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| **Instructions** |
| * IMPORTANT: This worksheet is completed by HRPP staff.
* Use this form when a PI requests to renew a 45 CFR 46.118 designation.
* CLICK™ IRB
	+ Upload completed worksheet to BOAT.
* See HRPP Manual 8-4, Request for 45 CFR 46.118 Designation for more information
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| **Completed by HRPP Staff.**  |
| Study ID.       | PI.       |
| Funding Status**[ ]** There have been revisions/modifications to the grant proposal AND [ ]  PI has submitted a copy**[ ]** There have been no revisions/modifications to the grant proposal |
| The PI has provided:[ ]  An explanation of whether there have been any changes to the initial request[ ]  A confirmation that no research involving human subjects has been or will be conducted prior to IRB review and approval of an IRB initial study[ ]  Provided an updated date by which the PI plans to submit a complete initial IRB study for review |
| **[ ]** Based on the information provided by the PI, the following criteria continue to be met: 45 CFR 46.118 designation may be granted if all of the following criteria are met (check boxes to confirm):* 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 projects is the institution’s responsibility.
	+ Research training grants in which activities involving human subjects remain to be selected.
	+ Project in which human subjects involvement will depend upon completion of instruments, prior animal studies, purification of compounds.
* PI has assured that no human subjects will be involved in any research study supported by these awards until the project is reviewed and approved by the IRB.
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| UPDATED date by which the PI plans to submit a complete IRB initial application for review.       |
| UPDATED date research involving human subjects is anticipated to begin.       |
| National Science Foundation.Is the project funded by the National Science Foundation? [ ]  Yes [ ]  No* If yes, also provide “NSF Template Letter” (Notification of 45 CFR 690.118 Determination for a Project Lacking Immediate Plans for Involvement of Human Subjects, their Data, or their Specimen).
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| **Determination** |
| Select one:[ ]  Renewed 45 CFR 46.118 designation granted[ ]  Request does not meet the criteria for renewed 45 CFR 46.118 designation 🡪 [ ]  PI notified that a New Study submission is requiredDate the 45 CFR 46.118 Designation is Valid Until\*:      *\*Add one month to date provided by PI for when an initial application will be submitted for review, with a limit of up to one year after date of the 45 CFR 46.118 determination*Comments:       |
| Name:       | Date:       |