Informed Consent Guidelines

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INFORMED CONSENT GUIDELINES

**Policy:**

Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, and appropriately documented, in accordance with and to the extent required by [45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116%23se45.1.46_1116#se45.1.46_1116) and [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117).

1. **General Requirements:**

A researcher may not involve human subjects in research unless he/she has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative. Usually, informed consent must be documented in writing, although under certain conditions written informed consent may be waived (see [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117)). In certain very specific situations discussed below, the requirement for informed consent may be waived or altered (see [45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116%23se45.1.46_1116#se45.1.46_1116) and [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117)).

**New to the Common Rule:**

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to the informed consent requirements. See

[45 CFR 46.116](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116%23se45.1.46_1116#se45.1.46_1116) and [45 CFR 46.117](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML%23se45.1.46_1116#se45.1.46_1117).

Posting of clinical trial consent form if the research is funded through the NIH. See [45 CFR 46.116(h)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116).

An investigator must create circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate. The possibility of coercion or undue influence must be minimized. The information that is given to the subject or the representative must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. No informed consent, whether written or oral, may include any language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, DHSS, or its agents from liability for negligence.

1. **Basic Elements of Informed Consent**:

The following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others that may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent to which confidentiality of records identifying the subject will be maintained (if applicable), and who will have access to the records.
6. For research involving more than minimal risk, an explanation as to whether any medical treatments or compensation are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

1. **Additional Elements of Informed Consent:**

When appropriate, one or more of the following elements of information shall be provided to each subject.

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject.
3. A statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.
4. The approximate number of subjects involved in the study.
5. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent.
6. Any additional costs to the subject that may result from participation in the research.
7. A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
8. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (*i.e.,* sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

A checklist to assist with the development of a consent form is included in Section VII.

**Elements of Broad Consent**

Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Please review [45 CFR 46.116 (d)](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116) for information that needs to be included.

1. **OUTLINE FOR PREPARING CONSENT FORM**

*Beginning Section:*

1. Who is doing the research.

2. The nature, purpose, and duration of the research--including the fact that the procedure is experimental (if applicable).

3. The uses to be made of the data.

*Middle Section:*

1. The method(s) to be employed.

2. The hazards, inconveniences and risks the subject will undergo, so far as they are known.

3. The availability of compensation and treatment, if injured.

4. The benefits that might be expected.

5. Disclosure of alternate procedures the subject may choose if the experiment is therapeutically related.

6. The conditions of participation, if any.

*End Section:*

1. A statement of the extent to which the data is confidential and a description of the procedures to be employed in maintaining that confidentiality, including who will have access to the data.

2. The fact that the subject is at liberty to withdraw his/her prior consent and discontinue participation in the research at any time without prejudice.

3. An offer to answer any questions, and instructions as to how to contact someone should questions arise later.

4. A place for the date of signing and for the signature of the subject and witness.

1. **Sample Consent Form**

**Consent to Participate in a Research Study:**

**Jasper County, Missouri, Superfund Site**

**Follow-up Childhood Lead Exposure Study, 2000**

A study is being done to see if children living near the Jasper County Superfund Site have lower blood lead levels than in 1991. The study is run by the Missouri Department of Health, along with the Jasper County Health Department, U.S. Environmental Protection Agency, Agency for Toxic Substances and Disease Registry, St. Louis University School of Public Health, and the Missouri Department of Natural Resources.

The project wants you and your child to join in this research study. We are asking you to be in this study because you have lived in Jasper County for 60 days or more and have a child between the ages of 6 to 72 months. Through this study, we hope to learn if the amount of lead in children's blood has improved after the Superfund clean-up efforts. We will also look at factors related to blood lead levels in these children.

You are free to join in the study or not and you may stop being in the study at any time. If you do not join, or stop, you will not be punished in any way. If you choose to be in this study, you will be asked to answer questions such as: the occupation, education, income and tobacco use of persons living in your home, cleaning habits, and your children's play. We will also draw about 1 to 2 teaspoons of blood from a vein in your child's arm. People trained to do this safely will take blood. People will take samples of the soil, dust and water in your home for testing as well as samples of soil from the yard around your home. All of this should take about two hours of your time.

Your child will feel a slight sting when we take blood from a vein. The hurt will be over quickly. The needle we use is sterile, so it will not harm your child. Also, the amount of blood we take will not harm your child at all. Your child may have a bruise from where the needle went in.

The possible benefits of being in the study include knowing your child's blood lead level. You will get tests results within 90 days. If your child had high blood lead levels, we will refer you to your private doctor or health department for follow-up at your own cost and there may be more samples taken from in and around your home. Helping to carry out this research may help us learn how to protect children from lead in the future.

What we talk about and your child's test results will be kept private to the extent allowed by law. We will keep all records in a locked file cabinet and only study staff will be allowed to look at them. Your name, your child's name or other facts that may point to you will not appear when we present this study or publish its results.

