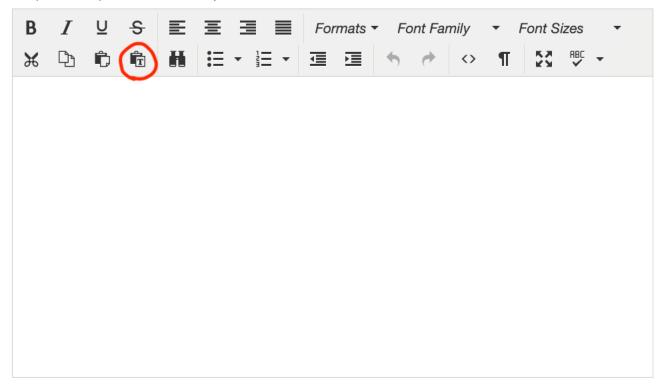## NEW SUBMISSION GUIDE FOR WIZARD FORM

- This form will assist researchers to fill out the IRB application (Wizard Form). Please read carefully before you begin your application.
- Supplementary forms are available in **Forms and Templates** on the IRBNet.

IMPORTANT TIP!

When you copy texts from external sources and paste them into the Rich text editor, please click the "Paste as Text" icon (see below) to avoid technical problems.

1. **Principal Investigator Information**
   This page is asking about PI information.

   > **NOTE**: Undergraduate students, graduate students, visiting scholars who are not paid by BSU, postdoctoral fellows, research assistants, classified staff, and any other temporary employees are not eligible to serve as Principal Investigator (PI) on a research study. Refer to the **Eligibility of Principal Investigators** policy for more information.

2. **Student Research Project**
   1) If this project is student-initiated as part of academic requirements (thesis, dissertation, class project, etc.), click **YES** and provide additional information about the student who owns the project.
   2) Point of Contact: If you want to designate the student as a point of contact, answer **YES**.

   > **NOTE**: A point of contact will assist in updating the IRB protocol record and communicating with the IRB administrator. Students are not authorized to be PIs, but they can be designated as a point of contact. Please note, while students may engage in the communication and submission process, the PI is still ultimately responsible for all areas of the project.

3. **Key Personnel**
   You need to add **ALL** research team members to key personnel. You can **ADD** as many as you need.

   > **NOTE**: You need to add the student in the previous page to the key personnel and provide additional information about the role and research activities they will conduct. For non-BSU team members, click other and provide the institution or organization name.

4. **Multi-Site and Collaborative Research Projects**
   If this project involves external collaboration with institutions and/or individuals, click **YES.**

   > **NOTE**: Researchers working with multiple institutions that hold Federalwide Assurances may request to have one IRB become the IRB of record that will review the protocol and oversight over some or all participating institutions. The IRB at each engaged institution makes the final decision on whether it will rely on another IRB or serve as the IRB of record.

   > **Required Supplemental Form: Reliance Agreement Request**

5. **Funding**
   If you have applied for funding or already received funding, you need to answer **YES** and provide the funding information. You also need to provide FCOI (Financial Conflict of Interest) information.

6. **Summary of Study**
   The following questions must be answered in lay language or language that can be understood by a person unfamiliar with your area of research. Area-specific jargon or term should be explicitly explained. Write all responses in narrative form.

   a. **Purpose of Study**
      Provide a brief summary of the project and state the objectives of the research, including research questions, hypotheses you have developed for the research, and relevant background information. You may want to explain how your study will contribute to general knowledge.

   b. **Rationale**
      Provide a concise description of the previous work in the field. Describe the data that the project is expected to provide and how the data will contribute to existing information in the field.

   c. **Research References/Citation**
      List any references/citations that you researched based on your study purpose and rationale for your project. If there are no references or citations used for your project, you should explain why.

