**Consent Waiver vs Required Elements**

## Consent requirements for non-exempt, human subjects research are defined by the HHS regulations in the Revised Common Rule and include detail on the content and method of documentation. There are a few options when crafting your consent process that will fulfill both the consent and documentation requirements:

|  |  |
| --- | --- |
| Consent  How and what information is shared between the researcher and the potential participant about their participation in the research activity | Documentation  How and whether the agreement between the researcher and participant is given and/or recorded |
| **Full Consent**   * Includes all the basic elements of informed consent | **Documented**   * Includes a physical or digital signature |
| **Altered Consent**   * Includes some of the basic elements of the informed consent | **Documentation Waived**   * Does not include a physical or digital signature.   *Often, this includes verbal consent, ‘click to consent,’ proceed onto the survey to demonstrate consent, etc.* |
| **Waived Consent**   * Skips the consent process, altogether. |

**Let’s walk through the regulations to see where your consent fits.**

The default process is a full consent. To craft or review a full consent, all of the following Basic Elements of Informed Consent need to be included.

Look and see whether all these criteria are fulfilled:

## Basic Elements of Informed Consent:Fulfilled Incomplete

|  |  |  |
| --- | --- | --- |
| 45 CFR 46.116(b) | | |
|  | 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 that are experimental; |
|  | A description of any reasonably foreseeable **risks** or discomforts to the subject; |
|  | A description of any **benefits** to the subject or to others that may reasonably be expected from the research; |
|  | A statement describing the extent, if any, to which **confidentiality of records** identifying the subject will be maintained; |
|  | 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; |
|  | 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; and |

If all elements are not included you can add either add them to your process, or note which are excluded, mark this section incomplete and move onto the next section.

Now, look and see if any of these conditional criteria apply to your project. If so, mark whether the associated elements are included in your consent process.

**Basic Elements of Informed Consent (Conditional):**Fulfilled Incomplete

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| 45 CFR 46.116(b) | |
|  | If the research involves the collection of identifiable private information or identifiable biospecimens:  **N/A**  (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. |
|  | If the research involves more than minimal risk:  **N/A**  An explanation as to whether any **compensation** and an explanation as to whether any medical treatments are available **if injury occurs** and, if so, what they consist of, or where further information may be obtained; |
|  | If there are any alternative procedures or courses of treatment:  **N/A**  Advantageous alternatives are disclosed; |
|  | If there are applicable additional elements:  **N/A**  Additional elements are included; |
|  | |  |  |  |  | | --- | --- | --- | --- | | Additional Elements of Informed Consent 45 CFR 46.116(c) | | | | |  | Audio/video recording or photographs\* | |  | Detail about data/biospecimen repository or specimen retention\* | |  | Use of direct quotes\* | |  | Participant follow-up/recontact\* | |  | Access to course grades/assignments, FERPA requirements\* | |  | Treatment or procedure may involve risks to the subject that are currently unforeseeable | |  | Anticipated circumstances under which the subject's participation may be terminated by the investigator | |  | Any additional costs to the subject that may result from participation in the research | |  | Consequences of a subject's decision to withdraw from the research and procedures to withdraw | |  | Significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject | |  | Approximate number of subjects involved in the study | |  | 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 | |  | Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions | |  | Whether the research will (if known) or might include whole genome sequencing | |  | Other: |   *\*common additional elements that are not explicitly listed in the regulations* |

If all the basic criteria are fulfilled (including the applicable conditional elements), you have established a full consent!

If not, and you would like to use a consent process that does not include all the basic elements of consent, you will need to justify why it is eligible for

* a **waiver** (no consent process at all) or
* an **alteration** (leaving out some of the basic elements)

The criteria for consent waiver or alteration are the same, and are listed here. Only **one** of the criteria set checkboxes need to be checked:

## **Waiver or alteration of consent** N/A Waiver/Alteration Eligible

|  |  |
| --- | --- |
| **46.116(f)(3)** | (i) The research involves no more than minimal risk to the subjects;  (ii) The research could not practicably be carried out without the requested waiver or alteration;  (iii) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format;  (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; AND  (v) Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation. |
| **46.116(e)(3)** | (i) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:  (A) Public benefit or service programs;  (B) Procedures for obtaining benefits or services under those programs;  (C) Possible changes in or alternatives to those programs or procedures; or  (D) Possible changes in methods or levels of payment for benefits or services under those programs; AND  (ii) The research could not practicably be carried out without the waiver or alteration. |
| **46.116(g)** | Screening, recruiting, or determining eligibility. An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:  (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or  (2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. |

## If none of the criteria sets apply, the consent will need to be updated to a full consent to be eligible for approval. Otherwise, you can submit this with a request for either a waiver or alteration of consent.

**Okay, you have your consent in place. Let’s walk through the regulations to see where your documentation fits.**

The default process is a documented consent process. To be considered documented, you need to be collecting a physical or digital signature.

Verify whether either of these criteria are fulfilled:

## Consent Documentation Fulfilled Incomplete

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| 45 CFR 46.117 | | |
|  | Informed consent will be documented with a **physical signature** |
|  | Informed consent will be documented with a **digital signature** |

If one of the documentation options above are fulfilled, you will be using a documented consent process!

If not, and you would like to use a consent process that does not include a physical or digital signature, you will need to justify why it is eligible for

* a **waiver of documentation** (not collecting a physical or digital signature)

The criteria for waiving documentation are listed here:

## Waiver of documentation of consent N/A Waiver Eligible

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|  | A waiver of documentation of consent is appropriate because the investigator is providing subjects or legally authorized representatives with a written statement regarding the research (required) AND one of the following sets of criteria is true: | | |
|  | | **46.117(c)(1)(i)** | The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. |
|  | | **46.117(c)(1)(ii)** | The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. |
|  | | **46.117(c)(1)(iii)** | If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to subjects and there is an appropriate alternative mechanism for documenting that informed consent was obtained. |

## If none of the criteria sets apply, the consent process will need to be updated to include a physical or digital signature to be eligible for approval. Otherwise, you can submit this with a request for a waiver of documentation of consent.

As long as criteria are fulfilled for the applicable consent and documentation methods, the consent process requirements are complete! You can indicate your consent and documentation processes here by choosing one option in each row:

## Consent-Specific Criteria for IRB Approval of Research Fulfilled Incomplete

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| --- | --- | --- | --- |
|  | | | **45 CFR 46.111** |
|  | **Informed consent** will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by, §46.116.  This will be achieved with (choose one):  **full consent**  **altered consent**  consent process will be entirely **waived** | |
|  | Informed consent will be recorded in accordance with §46.117.  This will be achieved using consent that is (choose one):  **documented**  **documentation appropriately waived** | |

## Notes: Click or tap here to enter text.

## Other Notes

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