Institutional Review Board: What You Need to Know

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Agenda

- What is IRB?
  - The Belmont Report
  - Common Rule
- New IRB Protocol
- Three Categories of Review Process
- New IRB website

What is IRB? (Institutional Review Board)

- Independent ethics committee, ethical review board
- Mission
  - To Protect human subjects in research, especially vulnerable populations
- Function
  - To review research involving human subjects to ensure their rights and welfare are adequately protected.
- The IRB has the authority to *approve, disapprove, monitor, and require modifications* in all research activities that fall within its jurisdiction as specified by both the federal regulations and institutional policy.

The Belmont Report

- Ethical Principles and Guidelines for the Protection of Human Subjects of Research, April 18, 1979

Respect for Persons
"Be courteous"

- People should be autonomous.
- Allow informed choice where participants can choose for themselves.
- Provide additional protections for those who need it (i.e., privacy)
- Informed consent, Respect for privacy

Beneficence
"Do good"

- Protect persons from harm
- Clearly identify and maximize anticipated benefits
- Minimize possible risks of harm.
- Good research design, Competent investigators, Favorable risk/benefit ratio

Justice
"Be fair."

- Requires that the benefits and burdens of research be distributed fairly.
- Equitable selection of subjects.
- Equitable selection of subjects (No coercion, no discrimination, no disadvantage/advantage

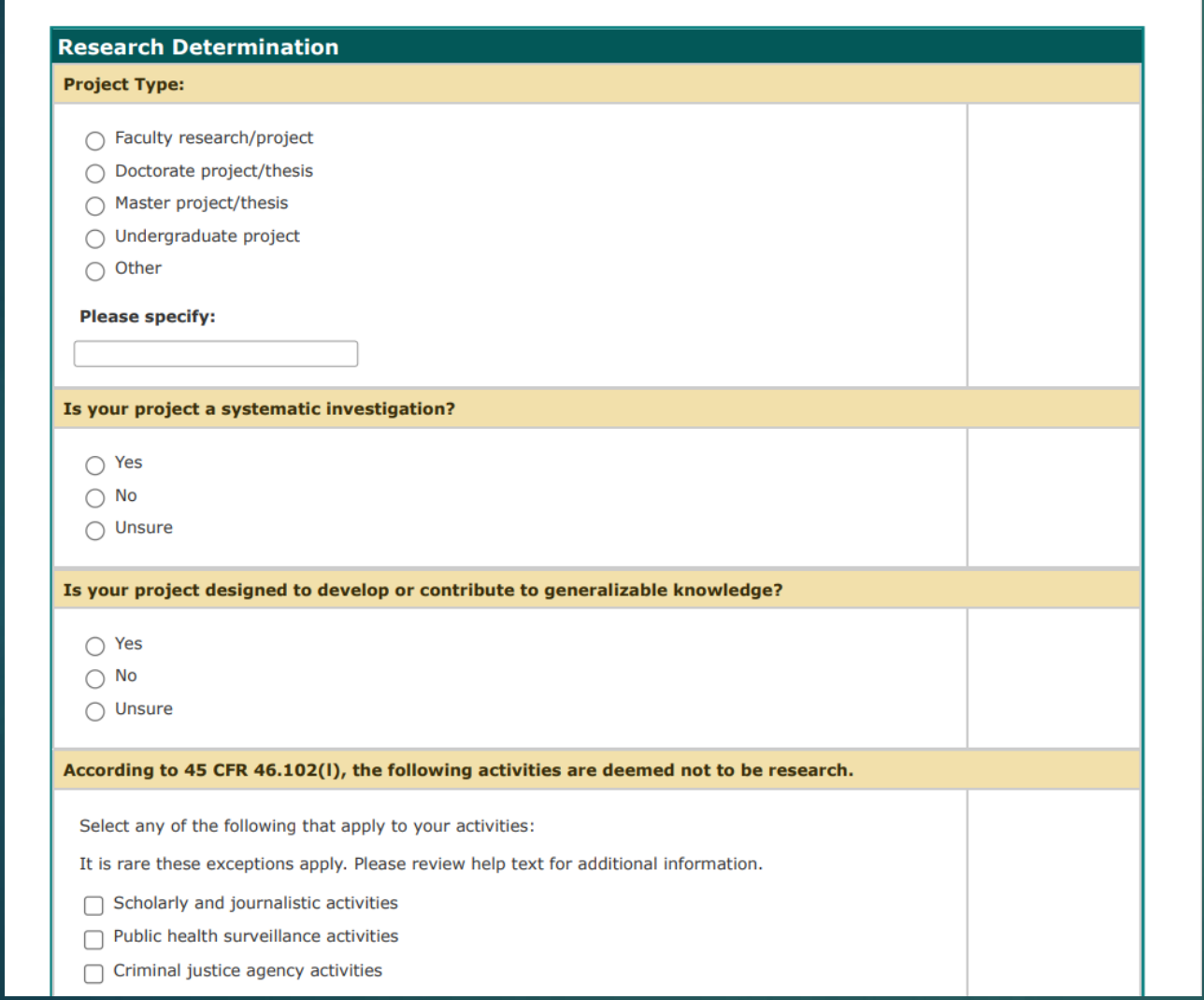
Common Rule

- A federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices.
- Applies to agencies that have signed an agreement to uphold.
- Outlines the requirements for assuring compliance by research institutions.
- Outlines the requirements for researchers' obtaining and documenting informed consent.
- Outlines protections for vulnerable populations (Subparts B-D).
- Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.

Changes to IRB application review process

- Once the IRB online review system, iRIS, is implemented, email submissions using the previous template will no longer be accepted.
  - The current estimate is in November.
- To submit an IRB application, a person with a valid TAMU SSO will be required.
  - For a student without SSO, a faculty advisor should submit his or her application on behalf of the student.
- All communication related to the application will take place through iRIS, ensuring streamlined and secure communication channels.

Section 1: Research Determination



Research Determination

Project Type:

- ○ Faculty research/project
- ○ Doctorate project/thesis
- ○ Master project/thesis
- ○ Undergraduate project
- ○ Other

Please specify:

Is your project a systematic investigation?

- ○ Yes
- ○ No
- ○ Unsure

Is your project designed to develop or contribute to generalizable knowledge?

- ○ Yes
- ○ No
- ○ Unsure

According to 45 CFR 46.102(l), the following activities are deemed not to be research.

Select any of the following that apply to your activities:

It is rare these exceptions apply. Please review help text for additional information.

- ☐ Scholarly and journalistic activities
- ☐ Public health surveillance activities
- ☐ Criminal justice agency activities

- Research refers to a **systematic investigation**, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.
  - A **systematic investigation** is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis, either quantitative or qualitative, to answer a question.
  - **Generalizable** means designed to draw general conclusions, inform policy, or generalize findings beyond a single individual, sample, or internal program. Examples of generalizable knowledge include publications or presentations outside of a program or class, theses, or dissertations, etc.

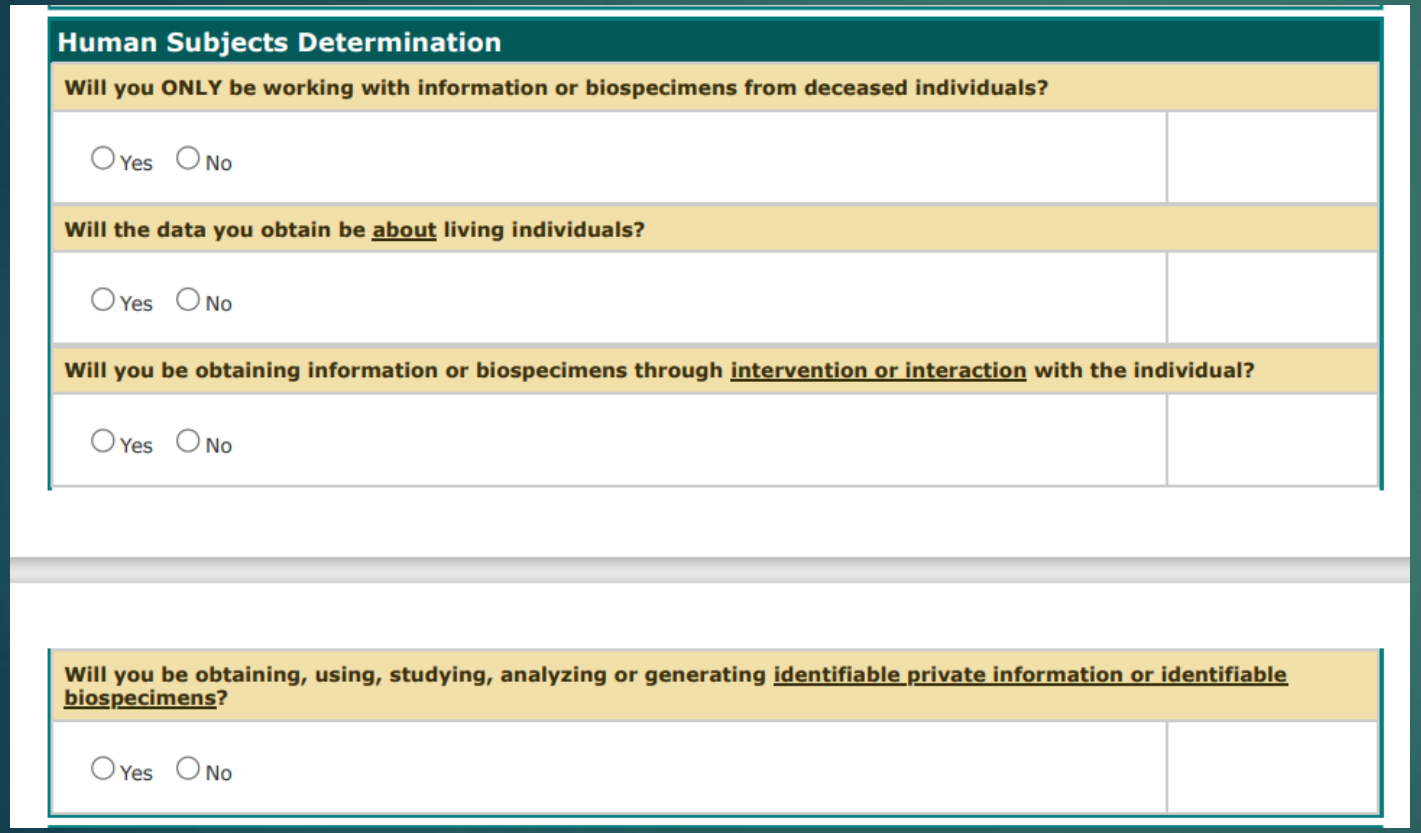
Activities Deemed Not to be Research

- Four types of activities deemed not to be research
  - Scholarly and journalistic activities
  - Public health surveillance activities
  - Information collection for criminal justice purposes
  - Operational activities for national security purposes

Activities Deemed Not to be Research (cont.)