7. **Study Design, Methods, and Procedures**
   a. **Data Collection Method(s)**
      You need to check all the methods you will use.

   b. **Study Design and Procedures**
      Describe the study design in detail and all procedures from screening through end-of-study that the human participant must undergo in the research project. Provide a description of all research procedures being performed and when they will be performed in sequential order. If the research involves more than one session (visit), specify the procedures to take place at each session, the amount of time for each session, and the total duration of the sessions. If multiple sessions are included, explain each session in detail. If you will use secondary data, provide the procedure(s) for obtaining the data.

   > **Required Supplemental Form: Data Security and Storage Form**
   > **Required Supplemental Form: Data collection document(s) (survey, measurement, etc.)**

   c. **Deception/ Incomplete Disclosure**

If the study involves incomplete disclosure or deception, describe the incomplete disclosure or deception and explain why it is necessary to answer the research question(s).

- **Incomplete Disclosure**: Researchers withhold information about the study purpose during the consent process because disclosing the study purpose in detail could significantly impact the validity of the study results.
- **Deception**: Researchers purposely mislead participants by providing them with false information about some aspect of the research during the consent process.

NOTE: If you plan to alter the consent process because you are using deception/incomplete disclosure as a research technique, you must check "**requesting alteration of the required element of informed consent**" and explain in the informed consent section.

Required Supplemental Form: Debriefing Statement

d. **Audio/Video Recording/Photography**
In this question, you need to describe:
- how the recordings or photographs will be used (e.g., accurate transcription purpose only, etc.),
- the type of recording being utilized (e.g., audio recording, video recording, photography, etc.),
- why it is necessary to the research and whether it is mandatory or optional to participate in the research,
- how the recordings will be utilized in the research (e.g., data analysis only or data analysis and presentations).

If audio/video-recording is mandatory for participation, provide your justification.

e. **Audio, Video or Photography in Publications**
If you plan to use audio/video recording and/or photography in your presentation, publication, or any other public setting, answer **YES**.

NOTE: If you plan to use audio, video recording, or photography, you must obtain the participants' permission.

Required Supplemental Form: Media Permission Form

f. **Data Analysis**
Describe the data analysis plan, including any statistical procedures or power analysis. If archival data analysis and/or secondary analysis is conducted, please provide the source (owner) of the data, the URL (if applicable), and the data type and describe the restrictions and any other related information.

g. **HIPAA**
If you will collect or use HIPAA data, you must answer **YES**.

Required Supplemental Form: HIPAA Data Use Form

h. **FERPA**
If you will collect educational records or information found in educational records as defined by FERPA, you must answer **YES**.

Required Supplemental Form: FERPA Data Use Form

8. **Participant Information**
If your study only uses secondary data or existing data, you may skip this section.

a. **Number of Participants/Age Range**

Provide the estimated number of participants and their age range. If you have multiple sessions, provide the numbers for each session.

b. Biological Sex/Gender/Sexual Orientation
If your recruitment targets a specific biological sex, gender identity, and/or sexual orientation(s) of the participant population, please check all of your plan. You also need to justify your plan.

c. Participant Population(s)
If your participants are adults who are able to provide informed consent independently, check the first option regardless of whether it is included in other categories or not. For example, if you will recruit students who are 18 years or older, you may click both adults and students. If any specific conditions apply that are not listed, click other and explain.

d. Protected Population(s)
If you plan to recruit participants from protected populations, provide justification.

e. Non-English Speakers
Non-English speakers may or may not be protected populations. Thus, you need to provide detailed information. If you plan to recruit non-English speakers, specify what language they will speak and how you will communicate with them (e.g., translator, PI can understand language, etc.).

> **NOTE**: You need to provide copies of all correspondence that will be used as a part of the research in English as well as in the native language of participants.

9. **BSU Student Recruitment**
BSU students can be recruited in several ways. If you plan to recruit BSU students, answer **YES** and provide additional information. You may want to provide additional information for recruitment via a department pool and from classrooms.
   1) **BSU Communication Center**
   2) **Department (Research) Pool**
      If recruiting via research pool such as department SONA, specify the name of the department and procedure.
   3) **From Classrooms**
      Provide course information including instructor's name. Describe if these students include those taught by any key research personnel or for whom any key research personnel has responsibility. If yes, provide an applicable justification for using these students and explain the steps you will take to minimize the possibility of undue influence/coercion.

