**Guidance Document**

**118 Determination**

**What is a 118 Determination?**

**45 CFR 46.118 Applications and proposals lacking definite plans for involvement of human subjects.**

This type of submission is used when funding is needed before finalizing research protocols, recruiting participants, or developing research materials where the funding agency is requiring IRB acknowledgment of human subjects research. The 118 determination is based on federal regulations (45 CFR 46.118) that allow for this type of deferment of IRB review for certain research projects. 118 Determinations can be granted to satisfy federal sponsor or funding agency requirements to allow investigators to have access to funding. This designation is only applicable to projects when it is known that human subjects will be involved, but definite plans are not available at the time of the human subjects application or grant proposal.

It is crucial to understand that a 118 determination is **not** an IRB approval for human subjects research. Full IRB approval is still required before any human subjects can be recruited, enrolled, or data collected from participants. **Human subject research activities cannot begin until a full application and all applicable material (e.g., recruitment, consents, surveys, tools) have been developed, submitted, and IRB approval (§46.111) has been obtained.**

**How do I apply for a 118 Determination?**

To receive a 118 Determination, you will need to submit an [Initial Application](https://o365coloradoedu.sharepoint.com/%3Ab%3A/r/sites/RIO-IRBOffice/Shared%20Documents/InfoEd/eRA%20Submission%20Guides/IRB%20Initial%20Application%20eRA%20Guide%20%287Nov22%29.pdf?csf=1&web=1&e=uZORJp) in eRA. You will complete the HRP-211 Initial Application eForm (located in the study record in eRA) to the best of your knowledge and upload a completed [118 Protocol Template](https://www.colorado.edu/researchinnovation/media/6401). No other supporting documents are required. *Note, the 118 Protocol Template is not the same as the Exempt and Non-Exempt Protocol Templates.*

**Are there any special considerations for follow-up submission?**

118 determinations receive a one-year approval. Before the expiration date, you will submit an [Amendment](https://o365coloradoedu.sharepoint.com/%3Ab%3A/s/RIO-IRBOffice/EZ6NLWWPbdBGvypSjtWIFaUBIwB-VkF63g66tAafIa864Q?e=cb5hCc) submission to obtain full IRB approval. This submission will include a completed Exempt or Non-Exempt Protocol Template, consent form(s), data collection tool(s), recruitment materials, and any other document(s) necessary to the conduct of the research. The templates and additional guidance for supporting documents are located on the [Templates & Resources](https://www.colorado.edu/researchinnovation/node/8496/human-research-irb/templates-resources#accordion-e157c7af15fe4839a45b23e49d18d483b-1) page.

**References:**

Code of Federal Regulations, 45 CFR 46.118. Retrieved from: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.118>