



**WORKSHEET: Requirements for Informed Consent Research**

NUMBER	DATE	PAGE
HRP-314B	02.05.2019	1 of 3

The purpose of this worksheet is to provide support for Reviewers reviewing proposed consent documents. This worksheet is to be used. It does not need to be completed or retained.

**1) Applicable Regulation (Check all that apply)**

- The research is FDA-regulated (*If checked, complete Sections 2, 3, 4 and 5*)
- The research is federally funded and subject to the 2018 Common Rule (*If checked, complete Sections 2 and 3 6 and, 7*)
- This research is subject to the GDPR because: (*if one of the alternatives below is checked, the research is subject to the GDPR and Section 8 must be completed*)
  - The research is obtaining identifiable data<sup>1</sup> (Personal Data) directly from living individuals located in a State belonging to the European Union (EU) or the European Economic Area (EEA).<sup>2</sup>
  - A collaborator from the EU/EEA is transmitting Personal Data of subjects located in the EU/EEA to a researcher in the US
  - The sponsor is an organization established in the EU/EEA and is subject to the GDPR

**2) General Requirements (All must be checked)**

- Consent will be obtained in manner that provides the subject with sufficient opportunity to discuss and consider whether or not to participate.
- The consent process is conducted in a manner that minimizes coercion and undue influence.
- Considering the potential subjects, the consent language is understandable.
- Information will be provided to prospective subjects in sufficient detail and in a format organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's understanding of the reasons why one might or might not want to participate.
- The consent does not include exculpatory language.
- The prospective subject is 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.
- A statement that study involves research.
- An explanation of the purpose of the research.
- A description of the procedures to be followed.
- Identification of any procedures which are experimental.
- The expected duration of the subject's participation.
- A description of any reasonably foreseeable risks or discomforts to the subject and when applicable, to an embryo, fetus, or nursing infant.
- A description of any benefits to the subject or to others, which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.
- The extent, if any, to which confidentiality of records identifying the subject will be maintained.
- Whom to contact for questions about the research
- Whom to contact if the subject believes he/she is injured because of the study
- Whom contact questions, concerns, or complaints about the research or about subjects' rights
- A statement that participation is voluntary.
- A statement that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled.
- A statement that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

<sup>1</sup> The GDPR considers coded data “identifiable,” if there is a link between the code and the identity of the individual.

<sup>2</sup> Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom.



**WORKSHEET: Requirements for Informed Consent Research**

NUMBER	DATE	PAGE
HRP-314B	02.05.2019	2 of 3

**3) Additional Elements of Consent (Include these elements, when applicable)**

<input type="checkbox"/>	Include if drug/device treatment study: 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) that are currently unforeseeable.
<input type="checkbox"/>	Include if A description of the foreseeable circumstances and/or reasons under which the subject's participation in the research may be terminated.
<input type="checkbox"/>	The anticipated expenses, if any, to the subject for participating in the research.
<input type="checkbox"/>	If subjects will be compensated for participation, a description of the prorated payment plan.
<input type="checkbox"/>	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination.
<input type="checkbox"/>	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.
<input type="checkbox"/>	The approximate number of subjects involved in the study.
<input type="checkbox"/>	If research is greater than minimal risk, an explanation as to whether any compensation is available if injury occurs and, if so, what it consists of, or where further information may be obtained.
<input type="checkbox"/>	If research is greater than minimal risk, 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.
<input type="checkbox"/>	For clinical trials and/or controlled drug/device trials (except Phase I drug trials) and pediatric device surveillance trials, the following statement: "A description of this clinical trial will be available on <a href="http://www.ClinicalTrials.gov">http://www.ClinicalTrials.gov</a> , as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
<input type="checkbox"/>	For research funded by NIH or if otherwise applicable, Certificate of Confidentiality Statement

**4) Additional Requirements for FDA-regulated Research (All must be checked)**

<input type="checkbox"/>	A description of the probability for random assignment to each treatment, when applicable.
<input type="checkbox"/>	A statement that the Food and Drug Administration may inspect the records.
<input type="checkbox"/>	A statement that the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
<input type="checkbox"/>	A statement that the investigator will ask a subject who is withdrawing whether the subject wishes to provide further data collection from routine medical care.

