Informed Consent – Defining Consent and Requirements

Informed Consent. Before conducting human subject research, researchers must receive explicit permission from research volunteers to participate in their research study. This explicit permission is called “informed consent.” Potential research volunteers must be provided enough and complete information to make an informed decision to participate in the study or to refuse to participate in the study. For participants to have a full and accurate understanding, language, cultural, and education factors need to be incorporated for valid consent. IRBs and researchers must make sure that informed consent includes the appropriate languages and translations available, included cultural distinctions, and can be accessible by all education levels. Consent must be given free from pressure or coercion. The required elements for informed consent, including the updated elements from the 2019 Final Rule that must be included on consent forms, are listed on the next page.
Informed Consent Checklist for Studies Beginning After January 21, 2019

☐ A statement that clearly explains:
   o the study or activity is research;
   o the purpose of the research and how the information will be used;
   o the anticipated time and any financial commitment a research volunteer can expect from participating in the study;
   o what the research volunteer will be doing during the study.

☐ Explanation of any experimental procedures.

☐ Statement free of pressure or coercion that participation in the research is voluntary. Researchers need to make clear that there will be no penalty or loss of benefits to an individual if he/she chooses not to participate or to stop participating in a study.
   o Reasons for why an individual may be asked to stop participating in a study, regardless of consent, need to be outlined.
   o Procedures on how to stop participating in a study, and what the consequences of ending participation may be, should be discussed during the consent process.

☐ A list of potential risks or discomforts.
   o If consequences to pregnancy or to research volunteers who become pregnant during the study are unknown, this must be discussed during the informed consent process.

☐ A list of potential benefits.

☐ Appropriate alternatives to study participation.

☐ The privacy and security measures taken to protect a volunteer's identifiable.

☐ If any identifiable data will be collected, including biological/DNA samples, researchers must disclose which of the following applies to the study*:
   o The data collected may be used in future studies by other researchers and consent will not need to be obtained again. Identifiable information will be removed for any future secondary use but, informed consent to use that de-identified data in future studies will not be required. By participating and providing consent in the first study, research volunteers are providing consent for his/her data to be used in all future studies.*
   o The data collected will only be used for the initial study and will not be shared beyond the research team or for any additional research. If additional research is conducted, the researcher must obtain consent from the volunteer again.*

☐ For research collecting genetic/DNA samples:
   o If biological samples or data are being or may be sold for commercial use, researchers need to disclose and discuss whether the research volunteer will receive a portion of the initial sale or any future profits.*
   o A disclosure if the samples may or will be used for whole genome sequencing. Whole genome sequencing identifies the entire DNA sequence of an individual. A debate regarding the ethics and privacy of whole genome sequencing is currently ongoing.*
   o Under what conditions an individual's research results will be disclosed.*

☐ Approximate number of study participants.

☐ Contact information for someone that participants can ask questions regarding the study or study process, learn more about his/her rights as a study participant, or to receive information and assistance for study related injuries.

* This symbol indicates these requirements for informed consent were added and implemented by the Final Rule for Human Research Protections on January 21, 2019. See HHS 45 CFR 46.116 (b)(c), Subpart A
Understanding Primary vs. Secondary Research. Primary research is when Researcher A conducts new research, collects new data, and uses the research collected for a pre-approved and identified research question/purpose. Researcher A will have received informed consent from the research volunteers who participated in the study. The research may or may not be collecting data that is identifiable (i.e. is clearly data from a specific research volunteer).

Secondary research is when a new researcher, Researcher B, uses the data collected by Researcher A to answer a new research question for a new research study. Researcher A may also want to use the data for a new research study. Depending on the research question, the type of data collected, whether the data is identifiable, and what was included in the original consent, Researcher B may or may not have to obtain consent from the research volunteers again. For example, the Final Rule allows in certain circumstances use of secondary data that is not identifiable. The research volunteers from Researcher A's study may have no idea how their data is being used by Researcher B in the new study. Before the Final Rule, if the data was identifiable, Researcher B would have to obtain consent from the volunteers to use their data again for the new research study.

