

			<h1>STANDARD OPERATING PROCEDURE</h1>
AUTHOR Denise J. Roe, DrPH	SOP #	DATE 10/30/20	TITLE Biostatistics Shared Resource

Overview: The goal of the Biostatistics Shared Resource (BSR) is to ensure excellent and timely biostatistical support in the design, development and analysis, in a cost-effective manner, for all Research Programs of the University of Arizona Cancer Center (UACC). The BSR provides a centralized home for Biostatistical support that includes a comprehensive repertoire of expertise and skills needed to support the scope of the research directions in the UACC portfolio.

Accessibility: To overcome the potential barriers to investigator use of the resource, the BSR has developed a centralized presence with a convenient visible location together with a spectrum of “contact points”. Initially, UACC investigators can contact the BSR directly and/or through the UACC website. Investigators new to UACC often are encouraged to contact the BSR by their Program Directors. UACC investigators also often approach BSR faculty members to discuss biostatistical support at UACC grand rounds, seminars, and retreats.

Assignment of Projects to BSR faculty/staff: After the initial contact, Dr. Roe discusses the project and assigns it to BSR faculty/staff according to the scientific area. Investigators who have established collaborative relationships with BSR personnel are encouraged to contact them directly when support is needed.

Prioritization: The resources of the BSR are available to all UACC members. Priority is given to funded UACC members. Unfunded investigators are given priority as follows: 1) Members applying for additional grants; 2) Associate Members who need assistance with the development of investigator-initiated clinical trials; 3) Junior faculty who have pilot project funding and need assistance with grant applications; 4) Short-term statistical analysis projects which will provide pilot data for grant submissions; and, 5) Short-term statistical analysis projects for manuscripts. This prioritization has been reviewed and approved by the BSR Internal Advisory Committee.

User Fee Policy and Chargebacks: There are no chargebacks for the development of investigator-initiated trials and grant development requests. CCSG funds, which represent only a part of the total effort in the BSR, catalyze the development of independent funding as well as the essential biostatistical involvement in UACC studies. When major projects receive independent funding, the biostatisticians of the BSR are supported at the appropriate FTE for their work. Smaller grants are encouraged to include a fixed dollar amount for BSR support, which is invoiced on a fee-for-service basis. The hourly rate has been established by the University of Arizona. When the fee-for-service methodology is applied, iLabs is used to invoice the appropriate investigator.

Data Management and Security: All data received by the BSR are HIPPA compliant with no patient identifiers. All BSR computers and laptops are password protected. Networked computers have backups performed routinely by UACC IT staff.

Reproducible Research: As part of its role in the UACC, the BSR has produced a series of internal Biostatistics technical reports. A technical report is a written exposition by the biostatistician for the benefit of the investigator. A detailed description of the statistical methods, results, and appropriate tables and figures are provided. All BSR personnel use reproducible statistical analysis procedures, which directly imbed results from the appropriate statistical software into the technical report.

Confidentiality: BSR personnel guard the confidentiality of statistical analysis results and do not share them with anyone except the designated UACC investigators upon analysis completion.

Effort Reporting: The BSR uses a REDCap database for documenting effort, based on advice received from the External Advisory Board. Previously, a BSR "hours" database was maintained; however, tracking hours of statistical activity is an invalid measure of appropriate statistical support. The REDCap database tracks information for each type of project, including grant applications, investigator-initiated trials, conference abstracts, manuscripts, and other data analyses. This allows the BSR to track productivity based on scientific contributions, which is more consistent with the BSR specific aims.