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.

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.

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), 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).

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.

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.

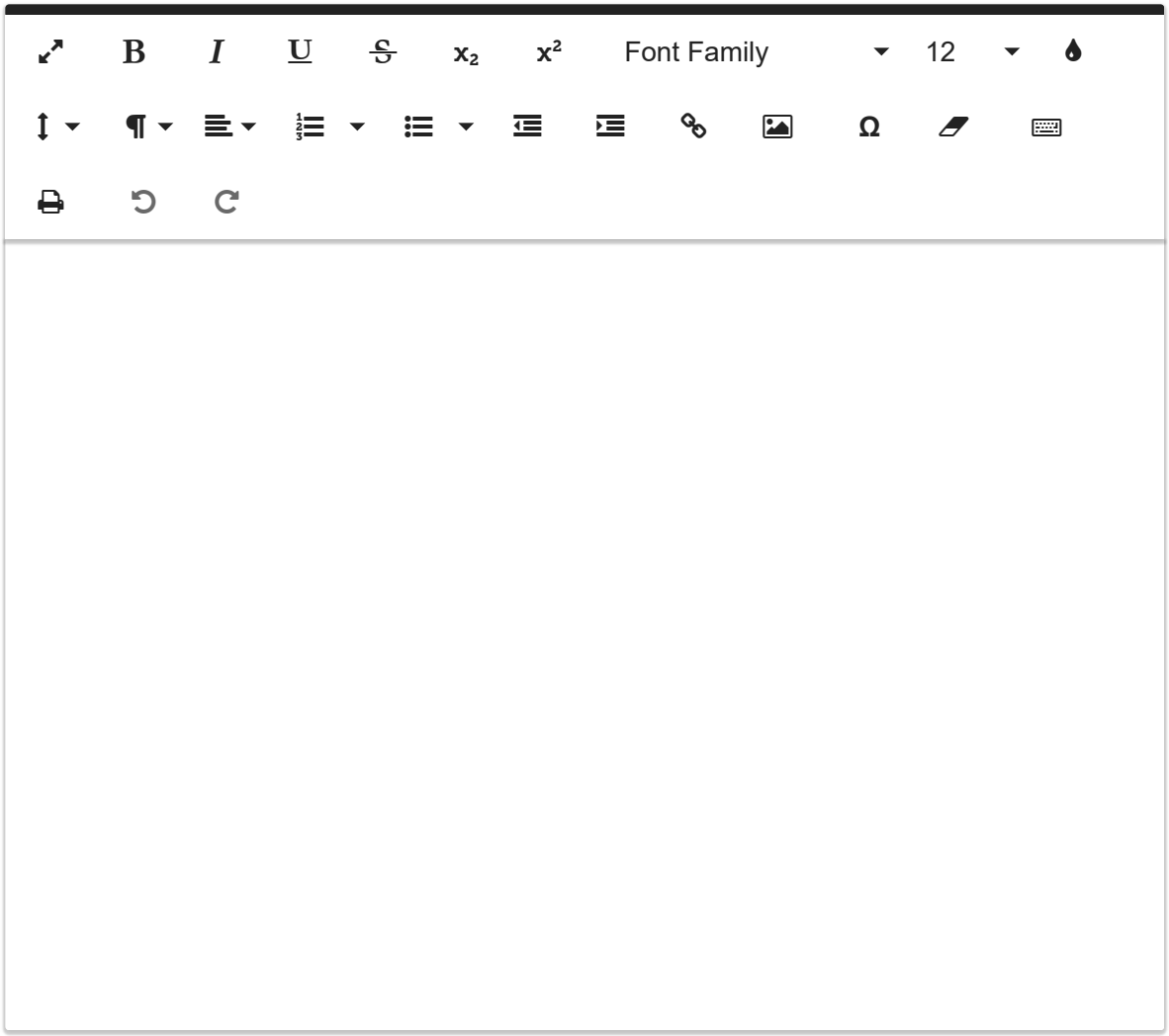
45 CFR 46.406: Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the disorder or condition, in which the risk is minor relative to the potential improvement in knowledge to be applied to general understanding.

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.

45 CFR 46.404

- [ ]
- [ ] 45 CFR 46.405
- [ ] 45 CFR 46.406
- [ ] 45 CFR 46.407

Please provide justification for each category that you marked above.



What are the ages of children research subjects? 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

Assent

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):

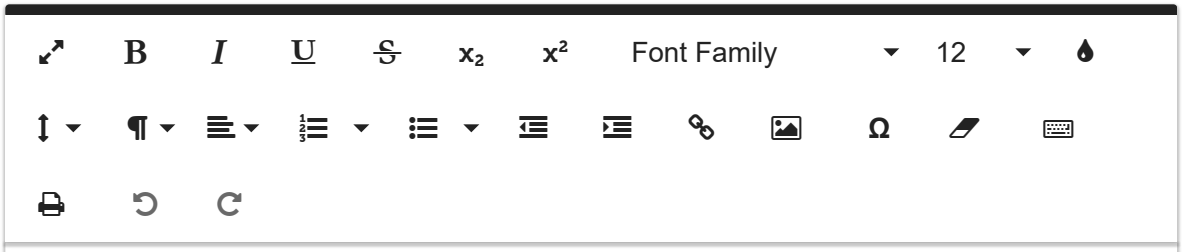
- **Category 1: The IRB can find permission from one parent is sufficient.**

- **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.**

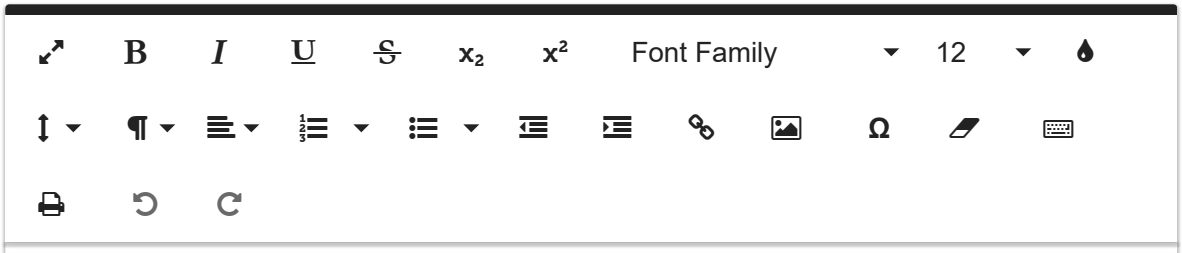
Will assent be obtained from all research subjects?

○ Yes ○ No

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



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



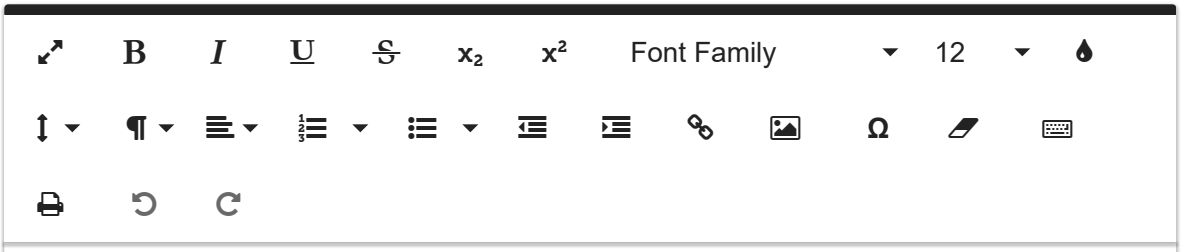
Is it possible that child research subjects will turn 18 during the course of the research?

○ Yes ○ No

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

○ Yes ○ No

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



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

○ Yes ○ No

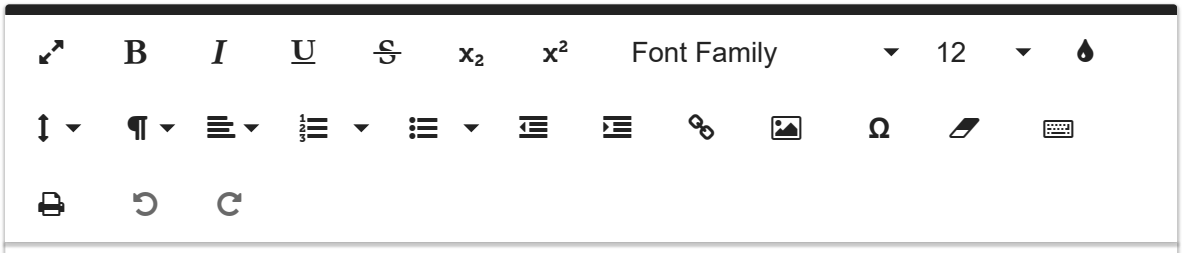
All investigators conducting studies involving wards of the state must comply with these requirements related to the consent process and documenting parental permission and assent:

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 research subjects/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.**

Does your research meet all of these conditions?