### Broad Consent.
Under the new provisions in the Final Rule, Researcher A could ask the research volunteer before the primary research study for Broad Consent in the Informed Consent process for permission to use their identifiable data in future research studies without obtaining informed consent again. This would allow ANY future researcher to be able to use the identifiable personal data from Volunteer A collected by Researcher A for a completely different secondary research study B without informed consent for the new secondary research study. If a research volunteer agrees to Broad Consent, they may not know how their identifiable data will be used or what generalizations about their community will be made in future research studies. Researcher A's consent form must be clear about how long the research volunteer's data will be stored for future research, and information about the types of research that might occur, including genetic research or research for commercial profit. These requirements are included in the Informed Consent Checklist on the previous page. Researcher A must provide one of two options on the study consent form: informed consent for this study only; or Broad Consent for any future study.
As mentioned above, the January 21, 2019 Final Rule included a new type of consent called Broad Consent, which only applies to the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. Biospecimens are “samples of material, such as urine, blood, tissue, cells, DNA, RNA, and protein from humans…” Broad Consent means that future research studies not discussed during the initial consent process can use the same identifiable private information and biospecimens collected during the original research study without the new researchers needing to obtain consent from the original research volunteers. Research volunteers providing Broad Consent may not know how their identifiable information and data will be used in future research.

This discussion of Broad Consent does not apply to certain types of de-identified data, which may be exempt from IRB review and does not require informed consent to analyze. Please refer to the list of exempt research in the Final Rule for more information. However, tribes or tribal IRBs may decide that all research requires tribal review, even though it might be exempt from IRB review based on the Common Rule, especially since the Common Rule allows tribes to implement more restrictive informed consent requirements. Check with the individual tribe for their research review requirements.

What does Broad Consent look like?
The Final Rule does not provide a template or guidance as to the format of how Broad Consent needs to look. The Final Rule does specify that Broad Consent needs to include all elements of the normal informed consent process, in addition to an explanation of Broad Consent and any boundaries on research for future research conducted under that consent. When secondary research is planned, an IRB needs to confirm that the research planned is within whatever boundaries were set by the researcher during the initial consent process in the primary research project.

Refusing Broad Consent
Research volunteers can refuse Broad Consent and request to provide only informed consent for a specific research study. This means that the researcher has consent to ONLY use the volunteer’s information for the current specified study. If the researcher or another research wants to conduct more or different research with the volunteer’s identifiable information, the researcher must obtain a new informed consent specifically for the new research study.

If a research volunteer refuses Broad Consent, “an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens [genetic samples].” Researchers will not be legally able to use a research volunteer’s information after the initial study is completed and cannot override the research volunteer’s decision.

In addition to individuals refusing Broad Consent, entities, such as IRBs, or even tribes, can also refuse to implement Broad Consent. An IRB can refuse a consent form for a study that includes Broad Consent, and refuse to approve that study. Similarly, a tribal IRB or tribe can decide not to implement Broad Consent and refuse to approve research studies that involve Broad Consent. Broad Consent is an alternative to the regular informed consent process. Therefore, entities can choose not to implement it under the Final Rule. Tribes may consider amending their research laws to incorporate their decisions on whether to implement Broad Consent since according to the Final Rule, researchers conducting research with federal funding under the Common Rule must follow tribal law.
An example of language used by an entity that has decided to not implement Broad Consent is included below:

“Broad consent is a new term introduced by the Final Rule that allows an investigator to seek prospective consent to unspecified future research. It’s intended for “secondary research use” of private identifiable information and identifiable biospecimens. Broad consent is required for exempt categories 7 and 8. Harvard University has decided not to implement Broad Consent.”

