External IRB Requests:
Checklist to Prevent the 7 Most Common Delays to HIPAA Review

HIPAA Authorization:

☐ There is a HIPAA Authorization for all study groups whose protected health information (PHI) will be accessed.

#6 – HIPAA Summary Form:

☐ Selected PHI items match the list of PHI that will be “USED” on the HIPAA Authorization.

#8 – HIPAA Summary Form:

☐ All entities that will receive PHI are listed on the HIPAA Authorization (in the section with bulleted sentences stating the people or groups that may use or share study information).

#9 – HIPAA Summary Form:

☐ Selected PHI items match the list of PHI that will be “DISCLOSED” on the HIPAA Authorization.

#9 – HIPAA Summary Form:

☐ Justifications for the disclosures of the selected PHI items are provided (Note: “Required for the study” is not a sufficient answer).

#9 – HIPAA Summary Form:

☐ If patient initials will be disclosed, “name” is selected. Also, “name” (or “initials”) is listed as PHI that will be “DISCLOSED” on the HIPAA Authorization.

Section D – HIPAA Summary Form:

☐ If a Waiver of HIPAA Authorization is requested (i.e. to screen for eligible participants), Section D of the HIPAA Summary Form is completed and the Waiver Agreement is signed.