Informed Consent Elements & Suggested Language - IRB Health & Behavioral Sciences

Elements highlighted in yellow are required.
See 45 CFR 46.116 for regulatory information concerning informed consent.

<table>
<thead>
<tr>
<th>Element and Suggested Language</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Title of the project</strong></td>
<td>For most projects, the title of the study should appear at the beginning of the document.</td>
</tr>
<tr>
<td><strong>2. Researcher name, credentials, institutional affiliation</strong></td>
<td>The Principal Investigator and Co-investigator(s) must be listed. For student projects, include faculty advisor(s). Other key personnel who engage in substantial interactions with subjects should be listed.</td>
</tr>
<tr>
<td><strong>3. Invitation to participate in a research study</strong> [PI name] invites you to participate in a research study about [topic/purpose]. The study is funded by [sponsor, if any].</td>
<td>See recommended language in the highlighted area. Include the following information: *description of how/why the potential participant was selected. *description of study objectives in lay terms, no more than 1-2 sentences. *statement of purpose, clearly articulating that the activity is research. *identification of study sponsor, if any. *if the study is a student project, a statement that the study is being conducted to fulfill an academic requirement (such as a thesis or dissertation). *estimate of the total number of subjects expected to enroll (not required but helpful for clinical research studies or when the research topic is sensitive).</td>
</tr>
<tr>
<td><strong>4. Description of subject involvement</strong> If you agree to be part of the research study, you will be asked to [select] *complete a survey *participate in an interview *participate in a focus group This will take about _____ minutes/hours/days</td>
<td>Select the appropriate option(s) provided in the highlighted area, or modify as needed. Clearly describe research activities. Provide a realistic estimate of time required to participate. If the study involves multiple activities, describe each, in the order they will be performed. Include time estimates for each phase, well as an estimate of the total time commitment.</td>
</tr>
<tr>
<td><strong>5. Benefits</strong> [select] *You will directly benefit from being in this study because [detail] *Although you may not directly benefit from being in this study, others may benefit because [details]</td>
<td>Select the appropriate option provided in the highlighted area, or modify as needed. Keep in mind that compensation is not a research benefit to the participant.</td>
</tr>
</tbody>
</table>
6. Risks and discomforts
[select]
There are no risks associated with this study because the data collection is completely anonymous and the topic is not sensitive.

The researchers have taken steps to minimize the risks of this study. Even so, you may still experience some risks related to your participation, even when the researchers are careful to avoid them. These risks may include the following [select]
* The questions are sensitive and may make you feel uncomfortable or embarrassed. You may remember or think about things that bother you. To reduce this risk [complete]
* The researchers have taken steps to minimize the risks of this study. Even so, there is a small chance that the information you provide could be unintentionally disclosed. To reduce this risk [complete]
* Some other risk specific to the study
*************************************************************************

Clinical injury language:
Please tell the researchers about any concerns or problems you have during the study. You should also tell your regular health care provider. The study will pay for research-related items or services that are provided only because you are in the study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.
*************************************************************************

Non-clinical injury language:
Please tell the researchers about any concerns or problems you have during the study. The study will pay for research-related items or services that are provided only because you are in the study. By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.
*************************************************************************

If the study is entirely free of risk, select the first option. Keep in mind that only studies with anonymous data collection on topics that are not sensitive meet this definition.

If the study is classified as more than minimal risk or it is clinical, the language to the left is required. Select from the list of risks or modify to fit your study. Be sure to include a description of the steps taken to mitigate the risks.

"The study will pay for" means the internal or external sponsor, or the PI. The University of Michigan will not pay for research-related injuries.
*************************************************************************

If the study is more than minimal risk but is not clinical, the language to the left is required.
**7. Compensation**

<table>
<thead>
<tr>
<th>Select</th>
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<tbody>
<tr>
<td><em>You will not receive any payment for being in the study</em></td>
</tr>
<tr>
<td><em>You will be reimbursed for your parking expenses</em></td>
</tr>
<tr>
<td><em>You will be reimbursed for your child care expenses</em></td>
</tr>
<tr>
<td><em>You will be given $____ for being in the study</em></td>
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<tr>
<td><em>You will receive _____ hours of psychology/other unit subject pool credit</em></td>
</tr>
<tr>
<td><em>You will not be expected to pay any costs related to the study</em></td>
</tr>
<tr>
<td><em>You will be expected to pay for your own transportation, parking, or child care, if needed</em></td>
</tr>
</tbody>
</table>

By agreeing to be in this study, you do not give up your right to seek compensation if you are harmed as a result of participation. Explain how compensation will be affected if the subject withdraws before the end of the study. The IRB recommends that compensation is prorated based upon the portion of the research that was completed.

