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| **Instructions** | | |
| * IMPORTANT: This worksheet is completed by HRPP staff. * Use this form when a 45 CFR 46.118 is requested. * 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. | |
| **Is this project conducted, supported, or required to comply with Revised Common Rule (2018 Requirements)?**  *No 🡪 Use Pre-2018 Common Rule Letter: 45 CFR 46.118 Determination Letter- Pre-2018 Common Rule*  *Yes 🡪 Use 2018 Common Rule Letter(s): 45 CFR 46.118 Determination Letter -Revised Common Rule* | | |
| The IRB office has received the funding proposal and/or has uploaded the funding proposal from Kuali Coeus. | | |
| **The 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. | | |
| Date by which the PI plans to submit a complete IRB initial application for review. | | |
| Date research involving human subjects is anticipated to begin. | | |
| **National Institutes of Health.** Is the project funded by the National Institutes of Health?  Yes  No   * If yes, advise PI via a comment that some institutes do not accept a 45 CFR 46.118 designation if human subjects will be involved within the first year of the award and that we recommend checking with the institute. If the institute does not accept a 45 CFR 46.118 designation, a complete IRB initial application will need to be submitted for review and approval. * If yes, does the project involve Genomic Data Sharing Certification?  Yes  No   + If yes, advise PI via a comment that the institute may require a full Genomic Data Sharing Certification, which typically requires review and approval of the complete IRB initial application. | | |
| **National Science Foundation.** Is the project funded by the National Science Foundation?  Yes  No   * If yes:   + For Pre-2018 Common Rule: 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) – Pre-2018 Common Rule:   + For Revised Common Rule (2018 Requirements):.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) – Revised Common Rule (2018 Requirements | | |
| **Determination** | | |
| Select one:  45 CFR 46.118 designation granted  Request does not meet the criteria for 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: |