○ Yes ○ No

1. **Describe how the consent process will be handled for Wards of the State.**
2. **How will the investigator ensure the guardian who signs the parental permission document is legally appointed to make decisions for the ward?**



Pregnant Women or Fetuses

To approve research that involves pregnant women or fetuses, the IRB must determine that the research meets the following conditions:

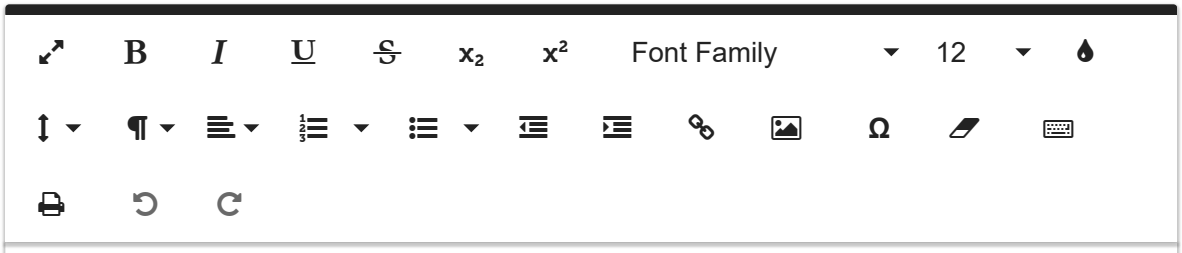
1. **Where scientifically appropriate, the conduct of preclinical studies, including studies on pregnant animals, and the conduct of clinical studies, including studies on non-pregnant women, provide data for assessing potential risks to pregnant women and fetuses;**
2. **The risk to the fetus is posed solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is no greater than minimal and the Purpose of the research is the acquisition of important biomedical knowledge that cannot be obtained by any other means;**
3. **Any risk that is posed represents the smallest risk possible in achieving the objectives of the research;**
4. **If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of direct benefit both to the pregnant woman and the fetus, or no prospect of benefit to the woman or the fetus, when the risk to the fetus is no greater than minimal risk and the purpose of the research is the acquisition of important biomedical knowledge that cannot be obtained by any other means, the pregnant woman's consent is obtained in accordance with all informed consent provisions.**
5. **If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is required. However, the father’s consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity, or the pregnancy is the result of rape or incest;**
6. **Each individual who provides consent is fully informed of the reasonably foreseeable impact of the research on the fetus or neonate;**
7. **For children who are pregnant, assent and permission are obtained in accordance with the provisions of the Special Protections for Children (45 CFR 46, Subpart D).**
8. **No inducements, monetary or otherwise, are offered to terminate a pregnancy;**
9. **Individuals engaged in the research play no role in deciding the timing, method, or procedures used to terminate a pregnancy; and**

10. **Individuals engaged in the research play no role in determining the viability of a neonate.**

Does your research meet all of these conditions?

○ Yes ○ No

Please describe any exceptions to the above conditions that will occur.



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.

Students attending a postsecondary school, such as BYU, have the following rights under FERPA:

- **To inspect and review their education records**
- **To seek to have their records amended**

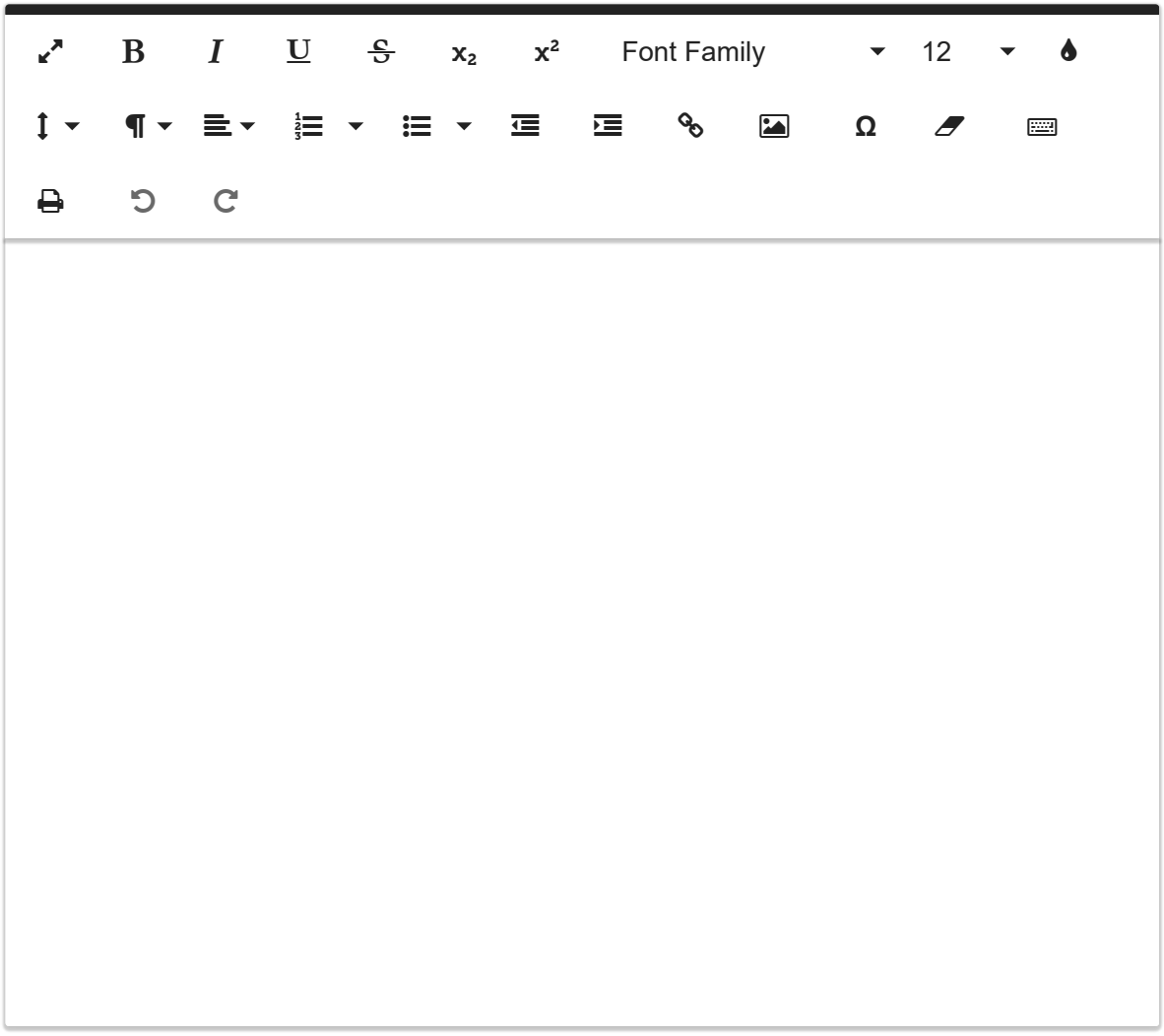
- **To have some control over the disclosure of information contained in the records**
- **To file a complaint with the U.S. Department of Education if BYU fails to comply with FERPA**

BYU may not disclose information contained in education records without the student's written consent except under certain limited conditions. Because BYU maintains a great deal of protected student information and data, video training is provided to help you understand and comply with FERPA: https://registrar.byu.edu/records-privacy-ferpa

Does your research meet all FERPA requirements?

○ Yes ○ No

Please describe any exceptions to the above requirements that will occur.



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.

The IRB will only approve research involving prisoners if the following findings are made:

1. The research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2):
    - **45 CFR 46.306(a)(2)(i):** Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
    - **45 CFR 46.306(a)(2)(ii):** Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
    - **45 CFR 46.306(a)(2)(iii):** Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.
    - **45 CFR 46.306(a)(2)(iv):** Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary (through OHRP) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of his intent to approve such research.
2. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. The information is presented in language which is understandable to the subject population;
6. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding

