

April 09, 2015

Subject: Revised IRB Forms – Apr 09, 2015

In an effort to keep the research community informed of new and revised Office of Human Research (OHR) policies and forms, a summary of recent changes is being provided. Please remember to always access the most current policies and forms on the [Division of Human Subjects Protection page](#) of the OHR website.

Thank you

The Office of Human Research

## Forms

Number	Title	Version
OHR-1	Proposal Transmittal and Approval Form	04/09/15
Changes: Added section name/numbers (formatting).		

Number	Title	Version
OHR-2	Summary of Interventional Human Subjects Research	04/09/15
Changes: Data confidentiality section modified to indicate that external monitors will only be given access to subjects' medical records as specified in the signed consent form.		

Number	Title	Version
OHR-3	Request for Waiver of Subject Authorization to Collect Protected Health Information	04/09/15
Changes: Clarification that all data that will be collected for the study should be reported in the response to question 1. Updated the data confidentiality section to match the OHR-2.		

Number	Title	Version
OHR-8	Informed Consent Document for Human Subjects Research	04/09/15
Changes: Signature page now includes lines for the printed name of all signatories. The subject's initials and date are no longer required on each page of the consent form. Information on what the subject should do in case of an emergency has been added.		

Number	Title	Version
OHR-8A	Informed Consent – Blood Draw	04/09/15
Changes: Signature page now includes lines for the printed name of all signatories. The subject's initials and date are no longer required on each page of the consent form. Information on what the subject should do in case of an emergency has been added.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-8B</b>	<b>Surrogate Consent for a Research Protocol</b>	<b>04/09/15</b>
Changes: Signature page now includes lines for the printed name of all signatories.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-8D</b>	<b>Addendum to Consent Form</b>	<b>04/09/15</b>
Changes: Signature page now includes lines for the printed name of all signatories. Information on what the subject should do in case of an emergency has been added.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-8K</b>	<b>Informed Consent Document for Human Subjects Research - CIRB</b>	<b>04/09/15</b>
Changes: Signature page now includes lines for the printed name of all signatories. The subject's initials and date are no longer required on each page of the consent form. Information on what the subject should do in case of an emergency has been added.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-9</b>	<b>Continuing or Final Review of Research Protocols Involving Human Subjects</b>	<b>04/09/15</b>
Changes: Due to the change described for the OHR-12B below, a list of investigator additions/removals has been added to this form.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-12</b>	<b>Amendment to Research Protocol</b>	<b>04/09/15</b>
Changes: The requirement for a revised consent form as described for the OHR-12B below has been removed from this form.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-12B</b>	<b>Adding Study Personnel</b>	<b>04/09/15</b>
Changes: When investigators are added and removed, the OHR-12B and OHR-12C must be submitted to the IRB. However, if the addition/removal of investigator is the only change, a revised consent form does not have to be submitted with the OHR-12B and OHR-12C. The addition/removal of investigators will be made to the consent form with the next required consent amendment or continuing review, whichever comes first. The requirement for a revised consent has been removed from this form.		

<b>Number</b>	<b>Title</b>	<b>Version</b>
<b>OHR-12C</b>	<b>Removing Study Personnel</b>	<b>04/09/15</b>
Changes: The requirement for a revised consent form as described for the OHR-12B above has been removed from this form.		

If you have any questions or comments about these changes, please contact [patrick.herbison@jefferson.edu](mailto:patrick.herbison@jefferson.edu) .