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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
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| **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.
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| **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:       |