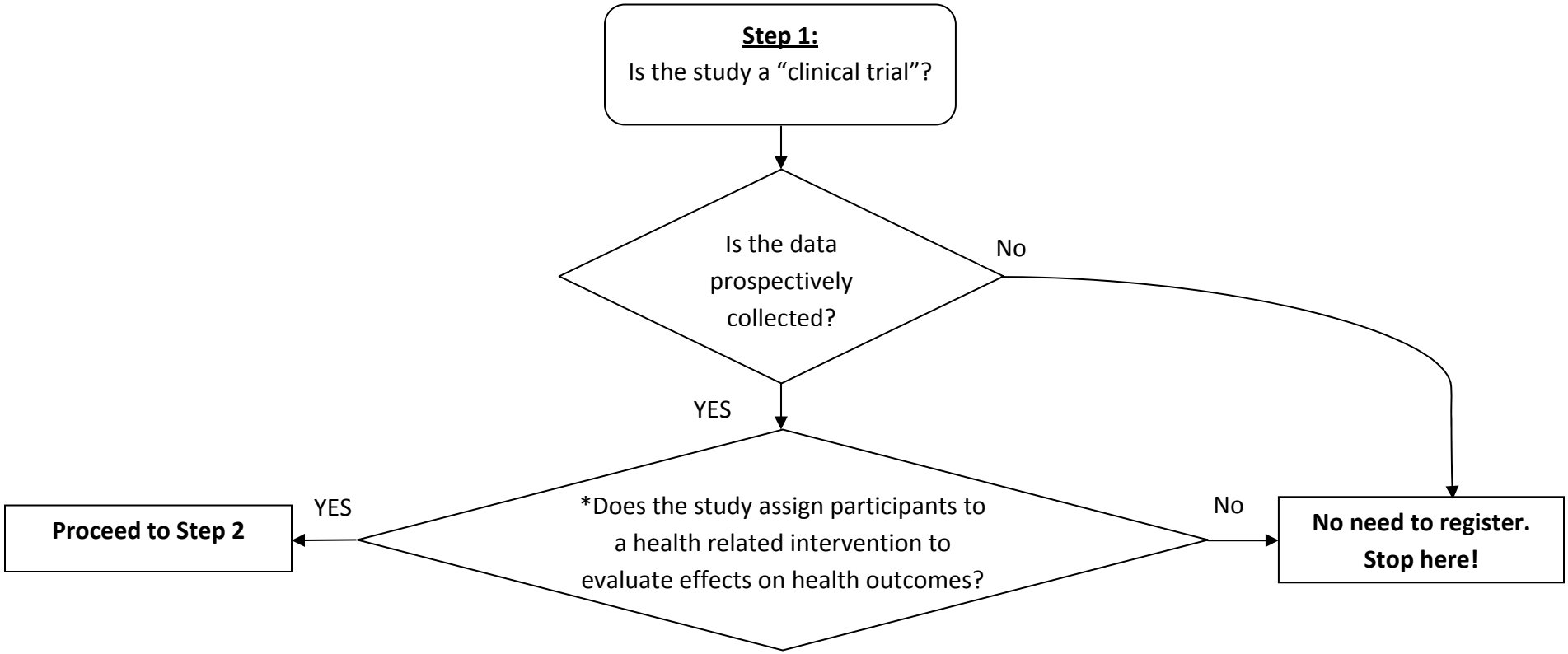
The ICMJE is expanding the definition of the types of trials that must be registered to include these preliminary trials and adopts the WHO's definition of clinical trial: "Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Health related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measure obtained in patients or participants, including pharmacokinetic measures and adverse events.

As previously, purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. The ICMJE member journals will start to implement the expanded definition of clinically directive trials for all trials that begin enrollment on or after 1 July 2008. Those who are uncertain whether their trial meets the expanded ICMJE definition should err on the side of registration if they wish to seek publication in an ICMJE journal.

ICMJE Clinical Trial Registration Decision Tree: Step 1

Here is a clinical trial registration decision tree to help you determine whether your trial should be registered. However, if you are in doubt as to whether your trial meets the ICMJE's definition of a "clinical trial" as described below proceed to Step 2.



*Health related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes).

