|  |  |
| --- | --- |
| **or-logo-stacked** | **Institutional Review Board**  **Human Research Protections**  **Review Checklist – Consent Requirements**  *Version October 2022* |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **General Requirements for Informed Consent [**[**45 CFR 46.116(a)**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)**] &** [**21 CFR 50.20**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.20)**]** | | | | | | | | | | | |
| 1 | Before involving a human subject in research covered by this policy, an investigator shall **obtain the legally effective informed consent of** the subject or the subject's legally authorized representative (LAR). [§46.116(a)(1) & §50.20] | YES |  | NO | |  |  | | | | |
| 2 | An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR **sufficient opportunity to discuss and consider** whether or not to participate and that minimize the possibility of coercion or undue influence. [§46.116(a)(2) & §50.20] | YES |  | NO | |  |
| 3 | The information that is given to the subject or the LAR shall be in **language understandable** to the subject or the LAR. [§46.116(a)(3) & §50.20] | YES |  | NO | |  |
| 4 | The prospective subject or the 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. [§46.116(a)(4)] | YES |  | NO | |  |
| 5 | 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. [§46.116(a)(5)(i)]  Basic Elements #1, 2, 3, 4, & 8:   * The fact that consent is being sought for research and that participation is voluntary * The purposes of the research, the expected duration of the prospective subject’s participation, and the procedures to be followed in the research * The reasonably foreseeable risks or discomforts to the prospective subject * The benefits to the prospective subject or to others that may reasonably be expected from the research * Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject | YES |  | NO | |  |
| 6 | 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’s **understanding** of the reasons why one might or might not want to participate. [§46.116(a)(5)(ii)] | YES |  | NO | |  |
| 7 | **No** informed consent may include **any exculpatory language** through which the subject or LAR 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. [§46.116(a)(6) & §50.20] | YES |  | NO | |  |
| **Basic Elements of Informed Consent [**[**45 CFR 46.116(b)**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116) **&** [**21 CFR 50.25(a)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25)**]** | | | | | | | | | | | |
| 1 | Statement that the **study involves research**, [§46.116(b)(1) & §50.25(a)(1)] | YES |  | NO | |  |  | | | | |
| Explanation of the **purposes** of the research, [§46.116(b)(1) & §50.25(a)(1)] | YES |  | NO | |  |
| Expected **duration** of the subject's participation, [§46.116(b)(1) & §50.25(a)(1)] | YES |  | NO | |  |
| Description of the **procedures** to be followed, and [§46.116(b)(1) & §50.25(a)(1)] | YES |  | NO | |  |
| Identification of **any procedures that are experimental** [§46.116(b)(1) & §50.25(a)(1)] | YES |  | NO |  | | N/A | | | |  |
| 2 | Description of any reasonably foreseeable **risks or discomforts** to the subject [§46.116(b)(2) & §50.25(a)(2)] | YES |  | NO |  | |  | | | | |
| 3 | Description of any **benefits** to the subject or to others that may reasonably be expected from the research [§46.116(b)(3) & §50.25(a)(3)] | YES |  | NO |  | |
| 4 | Disclosure of appropriate **alternative procedures** or courses of treatment, if any, that might be advantageous to the subject [§46.116(b)(4) & §50.25(a)(4)] | YES |  | NO |  | | N/A | | | |  |
| 5 | Statement describing the extent, if any, to which **confidentiality** of records identifying the subject will be maintained [§46.116(b)(5)] | YES |  | NO |  | |  | | | | |
| Include the possibility that the FDA may inspect the records [§50.25(a)(5)] | YES |  | NO |  | | N/A | | |  | |
| 6 | *For research involving more than minimal risk and expedited studies that are industry-sponsored*, 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 [§46.116(b)(6) & §50.25(a)(6)]  **NOTE: UCI’s standardized language in ICF template must be used.** | YES |  | NO |  | | N/A | | | |  |
| 7 | Explanation of **whom to contact for answers to pertinent questions about the research** and research subjects' rights, and [§46.116(b)(7) & §50.25(a)(7)]  **NOTE: UCI’s standardized language in ICF template must be used.** | YES |  | NO |  | |  | | | | |
| **Whom to contact in the event of a research-related injury** to the subject [§46.116(b)(7) & §50.25(a)(7)]  **NOTE: UCI’s standardized language in ICF template must be used.** | YES |  | NO |  | |
| 8 | Statement that **participation is voluntary**, [§46.116(b)(8) & §50.25(a)(8)] | YES |  | NO |  | |
| **Refusal** to participate **will involve no penalty or loss of benefits** to which the subject is otherwise entitled, and [§46.116(b)(8) & §50.25(a)(8)] | YES |  | NO |  | |
