Northwestern IRB Office – Reliance Workflows

When Northwestern is the IRB of Record All external sites Is the project a candidate for must obtain IRB the NU IRB to serve as the approval per their IRB of Record for external standard local sites? process All external sites Are the external sites engaged must obtain IRB and their IRB(s) willing to rely approval per their on the NU IRB? standard local process Yes If the project is federally funded it may be subject to Single IRB considerations. Please ensure that any Single IRB Letters of Support are acquired before you submit in eIRB+. The NU study team should prepare a new eIRB+ submission with all relevant study documents including a detailed reliance plan in the protocol. Our preferred process is to have the initial review proceed for the overall study and Northwestern site only, and to execute reliance agreements, and approve external site consent forms as appropriate, in a subsequent modification. If external sites will be added to an IRB approved project, that was previously NU only, please prepare an eIRB+ modification with updated study documents and a draft reliance agreement. A reliance plan should also be added to the protocol. Once submitted in eIRB+, the application will be reviewed following a normal process and any feedback will be communicated through eIRB+. The NU study team and PI are responsible for sharing reliance agreements and study documents to external sites, for external site study teams to share with their corresponding IRBs. Once the reliance agreement is fully executed, the NU is permitted to

review and approve external site documents (including consent

forms). The NU PI is responsible for ensuring all external sites

are notified of approved study documents.

When Northwestern Cedes IRB Review Is the project a candidate for Submit in eIRB+ for the NU IRB to cede IRB No standard review review to an external IRB? Yes Is NU engaged and the Submit in eIRB+ for external IRB is willing to be Nο standard review our IRB of Record? Yes If the project is federally funded it may be subject to Single IRB considerations. Please ensure that any applicable Single IRB Letters of Support are acquired from the proposed external IRB. The NU study team should prepare a new eIRB+ submission with all relevant study documents. If the NU activities are not clearly detailed in the sponsor's or lead site's protocol a Local Protocol Addendum may be required.

Once submitted in eIRB+, the NU activities and reliance agreement will be administratively reviewed. Any feedback will be communicated through eIRB+. If appropriate, the reliance agreement will be signed and returned through eIRB+. The NU study team and PI are responsible for sharing reliance agreements and relevant information to the external IRB.

A draft or partially executed reliance agreement should also be

included. The proposed external IRB is entitled to pick the type of reliance agreement we will utilize.

Once the reliance agreement is fully executed, the external IRB should approve the NU site and NU documents (including consent forms). If the approved NU documents contain the appropriate Northwestern local language, the study will receive our official acknowledgment and local activities may begin. The NU study team and PI are responsible for ensuring all reporting requirements and ongoing study updates are promptly provided for NU acknowledgement.