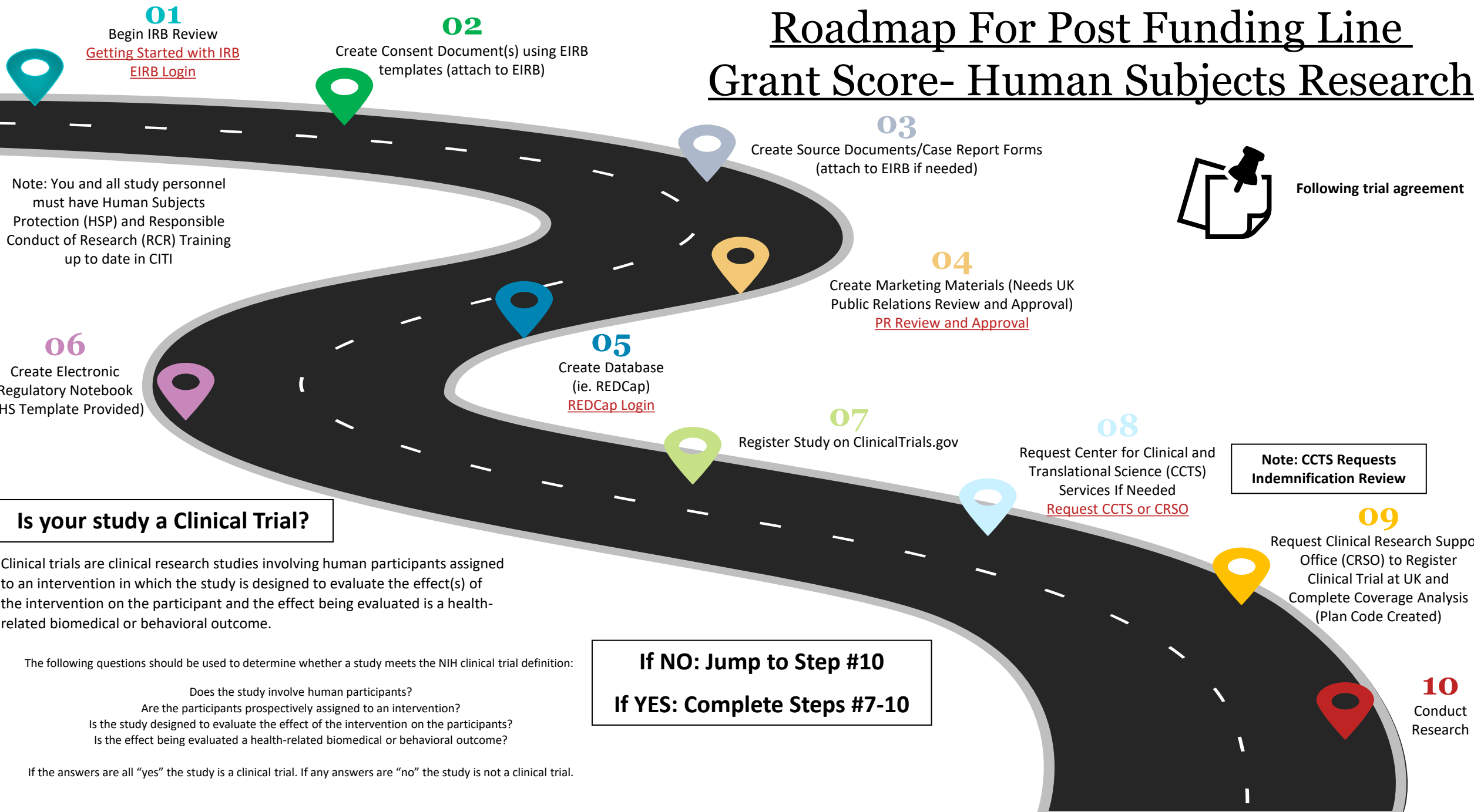
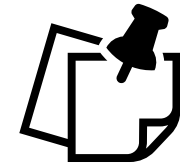


Roadmap For Post Funding Line Grant Score- Human Subjects Research



Note: You and all study personnel must have Human Subjects Protection (HSP) and Responsible Conduct of Research (RCR) Training up to date in CITI



Following trial agreement

Is your study a Clinical Trial?

Clinical trials are clinical research studies involving human participants assigned to an intervention in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related biomedical or behavioral outcome.

The following questions should be used to determine whether a study meets the NIH clinical trial definition:

- Does the study involve human participants?
- Are the participants prospectively assigned to an intervention?
- Is the study designed to evaluate the effect of the intervention on the participants?
- Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answers are all “yes” the study is a clinical trial. If any answers are “no” the study is not a clinical trial.

If NO: Jump to Step #10
If YES: Complete Steps #7-10

Note: CCTS Requests Indemnification Review