**Note:**

This checklist includes DMID-specific requirements for research participant informed consent form templates. Detailed background and instructional information are not included.

Text that appears as un-bolded print applies to all research studies. **Text in bolded print applies to those studies conducted under the Revised Common Rule 2018.**

|  |  |
| --- | --- |
| Review date: |  |
| DMID Grant #: |  |
| DMID Protocol #, version # and date: |  |
| ICF version # and date: |  |
| Under an IND or IDE? If Yes, 21CFR50.25 applies |  |

| **Regulatory Reference** | **Topic** | **Description** | **✓** |
| --- | --- | --- | --- |
| 45 CFR 46.116(a)(5)(i) | **Concise, Focused Key Information Is Presented First, Facilitates the Comprehension of Reasons Why Not to Participate** | **Consent form begins with a concise and focused presentation of key information that is most likely to assist a prospective subject or legally authorized representative (LAR) in understanding the reasons why one might or might not want to participate in the research** |  |
| **Organized, Presented in A Way That Facilitates Comprehension** | **This part is organized and presented in a way that facilitates comprehension** |  |
| 45 CFR 46.116(b)(1) ICH E6 4.8.10(a)  21 CFR 50.25(a)(1) | Research | A statement that the study involves research |  |
| 45 CFR 46.116(b)(1)  ICH E6 4.8.10(b)  21 CFR 50.25(a)(1) | Purpose | States the purpose of the study- safety and tolerability mentioned (If study objectives) |  |
| 45 CFR 46.116(c)(9) | **Whole Genome Sequencing** | **For research involving biospecimens, a statement 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)** |  |
| 45 CFR46.116(c)(6)  ICH E6 4.8.10(t)  21 CFR 50.25(b)(6) | Number of Participants | Approximate # of subjects involved in the study |  |
| 45 CFR 46.116(b)(3)  21 CFR 50.25(a)(3) | Benefits | A description of any benefits to the subject or to others which may reasonably be expected from the research |  |
| ICH E6 4.8.10(h) | No Benefits | The reasonably expected benefits. When there is no intended clinical benefit to the subject, the subject should be made aware of this |  |
| 45 CFR 46.116(b)(2)  21 CFR 50.25(a)(2) | Risks | A description of any reasonably foreseeable risks or discomforts to the subject Consider:   * Invasive procedures/tests e.g. Biopsy, LP, MRI etc. * Compare risks listed in ICF to the Protocol, PI/IB. * Social risks/stigma - non-treatment studies; consider for international sites; peer focus groups studies * Embarrassment from questionnaires/interviews * Anxiety re: waiting for test results (HIV, STIs, etc.)   Risks may or may not be required if study product is not primary objective even if it is study-provided |  |
| 45 CFR 46.116(c)(1)  21 CFR 50.25(b)(1) | Pregnancy Risks | 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 which are currently unforeseeable |  |
| ICH E6 4.8.10(g) | Pregnancy Risks | The reasonably foreseeable risks or inconveniences to the subject and, when applicable, to an embryo, fetus, or nursing infant |  |
| 45 CFR 46.116(b)(1)  21 CFR 50.25(a)(1) | Procedures | A description of the procedures to be followed |  |
| ICH E6 4.8.10(d) | Procedures | The trial procedures to be followed, including all invasive procedures |  |
| 45 CFR 46.116(b)(1)  21 CFR 50.25(a)(1)  ICH E6 4.8.10(f) | Experimental Aspects of The Trial | The aspects of the trial that are experimental (drugs, doses, procedures, randomization, etc.) |  |
| ICH E6 4.8.10(c) | Procedures | The trial treatment(s) and explanation of placebo control (if applicable) |  |
| Random Assignment | The probability for random assignment to each treatment is included in the informed consent form |  |
| 45 CFR 46.116(b)(1)  21 CFR 50.25(a)(1)  ICH E6 4.8.10(s) | Duration | Expected duration of the subject’s participation (length of time on treatment & follow-up) (subjects participation is not the same as the study duration) |  |
| ICH E6 4.8.10(e) | Responsibilities | The subject’s responsibilities |  |
| 45 CFR 46.116(b)(4)  21 CFR 50.25(a)(4) | Alternatives | A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject |  |
| ICH E6 4.8.10(i) | Alternatives | The alternative procedure(s) or course(s) of treatment that may be available to the subject, and their important potential benefits and risks or a statement to discuss alternatives with your physician |  |
| 45 CFR 46.116(b)(8)  21 CFR 50.25(a)(8)  ICH E6 4.8.10(m) | Voluntary Participation | A statement that participation is completely voluntary |  |
| A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled |  |
| No penalty for withdrawal |  |
| 45 CFR 46.116(c)(2)  21 CFR 50.25(b)(2)  ICH E6 4.8.10(r) | Termination of Participation | Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent shall be provided to each subject. Major reasons listed (safety, concomitant meds, etc.) [\*often ICF confuses study discontinuation with drug discontinuation reasons] |  |
| 45 CFR 46.116(c)(4)  21 CFR 50.25(b)(4) | Termination Procedures | Consequences of a subject’s decision to withdraw from the Research and Procedures for orderly termination discussed? Listed in protocol SOE? |  |
| 45 CFR 46.116(c)(5)  ICH E6 4.8.10(p)  21 CFR 50.25(b)(5) | New Findings | A statement that significant new findings developed during the course of the research which may affect willingness to continue participation, will be provided to the subject or to the subject’s legally acceptable representative in a timely manner |  |
| 45 CFR 46.116(b)(5) | Confidentiality | Describes the extent, if any, to which confidentiality of records identifying the subject will be maintained |  |
| 21 CFR 50.25(a)(5) | Confidentiality | A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained, and that notes the possibility that the FDA may inspect the records, (for clinical studies). Consider: entities listed in the protocol and the ICF |  |
| ICH E6 4.8.10(o) | Confidentiality | The records identifying the subject will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential. |  |
| ICH E6 4.8.10(n) | Confidentiality | That monitors, the auditors, the IRB/IEC, and the regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subject, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the subject or the subject's legally acceptable representative is authorizing such access. |  |
