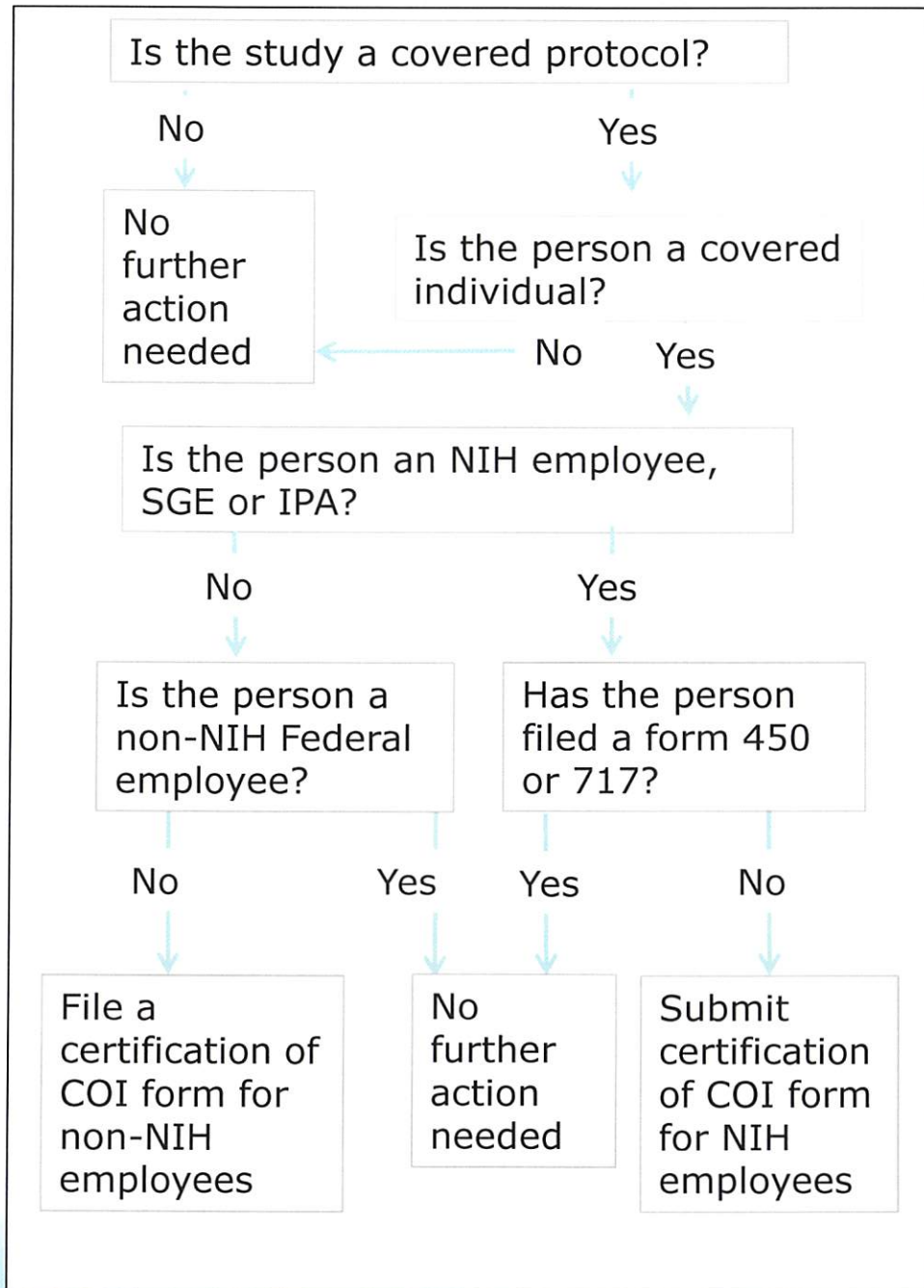


## SOP 21 Appendix B: Algorithm for Decisions Regarding Financial Disclosure



**Covered protocol:** Assessment of financial conflict of interest is required for all clinical research protocols that may lead to the financial benefit or loss of any individual or entity. This includes studies of investigational drugs and devices, studies whose research question involves a commercially available drug or device, studies involving a CRADA or Clinical Trials Agreement, studies involving collaborations with a substantially affected organization or studies involving intellectual property. NIH research protocols that are categorized as Teaching and Training, or Natural History studies are not covered research protocols, unless they meet the criteria listed above. Most interventional protocols will be covered protocols unless the intervention does not involve the criteria listed above (e.g. a behavioral intervention might not meet the criteria for a covered research protocol).

**Covered Individual:** Covered Individuals are personnel who have independent decisional roles in conducting a specific covered research protocol. These individuals are influential in the design, direction, or conduct of a covered research protocol, or engaged in the analysis or interpretation of data. Individuals who participate only through isolated tasks that are incidental to the research (for example, scheduling patient tests), and those individuals who support research of many protocols through the performance of routine patient care tasks are not covered individuals. Covered Individuals include the principal investigator, personnel whose resume or CV is provided to a sponsor, personnel listed on a FDA 1572 Form, and personnel who obtain informed consent or who make decisions about research eligibility. Others who have decisional responsibilities that meet the definition of a covered individual, e.g. as co-investigator, research nurse, associate investigators, or an individual who interprets or analyzes research data, are also covered individuals.