

S-I STUDIES

TIP SHEET FOR IRB MEMBERS

DEFINITIONS

- Sponsor-Investigator (S-I) – An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug or device is administered or dispensed. The S-I assumes the responsibilities of the sponsor (in addition to investigator responsibilities) when they hold the IND/IDE.
- S-I Study--At Emory we categorize studies in which an Emory Faculty member is Sponsor (holds the IND/IDE) as a sponsor-investigator study even when another investigator is the study PI.
- IND – Investigational New Drug
- IDE – Investigational Device Exemption

CONSIDERATIONS FOR NEW S-I STUDIES

- Study team must provide IND Study May Proceed letter or equivalent FDA correspondence indicating that there are no further restrictions on the study
- Office of Compliance checklist and review (must be complete before final approval issued)
- Protocol and Informed Consent Form clearly list the specific investigator as the “Sponsor-Investigator” and when sponsor is used it refers to the investigator who holds the IND/IDE. Study supporter should be used for the funding organization, if applicable.
- S-I must have appropriate processes for collecting, reviewing, analyzing and reporting to the FDA and other investigators any potential serious risks that qualify for reporting under the FDA’s IND Safety Reporting regulations. In addition, the S-I must copy the Emory IRB on any such reports and include an analysis of whether the S-I believes the event constitutes an UP.
- **MULTI-SITE STUDIES:** If the S-I has more than one site (making him/her a sponsor at an external site), a CRO or other site-monitoring alternatives may be required before IRB approval.

CONTINUING REVIEW

- IND Annual Report/IDE Progress report
- Office of Compliance continuing renewal checklist and review (must be complete before final approval issued)

AMENDMENTS

Additional considerations only apply to the following types of amendments:

- Change in Sponsorship (from one investigator to another which transfers sponsor responsibilities as a result)
- Major design changes (including a significant increase in projected enrollment) require an amendment to be filed with the FDA under the IND
- Addition of non-Emory research site locations