### Individual Rights and Amending Consent

Research volunteers have the right to refuse consent to any human subjects research study.  
- Under the Federal Policy for the Protections of Human Subjects, research participation is voluntary and free of “pressure or undue influence”.  
- Potential research volunteers cannot be punished or denied any benefits he/she would have been previously received, regardless whether asked to participate in the study.

Research volunteers can withdraw consent from study participation at any time.  
- The volunteers cannot be punished or denied any benefits he/she would have normally received.

Potential reasons for why research volunteers may be removed from a study by a researcher need to be discussed during the initial informed consent process.

Research volunteers have the right to contact a designated study official at any time to ask questions about the study process, the individual’s rights and protections as a volunteer, and how to access help for study related injuries or complications.

### Contact for Questions on Consent and Protections

The U.S. Department of Health and Human Services, Office for Human Research Protections created a printable document of “Questions to Ask When Deciding Whether to Volunteer for Research.” The document helps potential research participants ask the questions for greater understanding of the research.

Research is voluntary, and individuals should make sure they understand what they are volunteering for and their rights and protections as a volunteer. Even though a researcher might be pressuring someone to sign a form in a hurry or without reading it, they have the right to read it, consider it, and make sure they understand it. See the below chart for contact information where research volunteers can receive help with their protections and rights.
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<thead>
<tr>
<th>ORGANIZATION NAME</th>
<th>ROLE/QUESTION</th>
<th>CONTACT AND RESOURCES</th>
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<tbody>
<tr>
<td>Office for Human Research Protections</td>
<td>For general questions about regulations, the IRB review process, and protections for human research subjects.</td>
<td>Phone Numbers: (240) 453-6900 (866) 447-4777 (Toll-Free within the United States) Email: <a href="mailto:OHRP@HHS.gov">OHRP@HHS.gov</a></td>
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<tr>
<td>Office for Human Research Protections: Division of Compliance Oversight</td>
<td>If an individual needs to report an incident of non-ethical research practices, the Division of Compliance Oversight can answer questions and investigate violation reports.</td>
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<td>• Resources on Compliance: Common Rule and Rights</td>
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<td>• Guide on How to Report Violations</td>
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<td>• OHRP Determination Letters (Results of Reported Non-compliance)</td>
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<tr>
<td>Office of Human Research Protections: Division of Policy and Assurances</td>
<td>For questions related to IRBs or Federalwide Assurances and registration.</td>
<td>Email: <a href="mailto:IRBorFWA@hhs.gov">IRBorFWA@hhs.gov</a></td>
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<tr>
<td>U.S. Food and Drug Administration</td>
<td>For questions on human subjects research protections with studies under FDA regulations.</td>
<td>• Reporting Complaints Related to FDA-Regulated Clinical Trials</td>
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<td>• IRB Reporting: FDA Contacts</td>
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<tr>
<td>Specific Study</td>
<td>For every Human Subjects Research Study, a point of contact should be provided to all research volunteers to ask questions about the study, the participants’ rights, and assistance for study related injury.</td>
<td>• Check the signed copy of the research volunteer informed consent form. If there is no contact information, request this from the Investigator. If the Investigator cannot provide this information, contact OHRP at <a href="mailto:OHRP@HHS.gov">OHRP@HHS.gov</a></td>
</tr>
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Questions: NCAI Policy Research Center – email: research@ncai.org; website: http://www.ncai.org/prc
Endnotes

1 [45 CFR 46.116, Subpart A]
2 [45 CFR 46.107, Subpart A]
3 [45 CFR 46.116(a), Subpart A]
4 [45 CFR 46.116(e), Subpart A]
7 [45 CFR 46.104, Subpart A]
11 [45 CFR 46.116(e), Subpart A]
15 [45 CFR 46.116(a),(b)8, Subpart A]
16 [45 CFR 46.116(b)8, Subpart A]
17 [45 CFR 46.116(b)8, Subpart A]
18 [45 CFR 46.116(c)2, Subpart A]
19 [45 CFR 46.116(b)7, Subpart A]