- **Scholarly and Journalistic Activities**
  - Collection and use of information focused directly on the specific individuals about whom the information is collected
  - Examples *(adopted from OHRP)*
    - A journalism professor wants to write about the specific experiences of a group of first responders to the 9/11/2001 attacks on the World Trade Center to create a record of the events of that day. (No)
    - A group of psychologists hypothesized that certain characteristics may render a group of people to be more susceptible to PTSD following a traumatic event, like 9/11.To investigate their hypothesis, they conducted interviews and surveyed 9/11 survivors. They then analyzed the data, drew conclusions from it, and published the findings in a scientific journal to contribute to the academic literature on PTSD. (Yes)

Section 2: Human Subjects Determination



Human Subjects Determination

Will you ONLY be working with information or biospecimens from deceased individuals?

○ Yes ○ No

Will the data you obtain be about living individuals?

○ Yes ○ No

Will you be obtaining information or biospecimens through intervention or interaction with the individual?

○ Yes ○ No

Will you be obtaining, using, studying, analyzing or generating identifiable private information or identifiable biospecimens?

○ Yes ○ No

- Human subject
  - A living individual about whom an investigator conducting research obtains:
  - (1) information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or
  - (2) uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.

Is It Human Subject Research?

- Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture, cheek swab) and manipulations of the subject or the subject's environment that are performed for research purposes.
- Interaction includes any communication or contact between investigator and subject via any channels (e.g., face-to-face, surveys, etc.).
- Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Is It Human Subject Research? (cont.)

- Private information includes
  - (a) information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place
  - (b) information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record, GPA, income, sexual orientation, etc.). An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

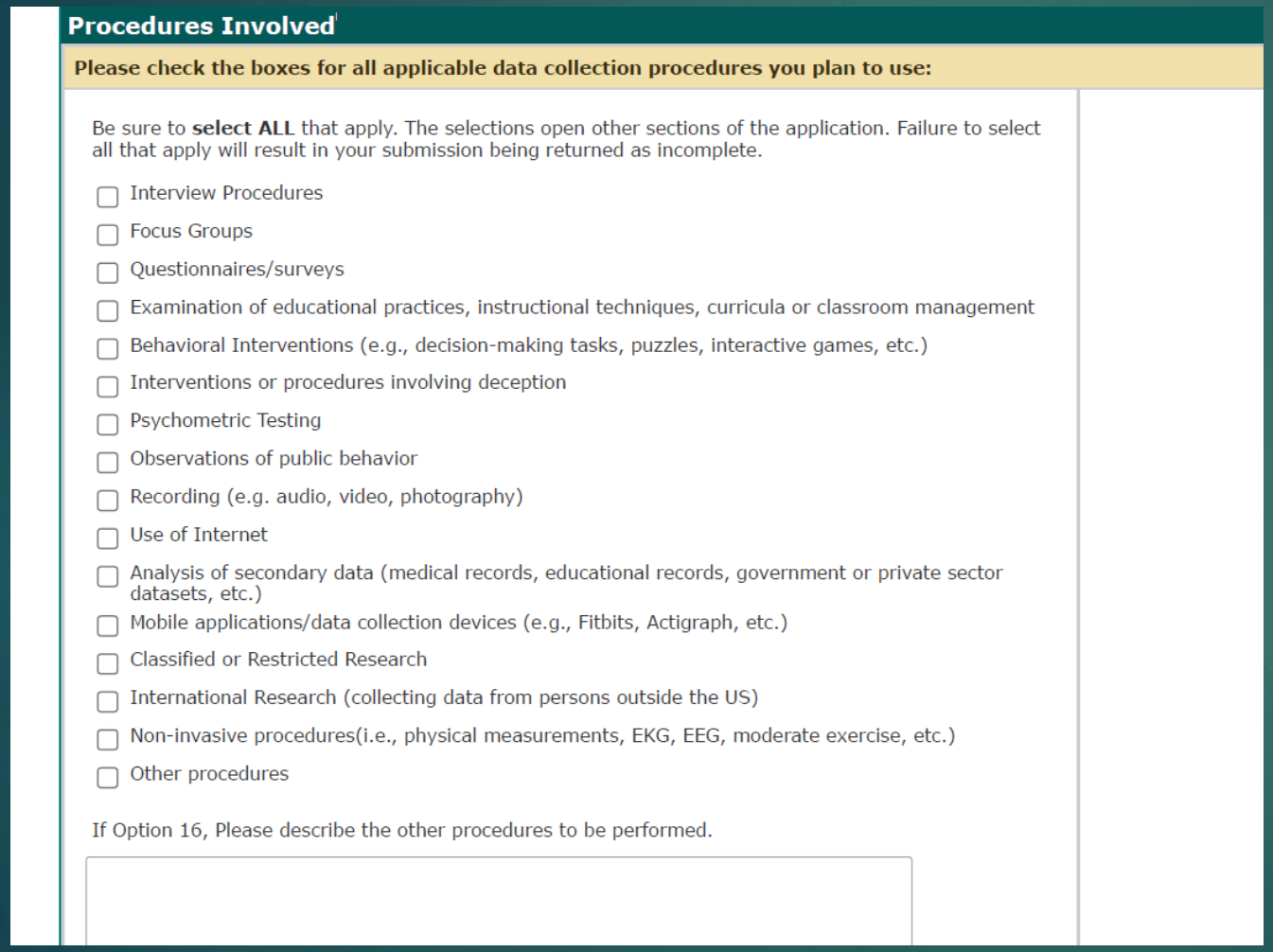
Is It Human Subject Research? (cont.)

- Examples (adopted from OHRP)
  - A researcher hypothesizes that some middle-aged women who died from COVID-19 had undiagnosed or untreated underlying heart disease. To investigate the hypothesis, the researcher plans to systematically review identifiable medical records of 400 deceased women ages 45-65 who were hospitalized with COVID-19 to look for commonalities like high blood pressure, high LDL, etc. (No)
  - A researcher hypothesizes that children who attend pre-kindergarten with rigorous academic instruction present with behavioral issues and attention deficit by first grade. To investigate this hypothesis, the researcher plans to interview 250 pre-kindergarten, kindergarten, and first grade teachers across the country. (Yes, and they are vulnerable populations.)

Section 3: IRB New Protocol Application Form

- PI information
- Research team members
- Purpose and Rationale of the Study
  - State the purpose of your study. Include the specific aims or objectives, or research questions that will guide your study.
  - Provide the scientific or scholarly background for proposed research based on the existing literature. State how completing the proposed research will add to existing knowledge.
- Collaborations
  - Will researchers from other institutions be involved in this project?
    - Yes
  - Research Team Members from Other Institutions:
  - Has another IRB or ethics committee reviewed the study, or will they in the future?
- Funding
- Related studies (Not literature review)

Section 4: Procedures Involved



Procedures Involved

Please check the boxes for all applicable data collection procedures you plan to use:

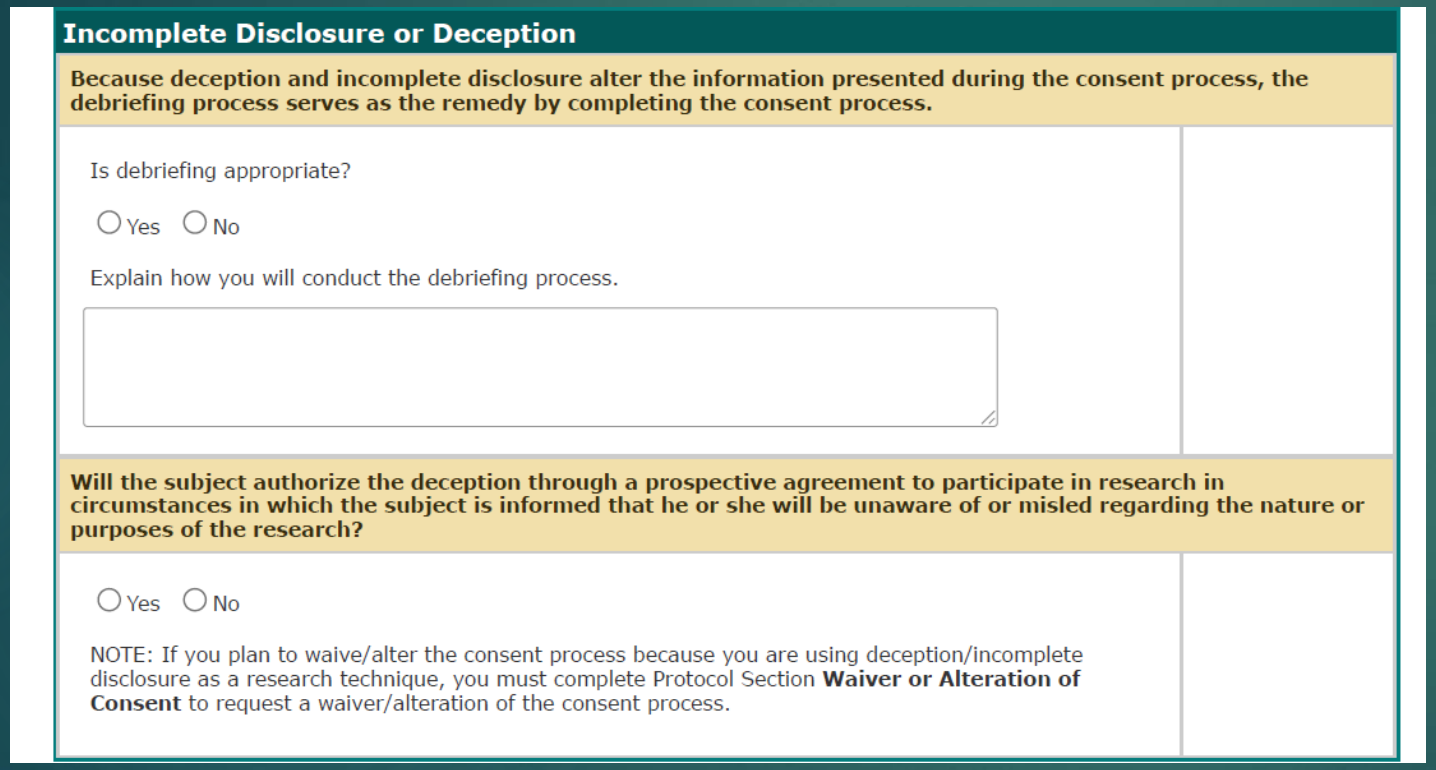
Be sure to **select ALL** that apply. The selections open other sections of the application. Failure to select all that apply will result in your submission being returned as incomplete.

- ☐ Interview Procedures
- ☐ Focus Groups
- ☐ Questionnaires/surveys
- ☐ Examination of educational practices, instructional techniques, curricula or classroom management
- ☐ Behavioral Interventions (e.g., decision-making tasks, puzzles, interactive games, etc.)
- ☐ Interventions or procedures involving deception
- ☐ Psychometric Testing
- ☐ Observations of public behavior
- ☐ Recording (e.g. audio, video, photography)
- ☐ Use of Internet
- ☐ Analysis of secondary data (medical records, educational records, government or private sector datasets, etc.)
- ☐ Mobile applications/data collection devices (e.g., Fitbits, Actigraph, etc.)
- ☐ Classified or Restricted Research
- ☐ International Research (collecting data from persons outside the US)
- ☐ Non-invasive procedures(i.e., physical measurements, EKG, EEG, moderate exercise, etc.)
- ☐ Other procedures

If Option 16, Please describe the other procedures to be performed.

