DECISION TREE FOR UC CLINICAL TRIAL DEFINITION*

Does the study involve human subjects research?**

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YES

Is the study a Phase 1-4 FDA regulated drug or biologic study or an FDA regulated device study?

Or

Is the study comparing two (or more) devices, biologics or drugs to assess safety, efficacy, benefits, costs, adverse reactions or outcomes?

NO

NO

YES

Are subjects prospectively assigned to an intervention^?

YES

Is the study a Phase 1-4 FDA regulated drug or biologic study or an FDA regulated device study?

Or

Is the study comparing two (or more) devices, biologics or drugs to assess safety, efficacy, benefits, costs, adverse reactions or outcomes?

NO

NO

YES

Is the study designed to evaluate the effect of the intervention on subjects?

YES

THIS STUDY MEETS THE UC DEFINITION OF A CLINICAL TRIAL.

THIS STUDY DOES NOT MEET THE UC DEFINITION OF A CLINICAL TRIAL.

*For the purpose of determining applicability of the UC clinical trial F&A rate and applicable contract terms.

**See the IRB determination of human subjects research form at: https://tinyurl.com/HSdetermination.

^An intervention, in the context of the UC definition of a clinical trial, is the manipulation of a subject via the controlled testing of a drug, device, treatment or diagnostic under an approved protocol. A blood draw, on its own, may not be sufficient to constitute an intervention.

Please contact or-ctcontracts@uci.edu or Anne Demarie at ademarie@uci.edu if you have any questions.