**5) Additional Requirements for ICH E-6(R2) for FDA-regulated Research for drug studies (All items with "\*" must be checked)**

<input type="checkbox"/>	A statement indicating the IRB has approved the research.
<input type="checkbox"/>	A description of the subject's responsibilities.
<input type="checkbox"/>	The important potential benefits and risks of alternative procedures or courses of treatment.
<input type="checkbox"/>	When there is no intended clinical benefit to the subject, a statement to this effect.
<input type="checkbox"/>	A statement that the monitors, auditors, IRB, and regulatory authorities will be granted direct access to the subject's original medical records for verification of clinical trial procedures and data, without violating the confidentiality of the subject, to the extent permitted by applicable laws and regulations and that, by signing the consent document, the subject or LAR is authorizing such access.
<input type="checkbox"/>	That 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.

**6) Requirements for Research Subject to the 2018 Common Rule (All must be checked)**

<input type="checkbox"/>	The informed consent begins with a concise/focused presentation of the key information that is likely to assist a subject in understanding the reasons why one might or might not want to participate.
<input type="checkbox"/>	The informed consent is organized and presented in a way that facilitates comprehension.

**7) Additional Requirements for Research Subject to the 2018 Common Rule (Check all that apply)**

<input type="checkbox"/>	When the research involves biospecimens, the following statements must be included: <ul style="list-style-type: none"> <li>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.</li> <li>A statement as to whether the research will 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)</li> </ul>
<input type="checkbox"/>	A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.



**WORKSHEET: Requirements for Informed Consent Research**

NUMBER	DATE	PAGE
HRP-314B	02.05.2019	3 of 3

<input type="checkbox"/>	If private identifiable information or identifiable biospecimens are being collected, one of the following statements must be included: <ul style="list-style-type: none"> <li>(i) A statement that identifiable private information and/or identifiable biospecimens might be used for future research studies or distributed to another investigator for future research after removing the identifiers, without additional informed consent from the subject; or</li> <li>(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.</li> </ul>
<input type="checkbox"/>	For research involving biospecimens: <ul style="list-style-type: none"> <li>• A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will share in this commercial profit</li> <li>• 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)</li> </ul>
<b>8) Additional Requirements for Research Subject to the GDPR (All must be checked or marked NA)</b>	
<input type="checkbox"/>	The consent includes language indicating that the subject's personal data will be collected or used to conduct the research.
<input type="checkbox"/>	If sensitive personal data <sup>3</sup> are being collected or used, explicit consent is requested. <input type="checkbox"/> N/A
<input type="checkbox"/>	The Duration for which personal data will be retained is included
<input type="checkbox"/>	The categories of recipients of the research subject's personal data is included
<input type="checkbox"/>	Information on how personal data will be protected is included
<input type="checkbox"/>	Notice of subjects' rights is included <ul style="list-style-type: none"> <li><input type="checkbox"/> Right to access, correct or withdraw personal data</li> <li><input type="checkbox"/> Right to restrict the types of activities the research team can do with the data</li> <li><input type="checkbox"/> Object to using data for specific types of activities</li> <li><input type="checkbox"/> Withdraw consent to use data for the purposes outlined in the consent document</li> </ul>
<input type="checkbox"/>	Personal Data will be transferred to the US and the United States does not protect personal data in the same way it is protected in the EU/EEA <input type="checkbox"/> N/A
<input type="checkbox"/>	Treatment decisions that could significantly affect a person will be based solely on personal data and the decision is automated. <input type="checkbox"/> N/A
<input type="checkbox"/>	Privacy Officer Contact <sup>4</sup> Information for questions, complaints or if the subject wants to make a request relating to the rights

<sup>3</sup> The following personal data is considered 'sensitive' and is subject to specific processing conditions: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs; trade-union membership; genetic data, biometric data processed solely to identify a human being, health-related data; data concerning a person's sex life or sexual orientation.

<sup>4</sup> For UC Davis, the Privacy Officer is Sharalyn Rasmussen at (916) 734-8808 or by email at [smreed@ucdavis.edu](mailto:smreed@ucdavis.edu)