- Describe the study plan, including a detailed description of each procedure you checked off above.
- Describe the duration of an individual's participation in the study for each study activity and the estimated total time for each participant to complete all study activities.
- Describe the duration of an individual's participation in the study for each study activity and the estimated total time for each participant to complete all study activities.

Section 5: Incomplete Disclosure or Deception



Incomplete Disclosure or Deception

Because deception and incomplete disclosure alter the information presented during the consent process, the debriefing process serves as the remedy by completing the consent process.

Is debriefing appropriate?

○ Yes ○ No

Explain how you will conduct the debriefing process.

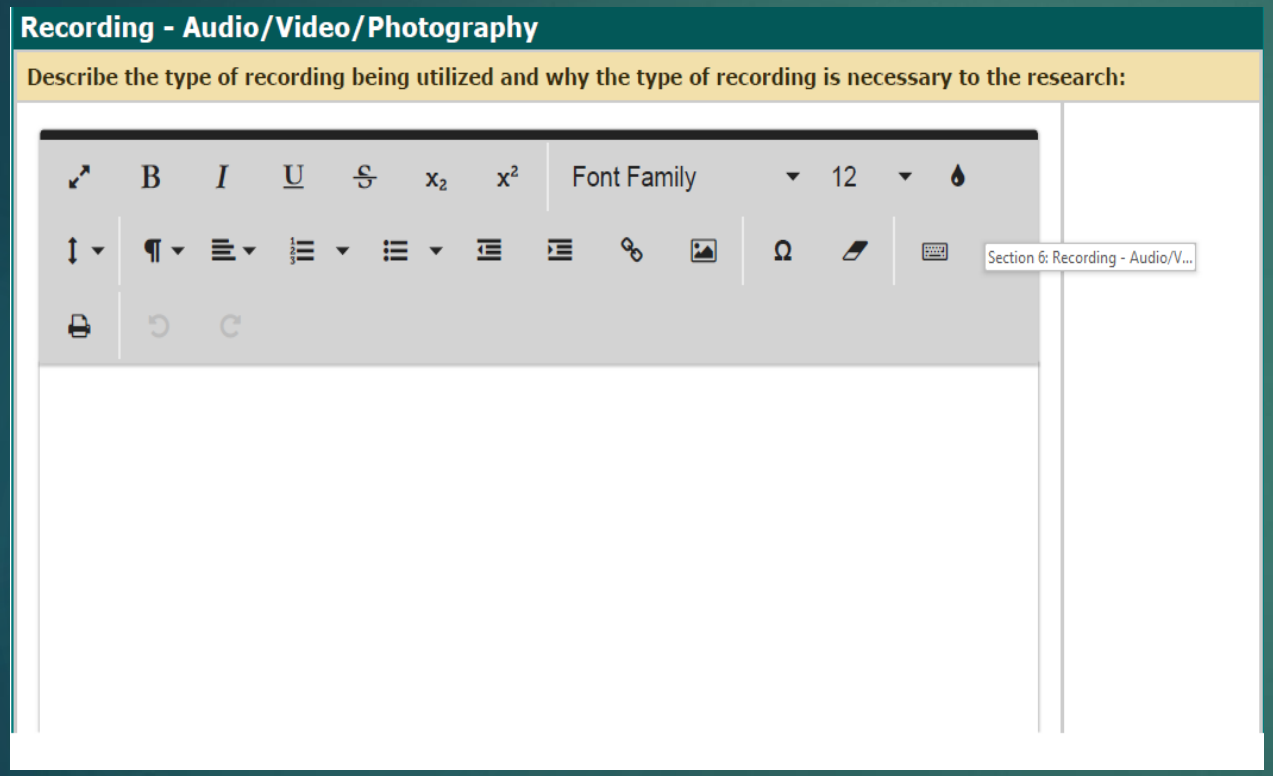
Will the subject authorize the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research?

○ Yes ○ No

NOTE: If you plan to waive/alter the consent process because you are using deception/incomplete disclosure as a research technique, you must complete Protocol Section **Waiver or Alteration of Consent** to request a waiver/alteration of the consent process.

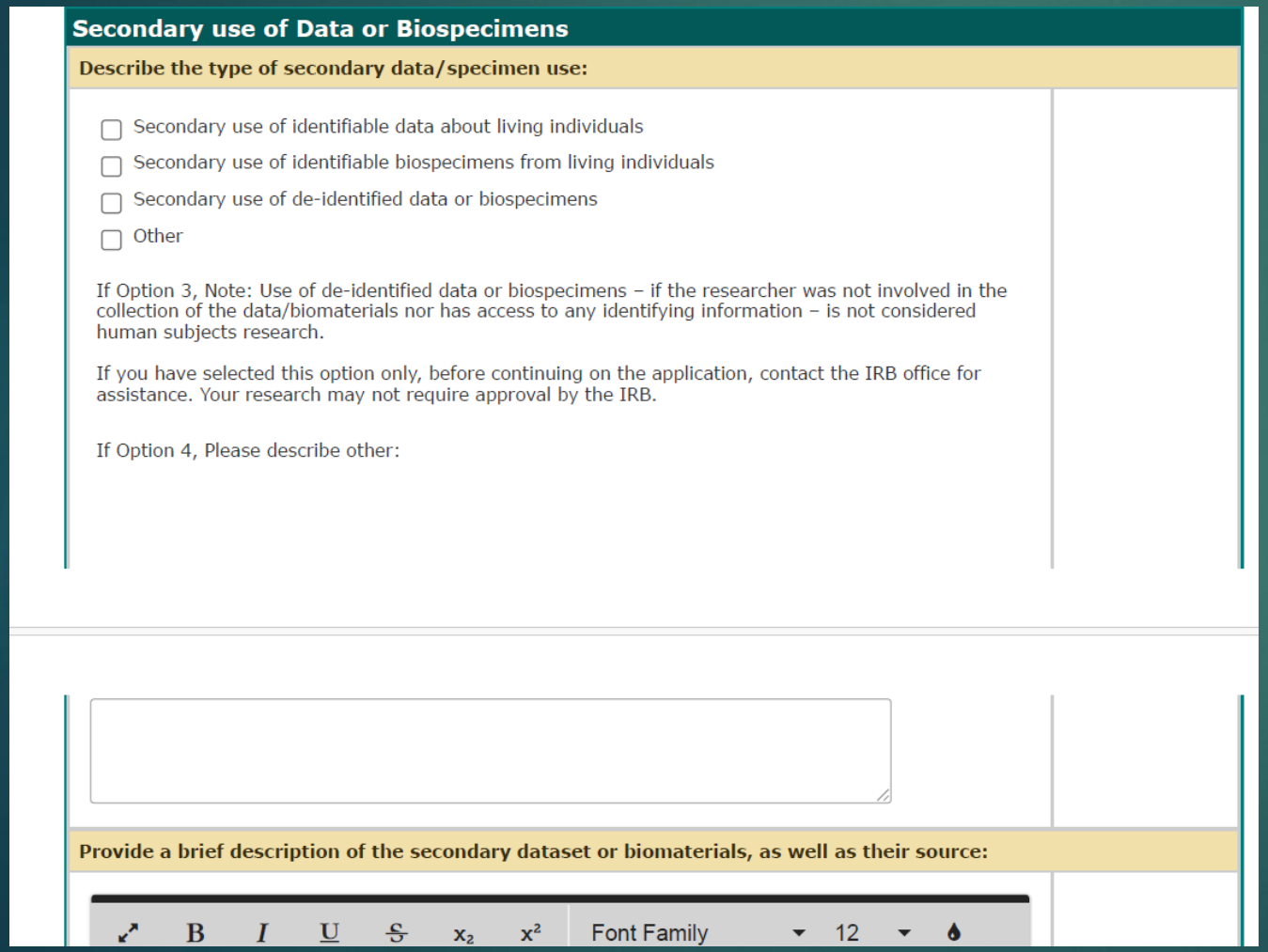
- Requirements
  - Inform your human subjects that the research involves deception.
  - No need to inform what it is.

Section 6: Recording - Audio/Video/Photography



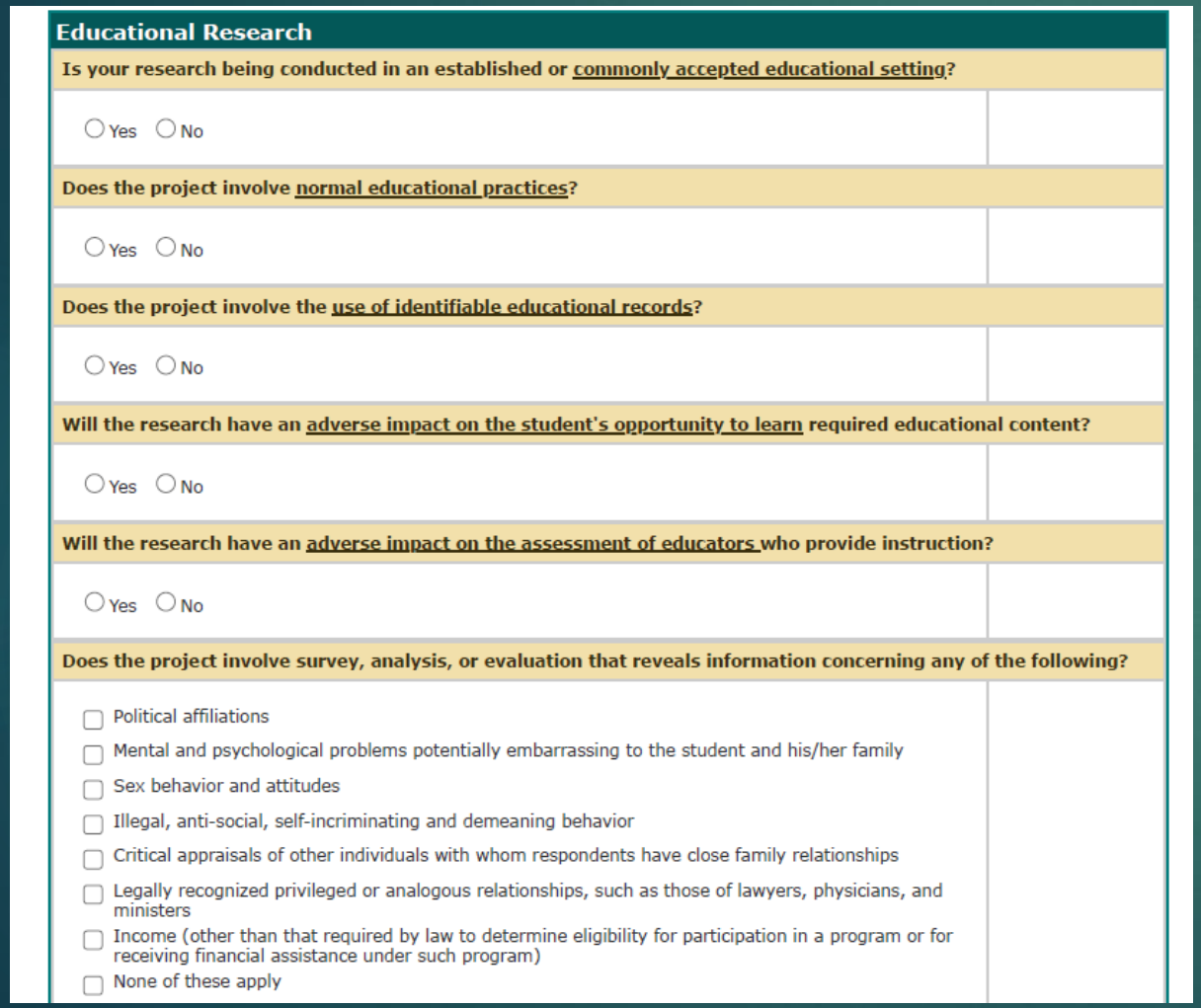
- Is recording mandatory to participate in the research?
- Provide a rationale as to why recording is mandatory (not optional) for subjects to participate in this research project.
- Describe how and where the recordings will be stored, who will have access to them, and if/when they will be destroyed:
  - Provide details on the data security plan for the RECORDING ONLY.
  - Do NOT just copy/paste from the general data security plan.
- Recommendation
  - Minimize recording

Section 7: Secondary use of Data or Biospecimens



- Does the secondary data/biospecimens contain sensitive information about the research participants?
- Was anyone on your research team involved in the original collection of these data or biospecimens?