10. **Participant Inclusion/Exclusion Criteria**
If your study only uses secondary data or existing data, you may skip this section.
Describe the set of conditions that must be met in order to participate in the study (including the age range of the participants) and the set of conditions that will disallow participation in the study.

11. **Recruitment and Screening Procedures**
If your study only uses secondary data or existing data, you may skip this section.

a. Recruitment Procedures
Select ALL methods that you plan to use to ask potential participants to participate in the study. You also need to address:
   o   the recruitment strategies you will use for each group of participants.
   o   how potential participants will be identified for recruitment.
   o   how potential participants will learn about the research and how they will be recruited (e.g., flyer, email, web posting, telephone, etc.).
   o   if applicable, how and where you will get the email addresses of potential participants.
   o   who will approach potential participants to take part in the research and what will be done to protect participants' privacy in this process.

b. Screening procedures

If a screening/pre-screening process occurs for recruitment, describe the procedures (e.g., online questionnaire, etc.) and what you will do with the data for people who do not qualify for your study. If you will use data of those who do not qualify for your study, explain and justify using the data.

<div style="border:1px solid;">

Required Supplemental Form: Recruitment message(s): Email, flyer, SNS message, etc.

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12. Financial Expenses
If participants will incur any financial cost to participate in the study, answer **YES** and describe any costs that participants may be responsible for participating in this project (e.g., parking, cell phone-related costs, gas, etc.). You may want to explain if you will reimburse participants for the costs or not.

13. Compensation
a. Compensation Description
If you provide participants any compensation or incentive, answer YES. You need to explain:
- o the payment method, including how much money or other compensation will be provided for which activities.
- o whether all or only some participants will receive compensation. If the latter case, explain how many participants will receive the compensation.
- o the source of funding for monetary compensation if the project is not funded by any agencies.
- o the amount of credit and procedure, if research credit or extra credit is provided.
- o available compensation in the event of research-related injury. If the research involves more than minimal risk to participants, describe the risk.

<div style="border:1px solid;">

NOTE: If you use the BSU Communication Center for recruitment and/or receive BSU funds, you will need to contact the BSU Office of University Controller (765-285-8444) or visit their website for procedures and policies.

</div>

b. Eligibility or Condition for Compensation
- o Describe whether compensation will be prorated if there are multiple research activities or if a participant withdraws from the study before finishing.
- o Explain whether participants will receive incentive/compensation or research credit if they withdraw from the study (during or after). If prorated, provide details.

14. Project Site Location and Platform
a. Research Activities
This question is asking if the project requires any in-person activities. If any in-person activities are necessary, you need to submit COVID-19 Safety plan.

<div style="border:1px solid;">

Required Supplemental Form: COVID-19 Safety Plan

</div>

b. Project Location Platform
If your study only uses secondary data or existing data, skip this section.
Provide all location and/or platforms where your study will be conducted. This location is a place where you will interact with participants or participants will do any research-related work. Do not check your office or any place where only the research team will work.

NOTE:
- ✓ Do not select social media if you use it only for recruitment.
- ✓ Be sure to review each site's terms of service and agreements before using any social media site for research or recruitment.
- ✓ Some school systems, including Muncie Community Schools (MCS), require an additional research review process.
- ✓ Any research that is conducted at non-BSU institutions or organizations is required to obtain a Letter of Support. The Letter of Support must be on the institution's or organization's letterhead and signed by a person of authority to grant access to the site for the study (i.e., Director, Manager, Principal, Superintendent, etc.). The Letter of Support must be uploaded on IRBNet as part of your package submission. An email message is NOT sufficient to meet this requirement.
- ✓ If you recruit participation outside the U.S. and the study occurs in other countries, you need to submit the **International Study Form**.

Supplemental Form: Letter of Support, International Study form

15. Potential Risks/ Discomforts
If there are any anticipated or potential risks or discomforts to the participant(s) during the study, answer **YES**.