Include a description of any costs that might be incurred by participants, such as transportation or parking.

This statement is required if the study poses greater than minimal risk to subjects.

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**8. Confidentiality**

We plan to publish the results of this study, but will not include any information that would identify you. There are some reasons why people other than the researchers may need to see information you provided as part of the study. This includes organizations responsible for making sure the research is done safely and properly, including the University of Michigan, government offices or the study sponsor [name, if any].

To keep your information safe, the researchers will [select]*Your name will not be attached to any data, but a study number will be used instead.*

*The data will be kept on a password-protected computer using special software that scrambles the information so that no one can read it.*

Include the bracketed material if appropriate to your study.

Language regarding abuse should be used only if the research might be conducted with participants or in situations in which physical abuse might be a possibility. Some research topics present the possibility that a participant might disclose information about the abuse of children or vulnerable adults. Some professions are required to report abuse. The State of Michigan has statutes about the reporting of abuse. The following document provides information about abuse reporting requirements in other states: http://www.ndaa.org/pdf/mandatory_reporting_state_statutes.pdf

In such situations, reporting suspected abuse supercedes the promise of confidentiality in research and must be disclosed in the consent document.
8. Confidentiality (continued)
The data or specimens you provide will be stored [describe]
The researchers will retain the data/specimens for [duration]
The researchers will dispose of your data/specimens by [date]
The data/specimens will/will not [select] be made available
to other researchers for related studies following the completion
of this research study and will/will not [select] contain
information that could identify you.

Describe how/where data or specimens will be stored, such as on a
password-protected, encrypted laptop, in a locked file cabinet, on a
university-maintained server, and the like. Indicate how long you expect to
retain the data and when you will dispose of the data, and by what means.
If you plan to retain the data for future research or to share it with other
researchers, disclose those details here.
For more information on safe computing, visit
http://www.safecomputing.umich.edu/

10. Voluntary nature of the study
Participating in this study is completely voluntary. Even if you
decide to participate now, you may change your mind and
stop at any time.

If you decide to withdraw early [select]
*the information or data you provided will be destroyed
*the information or data you provided cannot be destroyed
because it is not linked to you either directly or by a code
*You may also want to discuss it with your health care provider
[details]

Select the appropriate option, or modify as needed. Be clear about
what will happen to the participant's data if they choose to withdraw
early.

Include if the study is clinical

11. Contact information
If you have questions about the study, including scheduling or
your compensation for participating, you may contact [PI (and
faculty advisor, if PI is a student)]

See recommended language in highlighted area. Provide contact
information for the PI, including phone, mailing and email address. If the PI
is a student, provide contact information for the faculty advisor. Clearly
state that participants should contact the study team for questions about the
research.

The highlighted area contains required language for all non-exempt studies.
If the project is primarily managed by another institution, that institution's
Use the toll-free number if appropriate.
**For research conducted outside the US, use the US Country Code
as part of any UM contact information. (For example, calling the US
from Australia would be 0011+1+XXX-XXX-XXXX. See
http://www.countrycodes.com/
Country Code number to use.)
reviewed the project, provide the contact information (email, telephone,
address, as applicable) for the committee. IRB-HSBS may require you
to provide contact information for a local individual or organization
that can assist subjects in relaying questions or complaints to the IRB,
particularly for projects involving more than minimal risk to subjects.
### 12. Consent

By signing this document, you are agreeing to be in the study. You will be given a copy of this document for your records and one copy will be kept with the study records. Be sure that questions you have about the study have been answered and that you understand what you are being asked to do. You may contact the researcher if you think of a question later.

*I agree to participate in the study.*

Printed Name  
Signature  
Date

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<table>
<thead>
<tr>
<th>Signature of legal representative</th>
<th>This element is used only in the case of research involving individuals ages 18 or over who are legally unable to give their consent. It is not used for parental permission of research involving minors.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Printed name</td>
<td></td>
</tr>
<tr>
<td>Signature</td>
<td></td>
</tr>
<tr>
<td>Relationship to subject</td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
</tr>
</tbody>
</table>

**Audio/visual recording of subjects**

Select/modify as appropriate:
- *Audio/visual recording will be done as part of study procedures. Upon completion of the study, these recordings will be*
- *Please sign below if you are willing to be recorded*
- *You may/may not participate in this study if you are not willing to be recorded*
- *Signature*
- *Date*

Consent to conduct audio/visual recording does not require a separate signature line, but may instead be part of the overall consent to participate. Such recording should be described in the Description of Subject Involvement, and subjects should be told explicitly whether recording is a requirement of participation. The consent statement should indicate that the participant agrees to be recorded. In the section on confidentiality, describe the disposition of the recordings (e.g., they will be destroyed, archived, etc.). Be sure to specify whether you will conduct audio or visual recordings, or both.

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**Certificate of Confidentiality**

To protect your privacy, the researchers have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

For studies involving disclosure of sensitive or illegal information, the IRB may require the study team to obtain a Certificate of Confidentiality (granted by the NIH). This protects the data from compelled disclosure, such as through a subpoena. The language to the left is recommended language from the CoC Kiosk at: http://grants2.nih.gov/grants/policy/coc/appl_intramural.htm
**Certificate of Confidentiality (continued)**

A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances:

- [describe]

A new Federal law, called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law will protect you in the following ways:
  * Health insurance companies and group health plans may not request your genetic information that we get from this research.
  * Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
  * Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law by May 21, 2010. All employers with 15 or more employees must follow this law as of November 21, 2009. Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

**Availability of further information**

If significant new knowledge is obtained through the course of the research which may relate to your willingness to continue participation, you will be informed of this knowledge.

As stated in the last line of the CoC language to the left, researchers must describe the conditions under which they would disclose information about a participant, such as in the case of child abuse. If no voluntary disclosures will be made, state this.

If you are collecting genetic information in a repository, the language to the left is required.

The language to the left is typically included for clinical research. Include it in Section 10, Voluntary nature of the study.
Protected health information/HIPAA

Agreeing to be in this study gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

* Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
* Mental health care records (except psychotherapy notes not kept with your medical records)
* Alcohol/substance abuse treatment records
* Your AIDS/HIV status
* All records relating to your condition, the treatment you have received, and your response to the treatment
* Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

* The researchers may need the information to make sure you can take part in the study.
* The researchers may need the information to check your test results or look for side effects.
* University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
* Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly
  - Learn more about side effects
  - Analyze the results of the study
* Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study
* The researchers may need to use the information to create a databank of information about your condition or its treatment.
* Information about your study participation may be included in your regular medical or dental records (as applicable).

The language to the left is required if your project involves protected health information (PHI) obtained through a covered entity. You should modify the list of PHI you will obtain to fit your study. This should be included in the confidentiality section. Covered entities include:

* University of Michigan Health System (including hospitals and health centers, medical school, Michigan Visiting Nurses, Michigan Health Corporation, joint ventures)
* School of Dentistry
* School of Nursing (Nurse-Managed Centers ONLY)
* UM-Flint Urban Health and Wellness Center
* University Health Service
* Institute for Human Adjustment
* UM Autism and Communication Disorders Center
* UM Employee Benefits (only those units that manage UM health benefit plans, including medical, dental, vision, and healthcare Flexible Spending Accounts)

The language to the left should be included to accurately describe who will have access to the subject's PHI that you collect as part of your study.

Use the first sentence, and then select the appropriate option that best fits your study, or modify as needed.

You might want to define PHI for participants:
Protected health information (PHI) is defined as current, past or future information created or received by the University through its health care providers, health plans and contractors. It relates to the physical or mental condition of a patient or plan member, the provision of health care to that person, or payment for the provision of health care to that person. The term PHI does not generally include publicly available information, or information available or reported in a summarized or grouped manner. (University of Michigan Notice of Privacy Practices, effective 4/14/2003)
### Protected health information/HIPAA (continued)

As a rule, researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have cancelled your permission or the study is over. Examples of reasons for this include:

- To avoid losing study results that have already included your name.
- To provide limited information for research, education, or other activities (this information would not include your name, social security number, or anything else that could let others know who you are).
- To help University and government officials make sure that the study was conducted properly.

As long as your information is kept within the [covered entity], it is protected by the University of Michigan's privacy policies. For more information about these policies, ask for a copy of the University of Michigan Notice of Privacy Practices. Note that once your information has been shared with others, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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The language to the left describes the ongoing management of PHI. Modify the list to fit your study.

The language to the left is only applicable for PHI obtained through the covered entities described previously.