

## BIostatistics/CLINICAL RESEARCH COLLABORATION

The success of the UWCCC's clinical research program depends critically on a sound biostatistics component that effectively integrates statistical science into the clinical research conducted by the UWCCC investigators.

A major aim of the Biostatistics Shared Resource is in the design, conduct, and analysis of clinical trials and correlative studies in cancer. Primary activities include collaboration with UWCCC investigators on the design of trials, monitoring of the conduct, patient safety, integrity of the trial, validity of accumulating data; and analysis and publication of UWCCC coordinated trials.

Statisticians collaborate fully in the development of clinical trials and correlative studies by:

- Developing the experimental design of the study and any sections of the protocol that relate to statistical and data management issues
- Determining protocol-specific accrual targets i.e. sample size
- Reviewing the protocol in detail before submission to sponsor and/or PRMC/IRB

Protocols should be discussed with the Statistician as early as possible to determine objectives, endpoints, sample sizes, estimated duration of the study, etc. The Statistician is responsible for writing the statistical section; the study chair/PI is responsible for providing relevant background information regarding the study. Some protocols may already contain a statistical section, either written by a statistician at another institution, or modified from a previous statistical section. However, if a UWCCC statistician is to be involved in the study, the proposal must be sent to the UWCCC statistician for a statistical section addressing the issues of experimental design, endpoints, sample size, accrual rates, and planned analysis.

How to involve a statistician in UWCCC clinical research project:

1. Investigator contacts statistician as early as possible in the development of the concept for a study
  - a) Investigator may contact the statistician with whom they have an established relationship.
  - b) If the investigator does not have an established collaborative relationship with a statistician, s/he should request a consult through the web portal request system <https://ictr.wisc.edu/bard>. Under the ICTR membership question, it is not necessary to be an ICTR member to receive biostatistics support as a UWCCC member.
  - c) Or contact the Biostatistics Program Manager, Dori Kalish ([kalish@biostat.wisc.edu](mailto:kalish@biostat.wisc.edu)), who will assign a statistician for the collaboration.
  - d) Sound study design is feasible only when realistic and adequate background information is provided to the statistician. The investigator is expected to provide the statistician with:
    - i) Rationale for the study, e.g. relevant background information

- ii) Relevant literature on disease, agent, modality including historical data
  - iii) Endpoints
  - iv) Protocol concept if available
  - v) Expected accrual rate
  - vi) Feasible sample size
- e) Statistician will provide a statistical section within **1 week** of receiving the relevant information in d). In developing the statistical considerations section, the statisticians will look for:
- i) Clearly and correctly defined and prioritized study objectives
  - ii) Study design set up to answer the objectives of the study,
  - iii) Unambiguous criteria for the study population,
  - iv) Stratification factors, if relevant
  - v) Consistency between schema and protocol sections
  - vi) Study parameters and data collection that will provide data required for analysis
- f) Once the investigator has incorporated the statistical section, and addressed the comments and concerns, the protocol must be sent back to the statistician for review prior to submission to sponsor and to PRMC/IRB. The statistician is expected to return the protocol with comments within 1 week.
2. If there is a proposal to be submitted for funding, notify the Biostatistics Program Manager as soon as possible ( $\geq 2$  weeks prior to due date.)
- a) Provide to the Biostatistics Program Manager:
    - i) Title of project
    - ii) PI name
    - iii) Sponsor
    - iv) Inclusive dates
- The Biostatistics Program Manager will check with the statistician as to the complexity of the study and effort involved in order to develop a budget. The budget information can be provided within 1 week of receipt of the information from the statistician, or within 1 week of the initial draft of the statistical considerations section.
- b) The Biostatistics Program Manager will provide as required:
    - i) Salary information
    - ii) Budget
    - iii) Resources
    - iv) Budget justification
  - c) Provide the Biostatistics Program Manager with a copy of the proposal submitted (not necessary for NIH or CDC proposals,) or the executed agreement and protocol.