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| Michigan State University | |
| Human Research Protection Program | |
| <i>Subject: 45 CFR 46.118 Designation</i> | |
| <i>Section: 8-4</i> | <i>This policy and procedure supersedes those previously drafted.</i> |
| <i>Reviewed by: HRPP Director, Asst. to Asst. VP, MSU Legal Counsel, Asst. VP Regulatory Affairs</i> | <i>Approved by: Vice President of Research and Graduate Studies, 6-15-09</i> |
| <i>Related Sections:</i> | |

Policy

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.”

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 Responsible Project Investigator should submit an application to the IRB for 45 CFR 46.118 designation for the project. Designation under 45 CFR 46.118 is not to be used to simply 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 project. The IRB may grant designation under 45 CFR 46.118 if the following criteria are met:

- Application is being submitted to a federal department or agency
- 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 specific projects is the institution's responsibility
 - Research training grants in which activities involving human subjects remain to be selected
 - Projects in which human subjects' involvement will depend upon:
 - completion of instruments
 - prior animal studies
 - purification of compounds
- Assurance from the Responsible Project Investigator that no human subjects will be involved in any project supported by these awards until the project is reviewed and approved by the IRB

Once an activity is provided a designation under 45 CFR 46.118, the Responsible Project Investigator 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.

Procedures

The Investigator submits an application for 45 CFR 46.118 designation via the online review system available at <http://www.humanresearch.msu.edu>

The following information will be obtained in the application:

1. Date project activity (involving human participants) is anticipated to begin.
2. Project title.
3. Name and faculty/staff identification number(s) of the Responsible Project Investigator and faculty/staff or student identification number(s) of any additional investigator(s).
4. A one page description of the project with the level of detail currently known; what will be done, with whom, under what circumstances, and for what reason
5. Justification of why 45 CFR 46.118 designation is needed.
6. A copy of the funding proposal.
7. Contract & Grant application number (if applicable).
8. Name of the MSU Contracts and Grant officer assigned to the project (if applicable).
9. Date by which the investigator(s) anticipate human research plans will be definitive enough to submit for IRB review.
10. A formal, signed, written commitment that no contact will be made with and no data will be collected from human subjects prior to IRB review and full approval of the project.

When a request is received, the IRB will assign the request an IRB log number and initiate the 45 CFR 46.118 review process. One reviewer will be assigned to review the request. Should the request be satisfactory, the IRB will issue a letter indicating 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.

Renewed 45 CFR 46.118 Designation

If investigators wish to renew the 45 CFR 46.118 designation, a request must be sent to the IRB office prior to the expiration of the 45 CFR 46.118 designation date. A copy of any new and/or modified grant application material should be included within the request. The following questions should be addressed within the request:

1. Name of Responsible Project Investigator
2. Project title
3. Funding source, if any
4. The reason for requesting a renewed 45 CFR 46.118 designation and explanation why the project continues to meet the 45 CFR 46.118 designation
5. Date by which the investigator(s) plan to submit a complete initial IRB application for review
6. Confirmation that no research involving human subjects has been or will be conducted prior to IRB review and approval of an IRB application

The request will be reviewed and a renewed 45 CFR 46.118 designation may be granted should the request be satisfactory.