



Institutional Review Board

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UMD Kuali-IRB: Guide to Requesting a 118 Letter

Human Research Protection Office

Version 1.0

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Purpose

The purpose of this guide is to provide instructions on how to request a 118 Letter from the IRB Office.

The 118 Letter

The "118 Letter" is a memo from the IRB Office that your protocol is under review, but has not yet been fully developed. This will allow NSF to release your funds while you finalize your IRB submission materials.

Sometimes investigators require IRB approval in order to submit an NSF proposal. Most researchers will request a 118 letter from the IRB for their proposal. Once they receive the grant funding, they will submit the IRB initial application. For your reference, a description of 118 letters is below and can be found [here](#):

45CFR46.118 - Applications and proposals lacking definite plans for involvement of human subjects

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior



animal studies, or purification of compounds. Except for research waived under [**§46.101\(i\)**](#) or exempted under [**§46.104**](#), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the Federal department or agency component supporting the research.

In short, the regulations allow you to secure your grant funding now, even if your specific plans for human research aren't finalized yet. This applies to projects where you know you will work with humans eventually, but the specific details (like surveys or recruitment plans) are still being developed.

Requesting a 118 Letter

Who Can Submit a Request for a 118 Letter?

118 Letter requests **MUST** be created and submitted by the Principal Investigator. The IRB Office will **not** accept submissions from other research team members and the submission will be withdrawn.

Creating + Submitting the Request

1. Navigate to Kuali-IRB

Link to Kuali-IRB: <https://go.umd.edu/kuali-irb>. Use your **UMD credentials + Duo Mobile** to log in. Select UMD - College Park, if prompted, NOT UMaryland Baltimore. Click on "IRB" to access the Kuali-IRB Platform.

2. Create a new IRB Application Form

When you click on IRB on the Kuali Dashboard, you will see the screen below, which is called the **Document List**:

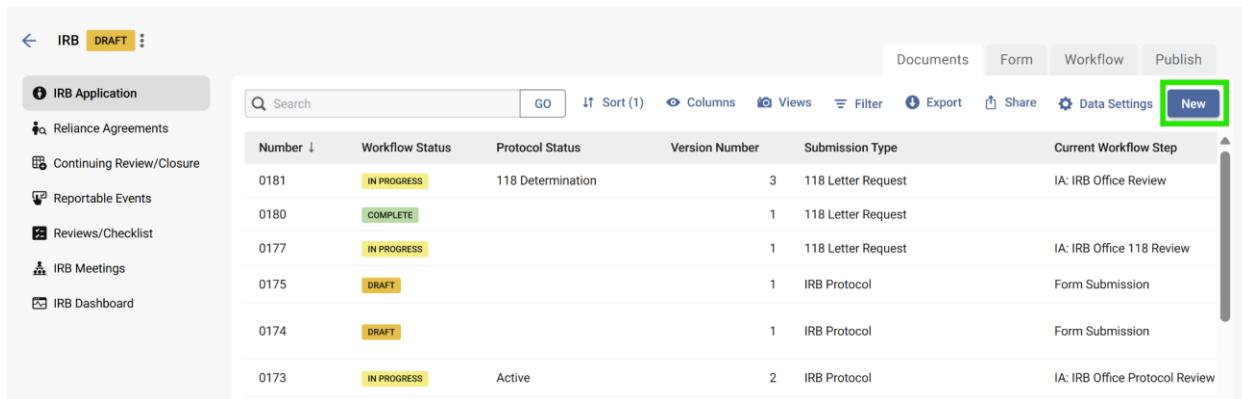
The screenshot shows the Kuali-IRB platform's 'Document List' interface. On the left, a sidebar is highlighted with a purple border. It contains several links: 'IRB Application', 'Reliance Agreements', 'Continuing Review/Closure', 'Reportable Events', 'Reviews/Checklist', 'IRB Meetings', and 'IRB Dashboard'. The main content area is titled 'No Records' and contains the text: 'This is where data will appear when people fill out your form.' Below this text are two buttons: 'Data Settings' and 'Fill out the form'. A cartoon character of a person sitting at a desk is positioned next to these buttons, pointing towards the 'Fill out the form' button.



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On the left-hand side (purple rectangle), you will see a list of the **IRB Forms**. Each form will open a View with a list of the Draft, In-Progress, and Complete submissions. **If this is your first submission, you will not see anything on this page (see image above).** To begin a new form, click “Fill out the form” (orange rectangle). This will open a new draft of the form.

Once you have drafted your first form in the IRB Application space, you will see a view similar to the one below. If you want to create a new form, the button to create a new form is in the top right-hand corner (green rectangle) “New”.

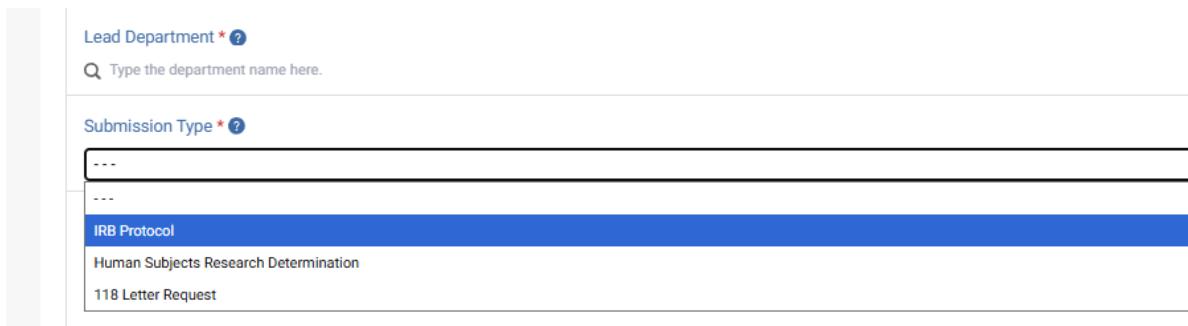


The screenshot shows the IRB Application interface. On the left, there's a sidebar with links: IRB Application (selected), Reliance Agreements, Continuing Review/Closure, Reportable Events, Reviews/Checklist, IRB Meetings, and IRB Dashboard. The main area is a table with columns: Number, Workflow Status, Protocol Status, Version Number, Submission Type, and Current Workflow Step. The table contains the following data:

