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SECTION I: GENERAL INFORMATION

As of **February 14, 2023**, the new 2022 consent form is **required** for all projects that have not been approved by the PPHS prior to that date.

- You can find the new 2022 adult, parental permission, legally authorized representative, Health & Hospitals (Queens/Elmhurst) forms, and a tracked/compared changes version (between the 2019 and 2022 templates) in the RUTH Library and/or on the PPHS website.
- PPHS has created a guidance ICF template to assist in creating your new ICF. You can find that on the PPHS website.
    - Research teams are encouraged to use the MODCR combo in RUTH when migrating to the 2022 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 "RUTH Alert - New Submission Option in RUTH - Effective 11/11/22" on the Research Road Map.
- After one year of transition, all local, active projects are required to use the 2022 ICF version by **February 14, 2024** unless otherwise noted.

SECTION II: REQUESTS TO RELY ON AN EXTERNAL IRB (R2R) PROJECTS

INITIAL R2Rs

For new initial R2Rs, please use the revised HRP-232R (version 05.22.2023 available in the RUTH Library > General tab).

- The revised HRP-232R (version 05.22.2023) 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, 1) certain language will need to be 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.

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

SECTION IIIA: CURRENTLY APPROVED PROJECTS INCLUDING R2S PROJECTS

- Currently approved projects, including R2S projects where the Mount Sinai IRB is serving as the sIRB, 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 2022 ICF, it is strongly encouraged to copy and paste the project's currently approved ICF language ***on to*** the new 2022 ICF template, using the following steps:

    1. Find the new 2022 ICF template in the RUTH Library.
    2. Enter your currently approved ICF language into the new 2022 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 2022 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 2022 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. See Section IIIC below.

- 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 irb@mssm.edu in the PPHS.

Section IIIB: Do I need to develop a new consent form and do I have to notify study participants?

At its most basic, determining the need to develop a new consent form and whether notification or re-consent is needed comes down to two questions:

1. **If the study obtains informed consent, is it still open to enrollment?**
    - If yes, then you will need to modify your consent to the new template.
    - If the study is not open to enrollment, you do not need a new consent form at this time.
        - However, if you need to re-consent participants in the future for another reason, OR you have participants who will turn 18 and need to be consented as adults, you will need to use the new template at that time.

2. **Is there ongoing or planned future contact with some or all of the participants, or are you continuing to access their medical records?**
    - If the answer is “yes” then either 1) notification (see Section IIIC below) and/or 2) re-consenting with the new consent form (as driven by the answer to Section IIIB, #1 above) must occur for the individuals where contact continues. See Section IIIC below.
    - If the answer is “no” for some or all of the participants, then for those individuals, no notification or re-consenting is required.
        - For participants in long term follow-up, which simply involves a look at the death registry, the PPHS will not consider that contact.
        - Participants in “static” biorepositories, (not ongoing chart review/annotations) then nothing further is required.
        - If the study had an intervention that is completed, there are samples or data left for future uses, and there is no ongoing contact with participants or their medical records, notification is not required.

Section IIIC: What does PPHS mean by "notification" and how to do it

If there is a newly updated consent form, notification is generally required:

RECONSENT:

- If the only change to the consent form is to adopt the new template language, then re-consenting is not required, but can be done if the research team prefers.

NOTIFICATION:

- Notification can be done by email, MyChart, regular mail or phone. Alternative methods may be discussed with PPHS.
- The details of the notification plan should be submitted to the PPHS using the HRP-235B, which will be submitted with the modification with the consent form revision.
- Multiple efforts to contact participants are not required.
- Acknowledgment of receipt by the participants is not required.
- Efforts and results should be documented in the research record.

If there is NO newly updated consent form:

- The notification should include the pertinent language from the revised future use and withdrawal sections. The future use language should not include all the options in the consent template but should be tailored to the individual study and should track the approved protocol.
- Notification can be done by email, MyChart, regular mail or phone. If there is a website for the study, or a regular study newsletter that will also be acceptable.
- The details of the plan should be submitted to the PPHS using the HRP-235B.
- Multiple efforts to contact participants are not required.
- Acknowledgment of receipt by the participants is not required.
- Efforts and results should be documented in the research record.

The PPHS understands that even with the flexibility outlined above, notification for some large and/or older studies may be challenging. In those circumstances, PPHS is happy to work with teams to develop a pragmatic plan that is not overly burdensome to the research team.