

WFUHS Use of the Copernicus IRB -

Introduction

An agreement has been executed and regulatory filings completed to allow Copernicus IRB to function as a reviewing IRB for Wake Forest University Health Sciences and North Carolina Baptist Hospital. This provides the opportunity to have an independent IRB review of human research studies in situations where review by an independent IRB is determined appropriate.

Criteria for recommending use of the Copernicus

Following are the circumstances when a research study may be recommended for review by Copernicus:

- The WFUHS IRB lacks the requisite expertise to conduct the review of the study
- Review by the WFUHS IRB would create an unresolvable conflict of interest
- The WFUHS identifies other compelling reasons for which review of a study by the Copernicus IRB would be in the best interests of the institution
- The Conflict of Interest Committee recommends review by an independent IRB as part of a management plan for an Investigator, whose research proposals present an individual or institutional conflict of interest.
- Investigator identifies an institutional conflict of interest and contacts the Office of Research

Procedures

Individual investigators and study sponsors can not request or require review of a study by the Copernicus IRB. The recommendation must come from the Office of Research.

1. All studies that are recommended for review by the Copernicus IRB must be recommended by the Office of Research (OR).
2. OR recommendations will be forwarded to the Dean of the School of Medicine who will provide formal approval for the review by Copernicus and will determine responsibility for the cost of the review.
3. The Dean of the School of Medicine will provide written approval for the use of Copernicus and forward this information back to the IRB or Conflict of Interest Committee.
4. The WFUHS IRB will communicate this information to the Principle Investigator.
5. The Principle Investigator will be responsible for the submission to the Copernicus IRB, all subsequent interactions and correspondence with Copernicus, and compliance with all determinations and requirements made by the Copernicus IRB.

The principle investigator is also responsible for compliance with all WFUHS institutional and IRB policies and procedures related to submission to the Copernicus IRB (i.e. notification of the submission, notification of any suspension or termination, etc.).

Responsibility for Copernicus Fees:

1. When institutional COI is identified on industry sponsored studies, the cost for Copernicus will be covered by the study budget.
2. When the IRB lacks the expertise to conduct the review of the study (prisoner studies, e.g.) WFUHS will pay the costs of Copernicus.
3. On PI initiated studies where there is an identified institutional conflict of interest, the responsibility for Copernicus costs will be determined by the Dean of the School of Medicine.