Guideline and Flow Chart When University of Rochester Relies on a Non-UR IRB

The University of Rochester (UR) may defer review of human subject research that requires expedited or convened board review to a non-UR IRB (e.g., independent IRB or another institution's IRB) when the research involves more than one site or the study is funded by the National Institutes of Health, as per OHSP Policy 504 RSRB Reliance for Review. When this occurs, UR becomes the Relying institution.

When the UR is the Relying institution, the UR Investigator is responsible for completing the eReliance Request form, ensuring all appropriate agreements are in place, and an institutional review is conducted according to Policy 504 RSRB Reliance for Review. The UR PI should follow the steps outlined on the UR Relying Institution Flow Chart on the following pages.

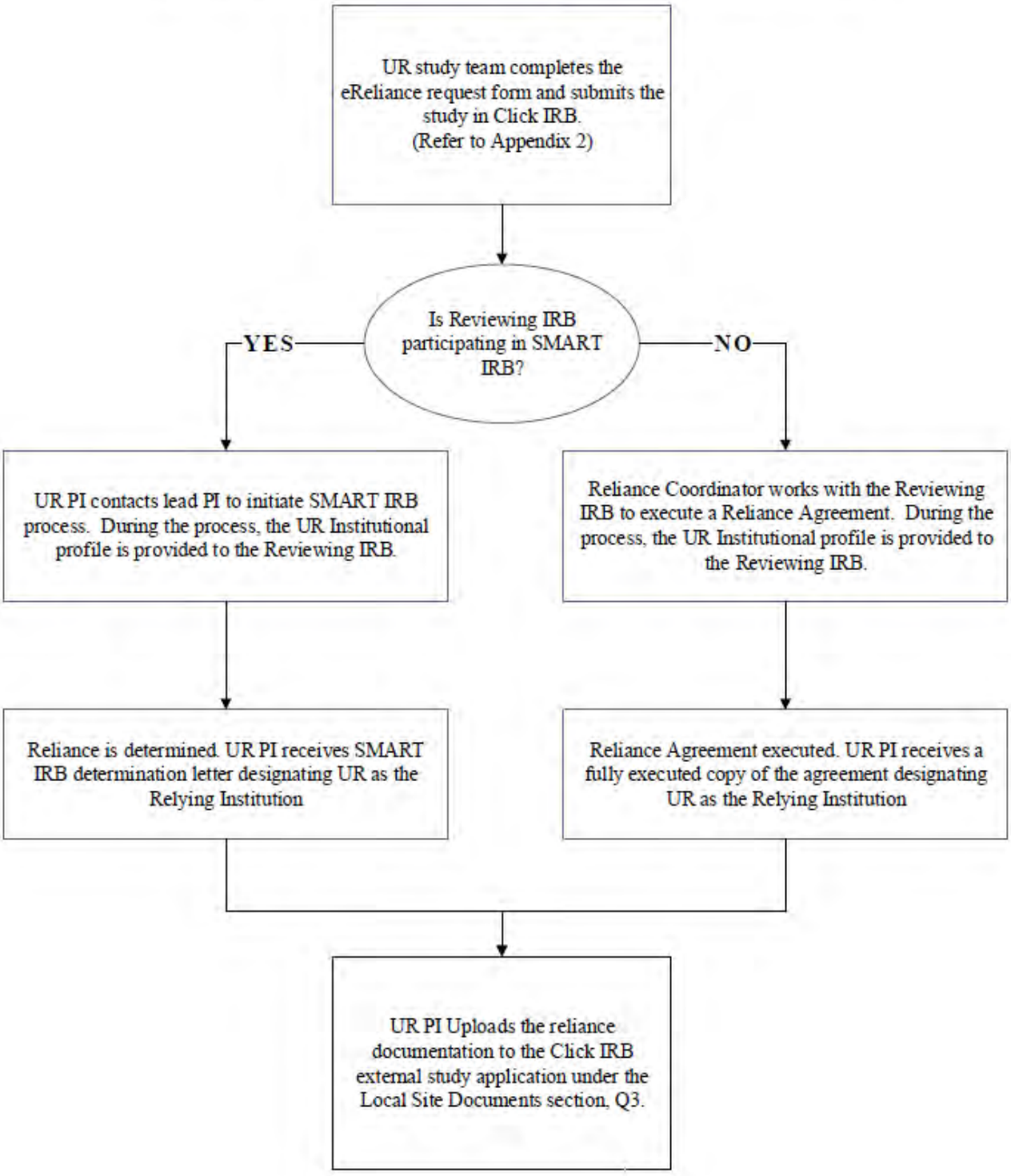
When the RSRB defers to a non-AAHRPP accredited IRB, the RSRB may assess whether the policies and procedures of the Reviewing IRB are consistent with the accreditation standards. The RSRB may obtain an assurance or request a self-evaluation from the Reviewing IRB (i.e. AAHRPP's Evaluation Instrument for Accreditation, FDA's self-evaluation checklist for IRBs), or another satisfactory process.

As part of this process, the RSRB will conduct an institutional review to ensure compliance with institutional policies, such as; human subject training requirements, compensation for injury, and conflict of interest. The RSRB may require a local protocol addendum to outline the specifics of how the research will be conducted at the University of Rochester, if the protocol is not specific. Many sponsor protocols do not adequately address local site procedures for some areas such as recruitment, consenting, etc. Consent documents must include the information outlined in the University of Rochester as Relying Institution Consent Language Requirements. Please consult with the RSRB if there are any questions with the standard language when negotiating with the sponsor or reviewing institution.

See the UR Relying Institution Flow Chart on the next page for the steps to obtain a Reliance Agreement (Appendix 1) and submit an External IRB application (Appendix 2).

Please note, any study using an Independent IRB (e.g., WIRB, Advarra) or reviewed by the National Cancer Institute cIRB, go directly to Appendix 2.

Steps to Obtain a Reliance Agreement – Appendix 1



UR Relying Institution Flow Chart – Appendix 2