| **Subject may discontinue** participation at any time **without penalty or loss of benefits** to which the subject is otherwise entitled [§46.116(b)(8) & §50.25(a)(8)] | YES |  | NO |  | |
| 10 | 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** [§46.116(b)(9)(i)]  Statement that **identifiers will 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 (LAR) [§46.116(b)(9)(i)]    Statement that **identifiers will NOT be removed** from the identifiable private information or identifiable biospecimens and 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 LAR | YES |  | NO |  | | N/A | | | |  |
| **Additional Elements of Informed Consent, When Appropriate [**[**45 CFR 46.116(c)**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116)**] &** [**21 CFR 50.25(b)**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25) **& (c)]** | | | | | | | | | | | |
| 1 | Statement that the particular treatment or procedure may involve **risks** to the subject that are currently **unforeseeable** [§46.116(c)(1) & §50.25(b)(1)]  The **risk profile** of all research-related interventions is **well known** and the research involves **no investigational drugs or devices**. | YES |  | NO |  | |  | | | | |
| Research **targets** **pregnant persons and/or persons of child bearing potential:**  Statement that the particular treatment or procedure may involve **risks to the embryo or fetus** that are currently unforeseeable [§46.116(c)(1) & §50.25(b)(1)]  The **risk profile** of all research interventions or interactions on embryos and fetuses is **well known**. | YES |  | NO |  | | N/A | | |  | |
| 2 | Anticipated **circumstances** under which the **subject's participation may be terminated by the investigator** without regard to the subject's or the legally authorized representative's consent [§46.116(c)(2) & §50.25(b)(2)] | YES |  | NO |  | | N/A | | | |  |
| 3 | Any **additional costs** to the subject that may result from participation in the research [§46.116(c)(3) & §50.25(b)(3)] | YES |  | NO |  | | N/A | | | |  |
| 4 | **Consequences of a subject's decision to withdraw** from the research and procedures for orderly termination of participation by the subject [§46.116(c)(4) & §50.25(b)(4)] | YES |  | NO |  | | N/A | | | |  |
| 5 | Statement that **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 [§46.116(c)(5) & §50.25(b)(5)] | YES |  | NO |  | | N/A | | | |  |
| 6 | Explain the **approximate number** of subjects involved in the study [§46.116(c)(6) & §50.25(b)(6)] **NOTE: Include # at UCI & total # for all study sites**  **Number of subjects** involved in the study is **not important** in making a decision to participate in research. | Yes |  | NO |  | | N/A | |  | | |
| 7 | 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; [§46.116(c)(7)]  **NOTE: UCI’s standardized language in ICF template must be used.** | YES |  | NO |  | | N/A | | | |  |
| 8 | Statement regarding whether **clinically relevant research results**, including individual research results, will be disclosed to subjects, and if so, under what conditions [§46.116(c)(8)] | YES |  | NO |  | | N/A | | | |  |
| 9 | 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) [§46.116(c)(9)] | YES |  | NO |  | | N/A | | | |  |
| 10 | *For clinical trials* approved by the IRB on or after March 7, 2012, include **ClinicalTrials.gov language** required by the FDA [§50.25(c)] | YES |  | NO |  | | N/A | | | |  |
| **Additional California or UCI Requirements of Informed Consent** | | | | | | | | | | | |
| 1 | Include **only study team members** currently authorized to **finalize informed consent** [HRP Policy 31] | YES |  | NO |  | |  | | | | |
| 2 | **HIV / Hepatitis / COVID-19 testing** disclosure for positive test [CA Health and Safety Code: [Sections 120500-120605](https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=120500&lawCode=HSC) & [Sections 120975–121023](https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=120975&lawCode=HSC)] | YES |  | NO |  | | N/A |  | | | |
| 3 | Research with **scans** (e.g., MRI, X-ray, CT), include risk language regarding **incidental findings** | YES |  | NO |  | | N/A | | | |  |
| 4 | Disclose **study compensation** [UCI HRP Policy 21] | YES |  | NO |  | | N/A | | | |  |
| *Compensation is* ***over $600***, language regarding **tax reporting** requirement is included [HRP Policy 21] | YES |  | NO |  | | N/A | | | |  |
| *Compensation is processed through the* ***UCI Office of Accounting***, language regarding releasing personal information to UCI Accounting is included [UCI HRP Policy 21] | YES |  | NO |  | | N/A | | | |  |
| Discloseguidelines for **lotteries, raffles, and/or drawings** [[DCA Legal Guide U-2](https://www.marincounty.org/~/media/files/departments/da/consumer-guides/u2.pdf)] | YES |  | NO |  | | N/A | | | |  |
| 5 | **COVID subject injury language** [HSRA [Countermeasures Injury Compensation Program (CICP)](https://www.hrsa.gov/cicp/about); effective 04-16-2020] | YES |  | NO |  | | N/A | | | |  |
