#### **Expectations of the IRB Application Process**

At times the IRB application is a time consuming process. This is mostly because the application is ill written, the research topic needs the full IRB committee to review, attachments are missing or not in order. The purpose of this document is for the applicant to understand what is expected so that application is quickly reviewed and research can start. We hope this document will be useful for you as you work on an IRB application.

# **Draft IRB Application**

Development of the IRB application should occur outside of the IRB Application online system. The IRB Application online system <u>is not a workspace to prepare drafts</u> of the application. Drafting in an editable document will allow the researcher and faculty advisor the ability to more efficiently review, comment, and edit. If desired, the researcher and faculty advisor may use the "<u>Working Draft Template for IRB</u> <u>Application</u>" for working out the details of the application.

## Submit Application and Documents for Review

Once the draft is complete and reviewed by your faculty advisor, the application can be input to the online IRB application system. For attachments, each section is limited to a single PDF document (e.g., one PDF for all CITI training completion reports, one PDF for consent and recruitment, one PDF for the research instrument). <u>Double check</u> all sections of the IRB application online have been completed before certifying and sending to your faculty advisor.

## **IRB Review**

Once an IRB application is submitted and approved by your faculty advisor, the review period for an IRB application may span from approximately 2 weeks to greater than 2 months depending on variables such as level of risk and/or if subjects are members of a vulnerable population. To improve application review timeframe, researchers should make use of RMU IRB guidance materials such as: Policy and Procedures, Informed Consent Guidelines, Applicant Checklists. Submitting incomplete applications will extend the overall review period.

The initial IRB review period begins after the faculty advisor approves the application and for most applications will span up to 15 days (vulnerable populations and/or greater than minimal risk will take longer). RMU's IRB committee is comprised of knowledgeable faculty and external members that are experienced in research and the protection of human subjects. Feedback from the committee is valuable and should be welcomed. IRB feedback may include:

- "Comments" that must be addressed; and/or
- "Suggestions" that could improve your project but are not necessarily required to be addressed for the purposes of IRB approval.

If the IRB has feedback on the application, it will be emailed to the researcher/faculty advisor and the application will be renewed to incorporate requested changes. *Do not make other changes to your application beyond those relating to IRB comments/suggestions.* It is requested that a re-submitted application is accompanied by an email summarizing changes. Emailing the IRB a red-line version of documents or sections that were changed is also helpful.

#### **Expectations of the IRB Application Process**

From the date that a revised application is approved by your faculty advisor, the second round of IRB review is expected to take approximately 7 days (vulnerable populations and/or greater than minimal risk will take longer). If additional comments from the IRB, the application may again be renewed for revision/resubmittal.

When an application has been approved by the IRB, the researcher will receive a finalization email that must be maintained with research records.

Any proposed changes to an approved IRB application must be emailed <u>irb@rmu.edu</u> as an addendum request and be reviewed by the IRB. When an addendum request has been approved by the IRB, the researcher will receive an approval letter via email that must be maintained with research records.

#### **IRB Application Process and Resources**



- IRB Main Page | Robert Morris University (rmu.edu)
- <u>Working Draft Template for IRB Application</u> Note this link is to an optional Google Doc. For security, take care to only share the working draft document with your faculty advisor. The form may also be downloaded to a Microsoft Word document; however, checkbox functionality will be lost.)