

## Informed Consent Required Elements

*(Please refer to DHS HHS OHRP 45 CFR 46, Subpart A; “The Common Rule” “2018 Requirements” for details)*

Except as provided in paragraph “c” of 45 CFR 46.117, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject’s legally authorized representative. A copy shall be given to the person signing the form.

<b>Basic Required Elements of Informed Consent</b> <i>(new elements of 2018 in bold)</i>	Citation
A statement that the study involves research	_ .116 (b)(1)
An explanation of the purposes of the research	
The expected duration of the subject’s participation	
A description of the procedures which are to be followed	
Identification of any procedures which are experimental	
A description of any reasonably foreseeable risks or discomforts to the subject	_ .116 (b)(2)
A description of any benefits to the subject or to others which may reasonably be expected from the research	_ .116 (b)(3)
A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	_ .116 (b)(4)
Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and what records may be examined by the research staff, IRBs, sponsor, their representatives, and possibly the FDA or OHRP.	_ .116 (b)(5)
For research involving more than minimal risk, a statement that emergency medical care will be arranged for a study-related illness or injury, and an explanation of whether funds are set aside to pay for this care and/or compensation, and if so by whom (e.g., sponsor, subject, insurer). Language must not be exculpatory.	_ .116 (b)(6)
Identification of whom to contact (a) on research team with questions, concerns, complaints or about a research-related injury; and (b) at the IRB for same issues and information about research subjects' rights.	_ .116 (b)(7)
A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.	_ .116 (b)(8)
<ul style="list-style-type: none"> <li>• <b>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 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; OR</b></li> <li>• <b>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</b></li> </ul>	_ .116 (b)(9) (i) and (ii)
Identification of funding source(s)	IRB requirement
<b>Additional Elements as Appropriate</b>	
A statement that the particular treatment or procedure may involve risks to the subject (or the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable	_ .116 (c)(1)
Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent	_ .116 (c)(2)
Any additional costs to the subject that may result from participation in the research	_ .116 (c)(3)
The consequences of a subject’s decision to withdraw from the research and procedures for orderly termination of participation by the subject	_ .116 (c)(4)
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	_ .116 (c)(5)
The approximate number of subjects involved in the study	_ .116 (c)(6)

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.	_.116 (c)(7)
A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and	_.116 (c)(8)
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)	_.116 (c)(9)
If monetary payment will be given, a statement informing the participant that their personal information (name, address, and social security number) will be collected for tax purposes and will be reported to the IRS if they receive over \$600 in one year from Emory.	IRB requirement
All information concerning payment, including the amount and schedule of payments	IRB requirement

Additional IRB Requirements

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In the case of minors (< 18yrs), the assent form is worded in age-appropriate reading level of the youngest subject in the age range and use simple terminology
A signature line for the subject, date of signature, printed name of the subject
A signature line for the principle investigator and date of signature
A witness' signature line

**Waiver of Requirement for Signed Consent Form**

The IRB may waive the requirement for the investigator to obtain a signed consent for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the principle risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern

**Or**

2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures, for which written informed consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.