| 6 | Include applicable template language that informs subjects of their rights related to **data retention** | YES |  | NO |  | | N/A | | | |  |
| 7 | ***NCI-funded research***,include required templateon the **Clinical Trials Reporting Program**.  **NOTE: UCI’s standardized language in ICF template must be used.** | YES |  | NO |  | | N/A | | | |  |
| 8 | Research involves a **Certificate of Confidentiality:**  ***NIH funded research*** that started or is ongoing on or after 12/13/2016, if research is biomedical, behavioral, or clinical in nature **and collects identifiable, sensitive information** (**including biospecimens**)  Non-federally funded research, seeking a **Certificate of Confidentiality**, include appropriate template language [HRP Policy 24] | YES |  | NO |  | | N/A | | | |  |
| 9 | Medical care statement pertaining to the **withholding of medical record** [[Cares Act](https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0945-AA16); effective 10/13/2021] | YES |  | NO |  | | N/A |  | | | |
| 10 | [**If biospecimens will be discarded**] Biospecimens (such as blood, tissue, or saliva) collected for routine labs will be discarded or destroyed once they have been used for the purposes described in this consent. [HRP Policy 15]  [**If specimens and / or information** derived therefrom will be collected from a research subject and used for research and / or **development purposes**] Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them. [HRP Policy 15] | YES |  | NO |  | | N/A | | | |  |
| 11 | Standard CalGINA template language for use when the study involves **genetic testing or access to genetic information**. [HRP Policy 15]  Alternate CalGINA template language for research that **involves individuals who have a diagnosis** and/or are being **treated for a genetic disease** or disorder. [HRP Policy 15] | YES |  | NO |  | | N/A | | | |  |
| 12 | The research involves ***no more than minimal risk*** and there is not even the appearance of a **financial conflict** of interest. [HRP Policy 25]  Disclose that that **no one** on the study team has a **significant financial interest** in the outcome of this study. [HRP Policy 25]  Disclose that a member of the study team has **personal financial interest** in either the Sponsor or another interested entity. The nature of this financial interest and the design of the study have been reviewed by the UCI Conflict of Interest Oversight Committee, and that this committee has determined that the investigator's financial interests would not compromise the quality or reliability of the study. [HRP Policy 25] | YES |  | NO |  | |  | | | | |
| 13 | **UCI witness signature box is included** [HRP Policy 35 & [ICH E-6 4.8.9](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)] | YES |  | NO |  | |  | | | | |
| 14 | For research that meets the California definition of “**medical experiments”, the Experimental Bill of Rights** must be included. [CA Civil Code: [Sections 24170–24179.5](http://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=20.&title=&part=&chapter=1.3.&article)] | YES |  | NO |  | |  | | | | |
| **Documentation of Informed Consent [**[**45 CFR 46.117**](https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1117) **&** [**21 CFR 50.27**](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.27)**]** | | | | | | | | | | | |
| 1 | *Except when signed consent has been waived,* informed **consent shall be documented by the use of a written** informed consent form approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. [§46.117(a) & §50.27(a)] | YES |  | NO |  | | N/A | | | |  |
| A **written copy shall be given to the person** signing the informed consent form. [§46.117(a) & §50.27(a)] | YES |  | NO |  | | N/A | | | |  |
| 2 | The **informed consent form may be either** of the following:  A **written informed consent** form that meets the requirements of §46.116 (and §50.25). The investigator shall give either the subject or the subject's 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. [§46.117(b)(1) & §50.27(b)(1)]  **Pre-2018 Common Rule**: A **short form** written informed consent form stating that the elements of informed consent required by §46.116 (and §50.25) have been presented **orally** to the subject or the subject's LAR. A copy of the summary shall be given to the subject or the subject's LAR, in addition to a copy of the short form. [§46.117(b)(2) & §50.27(b)(2)]  **2018 Common Rule**: A **short form** written informed consent form stating that the elements of informed consent required by §46.116 (and §50.25) have been presented **orally** to the subject or the subject's LAR, and that the **key information** required by §46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided. A copy of the summary shall be given to the subject or the subject's LAR, in addition to a copy of the short form. [§46.117(b)(2) & §50.27(b)(2)] | YES |  | NO |  | | N/A | | | |  |