



GUIDANCE: 2023 ICF Template Roll Out

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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

- Information will be provided by **December 31, 2022** for studies that use an External IRB. Since R2R projects involve negotiations with multiple IRBs, this process may take us until the end of December to 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



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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.