Types of NASH CRN Studies

(1) Main study

A main study is a study that is carried out by the entire NASH CRN group, is supported by funds from the NIDDK, NICHD, or a CRADA(s) with the NIDDK, and is done to carry out a stated objective of the NASH CRN. A main study has access to central resources of the NASH CRN such as the Data Coordinating Center and whatever subcontracts the NASH CRN sets up for central repository, drug distribution, etc. Main studies will have primary, secondary, and lesser objectives. Publications or presentations arising from a main study must be approved by the NASH CRN Presentations and Publications Committee prior to initiation, and the resulting manuscript or abstract must be approved by the NASH CRN Presentations and Publications Committee prior to journal submission. Authorship format for main papers arising from a main study may be of the modified corporate type (ie, named author is "The NASH CRN Research Group" with a footnote specifying the names of the writing committee members). Where allowed by the journal, a full credit roster will be included with the paper. Authorship format for secondary and lesser papers arising from main studies will be of the modified conventional type (ie, J Smith, E Brown, and the NASH CRN Research Group) or of the conventional type. Examples of NASH CRN main studies include the NAFLD Database, the PIVENS trial, and the TONIC trial.

(2) Substudy

A substudy is a study that is subordinate to the main NASH CRN studies, addresses a secondary objective(s), but is a required part of NASH CRN activities. A substudy involves new data collection – analyses of previously collected data are not considered substudies. The data collected in a substudy are considered part of the NASH CRN database. Funding for a substudy will come from the NIDDK, NICHD, or through a CRADA(s) with the NIDDK. A substudy has the same access to NASH CRN central resources as main studies. A substudy must be reviewed and approved by the NASH CRN Steering Committee prior to initiation. Publications or presentations arising from a substudy must be approved by the NASH CRN Presentations and Publications Committee prior to initiation, and the resulting manuscript or abstract must be approved by the NASH CRN Presentations and Publications Committee prior to journal submission. Authorship format for primary papers arising from a substudy will usually be of the modified conventional type (ie, J Smith, E Brown, and the NASH CRN Research Group). Where allowed by the journal, a full credit roster will be included with the paper. Authorship format for secondary papers arising from substudies will be of the conventional type. Examples of NASH CRN substudies include the Biomarkers Substudy and the Adult and Pediatric Genetics Substudies.

(3) Pilot or feasibility study

A pilot or feasibility study is a study that is carried out by one or more NASH CRN investigators using additional funds provided by the NIDDK to pursue determine feasibility of a study or to conduct a small scale study of NASH. Pilot and feasibility studies are not required NASH CRN activities but they have access to central NASH CRN resources and the data collected are part of the NASH CRN database. Depending on results and availability of funding, these studies may lead to larger studies in the NASH CRN. Investigators wishing to conduct a pilot or feasibility study must complete an application. Review and prioritizing of applications for pilot or feasibility studies will be the responsibility of the Pilot and Feasibility Studies Committee; the Pilot and Feasibility Studies Committee will make a recommendation to the NASH CRN Steering Committee as to whether the study should be approved. The NASH CRN Steering Committee must approve a pilot or feasibility study for it to proceed. The process and policy for publications arising from pilot or feasibility studies are the same as those for substudies.

(4) Ancillary study

An ancillary study is a study that is carried out on NASH CRN patients or related materials, but is not a required part of NASH CRN activities. An ancillary study involves new data collection – it is not an analysis of previously collected data from main studies or substudies. The data collected by the ancillary study are not part of the NASH CRN database. An ancillary study may be proposed by an investigator outside of the NASH CRN; however, a NASH CRN Steering Committee member must agree to serve as the liaison between the NASH CRN and the ancillary study. Funding for ancillary studies will not come from NASH CRN resources and an ancillary study will not use central resources such as those provided by the NASH CRN Data Coordinating Center. Investigators wishing to conduct an ancillary study must complete an application. The NASH CRN Ancillary Studies Committee will review the application for scientific merit (using the expertise represented by the Committee) and will assess whether the ancillary study represents undue burden for patients or could interfere with completion of the NASH CRN objectives. The Ancillary Studies Committee will make a recommendation to the NASH CRN Steering Committee as to whether the ancillary study should be approved; the NASH CRN Steering Committee must approve the ancillary study for it to proceed. Publications or presentations arising from ancillary studies do not need to be approved prior to initiation; however, publications arising from ancillary studies must be reviewed by the NASH CRN Presentations and Publication Committee prior to journal submission; the purpose of the review will be to assure that any statements about the NASH CRN protocol are accurate and that the NASH CRN resources used in the ancillary study are appropriately acknowledged. Authorship for ancillary studies will usually be of the conventional type, with an acknowledgment of the NASH CRN. Examples of potential ancillary studies include studies related to obesity in the NASH CRN population.