National Center for Complementary and Integrative Health

Guidance on Changes in Clinical Studies in Active Awards – When Is Prior NCCIH Approval Required?

Current National Institutes of Health (NIH) policy requires prior approval from the NIH awarding institute/center for a change in scope (*NIH Grants Policy Statement* (GPS) 8.1.2.5). One of the potential indicators of a change in scope is a change from the approved involvement of human subjects (grants.nih.gov/grants/guide/notice-files/NOT-OD-12-129.html).

Protocol changes that do **not** meet the criteria below of editorial or administrative updates should be considered amendments and therefore **must** be submitted and approved by NCCIH prior to implementation. To add further clarity, the following protocol changes are considered amendments and therefore require prior NCCIH approval:

- Any change that may affect patient safety (e.g., change in eligibility criteria; change in risk, regardless of whether risk is increased or decreased)
- Any change that changes scientific intent or study design, or affects human subject protection
- Addition/deletion of a site
- Addition/deletion of key study personnel
- A change of institution for key study personnel
- A change in enrollment targets.

Examples of protocol changes that NCCIH considers editorial or administrative updates to approved protocols and does not need to approve are:

- Typographical correction, unless the change results in a change in patient risk
- Rephrasing a sentence or section to add clarity as long as the change does **not** affect the scientific intent, study design, patient risk, or human subject protection
- Reformatting the document as long as the change does **not** affect the scientific intent, study design, patient risk, or human subject protection
- Address, telephone, or e-mail changes
- Addition/deletion of non-key personnel
- Standardization of protocol language inconsistencies, as long as the change does **not** affect the scientific intent, study design, patient risk, or human subject protection.