Section 8: Educational Research



Educational Research

Is your research being conducted in an established or commonly accepted educational setting?

○ Yes ○ No

Does the project involve normal educational practices?

○ Yes ○ No

Does the project involve the use of identifiable educational records?

○ Yes ○ No

Will the research have an adverse impact on the student's opportunity to learn required educational content?

○ Yes ○ No

Will the research have an adverse impact on the assessment of educators who provide instruction?

○ Yes ○ No

Does the project involve survey, analysis, or evaluation that reveals information concerning any of the following?

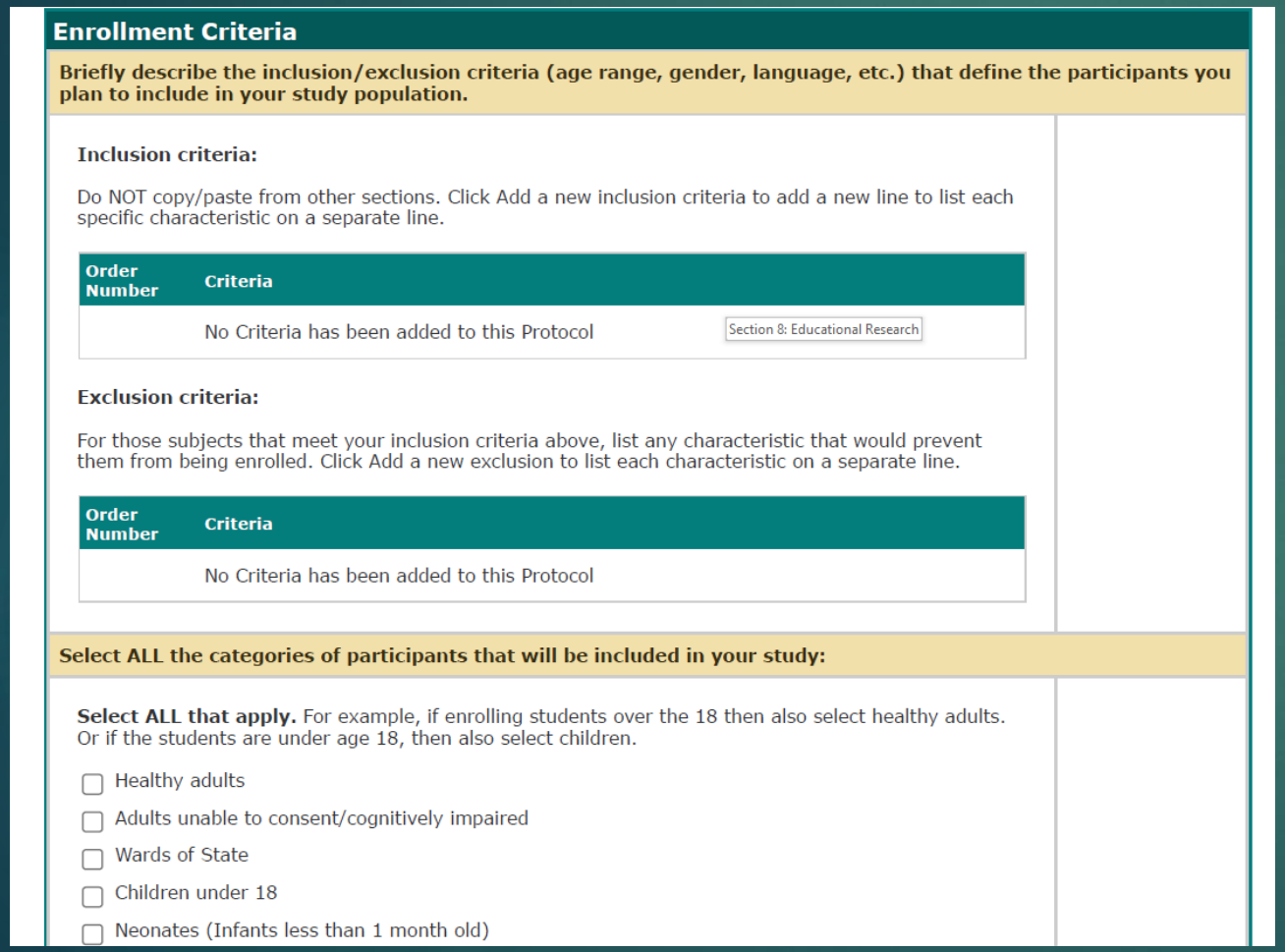
- ☐ Political affiliations
- ☐ Mental and psychological problems potentially embarrassing to the student and his/her family
- ☐ Sex behavior and attitudes
- ☐ Illegal, anti-social, self-incriminating and demeaning behavior
- ☐ Critical appraisals of other individuals with whom respondents have close family relationships
- ☐ Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
- ☐ Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program)
- ☐ None of these apply

- Recommendation
  - Ensure that there is no coercive participation (i.e., disadvantage of non-participation, too many credits for participation, etc.).
  - Do not use too much of class time for your research.

Section 9: Observation of Public Behavior

- Describe the public behavior you will observe.
- Describe the public setting where the observation will take place.
- Will investigators participate in the activities being observed?

Section 10: Enrollment criteria



Enrollment Criteria

Briefly describe the inclusion/exclusion criteria (age range, gender, language, etc.) that define the participants you plan to include in your study population.

Inclusion criteria:

Do NOT copy/paste from other sections. Click Add a new inclusion criteria to add a new line to list each specific characteristic on a separate line.

Order Number	Criteria
	No Criteria has been added to this Protocol Section 8: Educational Research

Exclusion criteria:

For those subjects that meet your inclusion criteria above, list any characteristic that would prevent them from being enrolled. Click Add a new exclusion to list each characteristic on a separate line.

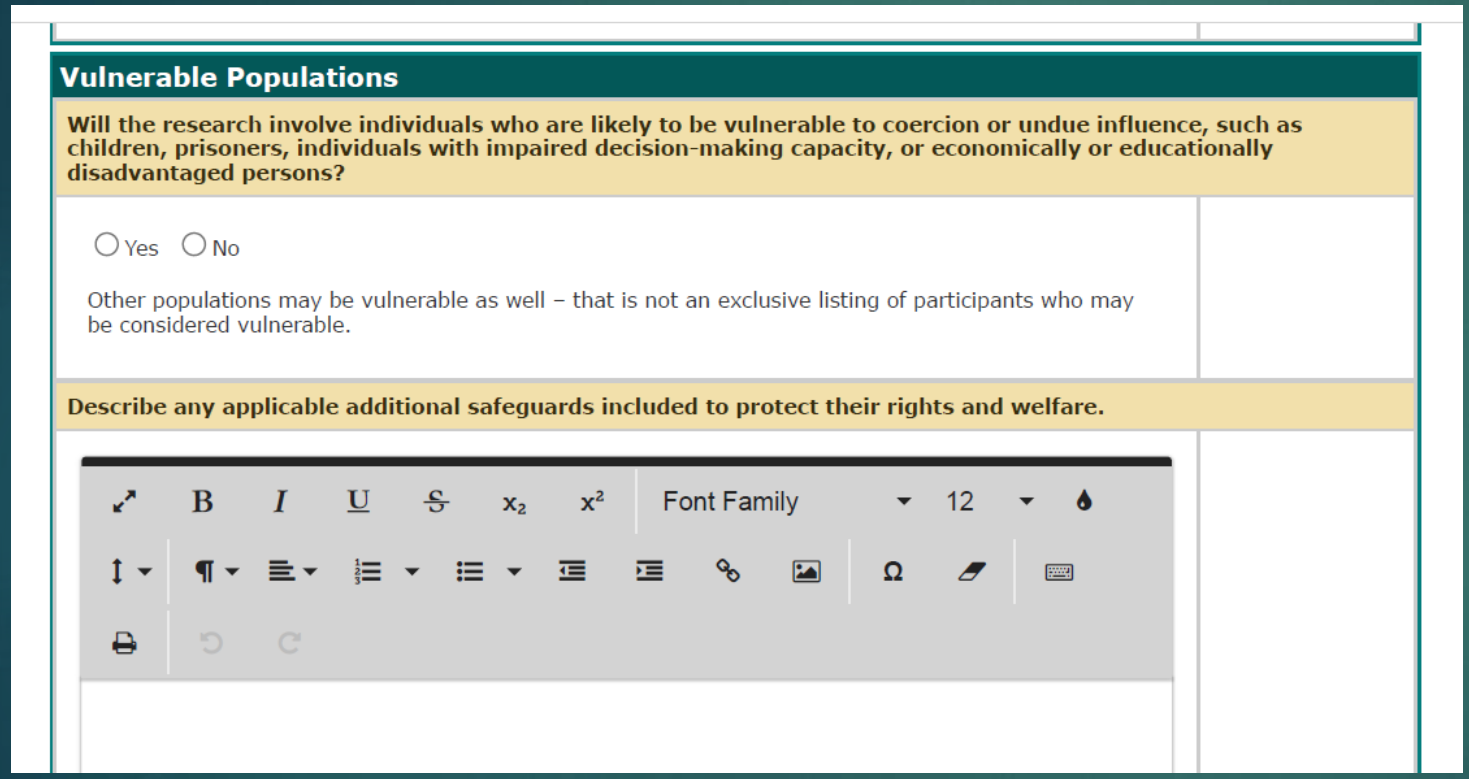
Order Number	Criteria
	No Criteria has been added to this Protocol

Select ALL the categories of participants that will be included in your study:

Select ALL that apply. For example, if enrolling students over the 18 then also select healthy adults. Or if the students are under age 18, then also select children.

