

CLINICAL TRIALS WHAT WILL BE CHECKED BY B&F

New Clinical trial:

- ✓ Does the PI have at least 1% effort?***
- ✓ Is the correct indirect rate being charged?*
- ✓ Is space accounted for?
- ✓ Is the IRB fee included?*
- ✓ Is the budget entered into SiteMinder?
- ✓ **Departmental signature on the SPAF signifies that the budget has been reviewed and is accurate.**

WHAT ELSE NEEDS TO BE INCLUDED IN THE ROUTING PACKET

- ✓ Is there an informed consent form? (Can be draft)
- ✓ Have they included the protocol?
- ✓ Is there a contract?
- ✓ Is there an effort calculator for each investigator?

*If the agency will not allow all or part of these fees to be included in the budget and you have had to include that cost in another line, please note this on the Blue Sheet to avoid further questions.

**If the sponsor or SiteMinder budget has a line item “investigator fee” that amount or greater should be carried to the effort calculator. If no fee is spelled out investigator makes “best estimate” for effort.

Amendments/Extensions:

- ✓ Original SiteMinder Budget
- ✓ Internal budget on additional amount

Indirect Rate Reminder

Industry Sponsored Trials	25%
Federal Clinical Trail – on campus	42.9%
Federal Clinical Trial – off campus	27.8%
Other Sponsored Research	53%

If a trial is sponsored by a Foundation that limits the indirects it will pay, an indirect cost waiver can be requested. It must be signed by the Executive Associate Dean for Research prior to routing the trial.

We cannot grant a waiver requested for a trial sponsored by a “for profit” agency without endangering our (Emory’s) non profit status.