Submitting a 118 Determination Request

Background
Anticipated research involving human subjects is often outlined in funding proposals. Some funders request a formalized IRB acknowledgment at this stage while researcher’s activities are still considered preparatory to research. Since the details are not yet developed or defined, researchers are unable to receive an IRB approval and can, instead, request a 118 Determination. ‘118’ is a reference to the specific regulatory entry outlining this situation.

A 118 determination request results in a formal determination memo acknowledging that research involving human subjects is anticipated, and that the researcher and the IRB are both informed. When research activities are fully drafted, 118 submissions in Kuali must be amended for consideration as a human subjects research protocol submission before any research with human subjects can begin.

1) Log into Kuali Protocols.
   How do I do that?

   Follow the link in a Kuali notification email OR
   • Log into Kuali Protocols using your CSU eID and password
   • Click the Protocols tile
   • Choose Meetings & Agendas menu option

2) Choose New Protocol in the top right-hand corner.

3) Enter basic project details and click Next.
   • Choose the Principal Investigator using the smart lookup field. Begin typing the PI’s name and wait for options to appear. Click on the correct one.
   Tip: If you have trouble finding the correct person, try typing their CSU email username. For example, claire.chance
Choose the Lead Unit using the smart lookup field. Begin typing the unit name or unit number and wait for options to appear. Click on the correct one.

Type the title of the project.

*Note: If this is associated with a funding proposal, please use the same title.*

4) Choose the 118 Determination application type.
5) Enter the basic details about dates and funding.

- **Tip:** When using the calendar lookup tool, you can click directly on the year to pull up the year dropdown or back on the date to bring up the months.
6) Click “Next,” to bring up the rest of the application.

7) Add additional personnel, if applicable, by clicking on Add Line.

8) In the resulting pop-up, enter the relevant information for additional personnel.
   Notes:
   - There are options for Researcher Roles and Contact Roles. Only one role needs to be selected, but multiple are allowed. This is up to you based on the individual's involvement.
   - You will also designate the individual's level of access to the protocol submission as Full Access (able to view and edit) or Read-Only.

9) Provide brief descriptions of the project summary, purpose and background.
   This information can be copy/paste from the proposal if you’d like. You can also include just a few sentences in each section to address the questions.
10) Provide basic information on the anticipated procedures by clicking Add Info.

Note: Understandably, researchers requesting a 118 Determination do not have detailed procedures crafted yet. That’s okay. This information will be updated and further defined at the point of a full protocol submission.

11) To minimize the prompts, choose “Other Procedure.”

This procedure is:
Note: Research procedures should be added by choosing the "Research Activity Involving Participants" radio button. Procedures that do not involve participants but support or instruct participants activities can be included by choosing the "Other Procedure" radio button (optional).

- Research Activity Involving Participants, Participants Data, or Biospecimens

- Other Procedure

You can add something as simple as this:

Add

Procedure Description
Surveys

This procedure is:
Note: Research procedures should be added by choosing the ‘Research Activity Involving Participants’ radio button. Procedures that do not involve participants but support or instruct participants activities can be included by choosing the "Other Procedure" radio button (optional).

- Research Activity Involving Participants, Participants Data, or Biospecimens

- Other Procedure

Please explain:
Survey detail will be provided at full submission.
12) In the Attachments section, upload the grant proposal document and/or other relevant information by choosing Add Info.

13) Submit!