- ☐ Healthy adults
- ☐ Adults unable to consent/cognitively impaired
- ☐ Wards of State
- ☐ Children under 18
- ☐ Neonates (Infants less than 1 month old)

Section 11: Vulnerable populations

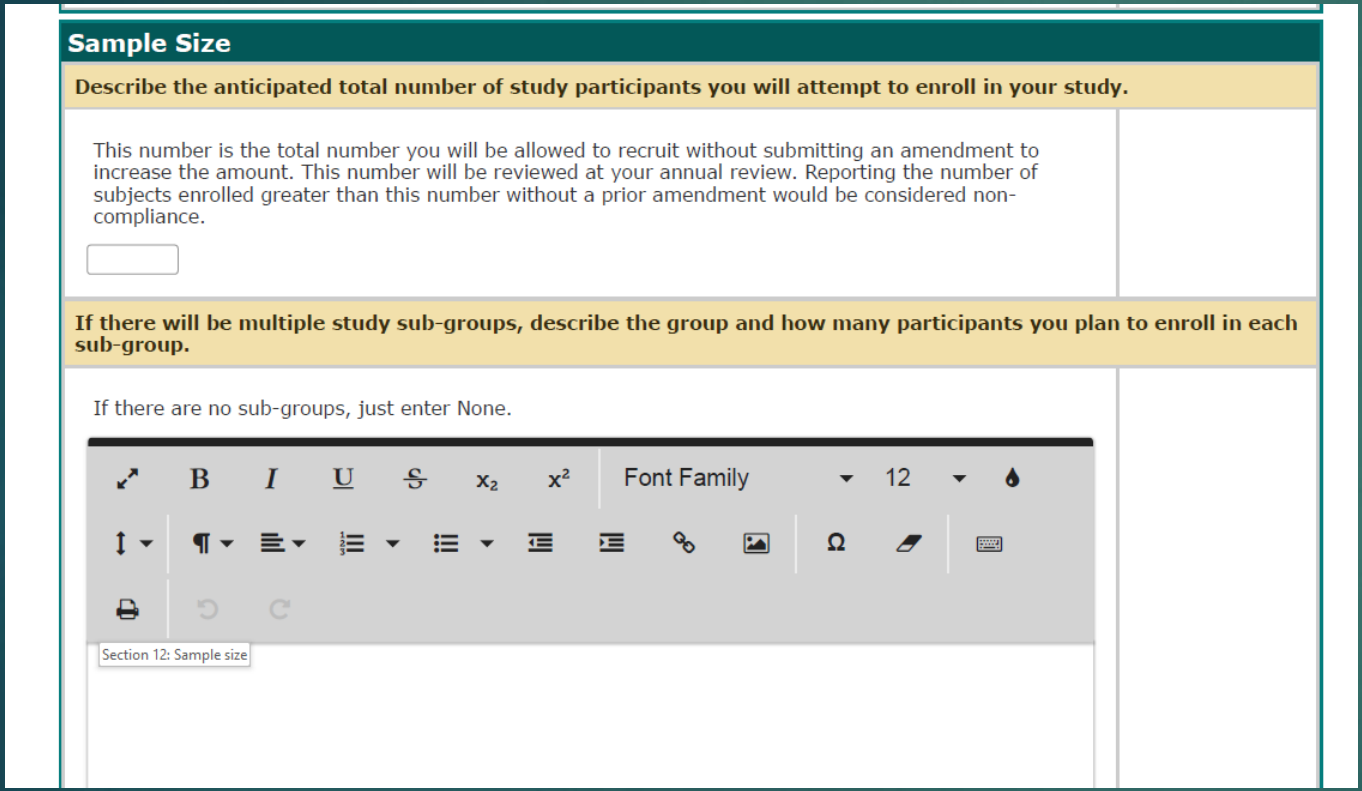


- Please explain the steps you will take to minimize the possibility of undue influence/coercion.
- Please explain the steps you will take to reduce coercion and undue influence for students or employees
-

Vulnerable Populations

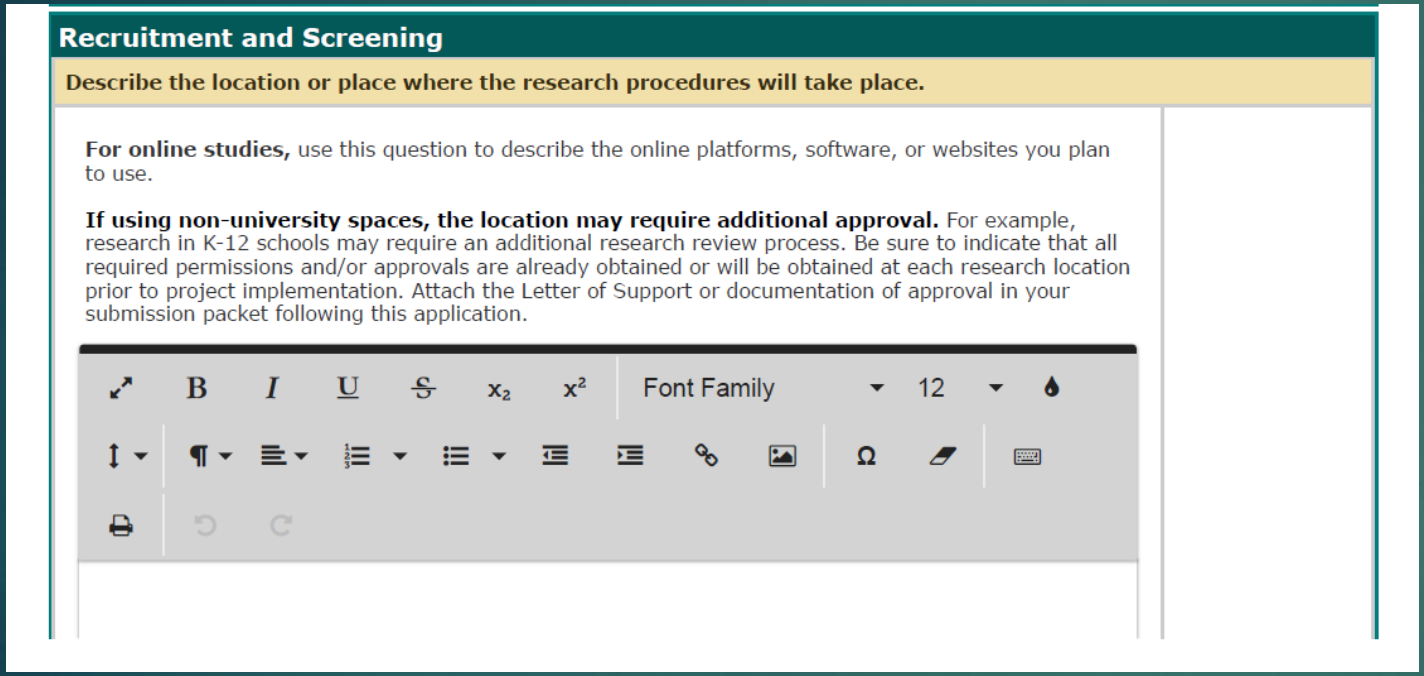
- Vulnerable Populations
  - Individuals who may have reduced autonomy or may be unduly influenced by coercion, such as children, prisoners or other institutionalized individuals, pregnant women, human fetuses or neonates, physically or mentally disabled persons, economically or socially disadvantaged individuals
- Protections for Vulnerable Populations
  - Subpart B: Additional DHHS Protections Pertaining to Research, Development and Related Activities Involving Fetuses, Pregnant Woman, and Human In Vitro Fertilization
  - Subpart C: Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
  - Subpart D: Additional DHHS Protections for Children Involved as Subjects in Research

Section 12: Sample size



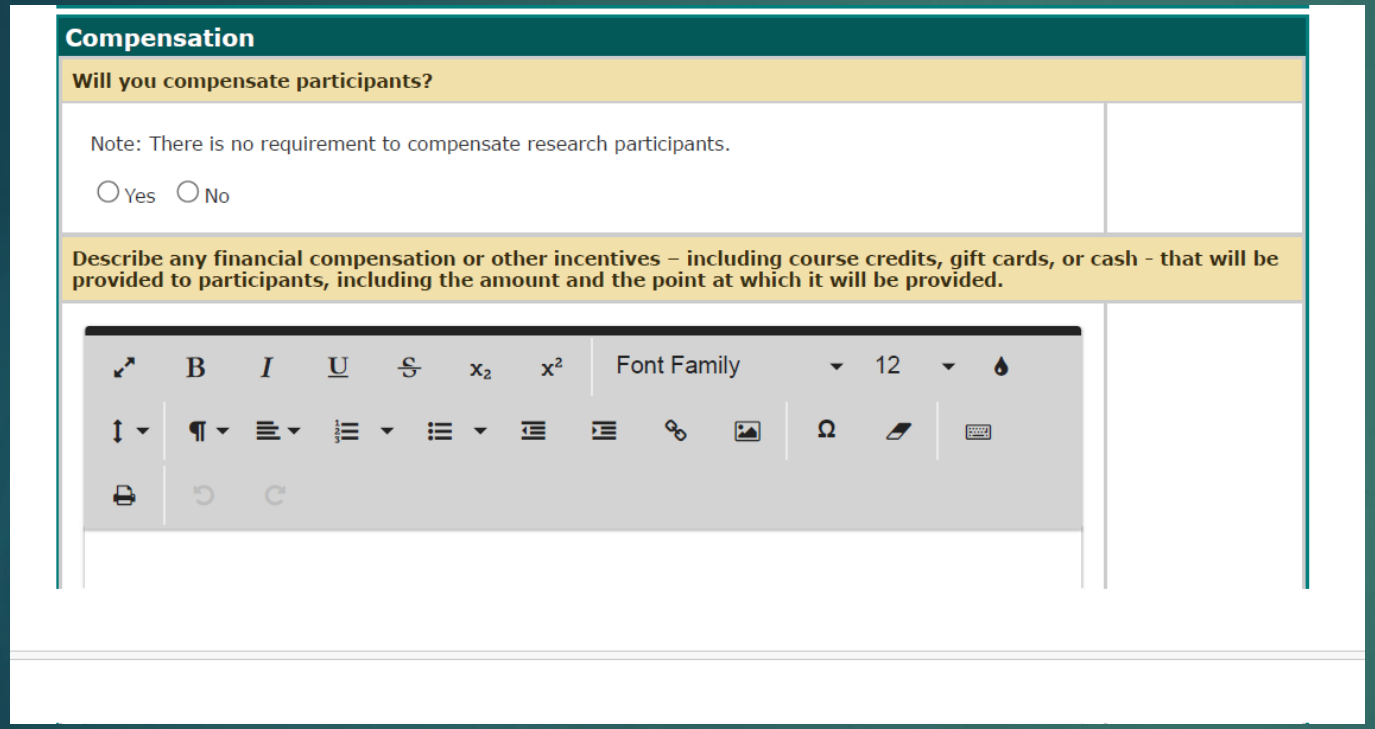
- Provide a justification for the sample size. Briefly explain why this number of participants is needed to answer your research questions.

