Figure 1: Decision tree –
Clinical Trial Definition
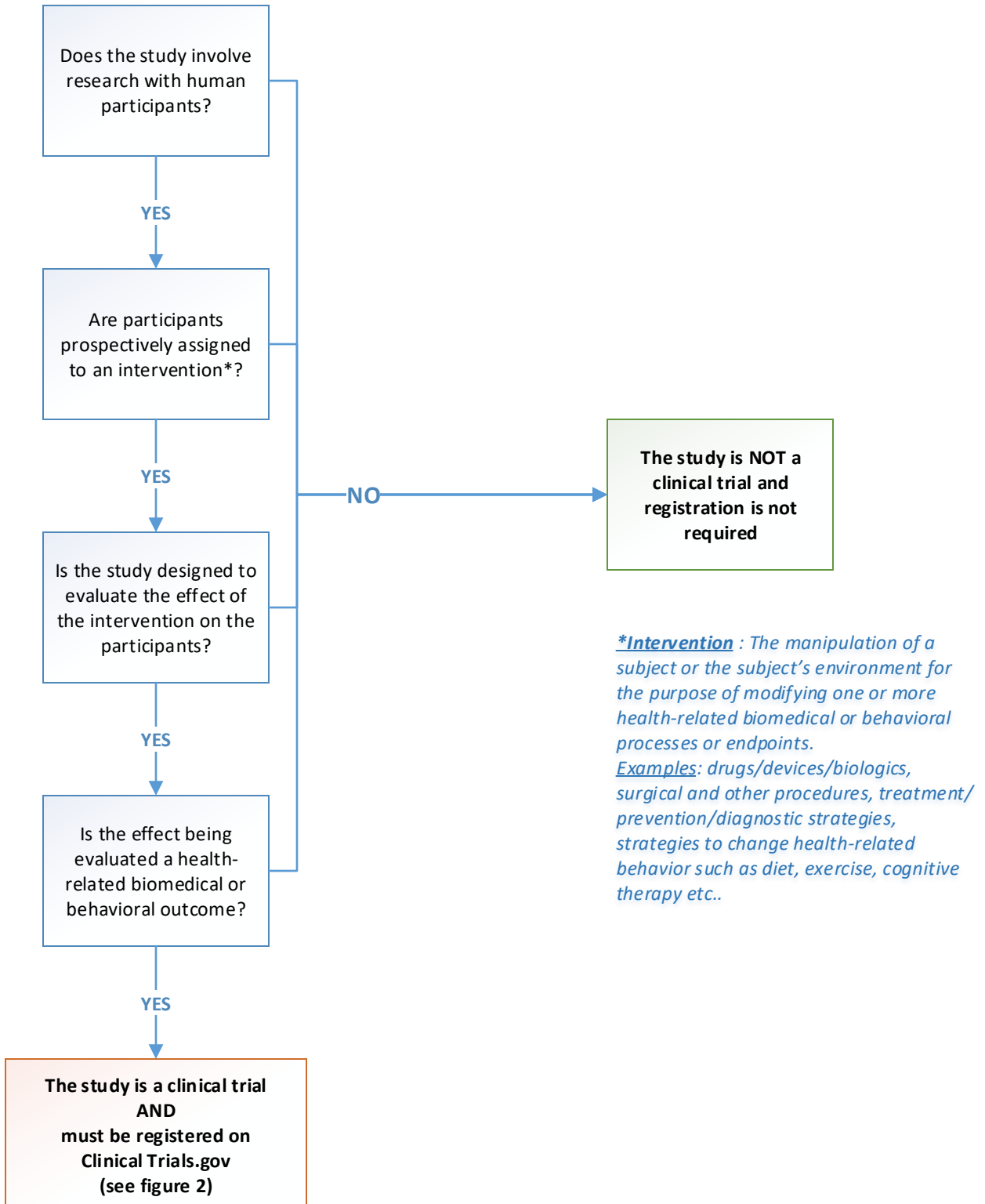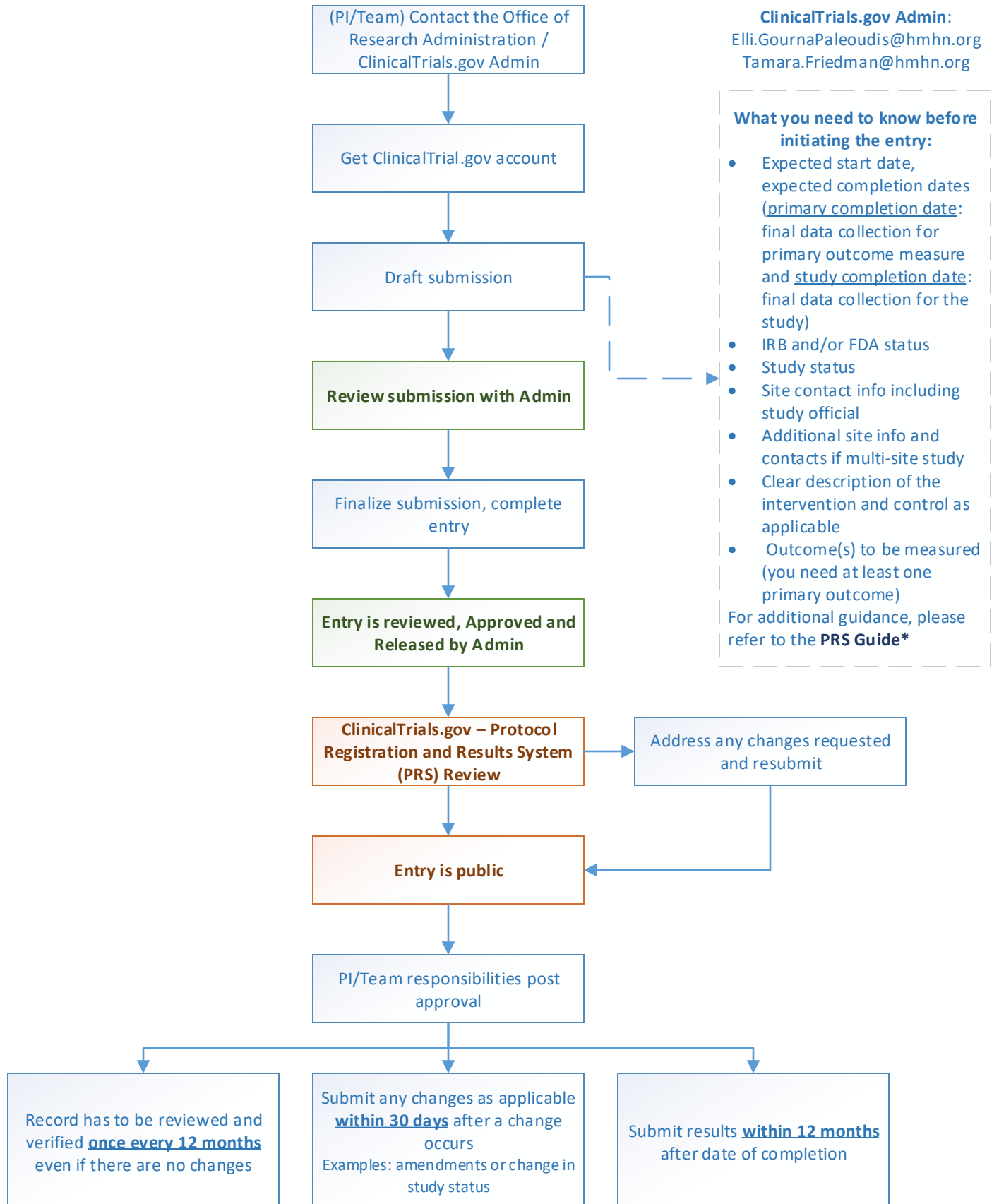
Does the study involve research with human participants?

