

**Institutional Review Board | 伦理委员会**

Request for Protocol Approval

Submitting the Form

Parts A and B, with signatures, may be scanned or faxed. Original signatures are not required.

Part C, with required appendices, should be sent as a single paginated Word file to [dku-irb@dukekunshan.edu.cn](mailto:dku-irb@dukekunshan.edu.cn)

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**Part A. Study Information**

* 1. **Project Title**

Descriptive but brief.

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**1.2 Project Information:**

1. Source of Funding:

(If research is externally funded, submit a copy of the application or the award.)

3. Research Site:

☐ Domestic

☐ International: Please list all countries:

☐ Both domestic and international site(s)

☐ National or multinational research platform or panel, such as Amazon Mechanical Turk

1. Potentially Vulnerable Subject Populations:Please check all that apply.

☐ Minors, as defined at research site (under 18 years old in NC)

☐ Students or employees of the researcher

**☐** Prisoners

**☐** Cognitively impaired subjects

**☐** Physically impaired subjects

**☐** Economically disadvantaged subjects

**Part B: Investigator Information and Assurances**

**Investigators: (Faculty, Graduate Student, Research Associate, Postdoctoral Fellow, Undergraduate Student)**

**All signatories certify to the following:**

1. I will not conduct the research until written approval is secured from the IRB. Note: Approval will not be provided unless certification to conduct research with human subjects is current.
2. I will conduct this study as described in the approved protocol.
3. If any changes are anticipated, I will submit a Request to Amend an Approved Protocol, and I will not implement the changes until I receive approval from the IRB.

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| --- | --- |
| Name: | Department or School: |
| E-mail Address: | Phone Number: |
| DKU status: ☐ Faculty ☐ Graduate student ☐ Postdoc ☐ Research associate ☐ Other: | |
| Signature: | Date: |

1. I will contact the IRB staff promptly if any of the following events occur: unanticipated risks of harm to subjects, protocol deviations, and findings during the study that would affect the risks of participation.

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| --- | --- |
| Name: | Department or School: |
| E-mail Address: | Phone Number: |
| DKU status: ☐ Faculty ☐ Graduate student ☐ Postdoc ☐ Research associate ☐ Other: | |
| Signature: | Date: |

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| Signature: | Date: |

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| Signature: | Date: |

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| --- | --- |
| Name: | Department or School: |
| E-mail Address: | Phone Number: |
| DKU status: ☐ Faculty ☐ Graduate student ☐ Postdoc ☐ Research associate ☐ Other: | |
| Signature: | Date: |

If there are more than five members of the research team, copy and paste the researcher information and signature block.

**Faculty Advisor(s) for Graduate Students, Undergraduate Student and Postdoctoral Fellows**

**All signatories certify to the following:**

1. I have read and approved the protocol.
2. I assume responsibility for ensuring that my advisees are aware of the responsibilities as investigators.
3. I ensure that the IRB will be immediately notifies in the event of unanticipated risks to subjects, protocol deviations, or findings during the study that would affect the risks of participation.

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| --- | --- |
| Name (Last name, First name): | University Department or School: |
| E-mail Address: | Phone Number: |
|  |  |
| Signature of Faculty Advisor | Date |

|  |  |
| --- | --- |
| Name (Last name, First name): | University Department or School: |
| E-mail Address: | Phone Number: |
|  |  |
| Signature of Faculty Advisor | Date |

**Departmental Contact**

This section should be completed when a departmental staff member assists in protocol preparation and record keeping and would like to be copied on correspondence from the IRB.

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| Name: |
| E-mail Address: |
| Phone Number: |
| Type of Correspondence: ☐ Approval and Reminder Notices ☐ All correspondence related to the submission ☐ Other, as described: |

**IRB USE ONLY\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Human Subjects Administration**

*This section is to be completed by IRB staff or IRB members only.*

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| ☐ **APPROVED** | |
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| Signature of **☐** Human Subjects Administrator or **☐** IRB member | Date |

**Part C: Research Plan**

**2. Research Question**

2.1 What is the research question?

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2.2 Provide background information about the research question that will help the reviewer understand your research. Avoid discipline-specific jargon.

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**3. Description of Activities**

3.1 Describe the study activities that you will ask participants to perform? If the study involves observation, describe the setting and events that you will observe.

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3.2 How much time will be required to participate in the study? Include all phases of the study such as screening, time to complete study activities, and follow-up studies, as applicable.