Section 13: Recruitment and Screening



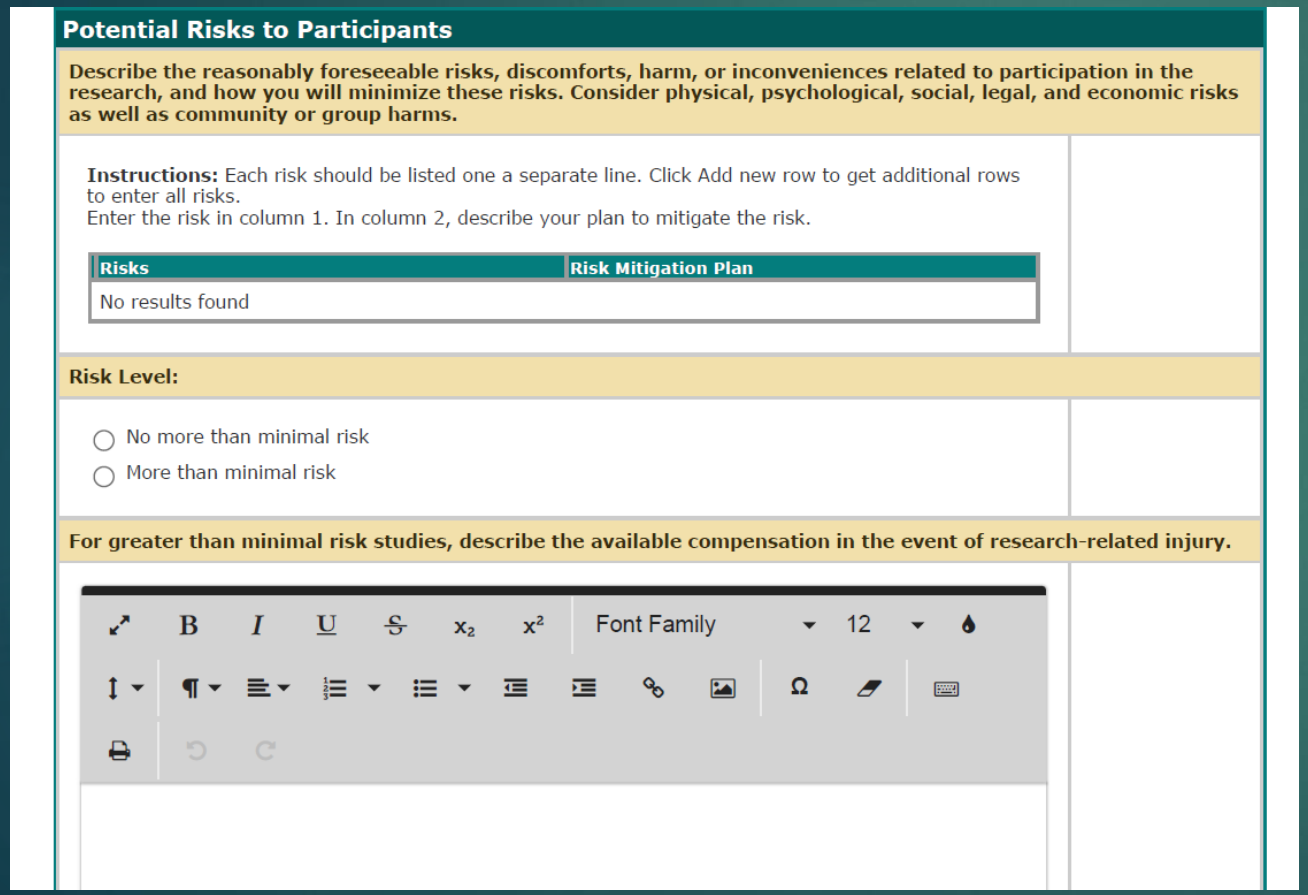
- Select all methods that you plan to use to recruit potential study participants:
  - Flyers/posters
  - Mailers/U.S. Post
  - Online ads
  - Email
  - Social media/online networking sites/Amazon Mturk
  - TV, radio
  - Student pool
  - Presentations in meetings or classes
  - Phone or in-person conversation
  - Other: Please describe:
- How will you locate individuals who might be eligible to participate in your study?
- How will you access/collect information to determine which people are eligible to participate in your study?
- How, where, when and by whom will contact be made with people who might be eligible to participate in your study?

Section 14: Compensation



- Recommendation
  - Compensation should not be tempting or incentivizing.

Section 15: Potential Risks to Participants



Potential Risks to Participants

Describe the reasonably foreseeable risks, discomforts, harm, or inconveniences related to participation in the research, and how you will minimize these risks. Consider physical, psychological, social, legal, and economic risks as well as community or group harms.

Instructions: Each risk should be listed one a separate line. Click Add new row to get additional rows to enter all risks.
Enter the risk in column 1. In column 2, describe your plan to mitigate the risk.

Risks	Risk Mitigation Plan
No results found	

Risk Level:

- ○ No more than minimal risk
- ○ More than minimal risk

For greater than minimal risk studies, describe the available compensation in the event of research-related injury.

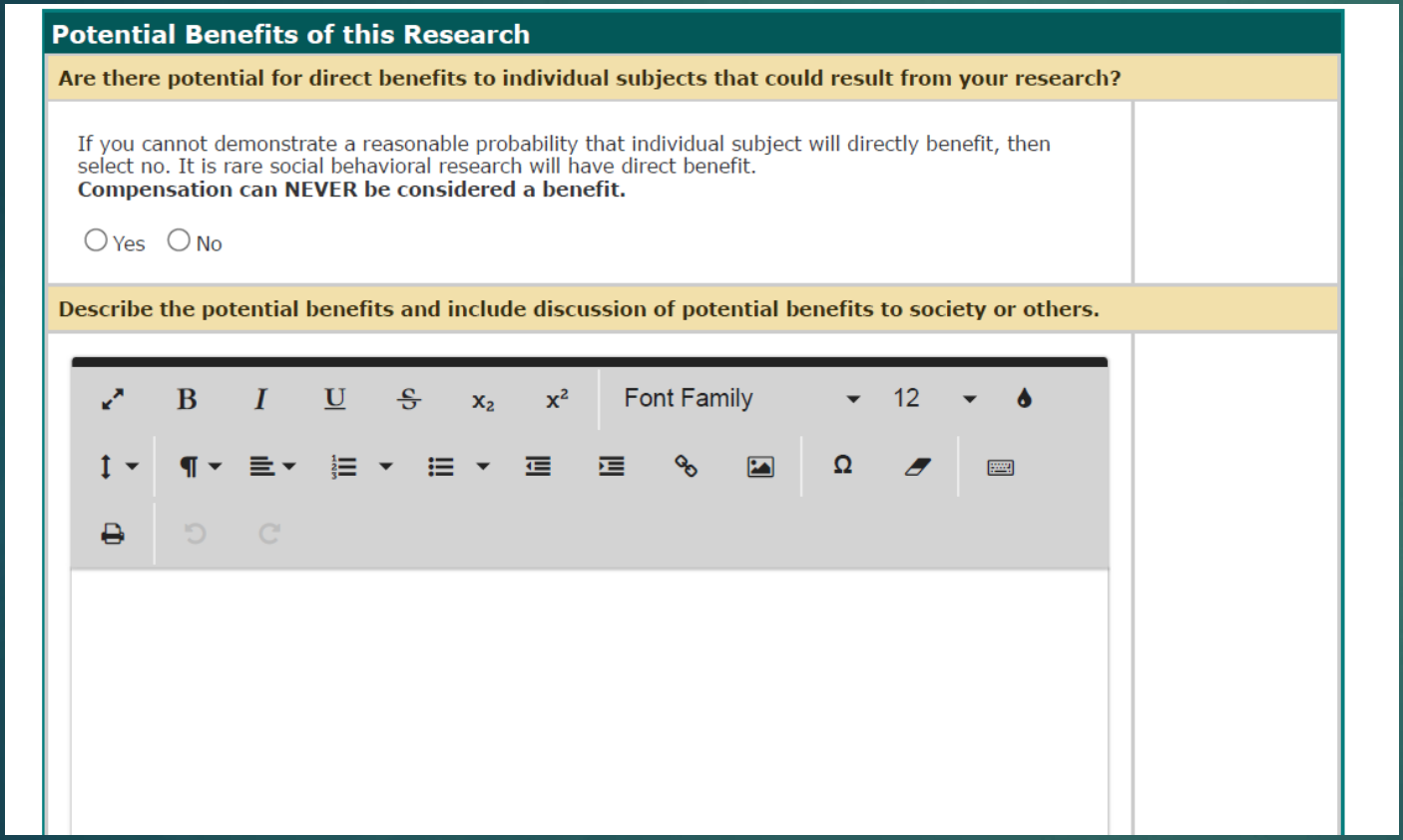
Font Family 12

- Would disclosure of the human subjects' responses outside the research study place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation?
- Recommendation
  - Fully inform your human subjects of ANY potential risks.

How To Implement Protection : No Greater Than Minimal Harms

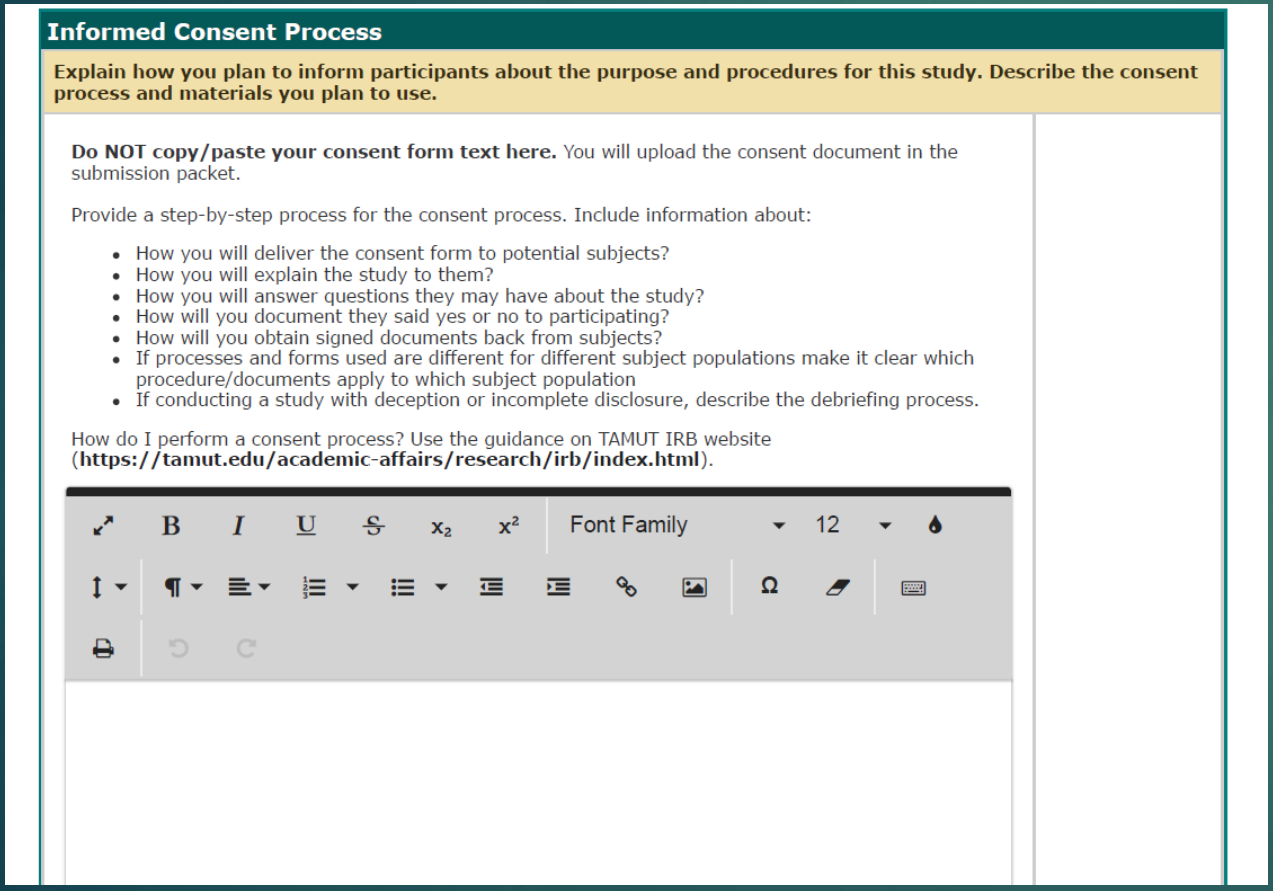
- No greater than minimal risks
  - Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
  - Risks are minimized (consistent with a sound research design and does not unnecessarily expose subjects to risk)
  - Vulnerable populations (e.g., Prisoners, children, etc.) May be likely to perceive greater harm or discomfort than other populations.
  - Risks are reasonable in relation to benefits
  - *Benign behavioral intervention means intervention or manipulation that is brief in duration, painless, harmless, not physically invasive, and not likely to have a significant adverse lasting effect on the subjects).*

Section 16 Potential benefits of this Research



- Payment/compensation/incentives for participating in the research are NOT benefits and cannot be described as research benefits in the consent process.

