

**Investigator Self-Evaluation Checklist**

Compliance with the revised Common Rule:

Changes to informed consent

*Use this checklist to determine if changes are needed to your currently approved informed consent documents to comply with the forthcoming changes to the Common Rule. If you have any questions about this form or the applicability of the revised Common Rule to your study, please contact the HRPP.*

**Key Information/Informed Consent**

**(mandatory for all consent documents, effective 10/4/18)**

Key Information[46.116(a)(5)(i)][[1]](#footnote-1) **Studies that are actively enrolling participants must update all study consent/assent documents to include Key Information. The HRPP has developed** [**consent templates and guidance documents**](https://www.brown.edu/research/conducting-research-brown/research-compliance-irb-iacuc-coi-export-control/irb/forms-and-policies#Consents) **to assist with this process.**

**Please evaluate whether the following applies to ALL of your current consent/assent documents:**

The IRB approved consent form includes the Key Information in the required format:  **No action**

Study procedures are conducted under a waiver of informed consent:  **No action**

Enrollment completed:  **No action**

Consent form is not consistent with the Key Information elements and/or required format:  **Modify\***

*\*If you need to modify your consent documents to comply with this new regulation only (i.e. none of the “Other Informed Consent Changes” below apply) please contact* [*Christiana Provencal*](mailto:christiana_provencal@brown.edu) *for further assistance with processing an abbreviated amendment submission.*

PLEASE NOTE: If your research study involves any of the activities in the chart below, you must submit a protocol amendment to revise your consent form(s) to include the relevant, required information. These changes will be reviewed in the order received; however, we will hold issuance of approval for these changes until January 21, 2019, as they cannot be implemented until that time.

**Other Informed Consent Changes**

**(when applicable, effective 1/21/19)**

Y

| **Does the project involve:** | **If Yes:, the consent from must include:**  (Please refer to the next page for sample language and suggested placement of the relevant information within the consent form.) |
| --- | --- |
| **The collection of identifiable private information or identifiable biospecimens?**  No  no action  Yes  see next column 🡪 amendment required | * A statement indicating if identifiers may be removed at some point during the study, and * If de-identified information or biospecimens, a statement indicating whether they will or will not be used or shared for future research |
| **Use of biospecimens (whether identifiable or not)?**    No  no action  Yes  see next column 🡪 amendment required | A statement indicating whether:   * Biospecimens may be used for commercial profit, and * The subject will share in that profit |
| **Clinically relevant results**  No  no action  Yes  see next column 🡪 amendment required | * A statement indicating whether the clinical results, including individual research results, will be returned to the subject, and if so, under what conditions |
| **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)  No  no action  Yes  see next column 🡪 amendment required | * A statement indicating that the research will or might include whole genome sequencing |

**SAMPLE LANGUAGE**

**A statement indicating if identifiers may be removed at some point during the study**

**Suggested section placement**: “Confidentiality” or “How will my information be protected?”

**Example**: *We will keep the information we collect about you during the research, including your [type of biospecimen] and information we learn from analyzing your [type of biospecimen]], [for future research projects/for study recordkeeping or other purposes (*describe*)]. Your name and other information that can directly identify you will be stored securely and separately from the research information we collected from you.*

**or**

**Example**: *We will not keep your name or other information that can identify you directly.*

**A statement indicating to subjects whether their data may be stored and shared for future research, even if de-identified**

**Suggested section placement**: “Confidentiality” or “How will my information be protected?”

If ***Deidentified*** Example:

*We may use or share your research information [and/or type of biospecimen] for future research studies, but it will be deidentified, which means that it will not contain your name or other information that can directly identify you. This research may be similar to this study or completely different. We will not ask for your additional informed consent for these studies. We may also share your deidentified information and [type of biospecimen] with other researchers here, at other institutions in the United States or around the world.*

If **not deidentified** Example(and you plan to retain and share identifiable information and biospecimens for unspecified future research):

*We will ask your permission to use or share some of your identifiable information or [type of biospecimen] with other researchers. The research may be similar to this study or completely different. These researchers may be here, at other institutions in the United States or around the world. You can be part of this current research project without agreeing to this future use of your information and [type of biospecimen].*

**A statement indicating that the research will or might include whole genome sequencing.**

**Suggested section placement**: “The Project” or “What is this the study about?”

**Example:** *This research will (or might) include whole genome sequencing.*

**A statement indicating if the biospecimens that are collected as part of the project could be used or shared with other entities for commercial profit and if the subject will share in that profit**

**Suggested section placement**: “The Project” or “What is this the study about?”

**Example**: *Biospecimens collected from you for this research may be used to develop new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially profit from the use of the data, biospecimens or discoveries from this research. You will not have rights to these discoveries or benefit financially from them.*

**A statement indicating if whether clinically relevant research results, including individual research results will be disclosed to subjects, and if so under what conditions.**

**Suggested section placement**: “Procedures” or “What will be done?”

If clinically relevant results **will be returned to participants** Example:

*We may learn things about your health as part of the research. If this happens, this information will be provided to you. [Insert a description of the types of research results that may be returned, under what circumstances subjects will be provided research results, and how subjects will be notified.]* *You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.*

**or**

If clinically relevant results will **not be returned** Example:

*We may learn things about your health as part of the research, however we will not share this information with you because [describe rationale].*

1. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative 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, and provide sufficient information that a “reasonable person” would want to have. 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. [↑](#footnote-ref-1)