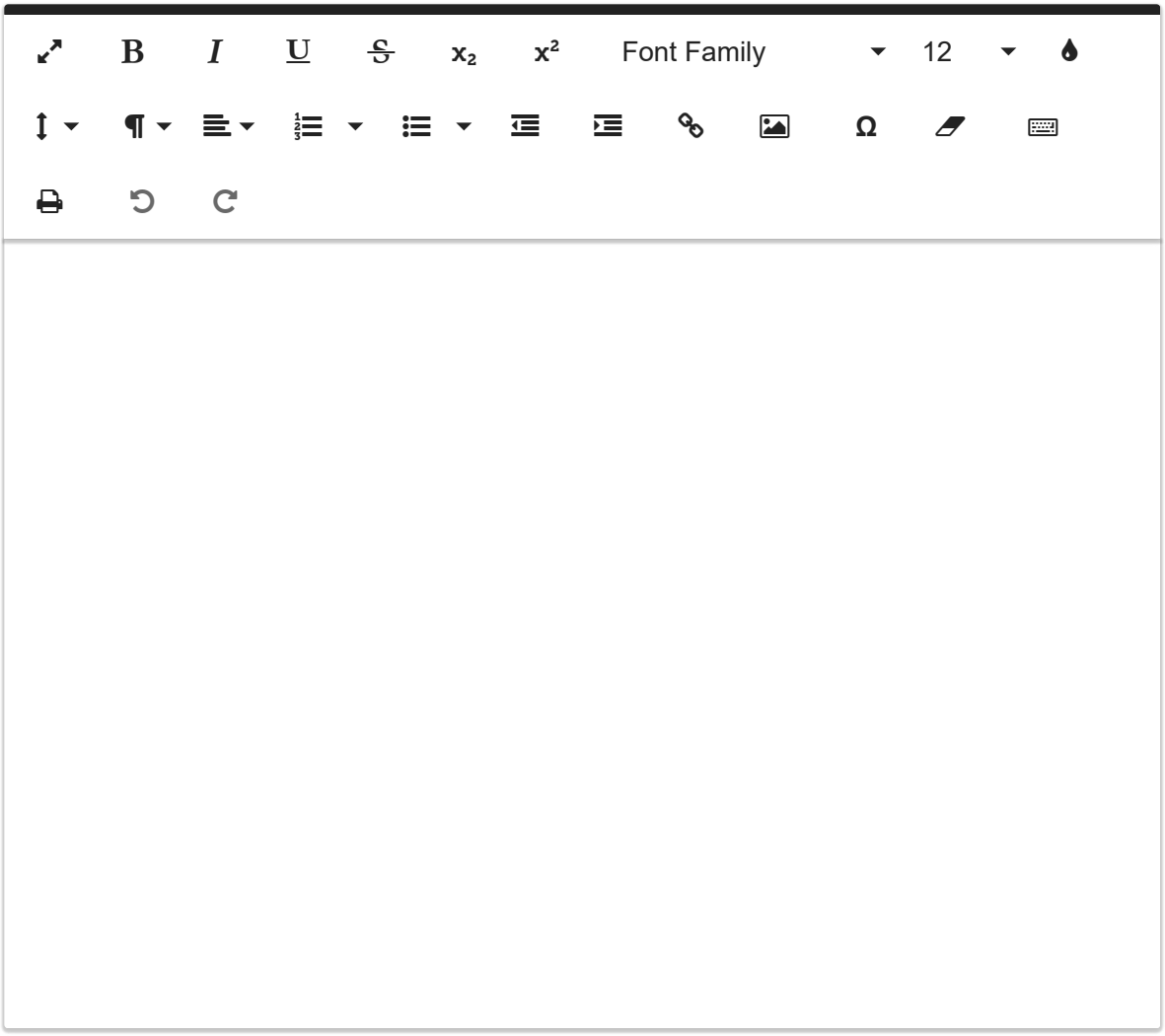
parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

7. Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

Does your research meet all of these conditions?

○ Yes ○ No

Please describe any exceptions to the above conditions that will occur.



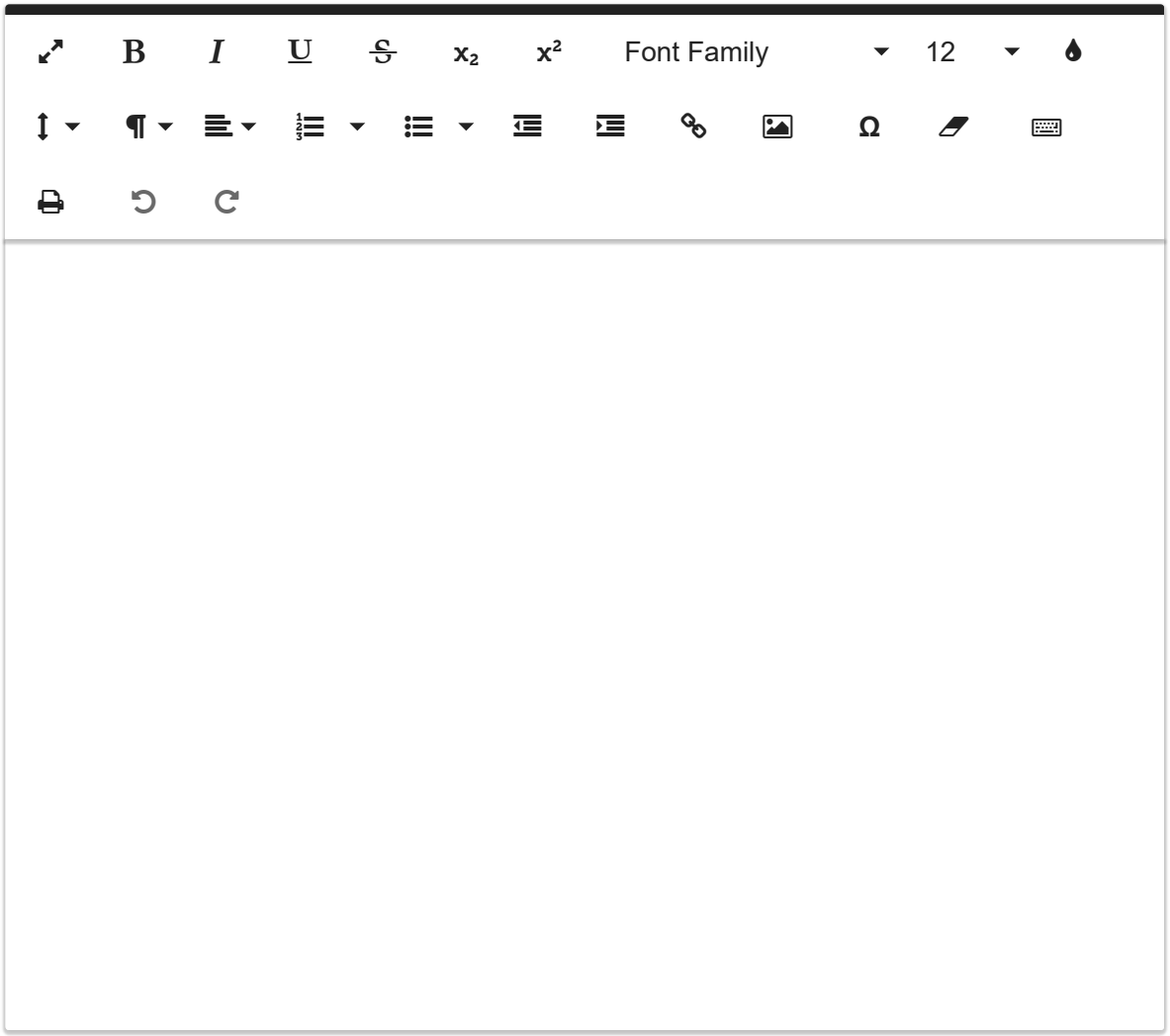
Note: The IRB must submit a Certification Letter to OHRP following review of DHHS-supported research involving prisoners. The purpose of this letter is to certify to the Secretary that the IRB approved the research under 45 CFR 46.305.

Cognitively Impaired Individuals

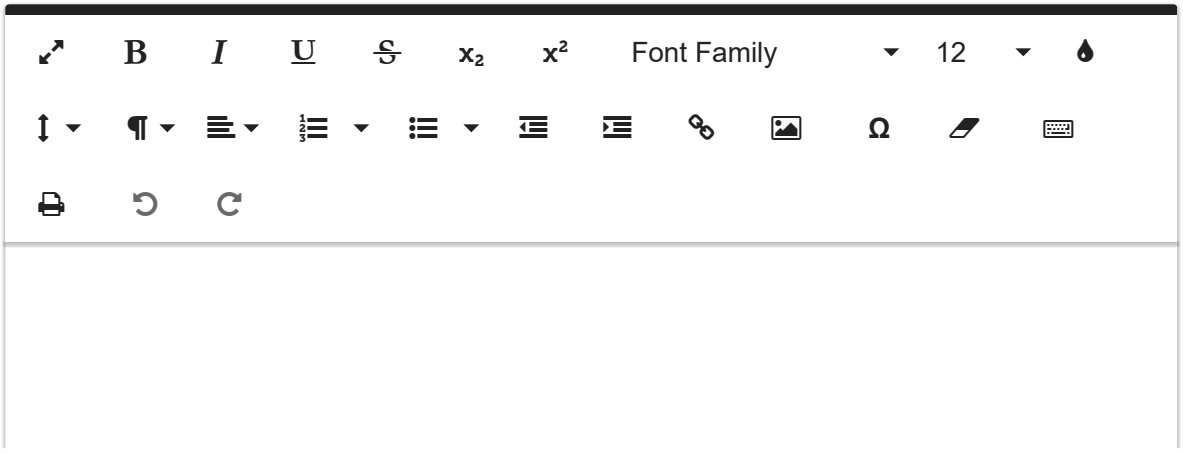
Studies involving subjects who are decisionally-impaired may take place over extended periods. The IRB will need to consider whether periodic re-consenting of individuals should be required to ensure that a subject's continued involvement is voluntary. The IRB may require that

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 research subjects' safety.