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3.3 List here all surveys, questionnaires, structured and unstructured interview questions, focus group guides, and any other instruments you will use to gather data. If you plan to conduct unstructured interviews, you will need to provide a description of the type and range of questions. Compile these documents as Attachment A. 

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3.4 If you are collaborating with a nongovernmental organization or association, or a clinic or other service provider, describe the research that each group will conduct.

Identify the activities that would be conducted by your collaborator even if you were not conducting research.

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**4. Participant Population**

4.1 List and describe your proposed participant population(s). Include the expected number of participants in each population.

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**Guide:** If your research will involve children (as defined at the research site), please read the Guide to Research with Children (<https://campusirb.duke.edu/node/63>). You will need to prepare parental permission and child assent forms.

**5. Recruitment**

5.1 How do you plan to recruit potential participants?

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5.2 Check all the recruitment methods that apply and provide text and or scripts for each method.

☐ Introductory letter or e-mail messages

☐ Flyers/posters

☐ Newspaper ads

☐ Text for social networking sites or other on-line recruitment

☐ Script(s) for personal contact

☐ Other. Please describe:

5.3 If you plan to screen potential participations, describe the process, include the screening instrument in Attachment A. Explain what you will do with information you gather about subjects who will not be chosen to invite AND for those who are chosen.

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**6. Risks of Harm**

There are three parts in this section:

Part 1: Risks associated with information that identifies participants

Part 2: Risks associated with the research topic

Part 3: Physical risks

6.1 Risks of Harm Part 1: Risks Associated with Information that Identifies Participants

This section addresses the collection of direct identifiers such as names and email addresses, and the collection of indirect identifiers that could be used to deduce the names of research participants.

Images of participants’ face are considered direct identifiers. Currently audio-recordings are not.

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| 6.1.1 Recruitment |

Do you need individually identifiable information to contact and recruit participants, for example, email addresses?

☐ No

**☐** Yes

If yes, please describe the identifiers and explain what you will do with the identifiers when the recruitment process is complete. Note: If the identifiers will be associated with research data, you will need to answer the questions in the next section, Data Collection and Storage.

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| 6.1.2 Data Collection and Storage |

Do you plan to collect individually identifiable information (direct or indirect) that will be associated with participants’ responses? Note: If you create a key linking direct identifiers with unique identification numbers, the data are considered identifiable.

☐ No

**☐** Yes

If yes, describe the direct identifiers you will associate with participants’ responses.

If relevant, describe data you will collect that could be used by someone with knowledge about the study population to deduce someone’s identity. Explain why it is necessary to collect identifiers.

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Would the inadvertent disclosure of identifiable data place subjects at risk of harm?

☐ No

**☐** Yes

If yes, please provide answers to the following questions to help the IRB assess your data protection procedures. The data protection plan will be reviewed by Duke’s Information Technology Security Office which will make recommendations about the best way to protect the data.

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| 6.1.3 Review of Data Management Plan |

1. What specific harms could occur if individually identifiable data were disclosed?

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1. Will the data be in paper or electronic form?

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1. At what points during the data collection process will data be associated with identifiers?

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1. If you are conducting field research, how will the data be transferred to the main research site?

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1. Will you use personal devices such as laptops or thumb drives to gather and store data?

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1. If you will store the data on a protected server, identify the server.

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1. Who is your departmental or unit IT contact?

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1. Who is responsible for the security of the data?

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1. Do you plan to create a key linking unique identifiers participants’ response?

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1. Who will have access to the identifiable data? (List by name**.)**

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1. How will access to the data be controlled?

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1. What are the plans for de-identifying data?

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13. What is the security level of the data in DMP?

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| 6.1.4 Reporting |

Ifyou will use participants’ names in your research reports, please explain how you will secure permission to do so.

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Ifyou will not use names, but based on your research topic, setting, and reported characteristics of your subjects, their identities be readily deduced, discuss the rational for using the data in your reports and possible risks of harm to your subjects.

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6.2 Risks of Harm Part 2: The Research Topic

If your research questions have the potential to upset or distress participants, please discuss.

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Describe the strategies you will use to mitigate the risks.

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6.3 Risks of Harm Part 3: Physical Harm or Discomfort

If there are any risks of physical harm or discomfort, please describe.

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What steps will you take to mitigate the potential risks?

