Quick Reference for New Protocol Submissions

Why New Protocol Submissions Are Returned

The primary reasons why new protocol submissions are returned is that certain documents are not submitted, submitted documents are incomplete (i.e. missing required signatures), or incorrect form versions are used.

We are often forced to return submissions due to inconsistencies between documents. For example: the title on consent is not identical to title elsewhere, the protocol version/date differ between the consent and the protocol document, or the individuals listed as Co-Investigators on the Consent differ from those for whom Statements of Co-Investigators were submitted.

OHRS Website Resources and Information Sheets

Additional info sheets are available on the OHRS Website.

- OHRS Submit Guidance
- Determining if a Project Is Human Subject Research
- Review Process for New Adult Clinical Trials
- Common Issues Holding Up Protocol Reviews
- Guidance on Completing the Protocol Front Sheet
- Guidance on Completing Endorsement Forms
- Guidance on Priority List
- Guidance on Alert Pages
- Guidance on Completing the Radiation Safety Screening Form
- Guidelines for Writing A Specimen/Data Collection and Banking Research Protocol
- Guidelines for Writing A Social/Behavioral Science Research Protocol
- Guidance on PDF Files and Electronic Signatures

Protocol Formatting Guidelines

These guidelines apply to protocols initiated by DF/HCC Investigators.
For national trials initiated by other sponsors, protocols may be submitted as originally formatted and in PDF format.

Font	Times New Roman, 12 pt.
Margins	Left/Right – Minimum 0.5 inches Top/Bottom – Minimum 0.4 inches for the header and footer
Pagination	Pages must be numbered, centered at the bottom of the page.
Table of Contents and Appendixes	Please include a Table of Contents and include supplemental documentation (instruments, recruitment materials etc as appendices to the protocol.
Version Number and Date	Please include protocol version number and protocol date on the front page of the protocol document.

Forms: Current Versions, Accepted Formats, and Signature Requirements

Form requirements vary depending on the specifics of the project proposed. For further guidance, please consult the **New Application Submission Checklist** found at the bottom of each New Project Application.

	Current Version	Signatures Required
Endorsement Form *(Please refer to "Guidance on Completing the Endorsement Form" for more information on signature requirements).*	08.16.2017a	1. Biostatistician 2. Disease Program Leader 3. Conflicts of Interest Official, if applicable
Research Funding Form	09.23.2016	1. Overall DF/HCC Principal Investigator
New Project Application: Clinical Trials	10.02.2017	1. Disease Program Leader 2. Overall DF/HCC Principal Investigator
New Project Application: Non-Clinical Research	10.02.2017	1. Disease Program Leader 2. Overall DF/HCC Principal Investigator
New Project Application: Non-Human Subjects Research Determination	10.02.2017	1. Overall DF/HCC Principal Investigator
New Project Application – Single IRB	10.02.2017	1. Disease Program Leader 2. Overall DF/HCC Principal Investigator
New Project Application for Off-site Research	9.23.2016	1. Overall DF/HCC Principal Investigator
Statement of Principal Investigator or Statement of Site-Responsible PI	9.23.2016	1. Principal Investigator or Site-Responsible PI, as applicable
Statement of Co-Investigator	9.23.2016	1. Co-Investigator 2. Principal Investigator
Research Team Update Form	05.15.2017	1. Principal Investigator
Research Nursing/Pharmacy Protocol Screening Form	05.15.2017	None
Radiation Safety Screening Protocol Form	04.10.2015	1. Principal Investigator
Protocol Document	n/a	None
Consent Form for Biomedical Research	10.02.2017	None
Consent Form for Social / Behavioral Research	10.02.2017	None
Continued Participation in a Research Study by a Young Adult who has Reached Age 18	09.10.2008	None
Consent Form for Pregnant Partner	10.02.2017	None
Request for Waiver or Alteration to Use or Disclose of Protected Health Information in Research	07.01.2013	1. Principal Investigator
Alert Page	05.15.2017	None
BIDMC Confirmation of Investigator Resources and Proficiency	N/A	1. CCTO Director 2. CCTO Medical Director or Oversight Committee Chair

Beginning Monday, November 9, 2017, only the versions of the forms listed in this chart will be accepted.