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.



Other Vulnerable Populations

Please describe any other vulnerable populations that will be enrolled in the research, e.g., socially disadvantage, educationally, economically disadvantaged, cognitively impaired, migrants.

Compensation

How subjects may be compensated may take different forms, both monetary and non-monetary.

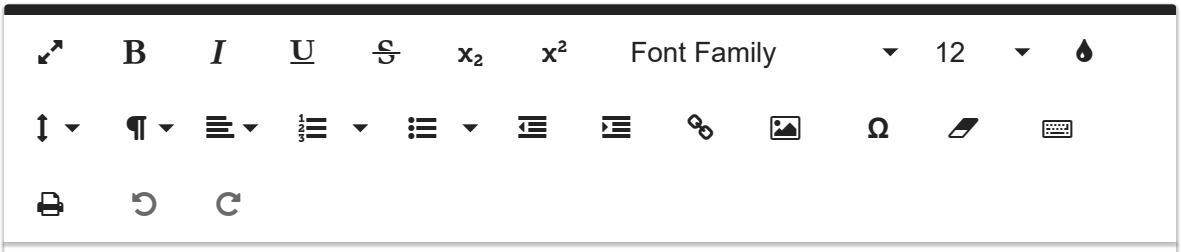
Research subjects may be offered compensation to offset the time and inconvenience involved in participating in research. Within bounds, it may also serve as an incentive for participation. It is not, however, to be considered a benefit of participation in the research.

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.



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

Font Family 12

Will compensation be prorated?

○ Yes ○ No

Describe how compensation will be prorated and, if available, the schedule of payment.

Font Family 12

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

Font Family 12

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 therapy that subjects would receive even if not participating in the research).

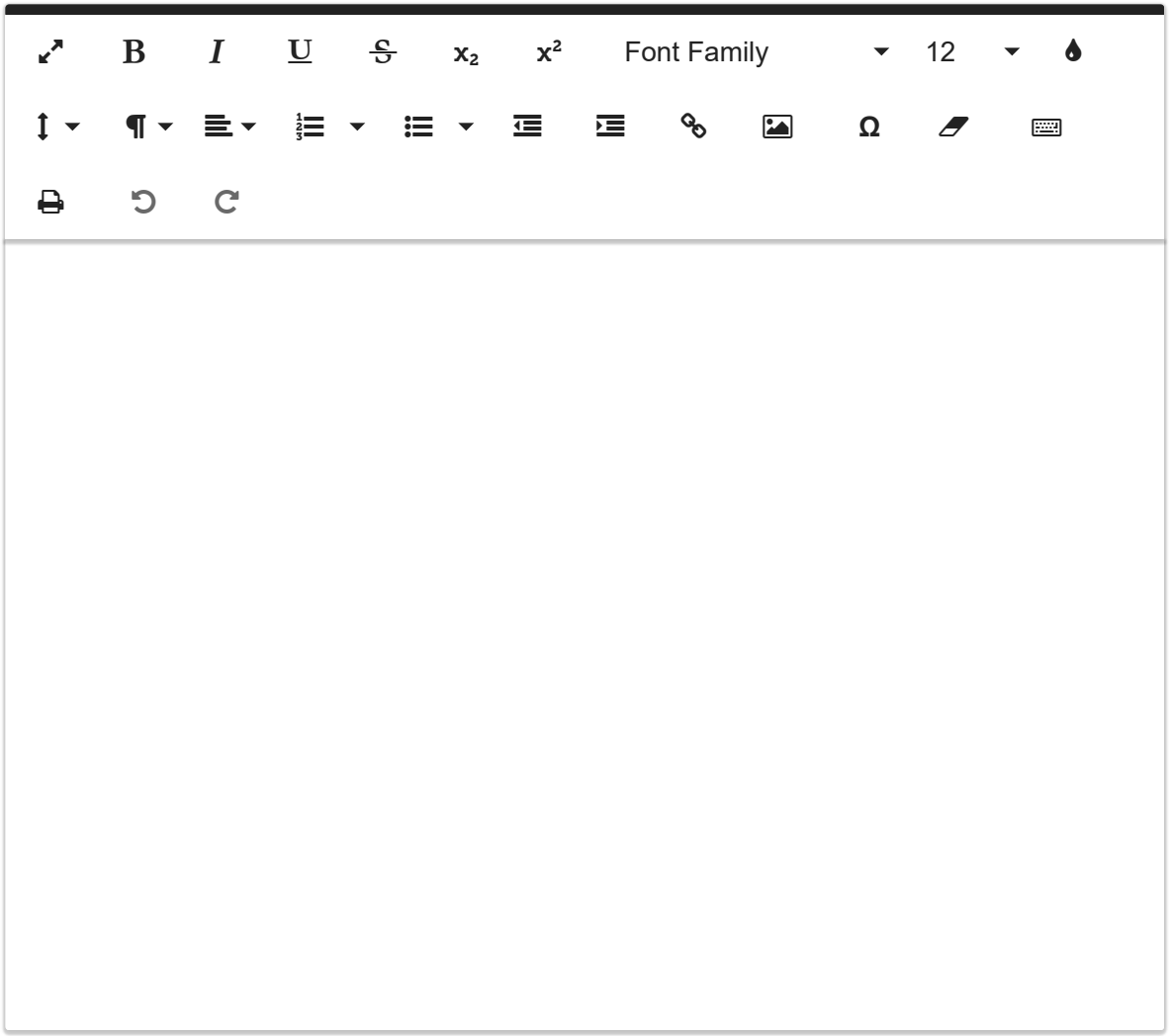
The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of

the research on public policy) as among those research benefits. In this section, please describe the possible benefits of participation.

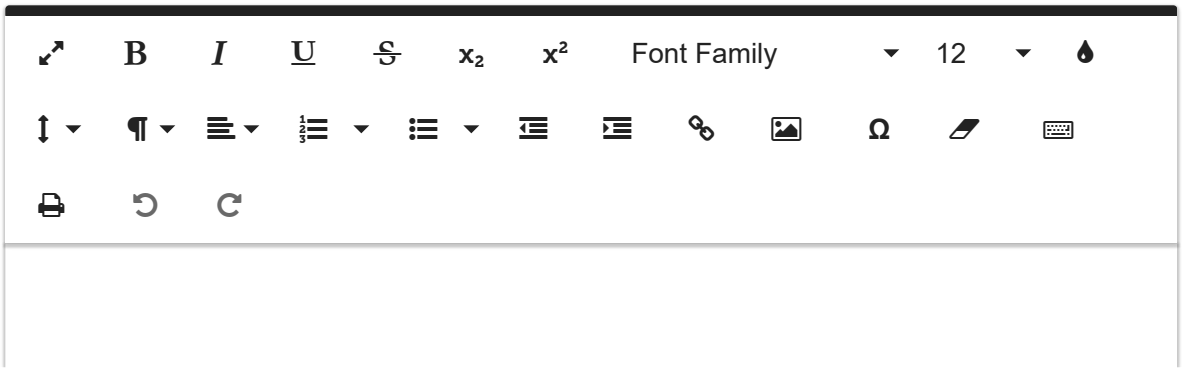
- **Direct benefit:** comes as a direct result of the subject's participation in the research
- **Indirect benefit:** may be incidental to the subject's participation

Will there be any direct benefits to the research subjects in your study? If so, what are they?

- **Do not include compensation as a benefit.**
- **Indicate if there is no direct benefit.**



Please list the potential benefits of the study to society.



Risks

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

Regulations state that *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 test [45 CFR 46.102(j)].

Based on that definition, is your study minimal risk?

- ◯ My study is minimal risk
- ◯ My study is more than minimal risk

Please complete the following table regarding risks to the subjects related to the subjects' participation in the research. Click "Add a new row" to add a row for each risk.

1. **Common risk types include:**
   - **Physical:** potential for pain, discomfort, infection
   - **Psychological:** potential for stress, discomfort, embarrassment
   - **Social:** potential for discrimination or stigmatization and disruption of personal and family relationships
   - **Legal:** potential for disclosure of illegal activity, negligence
   - **Privacy:** potential for personal information being accessed, used, or disclosed without the subjects' knowledge or consent, breach of confidentiality/security
   - **Economic:** potential for individuals to lose access to economic services, employment, insurability
2. **If applicable, describe risks to others who are not subjects (e.g., collection of sensitive health data that might affect sexual partners**

if disclosed, mandatory reporting of abuse, DNA testing that might affect family members or relationships).

