

Forms

The following sections (located in the menu below) will assist researchers by providing various tools and resources.

The IRB uses an electronic IRB submission system referred to as RSS. Never used the system before? Check the RSS Training section to learn more.

The IRB's Policy & Procedures Manual is available in UNMC Guides - <https://guides.unmc.edu/books/hrpp-policies-and-procedures>

- [Existing paper protocols](#)
- [FWAs - Federal Wide Assurance](#)
- [Miscellaneous](#)
- [Recruitment templates](#)
- [Short Forms](#)
- [Subject's rights & responsibilities](#)

Existing paper protocols

NOTE: THE PAPER FORMS ON THIS PAGE ARE ONLY TO BE USED FOR STUDIES THAT HAVE NOT BEEN TRANSFERRED TO THE ELECTRONIC SYSTEM (I.E. THEY ARE STILL IN PAPER FORMAT).

FORMS FOR EXISTING PAPER PROTOCOLS ONLY

Title	Version	Format
1. CR Biomedical Research	06/13/2022	Word
2. CR Social and Behavioral Research	06/13/2022	Word
3. CR Human Biological Materials	06/13/2022	Word
4. Study Completion Report	07/27/2010	Word
5. Request for Change in Protocol (<i>Depending on the nature of the change completion of a protocol addendum may be required. Please contact the ORA for details.</i>)	03/10/2014	Word
6. Request for Change* (Ads, Educational Items and Personnel Only)	05/14/2013	Word
7. Additional Personnel Change Form Pages (if more than four spaces needed)	08/17/2010	Word
8. P&T Drug Registry Form	04/14/2022	Word

FWAs - Federal Wide Assurance

The UNMC IRB Federal Wide Assurance documents can be found here:

Adult IRB Roster (FWA00002939)

Pediatric IRB Roster (FWA00002939)

Miscellaneous

Title	Version	Format
Investigator Assessment Checklist for Regulatory Documentation	9/17/2007	<u>Word</u>
Investigator Assessment of IRB	9/7/2007	<u>Word</u>

Recruitment templates

HRPP policy to review: [#3.5 Subject Recruitment Through Advertisements](#)

Recruitment Type	Format
Flier - full page	<u>Word</u>
Ad - one column	<u>Word</u>
Ad - two column	<u>Word</u>
Ad - six inch	<u>Word</u>

Short Forms

A Short Form may be used when a subject/LAR who cannot understand English is unexpectedly encountered, there is not sufficient time to develop and obtain IRB approval for a complete ICF written in language understandable to the subject/LAR, AND the research presents the prospect of direct therapeutic benefit to the subject.

Use of the Short Form is limited to enrollment of no more than three subjects per language in a given protocol. In order to enroll more than three subjects, the PI is required to have the complete ICF translated into the appropriate language and reviewed and approved by the IRB.

The investigator must complete a Short Form Request (available in RSS) for each subject, and submit to the ORA. Each request must be approved before the Short Form may be used.

Depending on the nature and duration of the research, the IRB may determine that the English version of the complete ICF must be translated into a language understandable to the subject and a copy given to the subject as soon as possible after enrollment. In general, this may be required for studies which are significant risk and of long duration.

Please refer to [HRPP Policy 5.5](#) (Use of the Short Form Consent Document) for detailed instructions.

English translations of these short forms is included at the bottom of the page. Translated Short Forms generously supplied by Office of Human Subjects Research - Johns Hopkins Medicine and the University of Utah. (Key: * - Johns Hopkins University; # - The University of Utah)

Short Forms

[Albanian Short Form](#) *

[Arabic Short Form](#) *

[Bulgarian Short Form](#) *

Burmese Short Form *

Cantonese Short Form *

Chinese Short Form *

English Translation *

Farsi Short Form *

French Short Form *

Greek Short Form *

Gujarati Short Form *

Haitian Creole Short Form *

Hebrew Short Form *

Hindi Short Form *

Hmong Short Form *

Hungarian Short Form *

Italian Short Form *

Japanese Short Form *

Karen Short Form (LLS)

- Karen Certificate of Translation

Korean Short Form *

Lao Short Form *

Luganda Short Form *

Mandarin Short Form *

Nepali Short Form *

Polish Short Form *

Portuguese Short Form *

Romanian Short Form *

Russian Short Form *

Swahili Short Form *

Spanish Short Form *

Thai Short Form *

Ukrainian Short Form *

Urdu Short Form *

Vietnamese Short Form *

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Subject's rights & responsibilities

Research Questions:

[Amheric - Research Questions & Rights and Responsibilities](#)

[English \(UNMC\)](#)

[English \(UNO\)](#)

[Spanish \(UNMC\)](#)

[Spanish \(UNO\)](#)

Rights of Research Subjects:

[English](#)

[English \(CHMC\)](#)

[French](#)

[Somali](#)

[Spanish](#)

Rights and What to know:

[French](#)

Karen

Interpretation Certificates:

Certificate 1

Certificate 2