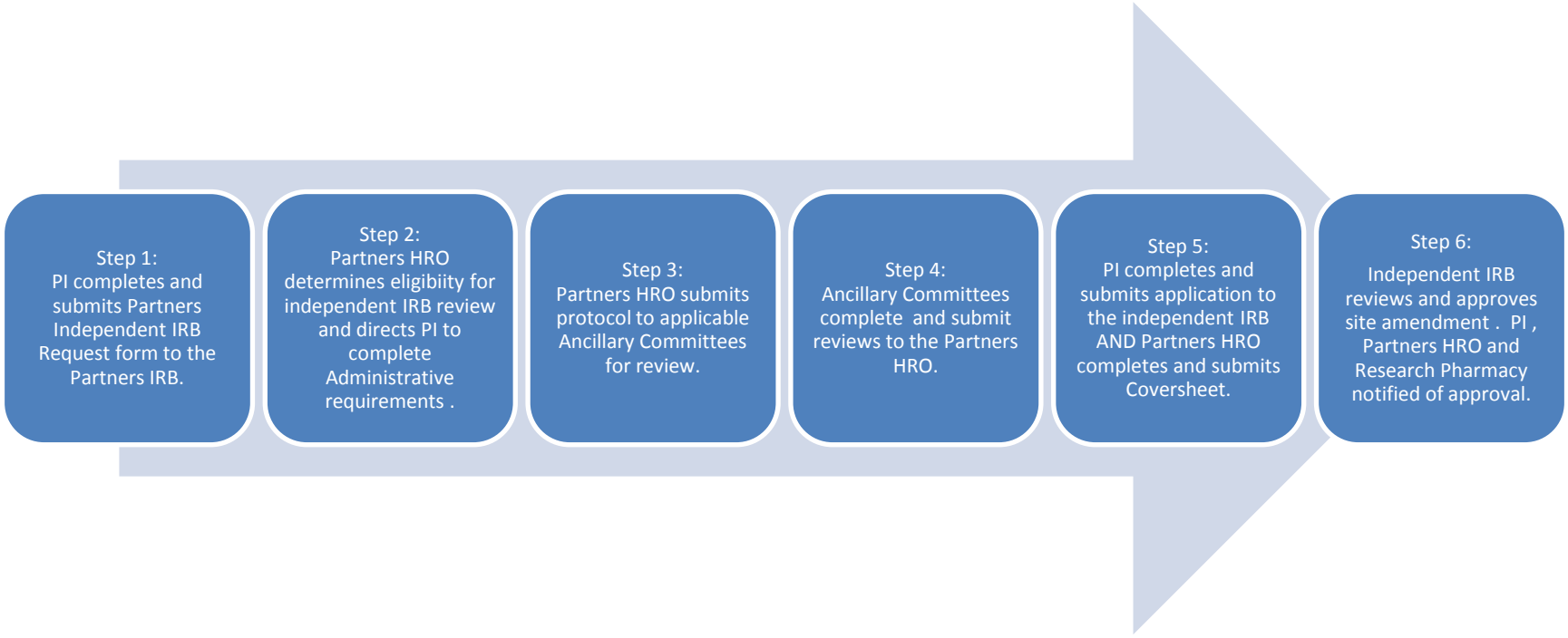
PROCESS FOR RELYING ON AN INDEPENDENT IRB FOR REVIEW OF PHASE III-IV INDUSTRY-SPONSORED RESEARCH



RESPONSIBILITIES

INVESTIGATOR	PARTNERS Human Research Office (HRO)	INDEPENDENT IRB
Complete Partners Independent IRB Request form and submit with Sponsor's Protocol, Consent Form and IDB to the Partners HRO.	Review Partners Independent IRB Request form to determine eligibility for Independent IRB review.	Receive PI application for addition of Partners as a site. Contact PI/Partners Human Research Office with questions.
If eligible, complete administrative requirements; e.g., PI, Dept Chair, Study Staff sign-offs; Financial Disclosure Forms (FDFs); ED/ OR/L&D sign off, and send to Partners HRO.	Send PI memo outlining administrative requirements and ancillary reviews.	Review; obtain additional information, as needed, to approve. Provide approval letter and approved consent forms to PI, Partners HRO, and Pharmacy.
Complete external independent IRB application.	Create Insight Cede Review form; email Ancillary Committees; enter Ancillary Committee determinations in Insight.	Notify PI, Partners HRO, and Pharmacy of pending sponsor amendments.
Follow independent IRB requirements for reporting unanticipated problems, adverse events, proposed changes in research, and continuing review.	Complete/submit Institutional cover sheet to Independent IRB and CC PI.	Review sponsor amendments and release approval letters and updated protocol and IRB-approved consent form(s) to the PI, Partners HRO, and Pharmacy when confirmed by HRO.
Report PI and Site changes to the Independent IRB.	Post approval letter and consent form in Insight.	Review reports of unanticipated problems and adverse events. Notify PI, Partners HRO, and Pharmacy of review outcome and any requirements.
Submit changes in Study Staff and, when applicable, FDFs to the Partners Human Research Office.	Post PI/Site changes and Study Staff changes in Insight.	Review continuing review information. Provide approval letter and approved consent forms to PI, Partners HRO, and Pharmacy.

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