3. **Do not indicate "No risk" or "N/A". Instead, for studies with minimal risk (e.g., anonymous online questionnaire on a mundane topic) indicate "No more than risks that are found in everyday life."**

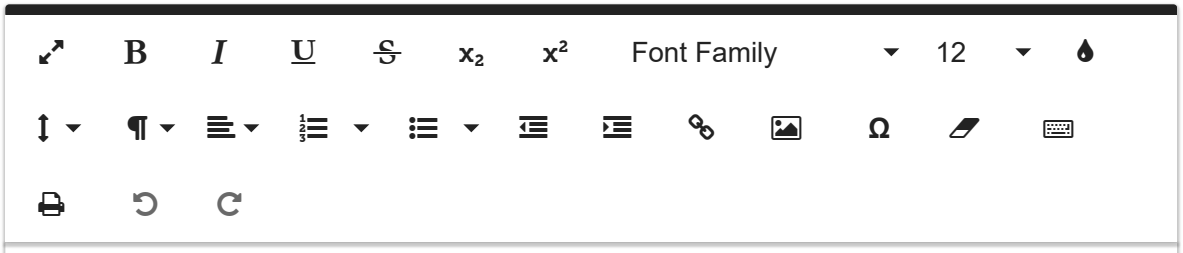
Note: Risks included here should be included in the consent form or cover letter, as applicable.

Type of risk	List the reasonably foreseeable risks, discomforts, hazards, or inconveniences related to the subjects' participation in the research. Include for the IRB's consideration a description of the probability, magnitude, duration, and reversibility of the risks.	Provides the measures you will use to minimize risks and to monitor subjects for safety (e.g., asking a subject at regular intervals to rate how they are feeling from 1 to 10, or to slowly crouch in order to check their balance.)
No records have been added		

Do you foresee that you might become aware of the need for medical or psychological services, for example, a national suicide hotline, BYU CAPs, list of local healthcare professionals, etc. as a result of the research procedures/interventions (e.g., suicidal ideations, PTSD, injuries)?

○ Yes ○ No

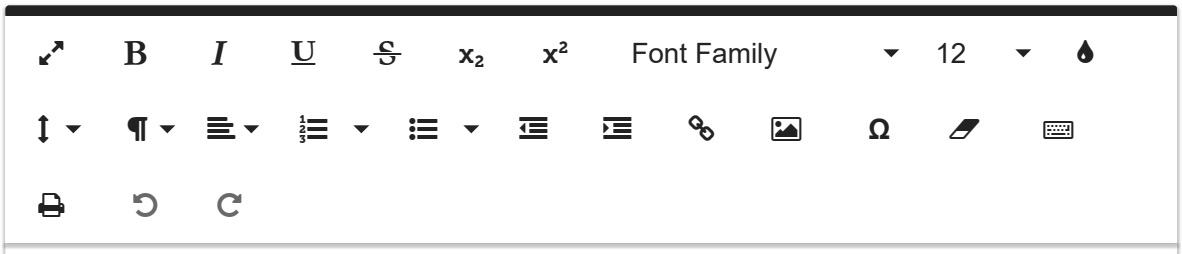
Please list the resources and describe how these resources will be made available to research subjects.



The IRB must determine the risks of participation do not outweigh the benefits. In your opinion, do the benefits or knowledge to be gained outweigh the risks to research subjects?

○ Yes ○ No

Provide justification for performing the research:



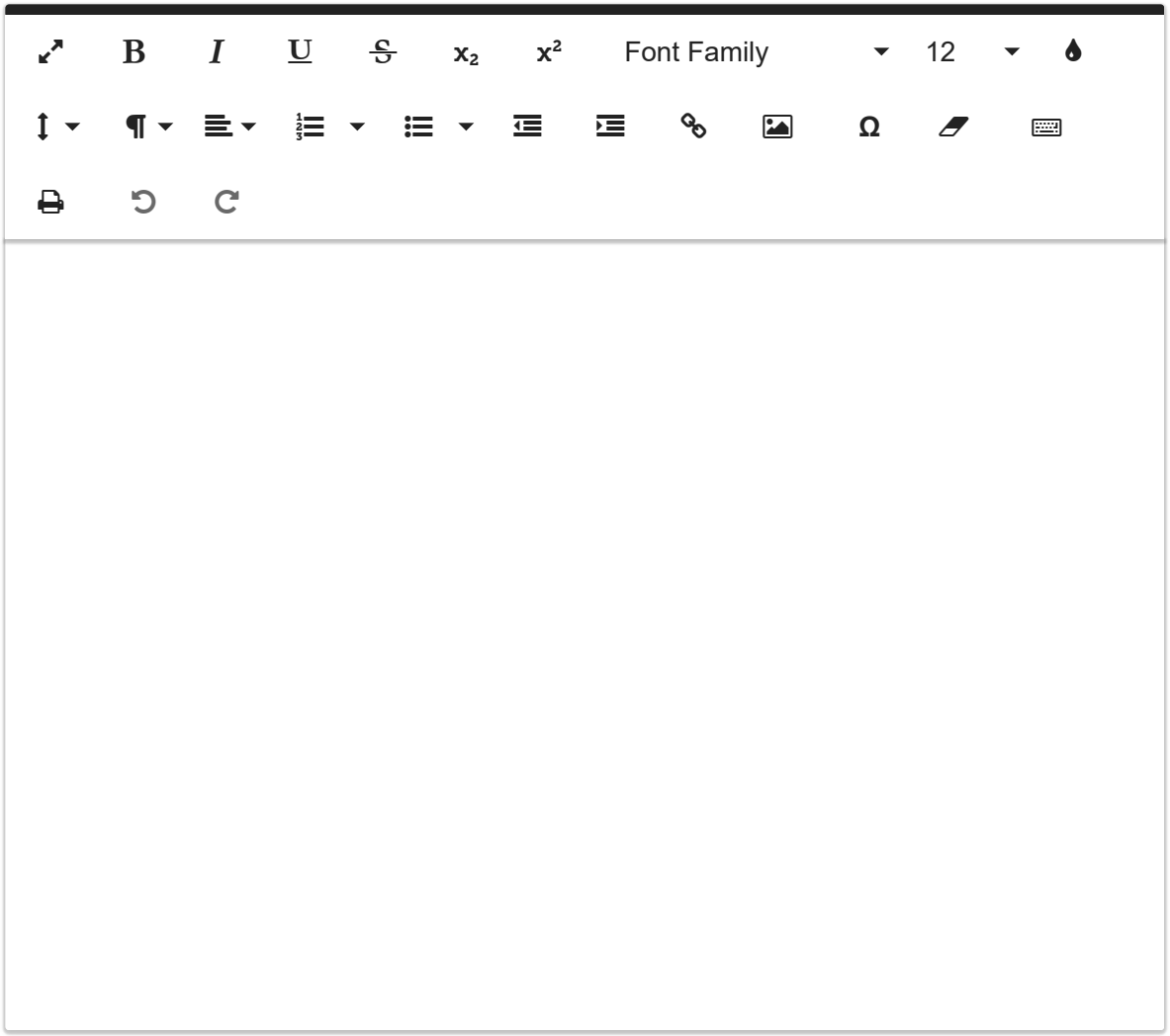
Data Safety Monitoring Plan

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.

Safety monitoring is required when research involves greater than minimal risk and is sometimes appropriate for other studies. Please describe:

1. **The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe (e.g., periodic reporting to the IRB, establishing a data monitoring committee, reporting data monitoring committee findings to the IRB and the sponsor).**

2. **What data you will review, including safety data, unexpected events, and data that show the ability to produce the intended results.**
3. **How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with subjects).**
4. **The frequency of data collection, including when safety data collection starts.**
5. **Who will review the safety data and with what frequency.**
6. **The statistical tests for analyzing the safety data to determine whether harm is occurring.**
7. **Any conditions that will trigger an immediate suspension of the research (e.g., a serious adverse event).**



Consent

Consent Process

There are several kinds of consent forms that may be used during research. Click here for more information from the BYU IRB SOP regarding Informed Consent.

Please check all that apply:

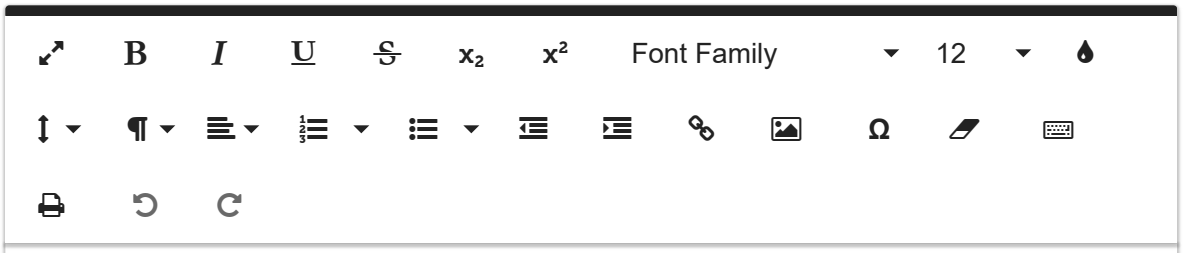
- [ ] I am obtaining informed consent, guardian/parental permission, and/or minor assent. I will use the standard consent form and subjects will sign the form.

