INFORMED CONSENT COMPLIANCE CHECKLIST

ITEM	Y/N	IF NO, TAKE THE FOLLOWING CORRECTIVE ACTION
Was informed consent obtained from each subject prior to the start of any study procedure(s)? (including screening procedures to determine eligibility)		▪ Report this deviation to the IRB according to policy: https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Informed_Consent_of_Research_Subjects.pdf
Was an IRB approved consent form (IRB approval stamp in footer) used to consent each subject?		▪ Report this deviation to the IRB
Was the consent form used for each subject a copy of the *most recently approved* version (check valid dates)?		▪ Report this deviation to the IRB
Is the consent form on file for each subject the *original* signed and dated version (not a photocopy)?		▪ Write a signed and dated note to file explaining why only a photocopy is available ▪ If the original was placed in the subject's medical record, make the switch
Are all pages of the consent form on file for each subject?		▪ Report this deviation to the IRB ▪ Write a signed and dated note to file confirming that all information was presented to the subject, and if possible, explain why pages are missing
Did all subjects receive a copy of their signed and dated consent form?		▪ Report this deviation to the IRB
Is there documentation to support that all subjects received a copy of their signed and dated consent form?		▪ Write a signed and dated note to file indicating that subjects were given a copy of the signed and dated consent form but it was not documented ▪ For all future subjects enrolled, document (e.g. in progress notes or on an enrollment log) that each subject was given a copy of the signed and dated consent form ▪ Consider using the Partners QI Documentation of Informed Consent template: https://partnershealthcare-public.sharepoint.com/_layouts/WopiFrame.aspx?sourcedoc=%7bF1184466-CCD4-43EB-AD83-AC277DC22228%7d&file=documentation-informed-consent-process.dot&action=default
If applicable, was a copy of each subject's signed consent form sent to/placed in subject's medical record? (If the study involves sensitive research, it may not be appropriate to place in the medical record).		▪ If applicable, write a signed and dated note to file explaining that the study involves sensitive research (e.g. drug use, genetics, infectious disease) and a copy will not be placed in the subject's medical record
Are all yes/no or similar options on the consent form complete (e.g. initialed) for all subjects?		▪ Assume the subject "does not" agree to the option unless the subject can complete the information at a later time ▪ Options completed after initial consent should be documented by a signed and dated note to file ▪ If any optional study procedures were done without the option section completed, report this deviation to the IRB
Did each subject sign and date the consent form for him/herself? (excluding IRB approved surrogate/parental consent)		▪ Report this deviation to the IRB ▪ Write a signed a dated note to file explaining any missing signature/date
Did an IRB approved study representative obtain consent for all subjects?		▪ Report this deviation to the IRB ▪ Check Insight to verify who is IRB-approved to obtain consent
Did the IRB approved study representative obtaining consent sign and date for him/herself?		▪ Report this deviation to the IRB ▪ Write a signed and dated note to file explaining who signed/dated for the study representative or if it was an omission, explain how and when consent was obtained
Did the subject and study representative enter the same date on the consent form? (Unless protocol IRB approved for mail consent, or other non in-person consent processes)		▪ Write a signed and dated note to file clarifying any dating discrepancies, noting when consent was obtained
Are all consent forms free of any handwritten changes (e.g. updated physician contact telephone number)?		▪ Submit an amendment to the IRB updating the consent form if necessary to avoid future corrections

Are all corrections (e.g. wrong date) initialed and dated?		▪ Write a signed and dated note to file clarifying any corrections made
Are original copies of all IRB approved consent forms on file?		▪ Obtain missing versions of the IRB approved consent forms from the protocol administrator
If any non-English speakers were enrolled, was the appropriate consent form (written translation of entire English form or short form) used?		▪ Report this deviation to the IRB ▪ Review Partners policy on consent of non-English Speakers: https://partnershealthcare-public.sharepoint.com/ClinicalResearch/Non-English_Speaking_Subjects.pdf
Is the number of subjects who have signed the consent form (i.e. enrolled) more than the target enrollment goal approved by the IRB?		▪ If **YES**, Report over-enrollment as a violation to the IRB ▪ Submit an amendment to the IRB requesting an increase in the enrollment goal
Was the consent form signed after IRB approval expired, but before new approval obtained?		▪ If **YES**, report this deviation to the IRB, and request permission to retain the subject in the study.