

# BIostatISTICS

## SHARED RESOURCE

**DIRECTOR: WILLIAM BRADY, PhD**  
**CO-DIRECTOR: GREGORY WILDING, PhD**

The mission of our “core” is to

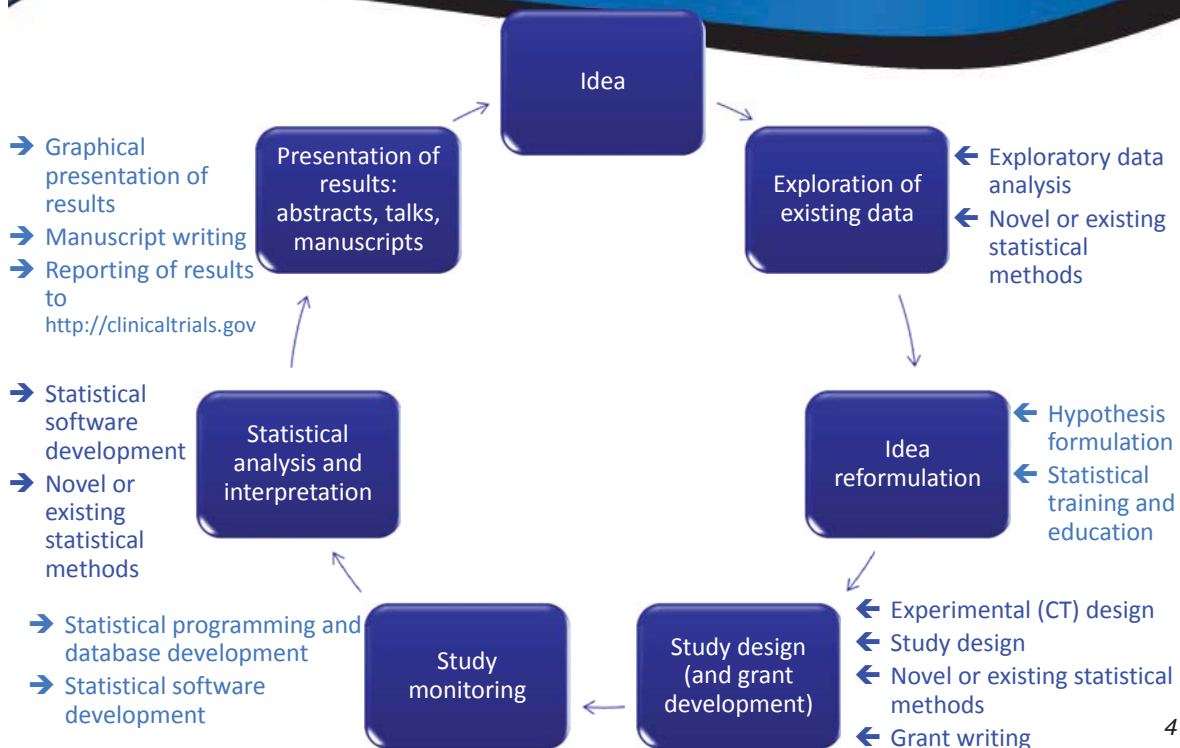
- provide strategic service in the design, oversight, implementation, analysis, publication, and reporting of scientific studies by CCSG program members and other Roswell faculty and staff.
- This includes
  - articulating study objectives and hypotheses
  - conceiving appropriate cost-effective designs and models for achievement of study objectives
  - assuring that modern and appropriate statistical methods are used
  - monitoring interim and final analyses
  - co-authoring abstracts, presentations, and manuscripts.

## What types of studies do we work on?

- Clinical trials: phase I, II, III
- Basic science and translational research projects
- Epidemiological studies
- Surveys
- Retrospective review of existing data, e.g., tissue banking studies
- External data sources, e.g., SEER
- Quality of life studies
- Teaching classes at UB and RPCI
- And others...

