UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

OIA-314B WORKSHEET: Requirements for Informed Consent

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

	1 Applicable Regulation (Check all that apply)
☐	The research must comply with the general requirements for informed consent.[1] ***(If checked, complete Sections 2 and 3)***
☐	The research is Food and Drug Administration (FDA)-regulated. ***(If checked, complete Sections 4 and 5***)
☐	The research is federally funded and subject to the 2018 Common Rule. ***(If checked, complete Sections 6 and 7)***
☐	The research will be conducted at UCSD and/or Rady Children's Hospital San Diego (RCHSD). ***(If checked, complete Section 8)***
☐	This research is subject to the General Data Protection Regulation (GDPR) because: ***(if one of the alternatives below is checked, the research is subject to the GDPR and Section 9 must be completed)*** ☐ The research is obtaining identifiable data[2] (personal data) directly from living individuals located in a state belonging to the European Union (EU) or the European Economic Area (EEA), or United Kingdom (UK).[3] ☐ A collaborator from the EU/EEA/UK is transmitting personal data of subjects located in the EU/EEA/UK to a researcher in the US. ☐ The sponsor is an organization established in the EU/EEA/UK and is subject to the GDPR.
	2 General Requirements (All must be checked)
☐	Consent will be obtained in a 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 that 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.
☐	How to contact the research team for questions, concerns, or complaints about the research.
☐	How to contact someone independent of the research team for questions, concerns, or complaints about the research; questions about the subjects' rights; to obtain information; or to offer input.
☐	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.
	3 Additional Elements of Consent (Check all that apply)
☐	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.
☐	The foreseeable circumstances and/or reasons under which the subject's participation in the research may be terminated.

[1] 45 CFR 46.116(a), (b), & (c)
[2] The GDPR considers coded data "identifiable," if there is a link between the code and the identity of the individual.
[3] 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, and Sweden are included in EU. Iceland, Liechtenstein and Norway are included in EEA. The United Kingdom (UK) follows the UK Data Protection Act.

☐	Whom to contact in the event of a research-related injury to the subject.
☐	The anticipated expenses, if any, to the subject for participating in the research.
☐	If subjects will be compensated for participation, a description of the prorated payment plan.
☐	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
☐	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.
☐	The approximate number of subjects involved in the study.
☐	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.
☐	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.
☐	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 http://www.ClinicalTrials.gov, 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."
☐	For research funded by National Institutes of Health (NIH), or if otherwise applicable, certificate of confidentiality statement.
☐	When using electronic consent, a clear statement of subject's rights with respect to the electronic document(s).
☐	For research that meets California's definition of medical experiment, the "Experimental Research Subject's Bill of Rights."
☐	For research conducted outside the US, disclosure of risks due to local context as applicable.
4	**Additional Requirements for FDA-regulated Research (Check all that apply)**
☐	A description of the probability for random assignment to each treatment, when applicable.
☐	A statement that the FDA may inspect the records.
☐	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.
☐	For studies in which partial withdrawal is an option, the main informed consent document must contain a statement that the investigator will ask a subject who is withdrawing whether the subject wishes to provide continued follow-up and data collection.[4]
5	**Additional Requirements for ICH E-6(R2) for FDA-regulated Research (Check all that apply)**
☐	The approval of the IRB.
☐	A description of the subject's responsibilities.
☐	The important potential benefits and risks of alternative procedures or courses of treatment.
☐	When there is no intended clinical benefit to the subject, a statement to this effect.
☐	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 legally authorized representative is authorizing such access.
☐	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)**
☐	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.
☐	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)**

[4] Consent for the continued follow-up and data collection must be documented on a consent document approved by the IRB. This additional document must allow the subject to clearly identify study components to which they continue to consent.

☐	When the research involves biospecimens, the following statements must be included: • 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. When study is conducted at UCSD or another UC, the Moore Clause can be used to meet this requirement. • 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).
☐	When the research involves any diagnostic procedures, the following statement must be included: • A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
☐	If identifiable private information or identifiable biospecimens are being collected, one of the following statements must be included: (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 (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.
8	**Additional Requirements for Research Conducted at UCSD and/or RCHSD *(All must be checked or marked NA)***
☐	Withdrawal of consent is not required to be delivered in writing
☐	HIPAA authorization language is not included in the consent except to state that subjects would need to sign a separate document to provide such authorization. ☐ N/A, HIPAA does not apply to study
☐	Protocol-mandated regimens, experimental drugs and devices are not referred to as "treatment" without qualification, e.g., qualify as "study treatment." ☐ N/A, study does not have any protocol-mandated regimens, drugs, or devices.
9	**Additional Requirements for Research Subject to the GDPR *(All must be checked or marked NA)***
☐	The consent includes language indicating that the subject's personal data will be collected or used to conduct the research.
☐	If sensitive personal data[5] are being collected or used, explicit consent is requested. ☐ N/A, sensitive personal data are not being collected or used.
☐	The duration for which personal data will be retained is included.
☐	The categories of recipients of the research subject's personal data are included.
☐	Information on how personal data will be protected is included.
☐	Notice of subjects' rights is included ☐ Right to access, correct or withdraw personal data ☐ Right to restrict the types of activities the research team can do with the data ☐ Object to using data for specific types of activities ☐ Withdraw consent to use data for the purposes outlined in the consent document
☐	Personal data will be transferred to the US and the US does not protect personal data in the same way it is protected in the EU/EEA/UK ☐ N/A, personal data from the EU/EEA/UK is not being transferred to the US.
☐	Treatment decisions that could significantly affect a person will be based solely on personal data and the decision is automated. ☐ N/A, treatment decisions (e.g. randomization) are not automated or would not significantly affect a person.
☐	Privacy Officer Contact[6] Information for questions, complaints or if the subject wants to make a request relating to their rights.

[5] 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.

[6] For UCSD Health, the Privacy Officer is Ron Skillens who can be contacted at (858) 657-7487 or by email at hscomply@health.ucsd.edu. UCSD website: Contact Us (ucsd.edu). For UCSD Campus, the Privacy Officer is Pegah Parsi who can be contacted at (858) 822-4439 or by email at pparsi@ucsd.edu. Website: Contact (ucsd.edu). For Rady Children's Hospital San Diego, the Privacy Officer is Christina Galbo who can be contacted at (858) 966-8541.