HUMAN SUBJECTS RESEARCH DETERMINATION FORM

Please complete this form if you are unsure whether your project is considered human subjects research (HSR) and requires IRB review. If the IRB administrator or reviewer decides that your project is HSR, you must submit a full IRB application before starting your project. After completing this form, please send it to orihelp@bsu.edu.

If you have any questions, please contact our office at orihelp@bsu.edu.

Please note that the BSU IRB only makes the decision on whether IRB review is required.

Project Title:  
Principal Investigator:  
email:  
School/Department:  
Additional Contact person, if any:  
email:  

SECTION A: Human Subjects Research

1. Does this project involve human subjects?  
   □ Yes  □ No

2. Does the project involve the collection of information or biospecimens through intervention or interaction with the individual?  
   □ Yes  □ No
   
   • Intervention: physical procedure by which information or biospecimens are gathered or manipulations of the subject or the subject’s environment that are performed for research purposes.
   • Interaction: communication or interpersonal contact with the individuals, including electronic interaction.

3. Please check all that apply.
   
   □ The data collected for this project will be able to be applied more broadly to other settings, populations, and/or circumstances outside of the study.
   □ This project is designed to generate or contribute to generalizable knowledge.
   □ This project is designed to evaluate, assure, or improve performance within a department, classroom, or a specific setting.
   □ This study simply monitors an existing process for which there will be no manipulation of the existing process.
   □ This project is limited to one or more course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of routine class exercises or assignments.
   □ This project is limited to investigations or interviews (structured or open-ended) that focus on specific events or current/historic views.
   □ This activity is limited to interacting with individuals in order to obtain feedback on the types of questions that could or should be used to develop an instrument or questionnaire.
   □ Generalization of the project results to other settings is possible, but it is not the main intent of the project.

SECTION B: Project Information

1. Describe the purpose of the project.
2. Describe any interaction or intervention with human subjects, if applicable.

3. Describe any identifiable private information about human subjects that you will obtain for research purposes.

4. Describe your participation sample, including the estimated sample size. If you are recruiting any protected population(s), please describe the population(s).

5. What are your research questions, variables, and/or hypotheses?

6. If you are doing a survey, focus group, and/or interview, please submit your survey/interview questions with this form.

SECTION C: IRB Consideration

1. Why are you seeking this determination?
   - [ ] I am not sure if the activity project is human subjects research or not.
   - [ ] I plan to publish in a peer-reviewed journal, and I would like to know that IRB review is not required.
   - [ ] IRB review or determination of not HSR is required by one of the following:
     - [ ] Sponsor
     - [ ] Collaborator
     - [ ] Performance site
     - [ ] Journal
     - [ ] Entities providing data/Data holder
     - [ ] Other (describe: _____________)

For Official Use Only

- [ ] This project does NOT need IRB review.
  Date: ___________ Initials: __________________

- [ ] This project DOES need IRB review.
  Date: ___________ Initials: __________________

Additional note