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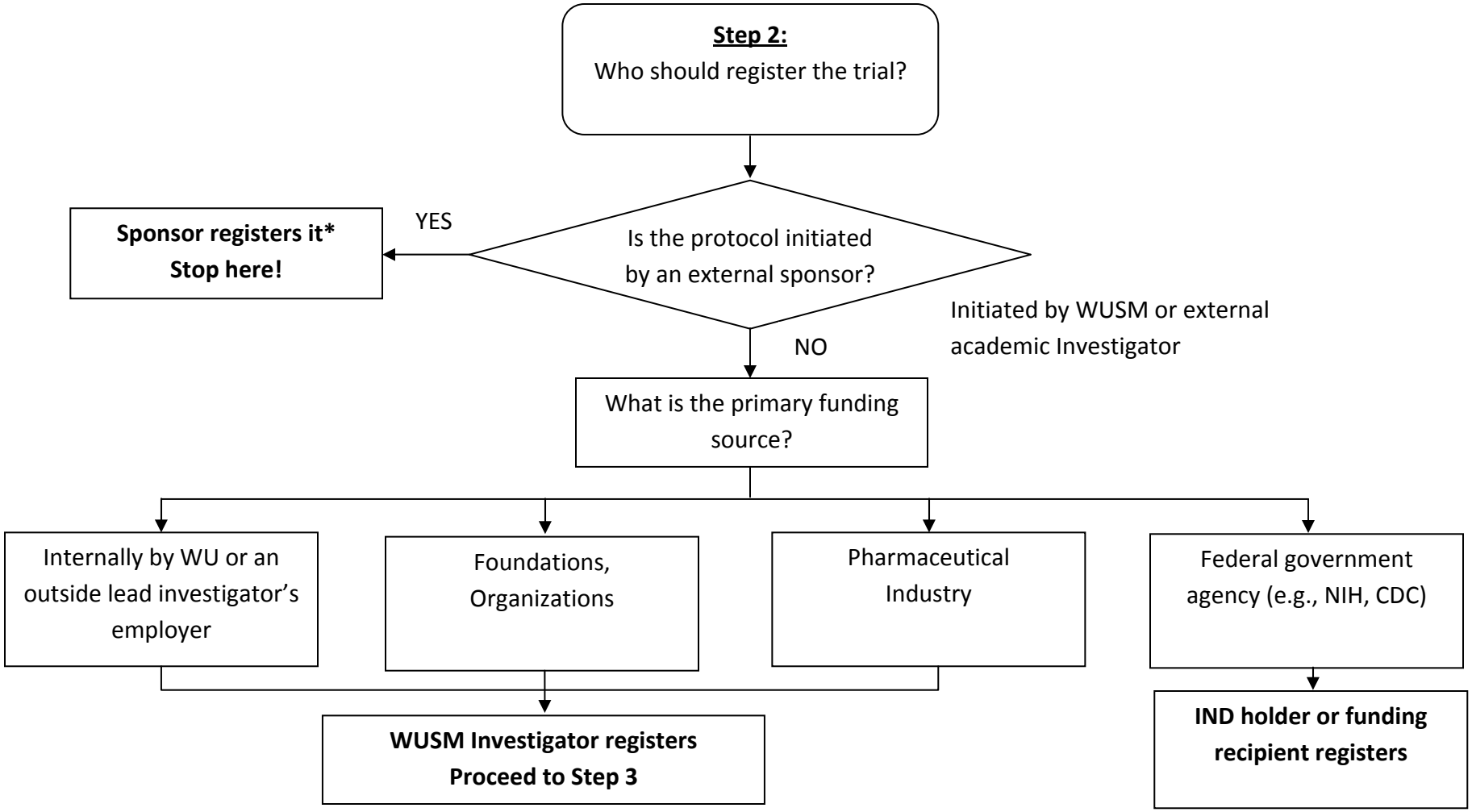
ICMJE Clinical Trial Registration Decision Tree: Step 2



* When negotiating the clinical trial agreements with outside sponsors or outside lead investigators, the CCS contracts group will require the sponsors or outside lead investigators to agree to register their trials. However, when the sponsor or the outside lead investigator refuses to be obligated to register the trial in the agreement, the CCS will notify the WU investigator and the WU investigator has the option of registering the trial.

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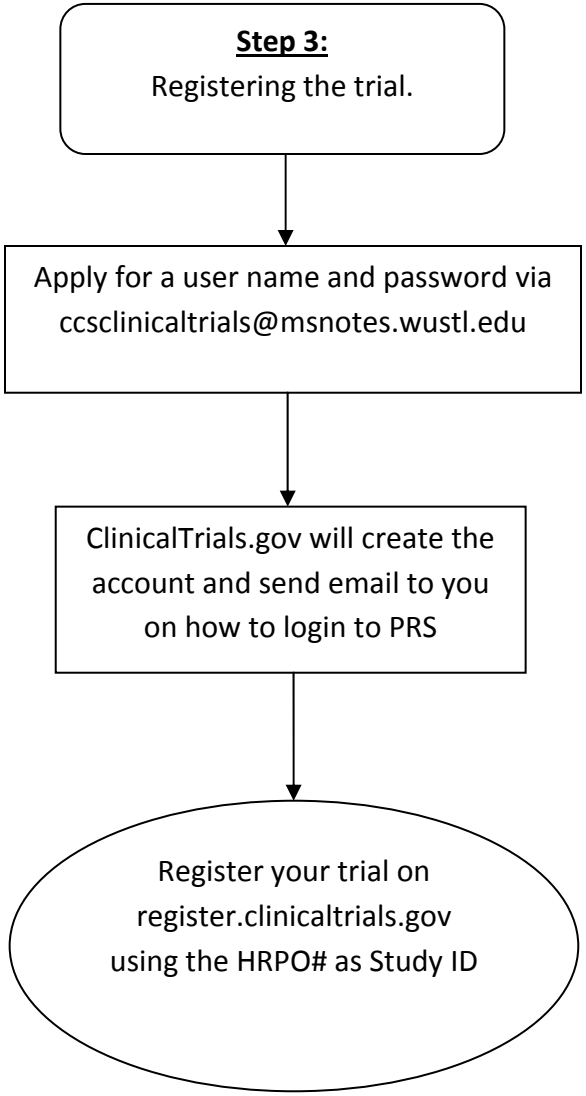
ICMJE Clinical Trial Registration Decision Tree: Step 3



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