The changes, as applicable, to the informed consent regulations are effective for all research that is approved on and after 21 January 2019. Research organizations, institutions, IRBs, and investigators will have to revise forms, documents, and practices to comply with revisions.

***Key Revisions***

1. **New process requirements** for the content, organization, and presentation of information and the process to facilitate a prospective subject’s decision about whether to participate in research.
2. **New requirements** for the basic and additional elements of consent.
3. **Electronic consent is allowed,** but must provide written copy.
4. **New broad consent** elements for storage, maintenance, or secondary research use of identifiable private information and identifiable bio specimens.
5. **Changes in the waiver and alteration criteria** for consent.
6. **New consent provision** that allows IRBs to approve a research proposal for which investigators obtain information or bio specimens without individual’s informed consent for the purpose of screening, recruiting, or determining the eligibility of prospective human subjects, provided certain conditions are met.
7. **New requirement to post,** to a federal website, a copy of an IRB-approved version of the consent form that was used for enrollment purposes for each clinical trial conducted or supported by a federal department or agency.

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| **Citation** | **Sub-part(s)** | **Description** | **Allowances/Limitations** |
| **46.116(a)** |  | General conditions for consent are now numbered, new addition of reasonable person standard, and key information requirement for informed consent presentation.  Broad consent may be obtained in place of informed consent obtained in accordance with the basic and additional elements, but only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable bio specimens. | A brief description of the five “factors” (elements) of consent should appear at the beginning of an informed consent process:  1. Consent is being sought for research and that participation is voluntary.  2. The purpose of the research, expected duration of the prospective subject’s participation, and procedures to be followed in the research.  3. The reasonably foreseeable risk/discomforts to the prospective subject.  4. The benefits to prospective subject or other.  5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. |
| (4) | The prospective subject or legally authorized representative (LAR) must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. | This is a new subsection and requires that subjects be provided with the information that a “reasonable person” (undefined) would want to have.  For certain types of research (e.g. research for which there is reason to believe subjects will find the research controversial or objectionable), a robust description of the research will be required to meet this reasonable person standard. |
| (5) (i) | Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. | When broad consent is obtained, the requirements imposed by 46.116 (a) (5) for the presenting of information for informed consent and prescribing order in which consent information is presented, do not apply. |
| (5) (ii) | Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR understanding of the reasons why one might or might not want to participate. |  |
| (6) | The reference to “oral or written consent” was moved to the first sentence of 46.116 (a). Otherwise the exculpatory considerations remain unchanged. |  |
| **46.116 (b)** |  | **No changes to the eight previous basic informational elements of consent, but a new requirement was added to include one of two statements about the collection of private information or identifiable bio specimens for future research:** | Requires using a brief statement to inform potential subjects about the possible use of their identifiable private information or bio specimens. |
| (9) (i) | A statement that identifiers might be removed from the identifiable private information or identifiable bio specimens and that, after such removal, the information or bio specimens 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 LAR, if this might be a possibility; or |  |
| (9) (ii) | A statement that the subject’s information or bio specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies. |  |
| **46.116 (c)** |  | **No changes to the six previous additional elements of consent, but three new requirements were added:** |  |
| (c) (7) | A statement that the subject’s bio specimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit. |  |
| (c) (8) | A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to the subjects, and if so, under what conditions. |  |
| (c) (9) | For research involving bio specimens, 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). |
| **46.116 (e)** |  | **Waiver of Alteration of Consent in Research Involving Public Benefit and Service Programs Conducted by or Subject to the Approval of State or Local Officials** |  |
| (e) (1) | If an individual was asked to provide broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable bio specimens and refused to consent, an IRB cannot waive consent. |  |
| (e) (2) | An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent set forth in 46.116 (b) or (c) provided the IRB satisfies the requirements of 46.116 (e) (3). | An IRB may not omit or alter any of the requirements described in 46.116 (a).  If a broad consent procedure is used, an IRB may not omit or alter any of the elements required under 46.116 (d). |
|  | (e) (3) | In order for an IRB to waive or alter consent described in this subsection, the IRB must find and document that: |  |
| (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:   * Public benefit or service programs; * Procedures for obtaining benefits or services under those programs; * Possible changes in or alternatives to those programs or procedures: or * Possible changes in methods or levels of payment for benefits or services under those programs;   AND |  |
| (e) (3) (ii) | The research could not practicably be carried out without the waiver or alteration. |  |
| **46.116 (f)** | (3) | In order for an IRB to waive or alter consent, the IRB must find and document that:   * The research involves no more than minimal risk to subjects; * The research could not practicably be carried out without the requested waiver or alteration; * If the research involves using identifiable private information or identifiable bio specimens, the research could not practicably be carried out without using such information or bio specimens in an identifiable format; * The waiver or alteration will not adversely affect the rights and welfare of the subjects;   AND   * Whenever appropriate, the subjects or LAR will be provided with additional pertinent information after participation. |  |
| **46.116 (g)** |  | An IRB may approve a research proposal in which an investigator will obtain information or bio specimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent , if either of the following conditions are met:   * The investigator will obtain information through oral or written communication with the prospective subject or LAR   OR   * The investigator will obtain identifiable private information or identifiable bio specimens by accessing records or stored identifiable bio specimens. | This is **not a waiver** of the consent requirement but rather an **exception** to the requirement. |
| **46.116 (h)** |  | **Posting of Clinical Trial Consent Form** |  |
| (h) (1) | For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency component conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms. | New subsection. |
| (h) (2) | If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted. | New subsection. |
| (h) (3) | The informed consent form must be posted on the Federal website after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol. | New subsection. |
| (i) | The informed consent requirements in this policy are not intended to preempt any applicable Federal, state, or local laws (including tribal laws passed by the official governing body of an American Indian or Alaska Native tribe) that require additional information to be disclosed in order for informed consent to be legally effective. | This section was renumbered and clarified, but otherwise unchanged. |
| (j) | Nothing in this policy is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe). |  |
| **46.117(a)** |  | Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed (including in an electronic form) by the subject or the subject’s LAR. A written copy shall be given to the person signing the informed consent form. | Specifically allows electronic signatures, but otherwise unchanged. |
| **46.117 (b)** |  | Except as provided in paragraph (c) of this section, the informed consent form may be either of the following: | This section remains unchanged. |
| (b) (1) | A written informed consent form that meets the requirements of section 46.116. The investigator shall give either the subject or the LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject’s LAR. | Reordered and clarified, but otherwise unchanged. |
| **46.117 (c)** | (c) (1) | An IRB may waive the requirement for the investigator to obtain a signed informed consent for some or all of the subjects if it finds **any of the following**:   * That 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 LAR will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern; * That 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;   OR   * If the subjects or LAR are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. |  |
| (c) (2) | In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or LARs with a written statement regarding the research. |  |

**References**

* Institutional Review Boards, 21 CFR § 56 (2015).
* National Institutes of Health (NIH). 2016. “Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.” Accessed September 30.
* Protection of Human Subjects, 21 CFR § 50 (2015).
* U.S. Department of Health and Human Services (HHS). 2017. “Federal Policy for the Protection of Human Subjects.” Federal Register 82(12):7149-274.
* U.S. Department of Health and Human Services (HHS). 2018. “Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period.” Federal Register 83(118):28497-520.
* Chadwick, G. L. (2017). Final Rule Material: Comprehensive Guide to Informed Consent Changes. Retrieved January 10, 2019, from <https://about.citiprogram.org/en/final-rule-resources/>