



# STATEMENT OF PRACTICE

## IRBMED Finalization of Study Documents

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*Effective: 02-12-2020*

### **I. STATEMENT OF PRACTICE**

IRBs are expected to review all the research documents and activities that bear directly on the rights and welfare of the subjects of the proposed research. This includes consent documents and processes, as well as the methods and materials that investigators propose to use to recruit subjects. These are evaluated before initial IRB approval and as part of continuing review, as applicable.

IRBMED finalizes the informed consent documents and the recruitment documents uploaded in IRB application with an approval date and, if applicable, an expiration date. The study team may add HUM numbers to other subject facing documents. The study team should add HUM# and U-M PI contact information to Emergency cards, unless sponsor formatting requirements prohibit this.

Although other study-related documents (such as the protocol, survey instruments, and other supporting materials) are part of the IRB review, IRBMED does not finalize them. However, per the study team request, these documents can be referenced in the “Supporting Documents” section of the IRB approval letter (in initial applications and amendments fill out 44.2 of the IRB application). When finalizing consent documents and recruitment materials, the finalize “Approval Date” is assigned in accordance with the date that the application was either “Approved” or “Approved with Contingencies.” This determination is made by the Board or by an Expedited Reviewer.

#### **A. New Study Applications:**

For new study IRB applications that are approved with contingencies, study activities may not begin until all outstanding contingencies have been met and verified with the IRBMED. Once verified, IRBMED will issue the IRB approval letter. At that time, informed consent documents and recruitment materials will be finalized (when possible).

For new study IRB applications that are approved with no contingencies, consent documents and recruitment materials will be finalized (when possible) after issuing the IRB approval letter.

Finalized documents are available under the “Documents” tab of the main work-space of the IRB application.

*Note: Currently, IRBMED electronic system does not support the finalizing of certain types of documents (such as PowerPoint presentations, JPG files, videos, etc.). This mostly occurs with the recruitment documents. For these types of documents, the study teams should indicate the IRB application (HUM) number within the body of the document.*

#### **B. Scheduled Continuing Review or Amendment Applications**

At the time of scheduled continuing review (SCR) or Amendments, approval dates (and, if applicable, expiration dates) are updated for all relevant documents. Study team members should continue utilizing



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the most recently approved informed consent documents and recruitment materials until the new/updated documents and materials are issued.

After subject recruitment permanently ends at U-M, recruitment materials are no longer in use and therefore, they will not be finalized. Similarly, informed consent documents will not be finalized after study interaction/intervention ends at U-M.

### C. Exceptions

Contact IRBMED for guidance related to any exceptions: (I) In the event that the study team makes an administrative error regarding the status of the study. (II) If there is a situation where the above process does not address the specific need of the study team.

#### Example(s):

1. A general example of IRBMED finalize:

Study ID: HUM00012345    IRB: IRBMED    Date Approved: 6/27/2017    Expiration Date: 6/26/2018

2. A screenshot of “Documents” functionality where approved documents are located:

The screenshot shows the IRBMED web application interface. The top navigation bar includes 'Path >>', 'My Home', 'Committees', 'Human Subjects Studies' (selected), 'Biosafety / IBC', 'Repositories', and 'Reports'. The main content area is titled 'TITLE OF THE STUDY' and 'Study Team'. The 'Documents' tab is circled in the navigation menu. Below the navigation, the page displays 'APPROVED DOCUMENTS' and a table of finalized documents.

Finalized Documents:	
name	version
Informed Consent - Clean - [REDACTED]	0.03
Recruitment Phone Script.docx.pdf	0.03
XX-Do Not Use_Consent [REDACTED]	0.03