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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 | | |
| **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. | | |
| 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). | | |
| **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 required  Date 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: |