| NIH Policy (NOT-OD-17-109) – effective on October 1, 2017 | Certificate of Confidentiality | A description regarding NIH Certificate of Confidentiality (CoC). |  |
| 45 CFR 46.116(b)(9) | **Information or Biospecimens For Storage or Future Use (one of the statements is required)** | ***[When stored or used for future studies]* 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 the 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** |  |
| ***[No future use]* 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** |  |
| 45 CFR 46.116(c)(8) | **Research Results** | **A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions** |  |
| 21 CFR 50.25(c)  42 CFR 11.22 – Trials Initiated on or after January 18, 2017 *NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information* | ClinicalTrials.Gov Language | For applicable clinical trials, the ClinicalTrials.Gov statement “A description of this clinical trial will be available on [http://www.ClinicalTrials.gov,](http://www.ClinicalTrials.gov/) as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time”. Shall be provided in informed consent documents |  |
| ICH E6 4.8.10(k) | Payment | Anticipated prorated payment for participation, if any, to the subject for participating in the trial |  |
| 45 CFR 46.116(c)(7) | **Commercial Profit** | **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** |  |
| 45 CFR 46.116(c)(3) ICH E6 4.8.10(l)  21 CFR 50.25(b)(3) | Costs | Potential additional costs to subject from participation  (consider: Who pays: subjects and/or their insurance? The sponsor? National health plan?) |  |
| 45 CFR 46.116(b)(6) ICH E6 4.8.10(j)  21 CFR 50.25(a)(6) | Compensation | For research involving more than minimal risk, an explanation as to whether any compensation is available if injury occurs |  |
| Medical Treatments Available | An explanation as to whether any medical treatments are available if injury occurs, if so, what they consist of, OR where further information may be obtained |  |
| Federal Antideficiency Act | Injury | *[When funded by a federal government contract]*The ICF must state: In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH or the Federal Government |  |
| *[When not funded by a federal government contract]*The ICF should describe the alternative resources, if any, for long-term medical care or financial compensation for research-related injuries |  |
| 45 CFR 46.116(b)(7) ICH E6 4.8.10(q)  21 CFR 50.25(a)(7) | Contact Information | Contact information or placeholder for questions about research, including concerns or complaints (note: same contact may be listed for study questions and research related injuries) |  |
| Contact information or placeholder for research related injuries |  |
| Contact information or placeholder for questions about subject rights (ideally, not study staff, usually IRB contact) |  |
| 45 CFR 46.116(a)(3)  21 CFR 50.20 | Understandable Language | Information given to a subject or LAR must be in language understandable to the subject or LAR |  |
| 45 CFR 46.116(a)(4) | **Information for A Reasonable Person** | **The prospective subject or 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 will have an opportunity to discuss that information** |  |
| 45 CFR 46.116(a)(5)(ii) | **Consent Form Overall: Organized, Presented in A Way to Facilitate Comprehension for Reasons to Participate or Not** | **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 legally authorized representative’s understanding of the reasons why one might or might not want to participate** |  |
| 45 CFR 46.116(a)(6)  21 CFR 50.20 | Exculpatory Language | No informed consent, whether oral or written, may include any exculpatory 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, the sponsor, the institution, or its agents from liability for negligence |  |
| 21 CFR 50.55  45 CFR 46.408  ICH E6 4.8.12 | Assent Process/Parental Permission (As Appropriate) | If the study includes minors, a signature line for parental permission by parent(s)/legal guardian is included.  Corresponding protocol must describe assent process. The respective site IRB will determine process and documentation. |  |
| 21 CFR 50 Subpart D  45 CFR 46 Subpart D  ICH E6 4.8.12  ICH E6 4.8.14 | Children in Research | If the study includes minors, explicitly stated or understood through text:  -Justification for the inclusion of minors  -Plans to obtain the subject’s informed consent when the minor reaches the age of majority, as applicable |  |
| 45 CFR 46 Subpart A  ICH E6 4.8.12  ICH E6 4.8.14 | Legally Authorized Representative | If the study requires consent by the subject’s legally authorized representative, explicitly stated or understood through text:  -Justification for inclusion of adults that cannot provide autonomous consent  -Plans to obtain informed consent when the subject gains the ability to provide autonomous consent, as applicable |  |
| ICH E6 4.8.12  ICH E6 4.8.14 | Legally Authorized Representative signature | If the study includes adults that cannot provide autonomous consent, a signature line for consent by the subject’s legally authorized representative is included |  |
| Public Readiness and Emergency Preparedness (PREP) Act – per Office of General Council, NIH Branch Requirement | PREP Act | When applicable, the ICF must state: “This vaccine and the clinical trial is covered by the Public Readiness and Emergency Preparedness (PREP) Act which limits your ability to sue if you develop a reaction to the vaccine. A Federal program has been created to help pay for medical care and other expenses related to reactions that are caused by the vaccine. To be eligible for this program, you must file a claim within one year of the vaccination. The program is administrated by the Health Resources and Services Administration. Information sheet about the PREP act, and the Federal program, including how to file a claim will be provided to you.” |  |
| When applicable, the protocol document must also include information regarding PREP Act implications (i.e., description of the purpose of the PREP Act, compensation for countermeasure-related injury, ability of participant to pursue a tort claim) |  |