**IRB Consent Checklist**

**Green shading** = Basic Elements – applies to most research

**Yellow shading** = Additional Elements – as applicable

**Pink shading** = Studies with ID Private Info or ID Biospecimen – as applicable

With NEW Revised Common Rule Elements   
 (effective 1/20/2019)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Study #** | **Reviewer Name:** | **Date:** | | |
| **#** | **Reference** | **Element** | **Yes** | **No** | **NA** |
| **NEW**  1 | 5CRF – 46.116(a)(4)  ***Required*** *for HHS studies only. May not be waived or altered.* | Subject is provided with **information** that **a reasonable person would want** to have in order to make an informed decision about whether to participate. |  |  |  |
| **NEW**  2 | 5CFR – 46.116 (a)(5)(i-ii)  ***Required*** *for HHS studies only. May not be waived or altered.* | The consent starts with a **concise and focused** presentation of **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**. This part of the informed consent must be organized and presented in a way that facilitates comprehension.  There must be sufficient detail relating to the research, organized and presented in a way that does not just a list isolated facts, but facilitates the subject’s understanding of the reasons to participate or not. |  |  |  |
| 3 | 2CFR – 50.25 (a)(1)  6CFR – 46.116(b)(1) | Explanation that the trial involves **research.** |  |  |  |
| 4 | 2CFR – 50.25 (a)(1)  6CFR – 46.116(b)(1) | **Purpose** of the research. |  |  |  |
| 5 | 2CFR – 50.25 (a)(1)  6CFR – 46.116(b)(1) | Explanation of the trial **procedures** to be followed, including all invasive procedures. |  |  |  |
| 6 | 2CFR – 50.25 (a)(1)  6CFR – 46.116(b)(1) | Identification of any procedures that are **experimental.** |  |  |  |
| 7 | 2CFR – 50.25 (a)(8)  6CFR – 46.116 (b)(8) | Explanation that the subject’s participation in the trial is **voluntary.** The subject may refuse to participate or withdraw from the trial, at any time, without penalty or loss of benefits to which the subject is otherwise entitled. |  |  |  |
| 8 | 2CFR – 50.25 (b)(6)  CFR – 46.116 (c)(6) | Approximate **number** of subjects involved in the trial. |  |  |  |
| 9 | 2CFR – 50.25 (a)(1)  6CFR – 46.116 (b)(1) | Expected **duration** of the subject’s participation in the trial |  |  |  |
| 10 | 2CFR – 50.25 (a)(2)  6CFR – 46.116 (b)(2) | Reasonably **foreseeable risks** or discomforts to the subject. |  |  |  |
| 11 | 3CFR – 50.25 (b)(1)  8CFR – 46.116 (c)(1) | Statement that the particular treatment may involve **risks** which are currently **unforeseeable**, to the subject or to the fetus, embryo or unborn child. |  |  |  |
| 12 | 2CFR – 50.25 (a)(3)  6CFR – 46.116 (b)(3) | Description of reasonably **expected benefits** to the subject or others from the research. |  |  |  |
| 13 | ICH – 4.8.10.c | Trial **treatment(s)** and **probability** for random assignments to each treatment if applicable |  |  |  |
| 14 | 2CFR – 50.25 (a)(4)  6CFR – 46.116(b)(4) | **Alternative procedure(s)** or course(s) of treatment that may be available to the subject. |  |  |  |
| 15 | 2CFR – 50.25 (a)(5)  6CFR – 46.116(b)(5) | Explanation on the extent records identifying the subject will be kept **confidential.** The possibility that the FDA, study monitor, auditor, IRB or other regulatory authority may inspect the subject’s records. |  |  |  |
| 16 | Meriter | Anticipated **payment**, if any, **to the subject** for participating in the research, including methods, amounts and schedule of payment. |  |  |  |
| 17 | 3CFR – 50.25 (b)(3)  8CFR – 46.116 (c)(3) | Additional costs to the subject for participating in the trial, if there are any. |  |  |  |
| 18 | 2CFR – 50.25 (a)(6)  6CFR-46.116(b)(6) | For research involving **more than minimal risk**,an explanation as to whether any **compensation** and an explanation as to whether any **medical treatments are available** if a **research-related injury** occurs and, if so, what they consist of, or where further information may be obtained. |  |  |  |

For revised consents:

If original consent was approved before the revised common rule went into effect (1/20/2019), then none of the new elements are required. The word **NEW** is printed in the first column as a guide.