Section 17: Informed Consent Process



- Are you requesting a waiver or alteration of the consent process?
- Will you obtain the participant's handwritten signature on the consent?
- You indicated you will be enrolling minors. Describe the informed consent process of parental permission and how the assent of the minor will be sought.
- You have indicated you will be enrolling persons unable to consent or with impaired decision-making capacity. Describe how you will access the capacity to consent.
- You have indicated you will be enrolling Non-English-speaking persons. Explain which language will be used by the individuals obtaining consent. Describe the process to ensure that oral and written information will be provided to participants in the language they are most comfortable with.

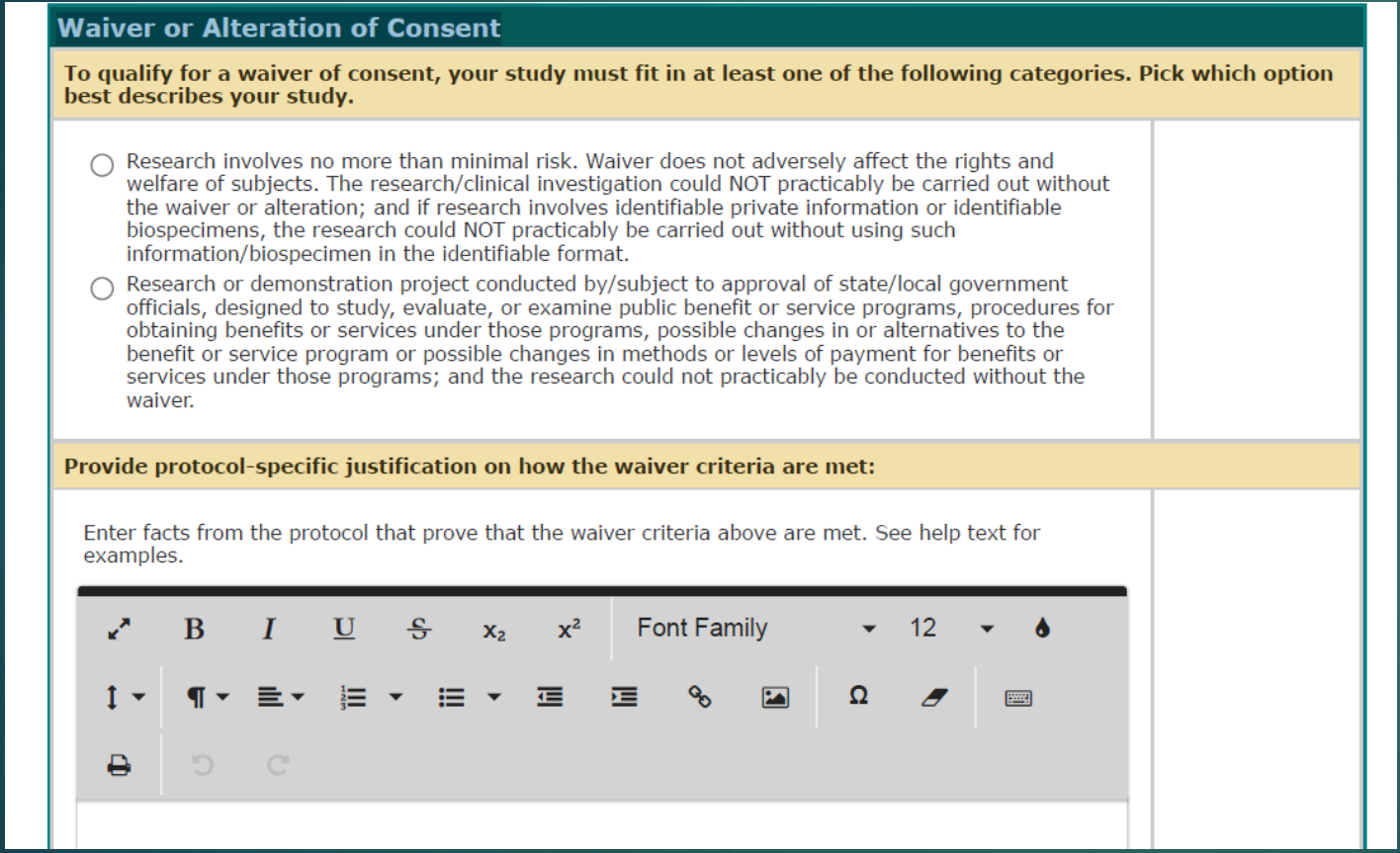
How to Implement Protection : Informed Consent

- Informed consent
  - Informed Consent will be Sought for Each Prospective Subject
  - Informed Consent will Be Documented
  - Research Plan Adequately Provides for Monitoring the Data Collected to Ensure Safety of the Subjects
  - Research Plan Adequately Protects the Privacy of Subjects and Maintains Confidentiality
  - https://www.tamut.edu/academic-affairs/research/irb/guidance.html

Section 18: Waiver of Documentation of Consent

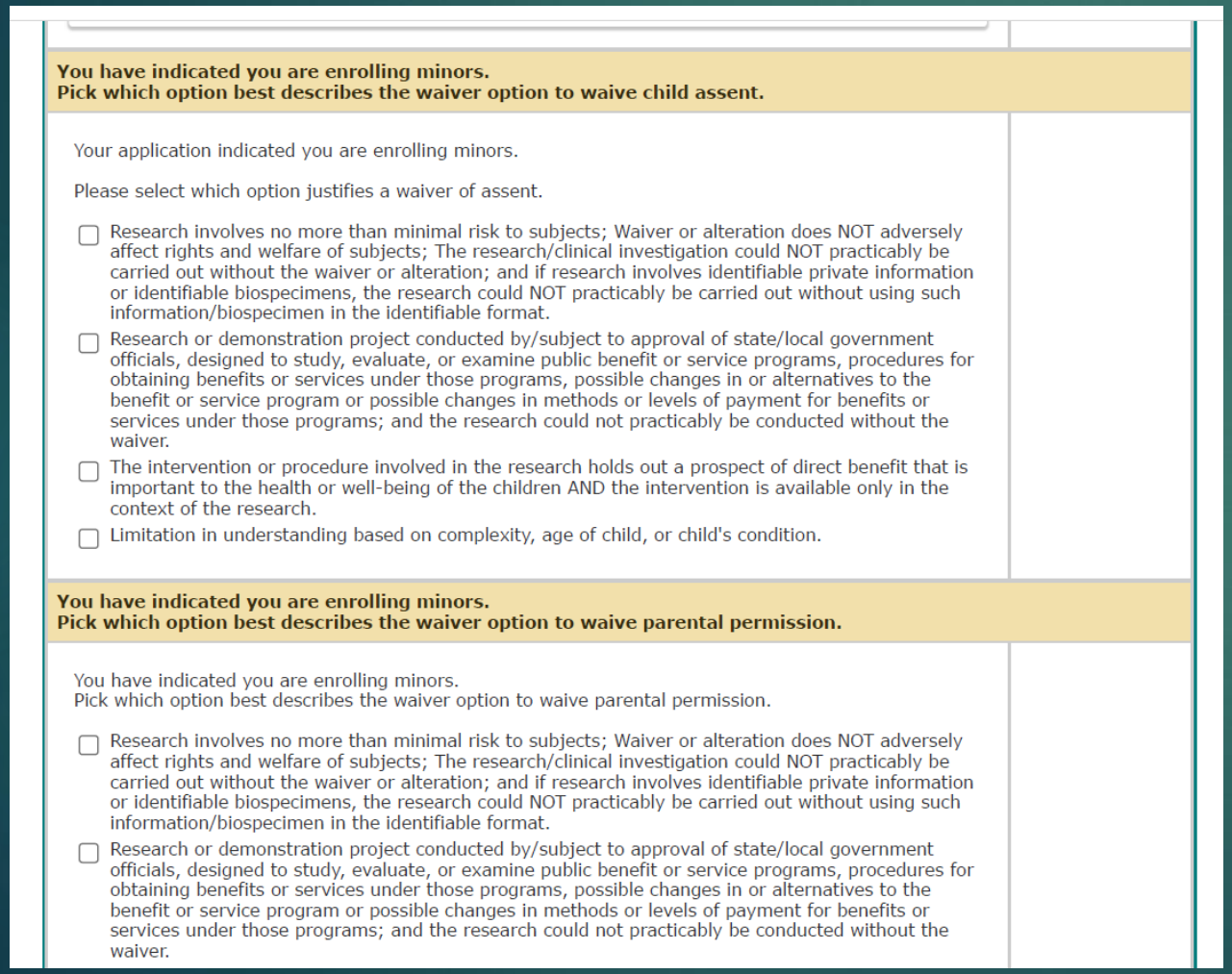
- Check the following criteria that apply:
  - The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant (or legally authorized representative) will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern.
  - The research presents no more than minimal risk of harm to participants 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 form is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained.
- Protocol-specific explanation for option one:

Section 19: Waiver or Alteration of Consent



- An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
  1. the research involves no more than minimal risk to the subjects;
  2. the research could not practicably be carried out without the waiver or alteration;
  3. if 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;
  4. the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
  5. whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Section 19: Waiver or Alteration of Consent



You have indicated you are enrolling minors.
Pick which option best describes the waiver option to waive child assent.

Your application indicated you are enrolling minors.

Please select which option justifies a waiver of assent.

- ☐ Research involves no more than minimal risk to subjects; Waiver or alteration does NOT adversely affect rights and welfare of subjects; The research/clinical investigation could NOT practicably be carried out without the waiver or alteration; and if research involves identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information/biospecimen in the identifiable format.
- ☐ Research or demonstration project conducted by/subject to approval of state/local government officials, designed to study, evaluate, or examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to the benefit or service program or possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be conducted without the waiver.
- ☐ The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children AND the intervention is available only in the context of the research.
- ☐ Limitation in understanding based on complexity, age of child, or child's condition.

You have indicated you are enrolling minors.
Pick which option best describes the waiver option to waive parental permission.

