

## AS Policy FAQs

What are examples of AS scientific or operational change requests that may need ASC review or CCC assistance, respectively?

### Scientific changes may include but are not limited to:

- Changes in aims, outcomes, study design
- Approach, e.g., new biomarkers, change in lab assays, new use of specimens including additional assays or change in assay procedure, use of leftover biospecimen from approved ancillary studies
- Addition or subtraction of WHI subcohorts or external cohorts
- Linking to external databases, e.g., cancer registries, Medicare data,
- Participant-involved study changes for new burden or change in burden to participants, e.g., change in number of participants or procedures, changes in participant-facing documents such as consent forms and questionnaires, and devices. If the proposed change will significantly add to participant burden or raises new human subjects issues, the modification must also be approved by the DSMB.
- proposals applying for industry funding.
- Changes in PI may need ASC review, e.g., if transitioning-out PI was a WHI sponsoring investigator and transitioning-in PI is not a WHI sponsoring investigator.

### CCC record-keeping and operational changes may include but are not limited to:

- Word-smithing of specific aims
- CCC sub-contract rebudgeting
- Funding source
- PI transitions not involving WHI investigator sponsorship, institution changes, funding submission date changes.