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**IRB Consent Checklist**

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| --- | --- | --- | --- | --- | --- |
| **#** | **Reference** | **Element** | **Yes** | **No** | **NA** |
| 19 | Meriter | Statement regarding potential for **financial gain** for the investigator and or participant |  |  |  |
| 20 | 3CFR – 50.25 (b)(5)  8CFR – 46.116 (c)(5) | 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**. |  |  |  |
| **NEW**  21 | 8CFR – 46.116 (c)(8)  ***Required*** *for HHS studies only.* | Statement regarding whether **clinically relevant research results**, including individual research results, **will be disclosed to subjects**, and if so, under what conditions. |  |  |  |
| 22 | 3CFR – 50.25 (b)(4)  8CFR – 46.116 (c)(4) | A description of the **consequences** of a patient’s decision to withdraw from the research and the procedures for orderly termination of the participation by the patient. |  |  |  |
| 23 | 3CFR – 50.25 (b)(2)  8CFR – 46.116 (c)(2) | Foreseeable circumstances and/or reasons under which the subject’s **participation** in the trial may be **terminated** by the investigator or sponsor. |  |  |  |
| 24 | 1CFR – 50.20  5CFR – 46.116(a)(2) | Statement that the patient was given **sufficient opportunity to discuss** and consider whether or not to participate, that minimizes the possibility of coercion or undue influence. |  |  |  |
| 25 | 2CFR – 50.25 (a)(7)  6CFR – 46.116(b)(7) | Person(s) to **contact** for further information regarding the trial and the rights of research subjects, and whom to contact in the event of a research-related injury. |  |  |  |
| 26 | 4CFR – 50.25 (c)  *FDA Studies Only.* | Statement for FDA research that, “A description of this clinical trial is available on <http://www.clinicaltrials.gov> as required by US law . . .” |  |  |  |
| **NEW**  27 | 8CFR – 46.116 (c)(7)  ***Required*** *for HHS studies.* | 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. |  |  |  |
| **NEW**  28 | 7CFR – 46.116(b)(9)  ***Required*** *for HHS studies.*  ***Future Use***  ***OR***  ***One Use*** | One of the following statements for research involving 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*** 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. |  |  |  |
| **(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.*** |
| **NEW**  29 | 8CFR – 46.116 (c)(9)  ***Required*** *for HHS studies.* | 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). |  |  |  |
| **NEW**  30 | CFR – 46.116 (d)(2)  ***Required*** *for HHS studies.*  ***Future Use*** | A general **description of the types of research that may be conducted** with the identifiable **private information** or identifiable **biospecimens**. This description must include sufficient information such that a reasonable person would expect that the consent would permit the types of research conducted. |  |  |  |
| **NEW**  31 | CFR – 46.116 (d)(3)  ***Required*** *for HHS studies.*  ***Future Use*** | A **description of the identifiable private information or identifiable biospecimens that might be used in research**, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens. |  |  |  |

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|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **#** | **Reference** | **Element** | **Yes** | **No** | | **NA** |
| **NEW**  32 | CFR – 46.116 (d)(4)  ***Required*** *for HHS studies.*  ***Storage & Maintenance*** | A description of the **period of time** that the identifiable private information or identifiable biospecimens may be **stored and maintained** (which period of time could be indefinite), and a description of the **period of time** that the identifiable private information or identifiable biospecimens may be **used for research purposes** (which period of time could be indefinite). |  |  | |  |
| **NEW**  33 | CFR – 46.116 (d)(5)  ***Required*** *for HHS studies.*  ***Future Use*** | Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that **they will not be informed of the details of any specific research studies** that might be conducted using the subject’s identifiable private information or identifiable biospecimens, including the purposes of the research, and that **they might have chosen not to consent to some of those specific research studies.** |  |  | |  |
| **NEW**  34 | CFR – 46.116 (d)(6)  ***Required*** *for HHS studies.*  ***Future Use*** | Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such **results may not be disclosed to the subject.** |  |  | |  |
| **NEW**  35 | CFR – 46.116 (d)(7)  ***Required*** *for HHS studies.*  ***Future Use & Storage*** | An explanation of **whom to contact** for answers to questions **about the subject’s rights** and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and **whom to contact in the event of a research-related harm**. |  |  | |  |
| 36 | Meriter | **Page numbering** (x of y pages) in document footer unless there’s only one page. |  |  | |  |
| 37 | Meriter | **Version date** and **version number** in document footer agree with iRIS version date and number. |  | |  |  |
| 38 | Meriter | **Protocol short title or IRB #** in document header or footer. |  | |  |  |
| 39 | Meriter | Correct Grammar, Formatting, Spelling |  | |  |  |

**Consent Checklist Regulatory References**

**Food and Drug Administration (FDA) Regulations**

**1CFR – 50.20** FDA general requirements of informed consent.

**2CFR – 50.25 (a)(1-8)** FDA **required** basic elements of informed consent.

(Same as CFR – 46.116 (b)(1-8) below).

3CFR – 50.25 (b)(1-6) FDA additional elements of informed consent. When appropriate, one or more of   
 these elements may be included.

4CFR – 50.27 (a) FDA requirements for documentation of consent.

**Health and Human Services (HHS) Regulations**

**5CFR – 46.116 (a)(1-6)** HHS general requirements for informed consent.

**6CFR – 46.116 (b)(1-8)** HHS **required** basic elements of informed consent   
 (same as CFR50.25 (a)(1-8) above).

7CFR – 46.116 (b)(9) HHS element for research involving identifiable private information or biospecimens.

8CFR – 46.116 (c)(1-9) HHS additional elements of informed consent. When appropriate, one or more of   
 these elements may be included (same as CFR – 50.25 (b)(1-c) above).

9CFR – 46.117(a) HHS requirements for documentation of consent.

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ICH – International Conference on Harmonization – Rules for conducting research in foreign countries.