
BIostatISTICS AND BIOMEDICAL INFORMATICS CORE



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I. EXECUTIVE SUMMARY

The purpose of the Biostatistics and Biomedical Informatics Core (BBIC) for this lung SPORE grant is to provide a comprehensive, multi-disciplinary resource for design of clinical and basic science experiments and clinical trials, the utilization of appropriate and innovative statistical and bioinformatics methodology and analysis techniques as well as descriptive summarization of resulting data. The BBIC has the following overall goals: to provide statistical and bioinformatics consulting and collaboration on the design, conduct, analysis and interpretation of all SPORE project research studies and cores, and to provide, manage and maintain a high-quality research database that supports the research projects and cores while preserving the confidentiality of all subject data.

II. CORE DESCRIPTION

In this Lung SPORE grant, the BBIC Core will serve as a focal point from which investigators may draw statistical and bioinformatics expertise for planning, management, and analysis of their studies. This Core will also utilize various novel research methodologies in the SPORE program projects including clinical trials and translational and basic science research projects. The large volume of information to be generated in this Lung SPORE grant requires a centralized database and data management structure that facilitates the entry, storage and retrieval of all data generated by the SPORE grant projects and permits the controlled exchange of information across the three projects and cores. This data repository will also contain data extracted from clinical databases at the Winship Cancer Institute. All IRB and HIPAA regulations will be strictly followed. By providing comprehensive biostatistical services, data management and bioinformatics expertise, this Core will facilitate achievement of all project aims and encourage exploratory analyses beyond those stated. The BBIC Core will also function as a hub to integrate and share the data and analysis results of all three projects and Cores to achieve the overall goals of the SPORE grant. The specific aims of this Core are:

Aim 1. Provide comprehensive statistical and bioinformatics support to the Lung SPORE projects

- 1.1 Design all experiments, clinical trials, and all other research studies.
- 1.2 Review protocols and monitor the ongoing progress of all studies.

1.3 Perform appropriate data analyses, interpret results and assist in reporting results and manuscript preparation.

Aim 2. Utilize statistical and bioinformatics state-of-the art methodology research

2.1 Use appropriate and innovative statistical and bioinformatics methodology according to the needs of the SPORE projects.

2.2 Employ and develop cutting-edge statistical and bioinformatics methods to Lung SPORE projects on an as needed basis.

Aim 3. Develop and maintain a data acquisition and management system

3.1 Develop a centralized database to meet the requirements of the new Lung SPORE grant.

3.2 Input, store, query, monitor and manage Lung SPORE projects data in the database.