Number	Workflow Status	Protocol Status	Version Number	Submission Type	Current Workflow Step
0181	IN PROGRESS	118 Determination	3	118 Letter Request	IA: IRB Office Review
0180	COMPLETE		1	118 Letter Request	
0177	IN PROGRESS		1	118 Letter Request	IA: IRB Office 118 Review
0175	DRAFT		1	IRB Protocol	Form Submission
0174	DRAFT		1	IRB Protocol	Form Submission
0173	IN PROGRESS	Active	2	IRB Protocol	IA: IRB Office Protocol Review

3. Complete the Form

Once the new IRB Application form is open, you must indicate this is a 118 Letter Request submission (as opposed to a Human Subjects Research Determination or an IRB Protocol for review) by answering the ‘Submission Type’ question on the first page with ‘118 Letter Request’.



The screenshot shows the 'Submission Type' question on the form. The question is 'Submission Type * ?'. Below it is a list of options in a dropdown menu. The '118 Letter Request' option is highlighted with a blue box. Other options visible are 'Human Subjects Research Determination' and 'IRB Protocol'.

Answer the questions on the form as they apply to the project. Guidance is available as description text and will appear when hovering over the  help text.



4. Submit the Form

Once you have completed the form, click "Submit" in the upper right corner of the page. This will send the form to the IRB Office for review.

For a visual demonstration of how to request a 118 letter, please view this Scribe:

https://scribehow.com/viewer/How_to_Request_a_118_Letter_on_Kuali_IRB_joeSPtHZTwCoh7aLNy90w

Addressing IRB Office Modifications

If the IRB Office requires modifications to the form prior to processing the 118 Letter, an email notification will be sent to the Principal Investigator that the submission requires modifications. The PI can click on the "View Task" button in the email to open the submission and begin editing. This task will also appear in their Kuali "Action List" with the workflow step: "IA: Modifications Required - IRB Office".

Once the modifications are complete, click "Mark Complete" in the upper-right-hand corner. You will have the option to leave a comment for the reviewer there.

NOTE: You cannot make edits to an application when it is opened via the Document List.

Should the IRB Office have additional modifications, the form will be sent back to the PI again.

Receiving the 118 Letter

Once the IRB Office processes the form, the Principal Investigator will receive an email from Kuali. The email notification serves as the 118 Letter.

Researchers may also find the 118 Letter on Kuali IRB. Here is a Scribe on how to find a Determination Letter in Kuali. In this case, look for an Email Sent with the note 'IA: 118 Letter'.
https://scribehow.com/viewer/How_to_find_a_Kuali-IRB_Approval_Letter_wSUVSItLRcyy0_wRhRO1A

Requesting an Extension

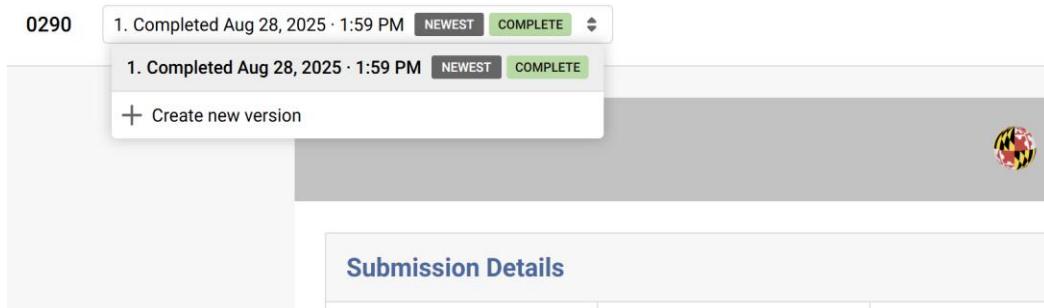
118 Letters are only valid for one year. If researchers need another year to develop the research protocol, they may request an extension of the 118 Letter. Please work with your ORA Administrator to ensure that this is an appropriate plan for your award.

To request an extension, researchers must create a new version of the existing 118 Letter.



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Step 1: To create a new version in Kuali, locate the IRB Application you wish to amend, open it, then find the Version Dropdown in the upper left-hand corner and select “+Create New Version”.



Note: Only the Principal Investigator has the ability to do this.

After clicking “Create New Version,” a new draft of the IRB Application will be created. Some fields may be retained from the last version and others may need to be addressed in each version.

Step 2: In the new version, a new **118 Letter Renewal** section will appear. Complete the entirety of the application form.

Step 3: Submit the IRB Application for review.

Step 4: The IRB Office will review the submission. If modifications are needed to the submission, the PI will receive an email from Kuali IRB to make the necessary changes.

Step 5: Once the IRB Review is complete, the PI will receive a notification of the renewed 118 Letter.