- [ ] I am requesting to waive consent. I will not use any consent form.
- [ ] I am requesting to modify consent. I will use the implied consent or a verbal consent statement.
- [ ] I am requesting to waive subjects' signature on the consent form. I will use the standard consent form but subjects will not sign the form.

Note: You will be asked to attach consent documents (e.g., information sheet, cover letter, verbal script, consent form) later in the submission packet.

Consent is an on-going process that starts when you first inform your research subject about the study through your recruitment/advertising efforts and ends when the research subject's data are no longer needed. Please consider the following questions when you describe the consent process. Please copy and paste statement numbers 1-7 below into the textbox to use as headers.

1. **Who will present the consent information and how will it be presented?**
2. **How will you assess if the research subject, or their legally authorized representative, understood the information? For example, will you use a translator? Will you have time for subjects to ask questions? Will you use visuals to help with the consent process?**
3. **How will you document consent?**
4. **Will you have subjects or legal guardians sign the form, or will you audio record their consent?**
5. **Will you use more than one form (if you use more than one version of the consent form)? For example, multi-phase studies may not use the same methods or the same target population and you may use different forms of consent for different phases.**
6. **When and where will research subjects receive the consent form?**
7. **Who will give them the consent form?**



Who are the persons who will provide adult consent, parental/guardian permission (on behalf of another), and child/youth assent?

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

- **Coercion:** when an overt threat or harm is intentionally presented by one person to another in order to obtain compliance
- **Undue Influence:** an offer of an excessive, unwarranted, inappropriate, or improper reward or other overture to obtain compliance

Both are ethically inappropriate ways of interacting with research subjects to influence them to enroll or to remain in studies.

Language of Target Population

What language will the prospective research subjects and/or the legally authorized representative understand?

- [ ] English
- [ ] Spanish
- [ ] French
- [ ] German
- [ ] Hmong
- [ ] Mandarin
- [ ] Portuguese
- [ ] Other

You marked "Other". Please list:

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

- [ ] English
- [ ] Spanish
- [ ] French
- [ ] German
- [ ] Hmong
- [ ] Mandarin
- [ ] Portuguese
- [ ] Other

You marked "Other". Please list:

Describe the process to translate consent forms and study materials.

Indicate the spoken language that study personnel obtaining consent will use.

- [ ] English
- [ ] Spanish
- [ ] French
- [ ] German
- [ ] Hmong
- [ ] Mandarin
- [ ] Portuguese
- [ ] Other

You marked "Other". Please list:

Describe how you will assess fluency of personnel obtaining consent to ensure that the translation is accurate.

Will any protocol-specific instruments be used in the consenting process, such as supplemental handouts, videos, or websites?

○ Yes ○ No

Please describe the protocol-specific instruments that you will use in the consent process. You will attach them later in the submission packet.

Regulations dictate that the prospective subjects must be given sufficient opportunity to discuss and consider whether or not participate in the study [45 CFR 46.116(a)(2)].

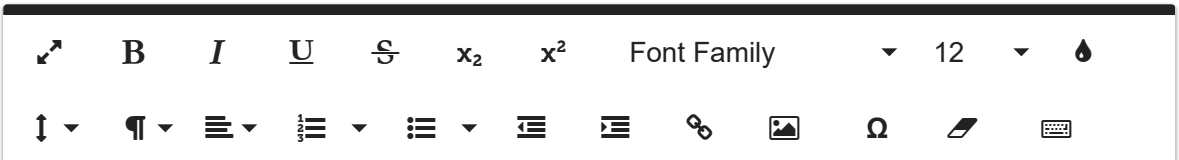
How long will research subjects have between the time they are told about the protocol and the time they must decide whether to enroll (weeks, days, hours, minutes, etc.)?

You marked "I am requesting to waive consent. I will not use any consent form" or "I am requesting to modify consent. I will use the implied consent or a verbal consent statement".

Waiver of one or more elements of consent is permitted provided that the research is no more than minimal risks and meets specific criteria [45 CFR 46.116(f)(3)(i-v)]. Alteration of consent is appropriate if one or more of the 5 required elements is not relevant to the research activity. Please select all that apply:

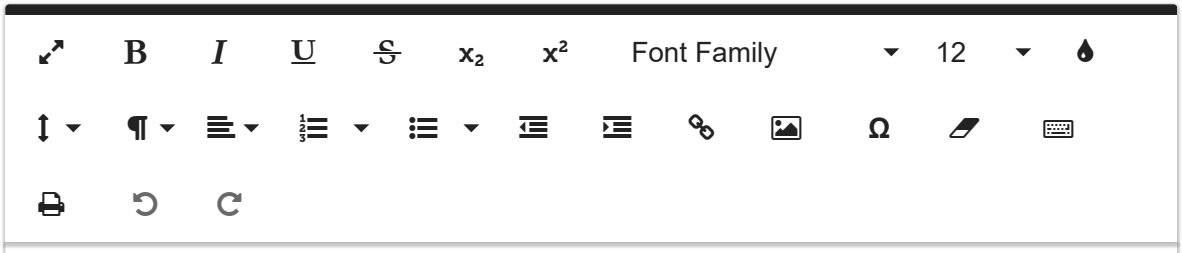
- ☐ The research involves no more than minimal risk to the subjects.
- ☐ The research could not practicably be carried out without the requested waiver or alteration.
- ☐ The research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried 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.

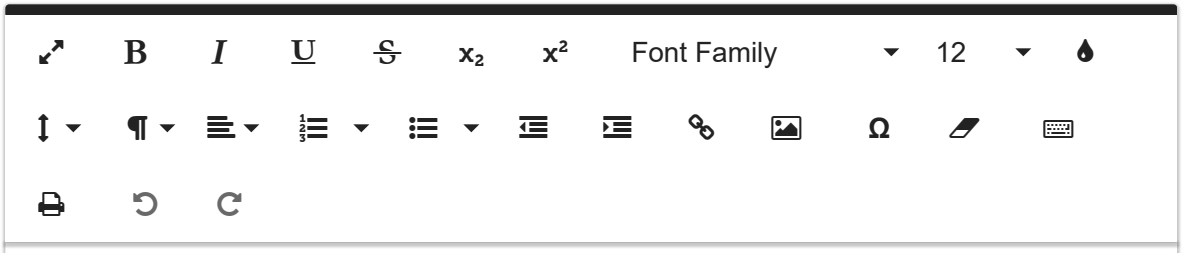


Please explain why it is impracticable to obtain informed consent.

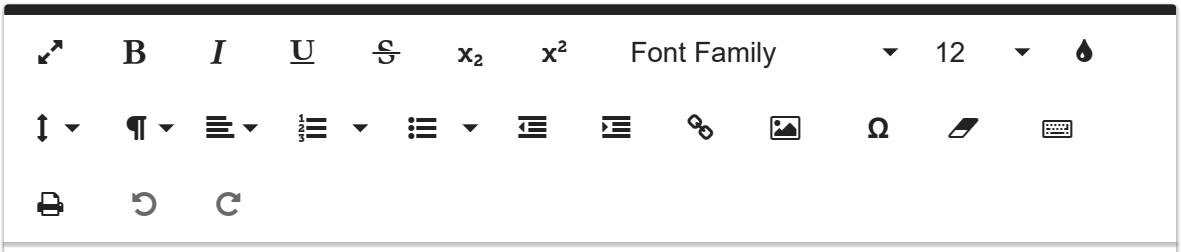
Please explain why it is impracticable to use deidentified information or biospecimens.



Please explain why the waiver will not adversely affect subjects.



Please decribe how pertinent information will be shared.



You marked "I am requesting to waive subjects' signature on the consent form".

