

ACE Ancillary Studies Policy

Introduction

The ACE Ancillary Study Committee (AASC) welcomes Ancillary Study proposals for review. Ancillary studies may provide valuable information beyond that explored in the context of the main trial, and will promote continued academic interest in ACE. Ancillary studies that have academic values in understanding either coronary artery disease or type 2 diabetes and thereby enhance the value of ACE are strongly encouraged. Ancillary studies, however, must not have a deleterious impact on the main study, particularly with respect to interventions which might confound the main study objectives or reduce patient retention. Approved Ancillary Studies will be reviewed regularly to evaluate their progress and impact on the main study.

Ancillary Studies

These are defined as studies or investigations that are distinct from the ACE main protocol but use ACE participants information, data, or samples. Such studies may involve the acquisition of data not obtained as part of the ACE study procedures, and may utilize information from some or all of the ACE participants. Ancillary studies require separate outside funding which must include provision for any ancillary study costs. In order to protect the integrity of the main ACE trial, Ancillary Study proposals require to be reviewed by the AASC and approval by the ACE Steering Committee. Studies that propose to analyze ACE data for novel study questions not included under the scientific aims of ACE can also be considered as ancillary studies. Wherever feasible, Ancillary Studies should involve more than one ACE site.

Ancillary Studies may:

- Require collection of data through additional questionnaires not originally used at ACE baseline or follow-up visits

- Require additional examination procedures that may require participants attend additional clinic visits or go to another testing location
- Make use stored biomarker and/or genetic samples
- Address study questions that are not part of the stated ACE scientific aims

Who Can Apply

Anyone may apply but all proposals must include at least one ACE Steering Committee member or site Principal Investigator.

Application Process

Applications must be submitted to ace@dtu.ox.ac.uk using the ACE Ancillary Study Proposal Form available via the ACE trial web site (www.ace-study.org). Please be certain that your contact information is correct, as additional information may be requested during the review process.

Proposals will be reviewed by the AASC who will make recommendations to the ACE Steering Committee who will make the final decision regarding approval or rejection. Participation of the specified ACE investigator will be confirmed prior to official review. The AASC may refer the proposal to another committee or body for expert advice. The applicant must notify the AASC when approved proposals obtain funding.

Ancillary Study Proposals

Proposals need to be compatible with the ACE informed consent, the population being studied and the data collected. Attention needs to be given to the sample sizes required, proposed statistical analyses, confidentiality issues and possible need for a separate informed consent. If access to ACE biomarker and/or genetic samples is need, details of specimen type, volume of specimen and laboratory methods should be given.

The ACE Ancillary Study Proposal Form should be completed in the first instance, which should include:

- Specific aims
- Background to the study and significance of the research question
- Potential significance to ACE
- Methods

Data, Statistical Analysis and Publication

At the discretion of the SC, analysis of Ancillary Studies may be performed by ACE statisticians or by the Ancillary Study investigators (with provision of anonymised ACE data sets as necessary). All data collected by Ancillary Studies will be made freely available to the main study for further use and analysis as the SC determines. All publications arising from Ancillary Studies must be approved by the SC and appropriately acknowledge the main study.

Timelines

Investigators should allow the following turn-around times for proposals:

- Two months from the time of receipt of application by the AASC to the initial review decision
- Two months from AASC approval to Steering Committee final decision
- All approved Ancillary Studies are required to provide an annual progress report to the ACE Steering Committee from the date of final approval