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| **Instructions** |
| * Use of the 45 CFR 46.118 provision may vary by funding agency; please assure that the funding agency will accept the 45 CFR 46.118 designation before submitting to the MSU Human Research Protection Program.
* CLICK™ IRB:
	+ Include the template with a New Study Submission.
	+ Upload the completed template to the Basic Information SmartForm page, Question 10.
* See MSU HRPP Manual Section 8-4, Request for 45 CFR 46.118 Designation, for more information.
 |
| **Complete Questions 1-5** |
| 1 | Study title.       |
| 2 | Explain why definite plans for research with human subjects would not normally be set forth in the application or proposal, even though you have knowledge that human subjects may be involved within the period of support.        |
| 3 | Date by which the investigator(s) anticipate human research plans will be definitive enough to submit for IRB review.       |
| 4 | Date research involving human subjects is anticipated to begin.       |
| 5 | Principal investigator indicates a commitment that no human subject research will occur prior to a complete review and approval of the study by the IRB.        |