**Sample Consent Form**

**Consent to Participate in a Research Study:**

**Jasper County, Missouri, Superfund Site**

**Follow-up Childhood Lead Exposure Study, 2000**

The only cost to you for being in this study is the time you must spend. The tests that we do for this study will be done at no cost to you. We will give you $15 to repay you for the time you take for being in our study, even if you are not able to finish.

As we said before, you are free to join in the study or not and you may stop being in the study at any time. If you do not join or stop, you will not be punished in any way. You may pull your child from the study at any time without giving a reason. Also, it is important that you know that you do not have to answer any questions asked by the study staff if you do not wish to. In any of these cases, you will not lose any services that you may expect apart from this study. If you choose to not be in this study, you may still have your child tested for lead by going to the Jasper County Health Department or to your doctor.

If you have any questions about how the study works, feel free to contact the study investigator(s) listed below. If you have any questions about your or your child's rights in the study, or if you believe your child has suffered harm as a result of being in this study, contact (name), the Chairperson of the Missouri Department of Health and Senior Services Institutional Review Board, at (phone number).

Investigator(s) on this study and contact information:

Name

Phone number

Email address

*I have read, or have been read, this consent form. I have had my questions and concerns answered so that all parts of the study are clear to me now. I believe that I see the purpose of the study as well as the potential risks and benefits that are involved. I have received a copy of this consent form. I agree to my and my child being a part of this study.*

Date

 Month/Day/Year

Parent/Guardian Signature

Parent/Guardian Name (Printed)

Witness Signature

Witness Name (Printed)

**Sample Consent Form**

**Consent to Participate in a Research Study:**

**Jasper County, Missouri, Superfund Site**

**Follow-up Childhood Lead Exposure Study, 2000**

I certify that I have explained to the above individual(s) the nature and purpose of this research study, the potential benefits and possible risks associated with participation, have answered any questions that have been raised, and have witnessed the above signature.

These elements of informed consent conform to the assurance given by the Missouri Department of Health and Senior Services to the Department of Health and Human Services to protect the rights of persons who are in research studies. I have given the participant a copy of this signed consent document.

Date

 Month/Day/Year

Investigator Signature

Investigator Name (printed) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Checklist for Preparing Informed Consent**

Name of Project      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date      \_\_\_\_\_\_\_\_

|  |  |
| --- | --- |
| 1. Is the length of the consent form appropriate? | ( ) Yes ( ) No ( ) N/A |
| 2. Is the language written at the appropriate level? | ( ) Yes ( ) No ( ) N/A |
| 3. Is each section of informed consent identified by a subheading? | ( ) Yes ( ) No ( ) N/A |
| 4. Are the elements of informed consent arranged in an appropriate sequence? | ( ) Yes ( ) No ( ) N/A |
| 5. Does the consent form begin with a clear invitation to participate? | ( ) Yes ( ) No ( ) N/A |
| 6. Is there a clear statement of the purpose of the research? | ( ) Yes ( ) No ( ) N/A |
| 7. Is the explanation of procedures adequate? | ( ) Yes ( ) No ( ) N/A |
| 8. Is the description of potential risks and discomforts adequate? | ( ) Yes ( ) No ( ) N/A |
| 9. Is the statement of potential benefits adequate? | ( ) Yes ( ) No ( ) N/A |
| 10. Is there a statement concerning alternatives to participation (required for therapeutic studies)? | ( ) Yes ( ) No ( ) N/A |
| 11. Are the financial obligations of the subject clearly stated? | ( ) Yes ( ) No ( ) N/A |
| 12. Is the assurance of confidentiality clear and complete? | ( ) Yes ( ) No ( ) N/A |
| 13. Is compensation in case of injury statement present (for more than minimal risk studies)? | ( ) Yes ( ) No ( ) N/A |
| 14. Is a subject withdrawal statement present? | ( ) Yes ( ) No ( ) N/A |
| 15. Are any economic incentives/rewards for participation clearly stated? | ( ) Yes ( ) No ( ) N/A |
| 16. Is there an offer to answer all questions? | ( ) Yes ( ) No ( ) N/A |
| 17. Is a concluding consent statement present? | ( ) Yes ( ) No ( ) N/A |
| 18. Are there dated subject and investigator signature blanks? | ( ) Yes ( ) No ( ) N/A |
| 19. Is there a witness signature blank (for more than minimal risk studies)? | ( ) Yes ( ) No ( ) N/A |
| 20. Is the name and telephone number of the investigator present on the consent form? | ( ) Yes ( ) No ( ) N/A |
| 21. Is there a Parent Consent Form (studies involving minors)? | ( ) Yes ( ) No ( ) N/A |
| 22. Is there a Child Assent Form (studies involving minors age 7-12)? | ( ) Yes ( ) No ( ) N/A |
| 23. Is there a Youth Assent Form (studies involving minors age 13-18)? | ( ) Yes ( ) No ( ) N/A |
| 24. If requesting broad consent, are all the required elements present? | ( ) Yes ( ) No ( ) N/A |

Comments