Use this request form if :

* you are applying to a federal department or agency for a grant, cooperative agreement, or contract, and
* you believe that your application meets the requirements under 45 C.F.R. § 46.118, where your plan on human subjects is not definite. See SOP 111, Section 118 Designation for more information.

Note: **no human subjects may be enrolled or no data may be collected on human subjects before the IRB has reviewed and approved your plan for human subjects research.**

If you are requesting Section 118 designation for an **institutional type grant** or a **training grant**, complete the following:

|  |
| --- |
| Grant Title (same as in your grant application): Click here to enter text. |
| Institution Name: Click here to enter text.  | Principal Investigator (PI) Name: Click here to enter text. |
| PI Phone Number: Click here to enter text. | PI Email Address: Click here to enter text. |
| Name of the federal Funding agency: Click here to enter text. |
| Specific aims of your grant application: Click here to enter text. |
| Who will select the subgrant PIs under your grant? Click here to enter text. |
| The name, duties, and authority of the finance officer for your grant:Click here to enter text. |
| How long do you expect the grant to last? Click here to enter text. |

If you are requesting Section 118 designation **for an indefinite project**, complete the following:

|  |
| --- |
| Project Title (same as in your grant proposal): Click here to enter text. |
| Principal Investigator (PI) Name: Click here to enter text. | PI Department: Click here to enter text. |
| PI Phone Number: Click here to enter text. | PI Email Address: Click here to enter text. |
| Additional investigators, if applicable: Click here to enter text. |
| Funding agency: Click here to enter text. | Date when you anticipate research activities to begin: Click here to enter text. |
| Date when you anticipate that your plan on human subjects becomes definite enough to submit for IRB review?Click here to enter text. |
| Description of your project and the reason justifying Section 118 designation: Click here to enter text.  |

**By signing below, I certify that no human subject will be enrolled or no data on human subjects will be collected for a study under my grant or for my project before the study or the project is reviewed and approved by the IRB.**

PI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Submit this request form to the Human Studies Program (HSP) at uhirb@hawaii.edu. The HSP will review the request and notify you in writing of its decision. Should you have any questions, please contact the HSP at 808-956-5007 or uhirb@hawaii.edu.

For completion by the HSP staff:

Is the designation appropriate? ☐ Yes. The expiration date, if applicable: Click here to enter text.

 ☐ No. Comments: Click here to enter text.