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Are there people who should be excluded from your study because of the potential risks?

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**7. Benefits**

**Notes:**

* The opportunity to participate in research is not a benefit.
* Compensation is not a benefit.

Describe any anticipated direct benefits of you research for individual participants. If your research provides no direct benefits to your participants state “None.”

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**8. Compensation**

8.1 Will you give participants gifts or payments?

**Note**: In some cultures, payment is not appropriate, but tokens of appreciation are.

☐ No

**☐** Yes

Ifyes, please explain:

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8.2 If you plan to pay, under what conditions will participants receive partial or no payment?

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**9. Photographs, Videos, and Audio-recordings**

9.1 Will you photograph or video-record your participants?

☐ No: Skip to 9.2

☐ Yes: Complete the following questions:

Describe which of your participants you will record and in what setting.

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Explain why the images (photos or videos) are necessary to answer your research question.

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Where do you plan to display, present, or distribute the images outside of your research team.

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9.2 Do you plan to audio-record participants either individually or in groups?

☐ No

☐ Yes: What will you do with the recordings?

☐ Destroy the recordings after I have made transcripts.

☐ Save the recordings for further research and education.

☐ Other, please describe:

**Guide**: For guidance about when photographic releases are needed and sample release language, go to the Guide for Releases for Images and Recordings at <https://campusirb.duke.edu/node/78>.



**10. Informed Consent Process**

**Discussion:**

The informed consent process involves two parts:

1. The process of sharing information about your research study and
2. The documentation (a signed consent form or an audio- or video-recorded statement by the research participant) that the process took place

You will always need to create a process for sharing information about your research study with prospective participants. In some circumstances it may be appropriate to request that the IRB waive the requirement to document consent.

You may be able to use an oral consent process without documentation if one or more of the following is true. Please check any that apply to your research.

☐ You are conducting in-person surveys and/or informal interviews in which the data you record are not identifiable

☐ Your participants do not read and write. (If there is a risk of harm, you will need a third-party witness.)

☐ The study data will be collected through a telephone

☐ The research will take place in settings where written consent is considered disrespectful or in settings in which asking people to sign a document would cause distress

☐ The primary risk to participants is a breach of confidentiality and a signed consent form would be the only documented link between individuals and their participation in the study. (Example: a study about people with HIV/AIDS.) If the subject wishes to sign a form, they may.

If you collect data on-line you will not need to collect signed consent forms. After providing information about the research, you give potential subjects the option to “click” to the survey if they would like to talk part in the study.

**Note**: When the consent process is oral, other than telephone interviews, researchers should give participants contact information in case the participants have any questions later. It may be appropriate to give them a copy of your oral script for reference.

**Guides**:

Guide to Writing Consent Forms and Oral Scripts at <https://campusirb.duke.edu/node/73>. The Guide provides an outline, including sample language.

**11. Putting Together Your Appendices**

Here is a checklist of possible items you might include as part of your appendices. Your appendices should be a single Word file. Check all that you will include:

**Appendix A: Research instruments:**

☐ Surveys, questionnaires, in-person interview questions, focus group guides, and/or instruments you will ask your participants to complete

☐ Description of the type and range of questions for life history or other open- ended/unstructured interviews

**Appendix B: Recruitment materials:**

☐ Introductory letter or e-mail

☐ Telephone contact script

☐ Personal contact script

☐ Flyers/posters

☐ Newspaper ads

☐ Other

**Appendix C: Informed Consent materials:**

☐ Oral consent script(s)

☐ Written consent form(s)

☐ Parental permission process (oral and/or written)

☐ Child assent process (oral and/or written)

☐ Combined adult consent (to participate) and parental permission (for child to participate)

☐ Contact information cards to give participants, when appropriate

**Appendix D: Releases:**

☐ Photograph and video releases

☐ Audio-recording release (needed only if you plan to keep the recordings and/or give them to a public archive)

**Appendix E: Permissions to Recruit Subjects or Conduct Research, if Needed:**

☐ Correspondence providing permission to conduct research, for example from a local department of public instruction, community leader, or head of a congregation

☐ Other, please describe:

Please use the following pages provided to include your appendices.

**Appendix A**

**Research Instruments**

**Appendix B**

**Recruitment Materials**

**Appendix C**

**Consent Materials**

**Appendix D**

**Releases**

**Appendix E**

**Permissions to Conduct Research  
(if necessary)**