Examples of potential risks/discomforts
- ✓ Use of deceptive technique: withholding information for the purpose of the study
- ✓ Possible coercion, intimidation, threat, or force to participate
- ✓ Use of private records (educational or medical records)
- ✓ Manipulation of psychological or social variables such as sensory deprivation, social isolation, or psychological stresses
- ✓ Revealing personal or sensitive information in survey or interviews
- ✓ Presentation of materials which the subject might consider sensitive, offensive, threatening, traumatic, or degrading
- ✓ Possible invasion of privacy of participants or their family
- ✓ Social or economic risk
- ✓ Possible harm or fatigue from physical activities
- ✓ Possible breach of confidentiality

You need to explain the risks or discomforts, whether the risk(s) is more than minimal risk or not, and what precautions and safeguards will be taken to minimize risks. For research involving the risk of physical injury, describe the available emergency care in the event of a research-related injury. For research involving psychological risks, describe any plans for intervention (including reporting that may be mandated by federal/state law or licensure) and the events or participant responses that would prompt the exercise of such plans.

Minimal Risk
According to the federal regulations at §46.102(i), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

16. Potential Benefits of Participation
If any anticipated benefits will be derived from this study, answer **YES** and provide details. Please refer to the examples below and/or guidance in the IRBNet Forms and Templates.

Direct Benefit: Any study that involves an intervention could have an anticipated direct benefit. In these studies, participants may receive some intervention (medical, behavioral, education, resources, or other) that they would not otherwise receive.
Indirect Benefit: A benefit to society and/or the community which arises from the results of the study.

NOTE: Payment/Compensation is not considered as a benefit.

17. **Informed Consent**
   a. **Informed consent overview**
   A protocol should include at least one of the consent options.

   > **Waiver of documentation(signature**): Applicable for internet research or verbal consent when a signature is not obtained.
   >
   > **Waiver of consent:** Applicable for research involving identifiable data or records (secondary data analysis) when asking to waive parental permission or other situation where consent is not possible.
   >
   > **Alteration of consent**: Applicable when some required elements of consent are eliminated, such as incomplete disclosure of the purpose of the research (deception).

   If you will use existing data for secondary analysis, you may want to click **Requesting a Waiver of Informed Consent.**
   If you are using deception or incomplete disclosure, you need to click **Requesting an Alteration of the Required Element of Informed Consent.**
   If your study is an anonymous survey, you may need to click **Requesting a Waiver of Documentation (Signature) of Informed Consent.**

   > **NOTE**:
   > ✓ BSU IRB will not allow a waiver of documentation (signature) of informed consent for virtual/remote interviews. You can either get signed consent (e-signature, physical signature, etc.) or record verbal consent. You need to address how to get signed consent (or verbal consent) for the virtual interview. Verbal consent should be recorded.
   > ✓ If English is NOT the participants' primary language, the informed consent must be translated into the participant's native language. Include the translated informed consent with your package and a statement as to how (or by whom) the informed consent was translated.

   b. **Consent and Assent Procedure**
   Describe the process to obtain informed consent from participants, including where and when the consent process will occur. Provide the type of consent you will obtain (hard copy of signed consent, online, verbal, etc.). If consent will be obtained in different ways for different participant groups, describe the consent process used for each participant group and/or study phase. If minors will not be asked to give assent, provide the justification.

   c. **Waiver of Documentation (Signature) of Informed Consent**
   You need to check the reason for applying for a waiver of signature. If you are not asking for a waiver of signature, skip this question.

   d. **Waiver of Informed Consent/Alterations of Informed Consent**
   If you are applying for a waiver or alteration of the Informed Consent, explain why. If not, skip this question.

18. **Smart List**
   The last page includes instructions and a list of all applicable documents/forms that need to be submitted in IRBNet in addition to the study application. The items on this page are generated based on the investigator's responses within the Wizard application form.

   > **NOTE**: If the investigator goes back to previous sections of the form and makes any revisions that affect the items included in this list, the listed items will change based on the revised responses.