

## 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**.