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PURPOSE

The purpose of this SOP is to develop a system to identify any potential conflicts of interest and/or financial interests that may affect the unbiased reporting of data from NACHO studies, or the direction of the NACHO consortium. This SOP is not designed to eliminate all conflicts of interest, but to recognize situations which may be subject to question, and to ensure that such situations are properly reviewed, supervised, or monitored if necessary. These policies will apply to all NACHO Executive Committee (EC) members, Scientific Committee (SC) members, Clinical Studies Committee (CSC) members, Study Chairs, and Data Safety Monitoring Committee (DSMC) members.

DEFINITIONS

Immediate Family – Immediate family is defined as a spouse, dependent child, or a member of the household of the individual filling out the Conflict of Interest (COI) form

Significant Financial Interest – A significant financial interest by the investigator or immediate family member is defined as anything of monetary value exceeding \$5,000 per annum or 5% ownership in the business, including salary, consulting fees, honoraria, equity interest, and intellectual property rights.

PROCEDURES

I. NACHO COI Form

The COI Form is listed as Attachment 1 and available on the NACHO website in the Member Resources section. All members of the EC, SC, CSC, members of the DSMC, and Study Chairs of each NACHO research study are required to complete the COI Form and to agree to abide by this SOP. Once the form is completed, each signee should retain the original copy and submit a copy to the NACHO Operations Center (OC) via email at NACHO.OperationsCenter@stjude.org. After submission to the NACHO OC, COI Forms with concerns will be reviewed by the NACHO EC.

II. Completion of COI Forms

a. **Roles** - There are three roles within NACHO that require the completion of a NACHO COI Form.

i. Study Design

As part of the procedure for submission of a Concept proposal to NACHO, the study chair(s) shall submit a COI Form or confirm that a current COI form is still accurate.

ii. Leadership Position /Determination of research priorities

All NACHO Standing Committee members must submit a COI Form before beginning their membership in that committee. NACHO Standing Committees include the EC, SC, and CSC.

iii. Data Safety Monitoring Committee

All members of the DSMC must complete a COI Form before beginning in their duties. Any ad hoc experts invited to a DSMC review must also complete a COI Form.

III. Review of COI

a. NACHO OC will review all COI Forms and keep these forms on file. If a COI Form raises the possibility of a conflict, NACHO OC will bring the conflict to the Executive Committee at the next scheduled meeting.

- b. If a COI is identified, that individual will receive instructions from the EC regarding their participation.
 - i. If a standing committee member has an identified potential conflict, a COI plan will be developed among the EC and NACHO OC.
 - ii. If a study chair has an identified potential conflict, the plan will include a requirement for a statement disclosing this potential conflict to be included in the written informed consent and protocol document for affected studies and will be included in all presentations regarding the affected studies (all forms of presentations including written, oral, slides, videos) and in all manuscripts. The disclosure statement will require approval by the NACHO EC.

IV. COI Updates

- a. If an individual acquires a financial interest or begins activities which would constitute a conflict subsequent to commencing the study, the individual must complete a new disclosure form and submit it to NACHO OC within 30 days.
- b. Individuals will be required to review their COI on a yearly basis attesting whether new conflicts have arisen.

Accessibility of Information

All requests for information regarding an individual's compliance with this policy must be submitted in writing to the NACHO OC. The only information that shall be disclosed is "confirmation at this time" or "inability to confirm at this time" that the particular individual is in compliance with the NACHO Conflict of Interest Disclosure SOP. No additional information shall be provided. A copy of the written request and NACHO's response shall be provided to that individual.

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the review of this SOP. Suggested changes must be proposed to and approved by the NACHO EC.

AUTHORIZATION

This SOP was developed by the SOP Ad Hoc Committee and reviewed and approved by the NACHO Executive Committee.

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
07/27/2022	V 1.0	Original documentation/publication.