YES

Are participants prospectively assigned to an intervention*?

YES

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

YES

Is the effect being evaluated a health-related biomedical or behavioral outcome?

YES

NO

The study is NOT a clinical trial and registration is not required

The study is a clinical trial AND must be registered on Clinical Trials.gov (see figure 2)

*__*Intervention__ : The manipulation of a subject or the subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes or endpoints.*
__Examples__: drugs/devices/biologics, surgical and other procedures, treatment/ prevention/diagnostic strategies, strategies to change health-related behavior such as diet, exercise, cognitive therapy etc..

Figure 2: Registration Process

ClinicalTrials.gov Admin:
Elli.GournaPaleoudis@hmhn.org
Tamara.Friedman@hmhn.org

(PI/Team) Contact the Office of Research Administration / ClinicalTrials.gov Admin

Get ClinicalTrial.gov account

Draft submission

Review submission with Admin

Finalize submission, complete entry

Entry is reviewed, Approved and Released by Admin

ClinicalTrials.gov – Protocol Registration and Results System (PRS) Review

Address any changes requested and resubmit

Entry is public

PI/Team responsibilities post approval

Record has to be reviewed and verified **once every 12 months** even if there are no changes

Submit any changes as applicable **within 30 days** after a change occurs
Examples: amendments or change in study status

Submit results **within 12 months** after date of completion

What you need to know before initiating the entry:
- Expected start date, expected completion dates (primary completion date: final data collection for primary outcome measure and study completion date: final data collection for the study)
- IRB and/or FDA status
- Study status
- Site contact info including study official
- Additional site info and contacts if multi-site study
- Clear description of the intervention and control as applicable
- Outcome(s) to be measured (you need at least one primary outcome)

For additional guidance, please refer to the **PRS Guide***