45 CFR 46.103, Assuring compliance with this policy – research conducted or supported by any Federal Department of Agency with definite plans to include Human Subjects.

“Certification is required when the research is supported by a federal department or agency and not otherwise exempted or waived under §46.101(b) or (i). An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by §46.103 of this Policy has been reviewed and approved by the IRB. Such certification must be submitted with the application or proposal or by such later date as may be prescribed by the department or agency to which the application or proposal is submitted. Under no condition shall research covered by §46.103 of the Policy be supported prior to receipt of the certification that the research has been reviewed and approved by the IRB. Institutions without an approved assurance covering the research shall certify, within 30 days after receipt of a request for such a certification from the department or agency, that the application or proposal has been approved by the IRB. If the certification is not submitted within these time limits, the application or proposal may be returned to the institution.” (45 CFR 46.103(f))

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

“Certain types of applications for grants, cooperative agreements, or contracts are submitted to 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. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under §46.101(b) or (i), 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 department or agency.” (emphasis added)

Certain types of applications for grants, cooperative agreements, or contracts may be 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. In such cases, the principal investigator (PI) should submit an application to the Institutional Review Board (IRB) for 45 CFR 46.118 designation for the research study. Designation under 45 CFR 46.118 is not to be used to delay submitting a human research application until such time funding is likely. It only applies in circumstances where insufficient information is known about the specifics of the research study. Although the designations are called “45 CFR 46.118 designations,” this designation is also applicable to other agencies’ requirements equivalent to 45 CFR 46.118. The 45 CFR 46.118 designation may also be applied to non-federal sponsors (e.g. foundation, industry) when the 45 CFR 46.118 criteria are met.

A designation under 45 CFR 46.118 may be granted if the following criteria are met:

- Application is being submitted to a federal department or agency or involves a non-federal sponsor
- Human subjects may be involved within the period of support
- Definite plans would not normally be set forth in the application or proposal
  - Institutional type grants when selection of specific research study is the institution’s responsibility
  - Research training grants in which activities involving human subjects remain to be selected
  - Research studies in which human subjects’ involvement will depend upon:
    - Completion of instruments
    - Prior animal studies
    - Purification of compounds
- Assurance from the PI that no human subjects will be involved in any research study supported by these awards until the study is reviewed and approved by the IRB

Once an activity is provided a designation under 45 CFR 46.118, the PI must submit an initial application to the IRB office for review and approval when definitive plans have been developed. No human subjects may be involved in research until the IRB review and approval has taken place.

**Initial Request**
To request a 45 CFR 46.118 designation, the PI submits an application for 45 CFR 46.118 designation via the Michigan State University (MSU) IRB online system.

When a request is received, the IRB office will assign the request an IRB number and initiate the 45 CFR 46.118 review process. An IRB administrator will be assigned to review the request. Should the request meet the criteria, the IRB administrator will issue a letter issuing the 45 CFR 46.118 designation. This designation does not allow research to be conducted involving human subjects; an initial application must be submitted and approved by the IRB to involve human subjects in research.
The 45 CFR 46.118 designation will be given an expiration date of one month past the date by which the PI anticipates human research plans will be definitive enough to submit for IRB review but not more than one year from the initial request.

**Renewed 45 CFR 46.118 Designation**
If a PI would like to renew the 45 CFR 46.118 designation, the PI must explain whether there have been any changes to the initial request, must provide a confirmation that no research involving human subjects has been or will be conducted prior to IRB review and approval of an IRB application, and provide an updated date by which the PI plans to submit a complete initial IRB application for review.

The request will be reviewed by an IRB administrator and a renewed 45 CFR 46.118 designation may be granted should the request continue to meet the criteria.