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GENERAL INFORMATION

On **February 14, 2023**, the new 2023 consent form will be **required** for all projects that have not been approved by the PPHS by that date.

- You can find the new 2023 ICF, parental permission, legally authorized representative, Health & Hospitals (Queens/Elmhurst) forms, and a tracked/compared changes version (between the 2019 and 2023 templates) in the RUTH Library and/or on the [PPHS website](#).
- Spanish versions of the ICF will be available over the next month.
- PPHS has created a guidance ICF template to assist in creating your new ICF. You can find that on the [PPHS website](#).
- All projects approved between today and **February 14, 2023**, are strongly encouraged to use the 2023 ICF template but not required.
- Research teams are encouraged to use the MODCR combo in RUTH when migrating to the 2023 ICF template at the time of their continuing review submission. If you do choose to submit a MODCR combo, please ensure that you submit these AT LEAST six (6) weeks in advance of your project's expiration date. For further information please see the [Research Road Map](#).
- The PPHS has created an ICF addendum for use by research teams for notifying research participants. See bullets below for further information.
- After one year of transition, all local, active projects are required to use the 2023 ICF version by **February 14, 2024** unless otherwise noted.

R2R PROJECTS (Studies under an external IRB)


INITIAL R2Rs

For new initial R2Rs, please begin using the revised HRP-232R (version 01.09.2023 available in the RUTH Library > General tab). Please note: negotiations are still in process with NCI CIRB. A separate notification/instructions will be sent when that process is complete.

- New initial R2R submissions submitted on/after 1/23/2023 will be returned if submitted using an older version of the HRP-232R unless an exception has been granted*.
 - *If you are currently actively negotiating with the sponsor, external IRB or PPHS, please email Jennifer Kucera (Jennifer.kucera@mssm.edu) to discuss whether an exception can be granted for your study.
- Studies that PPHS has released to submit to an external IRB (in the Pending sIRB state in RUTH), will automatically be granted an exception.
- For studies currently in Pre-Review in RUTH, the PPHS will evaluate and communicate with the study team about the need to switch to the revised HRP-232R/2023 ICF language on a case-by-case basis.
- The revised HRP-232R (version 01.09.2023) will now be the IRB Waiver of Jurisdiction that gets signed by PPHS for WCG, Advarra, BRANY and Alpha IRB.
 - The separate Waiver of Jurisdiction will no longer be required.

EXISTING R2Rs

For studies that are open to enrollment under an external IRB, certain language will need to be 1) updated on any applicable ICF(s), 2) approved by sponsor and the external IRB and 3) submitted to PPHS (at the time of another modification or Continuing Review, whichever comes first). The IRB of record is responsible for making the determination about the notification/re-consent plan.

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Please complete and attach the appropriate form (available in the RUTH Library > General tab) to your submission at the time of your consent form transition:

- HRP-235C: R2R Consent Transition for Existing Studies (General)
- HRP-235D: R2R Consent Transition for Existing BRANY Studies
- HRP-235E: R2R Consent Transition for Existing Studies under the NCI CIRB: *Please note: negotiations are still in process with NCI CIRB. A separate notification/instructions will be sent when that process is complete.*

NEW PROJECTS INCLUDING R2S PROJECTS

- Keep in mind per PPHS Service Pledge of 6 weeks, submissions made after **January 1, 2023**, are strongly encouraged to be made using the 2023 ICF template.
- Projects submitted but not fully approved by **February 14, 2023**, will be required to switch to the 2023 ICF regardless of submission status.

CURRENTLY APPROVED PROJECTS INCLUDING R2S PROJECTS

- Currently approved projects that are actively enrolling participants are not required to change the ICF until a modification impacting the ICF or continuing review application is submitted.
- When migrating to the 2023 ICF, it is strongly encouraged to copy and paste the project's currently approved ICF language **on to** the new 2023 ICF template, using the following steps:
 1. Find the new 2023 ICF template in the RUTH Library.
 2. Enter your currently approved ICF language into the new 2023 ICF template.
 3. Follow the regular steps to submit a modification application to change the consent form. For additional help, see the RUTH Submission Check list – Modifications.
 4. If migrating to the 2023 ICF at the time of continuing review submission, consider using the MODCR combo. For further information please see the [Research Road Map](#).
 5. If you have additional changes to your ICF (other than the 2023 ICF changes), you must provide a memo detailing each change and their location (i.e. On page 4, paragraph 3, sentence 1 the following change was made from xxx to yy).
- Reconsent is not required. However, some form of notification of the consent changes will have to be made to the active participants. An ICF addendum, for use when notifying enrolled participants of the changes to their current ICF, will be available for your consideration. Please check the PPHS website for the document on or before December 31, 2023.
- Projects that are Exempt or closed to enrollment are not required to make any changes.
- R2S projects: ICF changes should be IRB-approved for the overall study template before making changes to any site-specific ICFs. For questions about R2S processing contact Joseph Datko joseph.datko@mssm.edu in the PPHS.