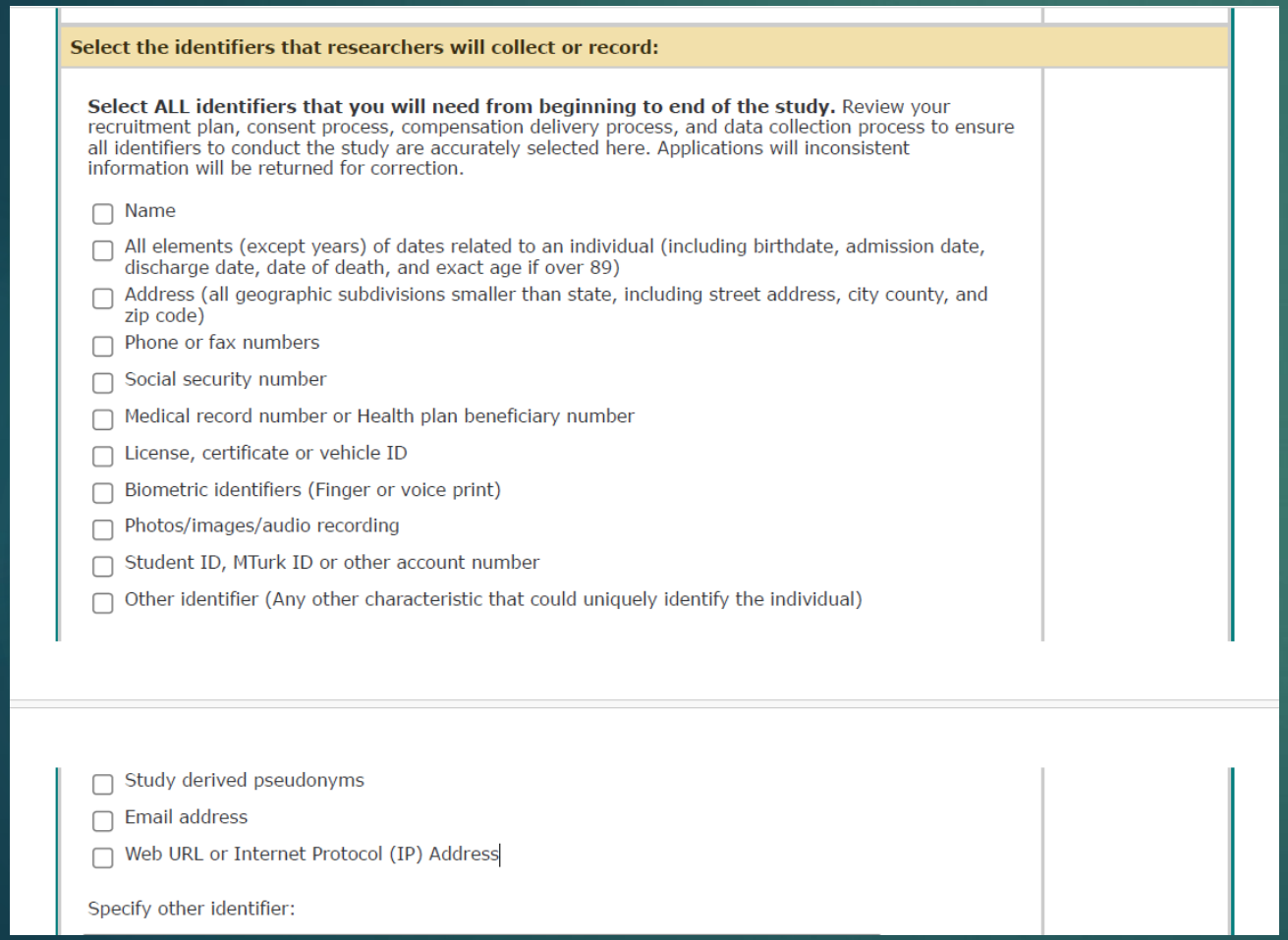
You have indicated you are enrolling minors.
Pick which option best describes the waiver option to waive parental permission.

- ☐ Research involves no more than minimal risk to subjects; Waiver or alteration does NOT adversely affect rights and welfare of subjects; The research/clinical investigation could NOT practicably be carried out without the waiver or alteration; and if research involves identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information/biospecimen in the identifiable format.
- ☐ Research or demonstration project conducted by/subject to approval of state/local government officials, designed to study, evaluate, or examine public benefit or service programs, procedures for obtaining benefits or services under those programs, possible changes in or alternatives to the benefit or service program or possible changes in methods or levels of payment for benefits or services under those programs; and the research could not practicably be conducted without the waiver.

Section 20: Privacy and Data Confidentiality

- https://www.tamut.edu/academic-affairs/research/irb/guidance.html
- Describe the steps that will be taken to protect participants' privacy interests.
  - This question is NOT asking how you protect confidentiality.
- Describe how and where research data will be stored and accessed by the research team.
- Select the methods you will employ to maintain good data security: (Select all that apply)
  - Password-protected computer
  - Password-protected data files
  - Encrypted data files
  - Research data limited to coded data
  - Master list or key to the coded data stored in separate location
  - Access to research data limited to study personnel only
  - Other
- Will access to any personal identifiers or collection or recording of identifiers be required?

Section 20: Privacy and Data Confidentiality (cont.)



Select the identifiers that researchers will collect or record:

Select ALL identifiers that you will need from beginning to end of the study. Review your recruitment plan, consent process, compensation delivery process, and data collection process to ensure all identifiers to conduct the study are accurately selected here. Applications will inconsistent information will be returned for correction.

- ☐ Name
- ☐ All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- ☐ Address (all geographic subdivisions smaller than state, including street address, city county, and zip code)
- ☐ Phone or fax numbers
- ☐ Social security number
- ☐ Medical record number or Health plan beneficiary number
- ☐ License, certificate or vehicle ID
- ☐ Biometric identifiers (Finger or voice print)
- ☐ Photos/images/audio recording
- ☐ Student ID, MTurk ID or other account number
- ☐ Other identifier (Any other characteristic that could uniquely identify the individual)

- ☐ Study derived pseudonyms
- ☐ Email address
- ☐ Web URL or Internet Protocol (IP) Address

Specify other identifier:

- Describe why each identifier is required.
- Does your study involve Protected Health Information (PHI) covered under HIPAA?
- How long will you keep the records after the study is completed?

Three review types: Limited review (Exempt)

- Eight Exempt Categories
  1. Normal educational practices in established educational settings
  2. Educational tests, surveys, interviews, or observation of public behavior
  3. Benign behavioral interventions
  4. Secondary research use of biospecimens or information for which informed consent is not required
  5. Evaluation of public benefit and service programs
  6. Taste and food quality evaluation & customer acceptance studies
  7. Storage and maintenance of identifiable materials for unspecified secondary research with broad consent
  8. Secondary research use of stored identifiable materials with broad consent

Is it Exempt? (cont.)

- Exemption 1: Normal educational practices in established educational settings
- Example (adopted from OHRP)
  - A researcher believes frequent breaks from instruction leads to better retention of historical facts. The researcher has a teacher use five out of every twenty minutes of a history class to let the students draw and compares test results to a second class where the students only receive history instruction.
    - Educational setting? Yes
    - Normal educational practice? Yes
    - Not adversely impact learning required content? No

Is it Exempt? (cont.)

- Exemption 2: Educational tests, surveys, interviews, or observation of public behavior
  - Not applicable to research involving children
- Example (adopted from OHRP)
  - A researcher wants to interview adult residents at a drug rehabilitation center to learn about their prescription drug addiction. The researcher will record the responses without any personal data and then publish findings in aggregate.
    - Is this activity an interaction covered by Exemption 2? Yes
    - Do the data include readily identifiable subjects' information? No
  - The researcher decides to expand the original study to include juveniles.

    No

Is it Exempt? (cont.)

- Exemption 3: Benign behavioral interventions
  - And data collection through verbal or written responses including audiovisual recordings if the adults agree prospectively
  - Not applicable to research involving children
  - Research involving deception
    - The subject authorizes to be deceived regarding the nature or purposes of the research through a prospective agreement to participate in such a study

Is it Exempt? (cont.)

- Example of Exemption 3 (adopted from OHRP)
  - A researcher interested in stress reactions asks adult participants to play an online computer game for 30 minutes with a timer that counts down. Participants' pupils are video-recorded to determine if there is a correlation between the dilation and amount of time left to complete the game. Is the activity a "benign behavioral intervention"?
    - Is the activity a "benign behavioral intervention"? Yes
    - Is there a permissible form of data collection? Yes
    - Can the identity be readily ascertained? ?
    - Would disclosure of the participants' times not place them at risk? Yes
  - The researcher attaches a heart monitor to participants to record pulses throughout the task.
    - Is the activity a "benign behavioral intervention"? No

Is it Exempt? (cont.)

- Example of Exemption 3 (adopted from OHRP)
  - Adult subjects are asked to be interviewed after watching a 30-minute video about clinical trials to determine if it influences their feelings about clinical research. In reality, however, the researcher is recording the participants to study their behaviors as he lowers the temperature throughout the video.
    - Is the activity a “benign behavioral intervention”? Yes
    - Is there a permissible form of data collection? Yes
    - Can the identity be readily ascertained? ?
    - Would disclosure of the participants’ times not place them at risk? Yes
    - Is the deception authorized? No

Three review types: Expedited

- Expedited
  - Reviewed by IRB chair or one or more experienced reviewers
    - The research presents no more than minimal risk to subjects.
      - Document review, surveys or interviews, collection of specimens, routine noninvasive procedures, etc.
    - The identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
    - The research is not classified.
    - The category or categories of research allowing review using the expedited procedure.
  - Approved for one year
  - For more details, refer to Section 13 of TAMUT IRB SOP

Three review types: Expedited

- Expedited (cont.)
  - 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects.
  - Category 8 Continuing review of research previously approved by the convened IRB (a) where the research is permanently closed to the enrollment of new subjects, and all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects; or (b) where no subjects have been enrolled and no additional risks have been identified; or (c) where the remaining research activities are limited to data analysis and report writing.

Three review types: Full Board Review

- Full Board Review (highest level of scrutiny)
  - Any study involving greater than minimal risk requires review by the convened IRB. Examples of studies that may involve greater than minimal risk:
  - Studies involving vulnerable populations. Clinical intervention studies that randomly assign human subjects to alternative experimental or placebo groups
  - Studies involving sensitive information connected to personal identifiers
  - PI is invited to meeting to clarify IRB concerns
  - Approved for one year
  - For more details, refer to Section 12 of TAMUT IRB SOP

TAMUT IRB

- Webpage: https://tamut.edu/Academics/Colleges-and-Departments/irb/index.html
- HRPP Institutional Official & Research Compliance Officer: Dr. Melinda Arnold marnold@tamut.edu
- IRB Members
  - Non-scientists
    - Jim Keever, M.D., J.D.
  - Scientists

Chair
Yusun Jung, Ph.D.

Jing Chen, Ph.D.

Sean Bailey, Ph.D.

Eunji Cho, Ph.D.

Patricia Humphrey, D.B.A

Sheila Moore, Ph.D.

Trisha Ray, Ed.D.

Questions?