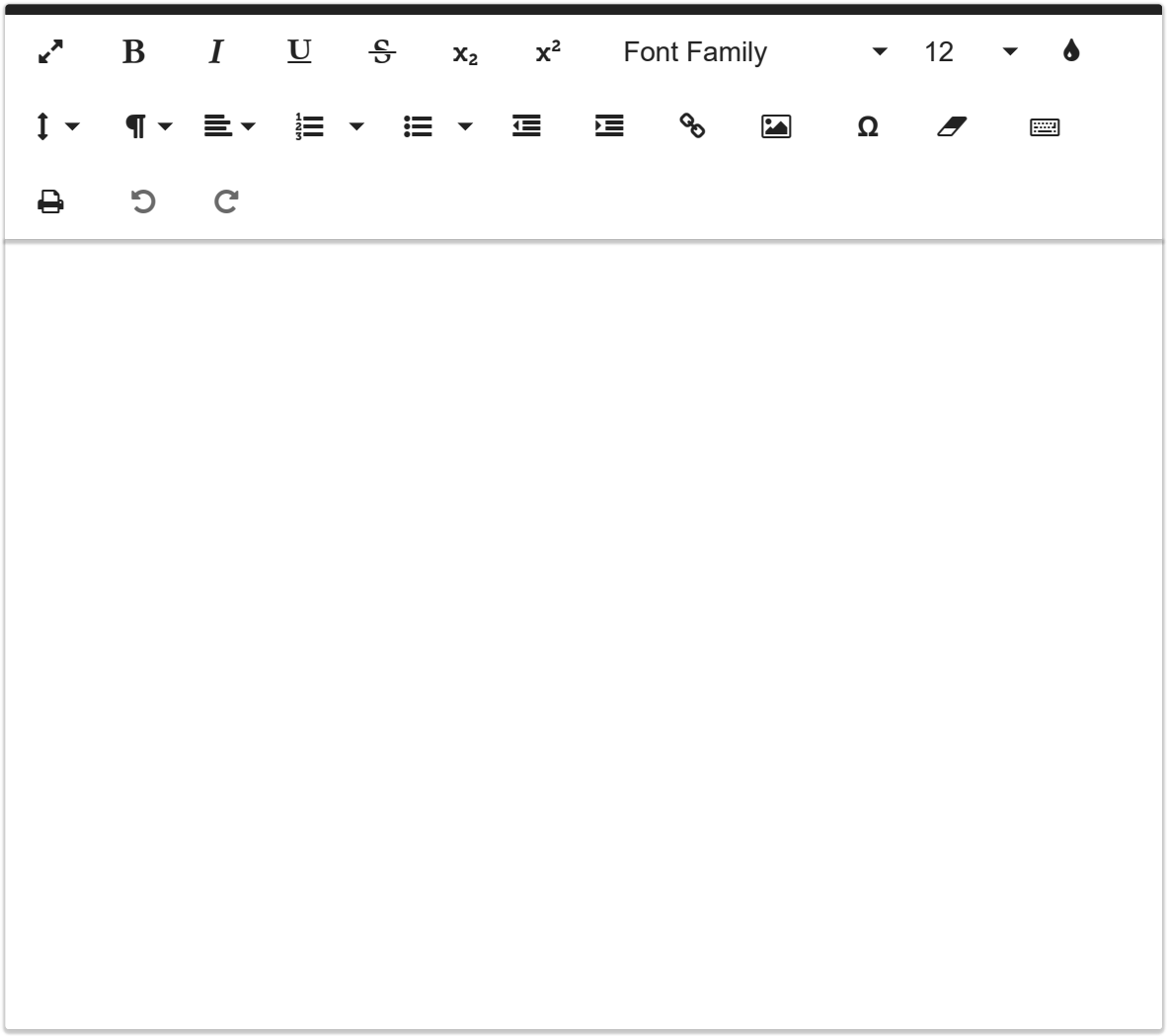
An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all of subjects if it finds any of the following [45 CFR 46.117(c)(1)(i-iii)]. Please select all that apply:

- [ ] 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
- [ ] 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
- [ ] 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

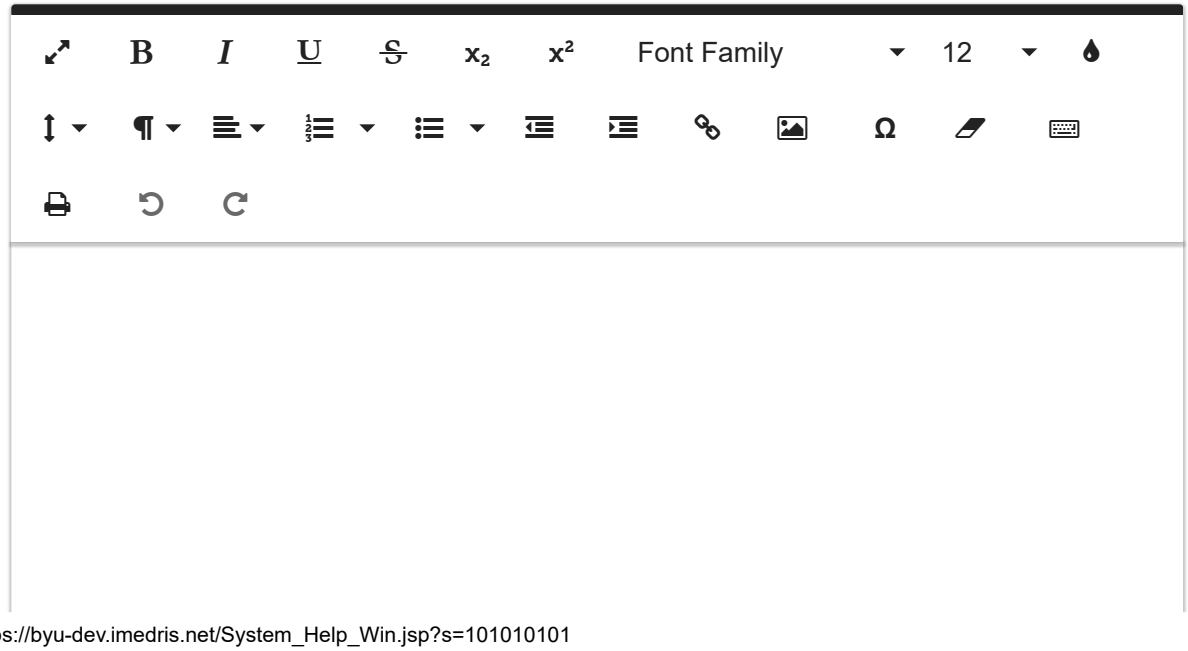
minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained

- [ ] Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.

Please explain why a breach of confidentiality could lead to potential harm for subjects.



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



Please explain

1. **The cultural context for why signing forms is not the norm**
2. **An appropriate alternative mechanism for documenting that informed consent was obtained**

Please describe how pertinent information will be shared

Confidentiality of Data and Privacy

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

Will you gather personal identifiers?

○ Yes ○ No

Please check all personal identifiers that you will have access to for this study:

- ☐ Name
- ☐ Date of birth
- ☐ Mailing address
- ☐ Email address
- ☐ Phone number
- ☐ Social security number
- ☐ Student IDs/NetIDs
- ☐ Medical records (including mental health records)
- ☐ IP address
- ☐ Biometric identifiers (physical and behavioral)
- ☐ Photos or images
- ☐ Audio recordings
- ☐ Video recordings
- ☐ Signatures or handwriting samples (other than signatures on consent form)

- [ ] Identifiable MRI scans
- [ ] Other

You marked "Other". Please describe:

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How will you collect data?

- ◯ 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)

Please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be maintained and protected.

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How will you store the data during data collection and analysis?

Data will be:

- [ ] Stored in a locked cabinet
- [ ] Stored in a locked office
- [ ] Stored on a restricted computer
- [ ] Stored behind a firewall system
- [ ] Stored in the cloud (e.g., Box)
- [ ] Stored in a shared file with limited access to research personnel only
- [ ] Password protected
- [ ] Encrypted
- [ ] Other

You marked "Other". Please describe:

Federal regulations require data to be kept for at least 3 years after study completion.

What will you do with the data?

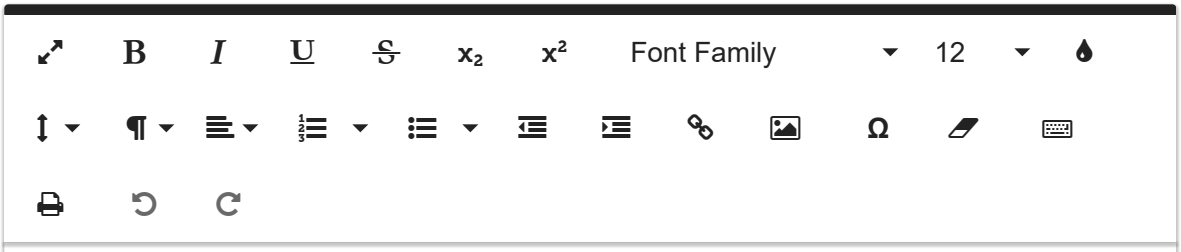
- ◯ All data will be destroyed 3 years after study completion
- ◯ Data will be maintained for future use

Who will use the data?

- ☐ Data will be used by the researchers listed in Section 3 of the application
- ☐ Data will be used by individuals outside the study team

Describe the plan for data use by the researchers when the active research phase is complete. Please copy and paste statement numbers 1-4 below into the textbox to use as headers.

1. **What data will be included in the long-term storage of data or specimens?**
2. **How long will the data or specimens be stored?**
3. **Where and how will data or specimens be stored?**
4. **When and how will personal identifiers be destroyed?**



Under what circumstances would data be shared with individuals outside the study team?

- [ ] Meta-analytic purposes
- [ ] As a requirement for publication
- [ ] For longitudinal comparisons with other datasets
- [ ] As a public dataset for secondary analysis
- [ ] Other

Information about sharing data should be disclosed to research subjects in the consent form.

You must work with the BYU HRPP to finalize the data use/data transfer agreement. You can contact them at BYU.HRPP@byu.edu.

