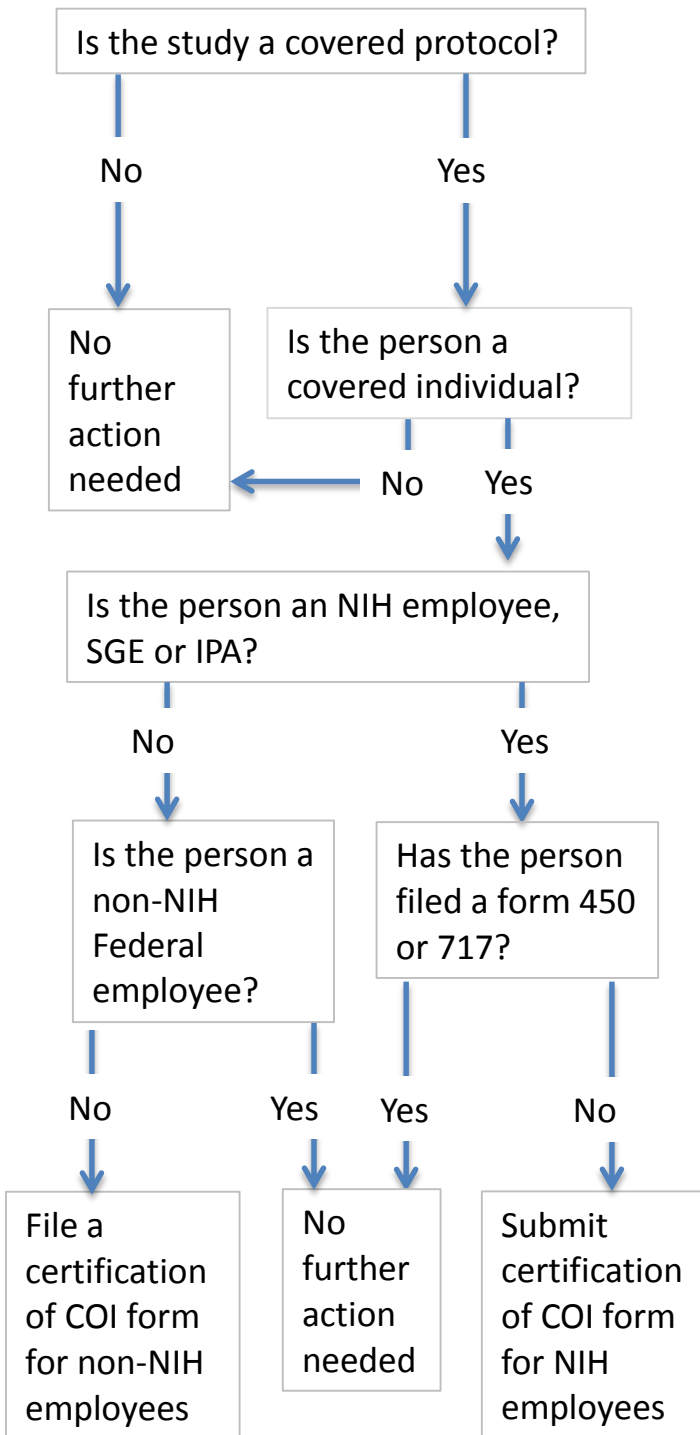


APPENDIX C: ALGORITHM FOR DECISIONS REGARDING FINANCIAL DISCLOSURE



Covered research protocols: Covered research protocols: For purposes of SOP 21, covered research protocols include: (1) studies of investigational drugs and devices, (2) studies with a research question about a commercially available drug or device, (3) studies involving collaborations with a substantially affected organization (SAO) or other for-profit entities when the entity is receiving data or specimens from the NIH for the purpose of developing a product, or (4) studies involving a technology/product not developed in an NIH lab which is evaluating the technology/product or comparing the technology/product to another technology/product or treatment. 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 Individuals: 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 engaged in human subjects research, including but not limited to individuals 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. The PI determines which individuals are “covered individuals” under this SOP. When protocols contain sub-studies that ask a research question about a product, it is possible that only those individuals involved in decisional roles in the sub-study are “covered individuals.”