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| **Graphical user interface, text  Description automatically generatedIRB CONSENT FORM APPLICATION**  **OHIO DEPARTMENT OF HEALTH (ODH)**  **Institutional Review Board (IRB)** |
| **PROJECT TITLE:** |
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| **PRINCIPAL INVESTIGATOR (PI)** | |
| Name: | |  |  |  |  | | --- | --- | --- | --- | |  | Agency/Institution: |  |  | |

**This application must be completed and submitted with all IRB protocols that include direct contact with subjects.**

**REQUIREMENTS**

All consent forms submitted to the ODH IRB must contain the following. We recommend providing background information prior to details of participation.

1. A brief description of your research design and the reasons why the subjects’ participation is necessary.
2. A statement that the subjects are being asked to volunteer to take part in your study.
3. A statement that if subjects choose not to participate, it won’t have a negative impact on any treatments or services they currently receive or may be eligible to receive.
4. A statement that that participation is voluntary and subjects can end their participation at any time for any reason (include the procedure for ending involvement).
5. A statement of how the subjects’ confidential or private information will be secured during the course of the study.
6. If applicable, an explanation of any mandatory reporting requirements and when and why they may be necessary.
7. A brief explanation of how the research will be conducted and what the subjects can expect to happen.
8. A description and explanation of the possible risks and benefits of participating, including a statement of how the risks will be minimized.
9. A description of any incentives being offered, including how and when they will be distributed.
10. An explanation of how the subjects’ information will be kept private, including information on how and when their data may be released, and specifically to whom.
11. A statement of whether the subject’s identity will be known by, or accessible to, any investigators or staff. If the subject’s identity is known or accessible, how will the subject’s identity be removed from the data? If the research is published or otherwise released to the public, how will the subjects’ identities be protected?
12. A statement regarding what will happen to the data at the completion of the project.
13. A statement whether information about the study will be available on the internet and how to access it.

**SUGGESTIONS**

1. Organize the form into the most logical format possible. We recommend starting with background information, then participation information and finally, voluntary withdrawal information.
2. Keep the language consistent throughout your document. Don’t interchange “study” and “research”, “private” and “confidential”, etc. Your meaning will be clearer if you use the same terminology throughout the consent form.
3. The subject’s affirmation should be worded to say that “I have been informed that…” or “This consent form has been explained to me…” Our board discourages the use of “I understand” because that implies a level of knowledge the subject doesn’t have. They only know what you have told them.

**CONSENT DETAILS**

1. Who are the subjects of your research? (check all that apply)

General Population – Adults  General Population – Adults with a Guardian for Legal Purposes \*

General Population – Minors \*  Professionals

*\*PLEASE NOTE: These populations usually require both a consent form for the parent or guardian AND an assent form for the subject.*

1. How will your consent form be presented to the subjects? (check all that apply)

Paper Form  Over Phone  Electronically

1. Will you have staff available to answer questions regarding the consent form?

Yes  No

1. Is your consent form based on a mandatory template provided by your institution?

Yes  No

**If Yes**, please provide a copy of the original template and contact information for the template owner.

Contact Person: Contact Phone:

Contact Email:

1. Have you confirmed that:

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| 1. The consent form is written at a reading level consistent with your subject population? (We recommend a 6th-8th grade reading level when working with the general public.) | Yes |
| 1. The document is free of spelling and grammar errors? | Yes |
| 1. The information throughout the consent form is consistent, both internally and with the rest of your application? | Yes |
| 1. The information is clearly understandable to your subject population? | Yes |
| 1. The consent form is short enough to be easily read by your subject population in one sitting? (If in doubt, please split it up into an information sheet and separate consent form.) | Yes |
| 1. The protocol includes both a consent form and an assent form if your subject population is under age 18 or may have legal guardians? | Yes  No  N/A |
| **If NO**, how will you capture their assent without a form? | |
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| Principal Investigator Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Principal Investigator Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |