

CONSENT FORM TEMPLATE FOR HUMAN SUBJECTS PARTICIPATING IN HEALTH OR BIOMEDICAL RESEARCH

BIOMEDICAL & HEALTH INSTITUTIONAL REVIEW BOARD (BIRB) COMMUNITY RESEARCH INSTITUTIONAL REVIEW BOARD (CRIRB) Michigan State University

Instructions to the Researcher

Informed consent is one of the most basic and important principles in the protection of human subjects in research. The approach of researchers toward the informed consent process is very important in ensuring its effectiveness. The consent process should be informative and empowering. It should give potential participants the information they need to decide to participate or not (being completely voluntary is another basic principle of human subject protection). No exculpatory language can be included in the consent form. For examples of exculpatory language, please visit <http://hhs.gov/ohrp/humansubjects/guidance/exculp.htm>.

Please remember that the consent form is only a part of the consent process. How you inform the participants, present and review the consent form with them, and answer their questions, are also parts of the process and should be built into your project design. If participants are non-English speaking, then the consent process and form should be provided in the appropriate language.

You may use this form as a template for developing a consent form. If you include paragraphs for each section and address the points given, then you should develop an effective consent form. Many sections have points that may or may not apply to your particular project – in those sections, use only the points that are needed in your consent form. **Many of the elements listed are required by federal regulations and if you do not include them you must apply for an alteration of informed consent, where you must provide a rationale for the omission in your application under Question 24b.**

The entire content should be in lay terms – define any technical terms. It is often suggested to aim for an 8th grade reading level for studies of the general population, but the reading level should correspond with the targeted population. Write in second person (“You are being asked…”).

Guidelines for electronic submission of Consent Forms to BIRB/CRIRB

The MSU IRBs are developing a system to make consent forms available electronically. Consent forms submitted by the researcher will be converted to a PDF format and when approved, can be emailed back to the researcher with an IRB-assigned footer. They will eventually be placed on line with the file associated with your project. The PDF will be print only. Once this system is fully functional it will allow you instant access to the latest approved consent form whenever you want it. If there are no revisions at the time of renewal, only the approval dates in the footer will be changed. However, to use this system you must adhere to the following:

1. Submit document in Microsoft Word format (xxx.doc).
2. Do not use text boxes in the consent form. They will not transform when converted to PDF.
3. Do not place a footer in your consent document or place any text within one inch of the bottom.
4. Leave a 1-inch margin at the bottom so BIRB/CRIRB can place the approval footer.

If you cannot use PDF printouts in your project (e.g. you need to use mail merge), let the IRB staff know and they can work with you to get the approval footer on your document. The current approved BIRB/CRIRB consent form with MSU IRB-assigned footer must be used.

For research that involves children (below 18 years of age in Michigan)

In some cases, a waiver of parental permission may be sought. Please refer to section 6-4-C, “Parental Permission and Child Assent” of the Human Research Protection Manual located on our website. In most cases, the parent(s) or legal guardian(s) must give permission on their behalf. The parental permission form should identify the child’s name, age, and relationship to the parent or guardian giving permission. Researchers must also obtain the assent from the child to the extent that the child appears capable of comprehending the investigational procedure and its implications.

For research that involves participants who have no capacity or diminished capacity

MSU has a policy which allows the IRB to permit proxy consent under certain parameters. Please consult Section 6-8-D, "Special Categories of Research Subjects: Individuals with Diminished Capacity," of the HRP Manual before developing your consent form and process.

For research that involves participants who are prisoners

This type of research is particularly sensitive and monitored. The regular language in the consent form is usually appropriate; however, researchers are advised to stress the voluntary nature of prisoners' consent and be meticulous in avoiding even the appearance of subtle or implied coercion and undue inducement.

For research that involves pregnant women, fetuses or neonates

Please consult Section 6-8-A, "Pregnant Women, Human Fetuses and Neonates" of the HRP Manual for requirements for research involving pregnant women, fetuses or neonates.

Documentation of Consent

The standard practice of consent is to obtain the signature of the participant, parent(s) or guardian(s), legal representative, or witness in order to document that the consent form was provided, read, and voluntarily signed. This is important for the protection of both the participant and the researchers. In some instances, with acceptable reasons, the IRB can grant a waiver of documentation (signature). In these circumstances, statements such as the following may be used: "You indicate your voluntary agreement to participate by completing and returning this survey." Or "You indicate your voluntary agreement to participate by beginning this phone interview."

Note to researcher when using this template

- Please use the appropriate headings to separate each section.
- Standard text is language that can be directly used or directly inserted. *Italicized text* is instructional language.
- Use only those statements that are appropriate – this template gives many different possibilities for many types of research, thus not all the statements are relevant for all projects.
- The size of a consent form may vary from one to several pages depending on the complexity of the study.

Research Participant Information and Consent Form

You are being asked to participate in a research project. Researchers are required to provide a consent form to inform you about the study, to convey that participation is voluntary, to explain risks and benefits of participation, and to empower you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Study Title:

Researcher and Title:

Department and Institution:

Address and Contact Information:

Sponsor:

1. PURPOSE OF RESEARCH: *(This is a required element of consent)*

Points to include:

- You are being asked to participate in a research study of...
 - *If appropriate, list any cooperating institutions (e.g., "This study is being conducted collaboratively by Institution A and Institution B".)*
- You have been selected as a possible participant in this study because...
 - *If appropriate, discuss how the researcher got the participant's name.*
- From this study, the investigators hope to learn...*(brief summary of project)*
- In the entire study, ____ people are being asked to participate. *(provide number)*
- Your participation in this study will take about _____. *(min., hours, wks, mos, or yrs.)*
- If you are under 18, you cannot be in this study without parental permission.

2. ALTERNATIVE OPTIONS *(This is a required element of consent only if alternatives exist)*

Points to include:

- If you decide not to take part in this study, you should know that there are other standard or alternative treatments that may be helpful in treating your condition. They include...
 - *Include record of success of standard treatment.s*
- If you decide to participate in this study, you may ask Dr. _____ to discuss these alternatives with you again at any time during your treatment.

3. WHAT YOU WILL DO: *(This is a required element of consent)*

Points to include:

- *Discuss what, if anything, the participants have to do, not do in the study.*
- *Describe the procedures chronologically.*
- *Discuss any special precautions (e.g. medication may make you drowsy..).*
- *Discuss randomization and placebos as appropriate.*
 - The patients in the study will be assigned by random, that is, by a method of chance, to one of the groups. You will have an equal chance of being in either group of the study (e.g. active drug vs. placebo, one drug vs. another drug).
 - This study is blinded. Neither you nor your physician will know what group you are in.
 - This is a placebo controlled study. There will be 2 (or more) groups of patients. One or more groups will receive the experimental drug; the other groups will receive a placebo. A placebo is an inactive substance which will have no direct effect on your illness.
- Dr. _____ and his/her associates will...
- *Clearly delineate what is being done for research and what is being done as part of standard care.*
- *Tell participant if you are going to provide them with any or all findings.*
- *If genetic testing, will the participant be told of the results?*

- *If yes, will the results make the participants upset?*
- *If yes, will counseling be offered? How will counseling be paid for?*
- *If tissues, blood, fluids, or genetic material will be used for future research, separate signoff is required.*
 - *Provide the following choices:*
 - I agree to allow my [tissues, blood, body fluids, DNA] to be stored and used for future research with identifiers. I may be contacted for future studies. Initials _____
 - I agree to allow my [tissues, blood, body fluids, DNA] to be stored and used for future research without identifiers. I will not be contacted for future studies. Initials _____
 - I do not want my [tissues, blood, body fluids, DNA] to be stored and used for future research. My samples will be destroyed after this study is over. Initials _____
 - *If the samples are stored without identifiers or linking codes, no further IRB approval is needed for future research on these samples.*
 - *If future work is done on your samples beyond the scope of this project, the researchers will present the research to an Institutional Review Board to review and approve and determine if your further consent is needed.*
 - *It is often appropriate to have a separate appendix to your main consent for future research on samples.*

4. POTENTIAL BENEFITS: *(This is a required element of consent)*

Points to include:

- *The potential benefits to you for taking part in this study are...*
- *or, You will not directly benefit from your participation in this study. However, your participation in this study may contribute to the understanding...*
- *Note that financial or other compensation is not considered a benefit of being in the project. This information belongs under Heading 8, "Costs and Compensation for Being in the Study."*

5. POTENTIAL RISKS: *(This is a required element of consent)*

Points to include:

- *The potential risks of participating in this study are...*
 - *List side effects with rates and pertinent details.*
 - *Include risks associated with sensitive questions, for example, distress, or discomfort.*
 - *Include risks of reporting illegal or compromising activities (e.g. sexual behavior).*
- *As with any research study, there may be additional risks to the participant that are currently unforeseeable.*
- *If applicable, discuss risks to pregnant women, unborn babies, and breastfeeding women.*
 - *If you were to, or might, become pregnant, the research might involve risks to the embryo or fetus that are currently unforeseeable.*
 - *There may be additional risks to pregnant women, fetuses, or embryos that are currently unforeseeable.*
- *If applicable, discuss reproductive risks to men and women.*
- *If applicable, include risks other than physical risk, for example, legal, employment, psychological, social, economic, reputation, etc.*
- *or, There are no foreseeable risks associated with participation in this study.*
- *If applicable, discuss the availability of referrals, counseling, or other services (e.g. suicide counseling).*
- *For genetic testing, can results be damaging to the participants in terms of insurability, employability, etc.*
 - *The knowledge obtained about you from the genetic testing poses no risks to you.*
 - *The knowledge obtained about you from the genetic testing may put you at risk for.....*

6. PRIVACY AND CONFIDENTIALITY: *(This is a required element of consent)*

Points to include:

- *The data for this project are being collected anonymously. Neither the researchers nor anyone else will be able to link data to you. – use only if applicable.*
- *If the data are being coded and a key maintained separately, inform the participants of the process.*

- Discuss how you will maintain the participant's privacy throughout the project (e.g. private conversations).
- State that "Information about you will be kept confidential to the maximum extent allowable by law...
 - In some studies you should discuss required reporting (e.g. child abuse) or other circumstances under which their information will be released (e.g. suicide or homicide)... unless there is a danger to yourself or others.
- Discuss how you will keep the information about the participant confidential.
 - Where will the data be stored and how will it be protected?
 - If the data are being sent somewhere else (e.g. central data base, another institution), discuss.
 - Who will have access to the data?
 - Researchers and Research Staff.
 - Institutional Review Board (IRB).
 - Sponsors, agencies (e.g. FDA), etc. - list names of organizations.
- The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.
- If participants will be identified, specific permission for identification must be obtained.
 - I agree to allow my identity to be disclosed in reports and presentations.

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Initials _____
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- Inform participants if they are being audiotaped or videotaped – indicate if this is required to be in the project, if not required, a separate check box with signature or initials is appropriate.
 - I agree to allow audiotaping/videotaping of the interview.

<input type="checkbox"/> Yes	<input type="checkbox"/> No	Initials _____
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7. YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW (This is a required element of consent)

Points to include: Include applicable statements

- Participation in this research project is completely voluntary. You have the right to say no.
- You may change your mind at any time and withdraw.
 - Provide participant with the possible consequences of withdrawal and any instructions associated with the withdrawal.
- You may choose not to answer specific questions or to stop participating at any time.
- Choosing not to participate or withdrawing from this study will not make any difference in
 - the quality of any treatment you may receive.
 - benefits to which you are otherwise entitled.
- Whether you choose to participate or not will have no affect on your grade or evaluation.
- If there are circumstances where the researchers may terminate participation (with regard to consent), describe.
- You will be told of any significant findings that develop during the course of the study that may influence your willingness to continue to participate in the research.

8. COSTS AND COMPENSATION FOR BEING IN THE STUDY: (This is a required element of consent)

Points to include:

- Discuss any costs to the participant (choose appropriate option below, if applicable).
 - Procedures being performed for research purposes only will be billed to your insurance company. As with any medical insurance, any costs in excess of what is paid by your insurance or other third party payer will be your responsibility.
 - Procedures being performed for research purposes only will be provided free of charge by...
- Discuss any compensation (amount, timing) to the participant.
 - You will be compensated....
 - You will receive...
 - You will not receive money or any other form of compensation for participating in this study.
- Note for researchers: Lotteries, drawings or raffles may require a state gaming license by law.

9. THE RIGHT TO GET HELP IF INJURED: (If applicable, this is a required element of consent)

- *Include one of the following standard paragraphs:*

1. No costs will be paid.

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact [*insert Principal Researcher's name and phone number*] with any questions or to report an injury.

2. Third party will pay.

If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. Any costs that are not covered or in excess of what are paid by your insurance, including deductibles, shall be paid by [*name of payee*]. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact [*insert Principal Researcher's name and phone number*] with any questions or to report an injury.

3. Alternative Injury Clause Language.

For projects that are funded - If the sponsor has requirements different or in addition to the statements above (i.e., U.S. Army), language will be negotiated with the IRB and other appropriate individuals (e.g., responsible project researcher, department, sponsor, legal counsel). In any case, "no informed consent, whether oral or written, may include any exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence." (45 CFR 46.116, 21 CFR 50.20)

- *If the study is not being performed at MSU facilities or is being performed by non-MSU researchers, the injury clause should state who will be responsible for providing emergency care and who will be responsible to pay for this treatment. A variation of the MSU clause above may be appropriate.*

10. CONFLICT OF INTEREST *(Include only if applicable)*

Points to include:

- *If there is a conflict of interest the researcher should disclose this on the consent form.*
 - *Significant financial interests.*
 - *Affiliation with sponsor.*

11. CONTACT INFORMATION FOR QUESTIONS AND CONCERNS *(This is a required element of consent)*

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher (name and complete contact information: mailing address, e-mail address, phone number)."

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 207 Olds Hall, MSU, East Lansing, MI 48824.

12. DOCUMENTATION OF INFORMED CONSENT.

Your signature below means that you voluntarily agree to participate in this research study.

Signature

Date

Signature of Assenting Child (13-17; if appropriate)

Date

You will be given a copy of this form to keep.

A signature is a required element of consent – if not included, a waiver of documentation must be applied for.