Human Subject Research – must have an IRB approved research study*

**Screening/Recruitment**

- Review patient records to determine eligibility
- Contact patients to determine interest in participating
- Prepare a list of potential subjects

**IRB approval of research has been obtained**

- IRB must approve a Waiver of Consent as this is a HSR activity (Form 502)
- IRB must approve a Waiver of Authorization (Form 502) as this is a use of PHI

**PHI may be accessed by or released to research team member**

- If PHI is disclosed/shared with a non-Aurora entity (except for patient) during the screening/recruitment process, an accounting of disclosure is necessary [see below]

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**If Screening log is to be used:**

- Must be submitted to IRB with request for Waiver of Authorization
- May be sent to sponsor (outside of Aurora) or reviewed by non-Aurora Workforce Member at Aurora. **However...**
  - If de-identified information (no HIPAA elements) is included on log, no accounting necessary [no PHI is disclosed]
  - If PHI is included on log, accounting of disclosure is necessary [Need to include information on Waiver of Authorization (above) regarding disclosure of PHI to sponsor]