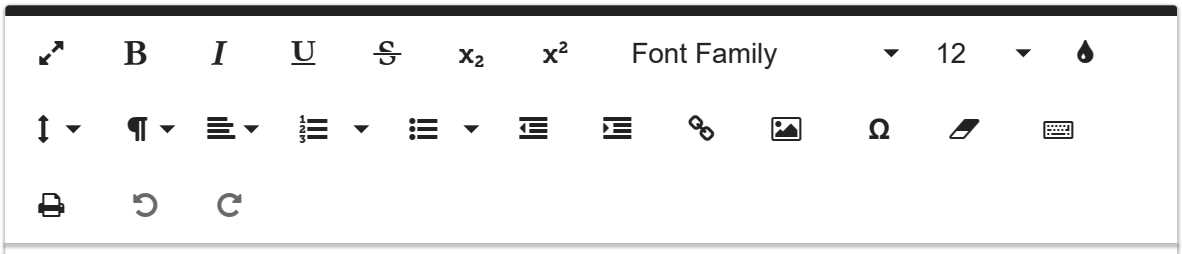
You marked "Other". Please describe:

What kind of data will be shared with individuals outside the study team?

- ◯ De-identified data only (all personal identifiers removed)
- ◯ Identifiable data (linked to subject by personal identifiers)

Please describe the anticipated terms and conditions to share data, for example, you will use Box to provide limited access to data, you will only share de-identified data, you will restrict the amount of time data can be used, etc.

1. **Who will have access to the data or specimens during long term storage?**
2. **Who is responsible for receipt or transmission of the data or specimens?**
3. **How will data or specimens be shared or transported?**



Privacy During Data Collection

Privacy: an individual's right to be free from intrusion or interference by others. Individuals have privacy interests in relation to their bodies, personal information, expressed thoughts and opinions, personal communications with others, and spaces they occupy. Research affects these various domains of privacy in

different ways, depending on its objectives and methods. An important aspect of privacy is the right to control information about oneself.

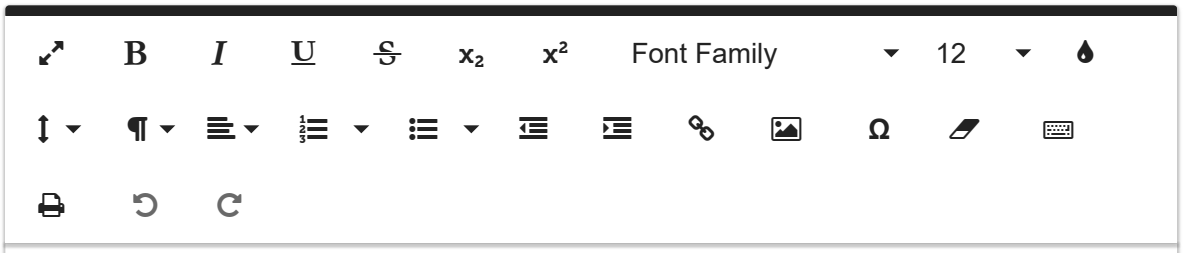
Sensitive Research Data: data is considered sensitive when disclosure of identifying information could have adverse consequences for subjects or damage their financial standing, employability, insurability, educational advancement, reputation, or place them at risk for criminal or civil liability.

Anonymous data: data that at no time has a code assigned that would permit the data to be traced back to an individual. Note that IP addresses are considered by the University and some international standards to be identifiable even though the address is linked to the computer and not specifically to the individual.

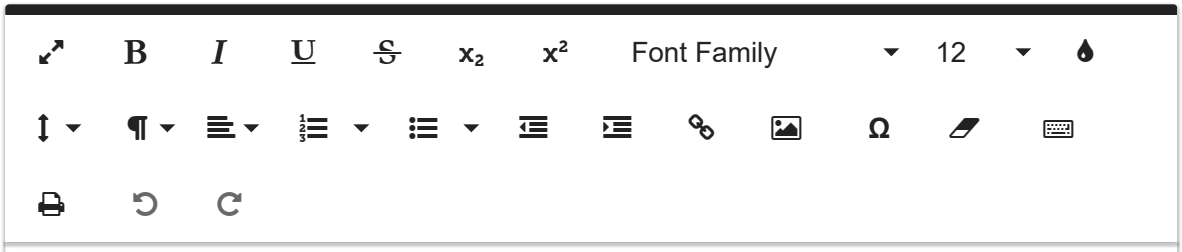
Indicate how subject privacy will be protected.

- [ ] Conduct conversation about the research in a private space
- [ ] 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 of shared with others without the subject's permission (see above definition of "sensitive research data").
- [ ] Other methods
- [ ] We will not interact directly with subjects
- [ ] We will not collect sensitive data (see above definition of "sensitive research data")
- [ ] Only anonymous data will be collected (see above definition of "anonymous data")

You marked "Other methods". Please describe:



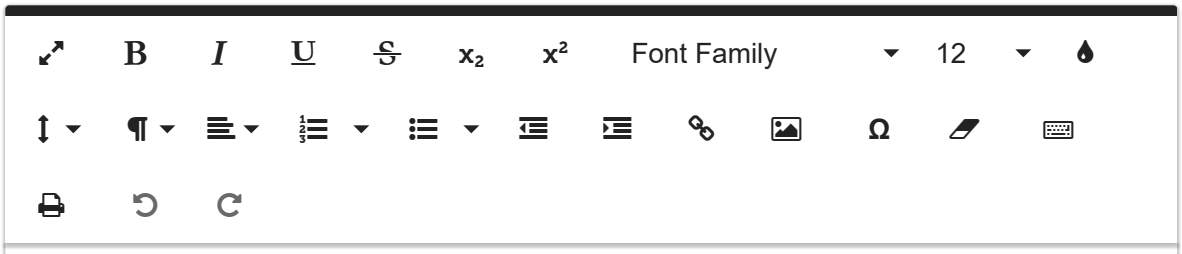
Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the subject's ability to privately provide information used for your study. For example, subjects may not want to be seen in areas that may stigmatize them or at times when they are working or completing other tasks.



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 data or responses.



Could a breach of privacy or confidentiality result in any significant consequences to research subjects, such as criminal or civil liability, loss of state or federal benefits, or be damaging to the research subject'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.

Note: In case of a breach, you should complete and submit the adverse events form.

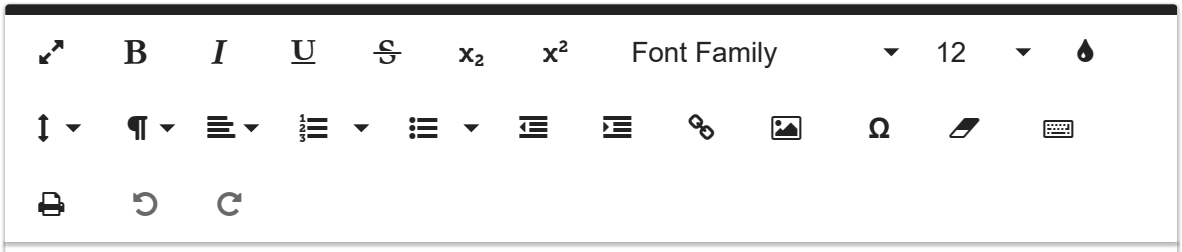
Do you anticipate that this study may collect information that state or federal law require to be reported to other officials, such as elder abuse, child abuse, or threat to self or others?

○ Yes ○ No

Describe any required reporting that might occur as a result of your research questions, study populations, and data collection methods including:

1. **Any suspicions (e.g., circumstantial, disclosed) of child abuse (physical, emotional, sexual) and neglect**
2. **Sexual discrimination and/or sexual violence that involves a student**
3. **Disclosure or signs of intention to harm oneself (i.e., suicidal ideation and/or plan)**
4. **Disclosure or signs of desire to harm others (i.e., homicidal ideation and/or plan)**
5. **Suspected abuse, neglect or exploitation of vulnerable adults (e.g., individuals with a disability, elderly persons)**

Provide the details of the reporting plan.



OPTIONAL: Information Page

If you are interested in how the IRB will categorize your study, please read this section. If not, please click the save and continue button to advance to the submission packet.

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 than he or she would throughout the course of a normal day or during routine physical exams or psychological tests.

Category 1: Research conducted in established or commonly accepted educational settings
Studies involving possible "adverse events" on student learning of the required education content and/or the assessment of educations do not qualify for this exemption.

Category 2: Research using tests, surveys, or observations
The scope is expanded to included 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.

Category 3: Research utilizing painless, brief behavioral interventions subjects would not find offensive or embarrassing
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.

Category 4: Secondary research uses of identifiable private information or identifiable biospecimens for which consent is not required
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.

Category 5: Research involving public benefit or service programs
In order for this exemption to be applied, the project must be published on a federal website.

Category 6: 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 probably 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.

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 or 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.
Examples: (a) hair and nail clippings in a non disfiguring 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 route 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 xrays or microwaves.
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 or 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, electroretinograpy, 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 (because it presents more than minimal risks to subjects) will be reviewed at a meeting of the fully convened IRB committee.