

Submitting a 118 Determination Request

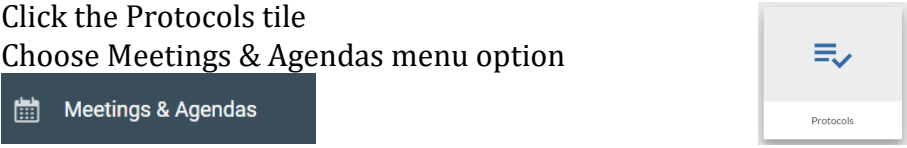
Background

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 Kualu must be amended for consideration as a human subjects research protocol submission before any research with human subjects can begin.

1) Log into Kualu Protocols.

How do I do that?

Follow the link in a Kualu notification email OR	
<ul style="list-style-type: none">• Log into Kualu 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

IRB - General Information

Principal Investigator
 claire.chance|

Lead Unit
 research integrity

Chance, Claire Natalie
 claire.chance@colostate.edu

Research Integrity + Comp...

- 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.

IRB - General Information

Principal Investigator
 Chance, Claire Natalie

Lead Unit
 Research Integrity + Compliance Review (CO-2011)

Title
 Project Title

Cancel
 Next

4) Choose the 118 Determination application type.

- Application Type
- NHSR
 - Exempt
 - Expedited
 - Full Board
 - Request for Reliance on an External IRB
 - 118 Determination

5) Enter the basic details about dates and funding.

118 Determination

118 Determination

Lacking Definite Plans

Certain types of applications for grants, cooperative agreements, or contracts are submitted to Federal departments and agencies. These include activities such as institutional type grants when selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior to the start of the project.

This Kualii application will result in an acknowledgement from the CSU IRB that you intend to submit a protocol.

Date project activity involving human participants is anticipated to begin:

June 25, 2021

When do you anticipate human research plans will be definitive enough to submit for IRB review?

June 25, 2021

Is this project currently funded or being submitted for potential funding?

Yes

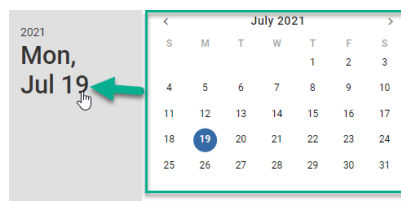
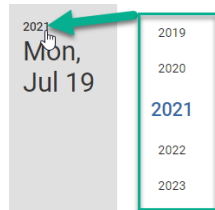
No

Date funding was received or is expected

June 25, 2021

As the PI submitting this request for 45 CFR 46.118 designation, I have accurately described the project and any human participants in this project.

- *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.*



RESEARCH INTEGRITY &
COMPLIANCE REVIEW OFFICE
COLORADO STATE UNIVERSITY

CSU Institutional Review Board

RICRO_IRB@colostate.edu

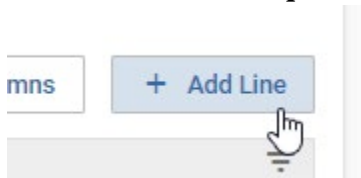
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<https://www.research.colostate.edu/ricro/irb/>

6) Click “Next,” to bring up the rest of the application.



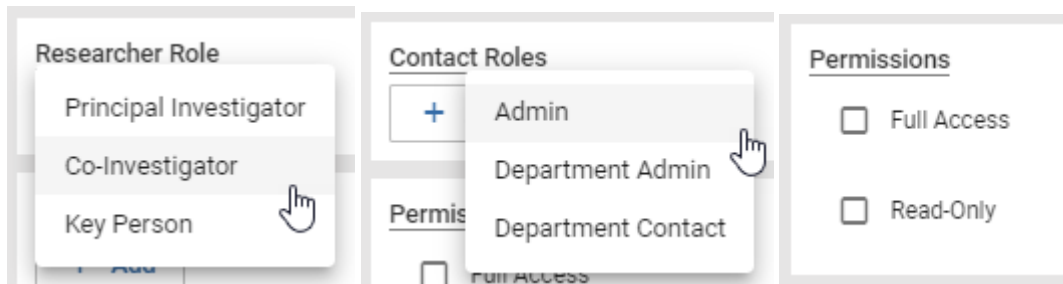
7) Add additional personnel, if applicable, by clicking on Add Line.



8) In the resulting pop-up, enter the relevant information for additional personnel.

Notes:

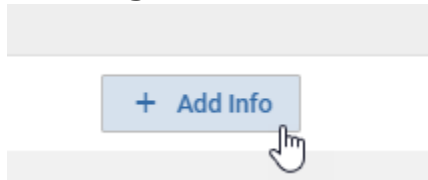
- There are options for Researcher Roles and Contact Roles. Only one role needs to be selected, but multiple are allowed. This is up to you based on the individual’s involvement.
- You will also designate the individual’s level of access to the protocol submission as Full Access (able to view and edit) 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

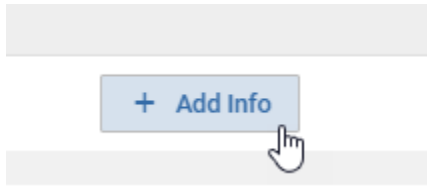
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Note: Research procedures should be added by choosing the "Research Activity Involving Participants" radio button. Procedures that do not involve participants but support or instruct participants activities can be included by choosing the "Other Procedure"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