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## How/where we fit in "a" scientific process



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## At its heart, the Biostatistics Core is a collaborative core

- We do provide services, e.g.,
  - Ad hoc power calculations
  - Assistance with specific analysis questions
  - etc.
- However, we are not truly a fee-for-service core—but a collaborative core and can be involved in the entire scientific process

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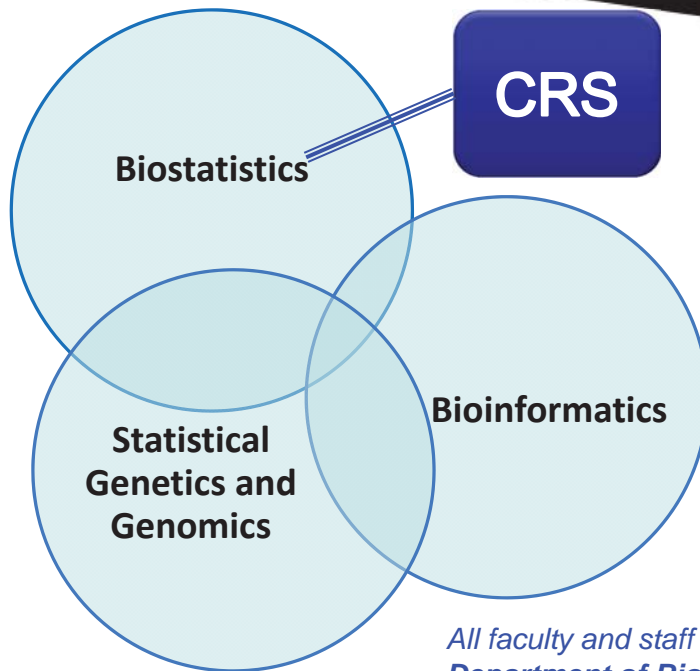
## Biostatistics Shared Resource Faculty and Staff

### 11 FTEs (6 faculty and 5 staff)

- Bill Brady, PhD (*Director of Biostatistics Shared Resource*)
- Greg Wilding, PhD (*Co-Director of Shared Resource; Vice-Chair of Biostatistics*)
- Alan Hutson, PhD (*Chair of Biostatistics and Bioinformatics*)
- **Qianqian Zhu, PhD** (*Director of Statistical Genetics and Genomics Resource*)
- **Kevin Eng, PhD**
- Austin Miller, PhD
- Kris Attwood, PhD
- Lili Tian, PhD
- Adrienne Groman, MS
- Wei Tan, MA
- Katy Wang, MA
- **Lori Shepherd, MS**
- Shiva Dibaj, MA
- Yang, Zhengyu, MS
- Xiwei Chen, MA

Administrator: Ellen Sanders  
Principal Secretary: Pam Jarrett

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This ensures the Institute has statistical coverage from *preclinical and clinical biostatistics* to *epidemiology* to *genetics and genomics* to *bioinformatics*.

*All faculty and staff in these cores are in the Department of Biostatistics and Bioinformatics* 7

- All faculty members are faculty (or adjunct) at UB
- Extensive collaboration (Hutson, Brady, Miller) with the Gynecologic Oncology Group (GOG), an NCI cooperative group, including membership on key GOG committees:
  - Protocol Development Committee
  - Developmental Therapeutics Committee
  - Phase I Committee
  - Rare Tumor Committee
  - Health Outcomes Research Committee

## Some selected areas of expertise in biostatistics

- Clinical trials design and analysis
- Epidemiologic statistical methods
- Diagnostic testing
- Computationally intensive statistical methods
- Exact testing
- Bootstrap and resampling methods
- Longitudinal data methods
- Survival and censored data methods
- Nonlinear modeling
- Monte Carlo simulation
- Mathematical statistics

## Some selected areas of expertise in statistical genetics and genomics

- Pharmacogenomics, genetic testing, and personalized medicine
- Statistical and bioinformatics analysis of genome, epigenome, and transcriptome data
- Developing power estimates for biomarker discovery
- Developing statistically sound and computationally efficient methods to pinpoint the causal genetic variants of human diseases utilizing high-throughput genetics and genomics data
- Collaboration with biologists and clinicians in genetic epidemiology studies utilizing approaches of Genome-Wide Association Studies (GWAS) and Next-generation Sequencing (NGS)

- **Alan Hutson** is Co-PI of the RPCI Biostatistics and Medical Informatics Core for the Ovarian SPORE
- **Two core members** received 2013 Alliance Grants
  - **Qianqian Zhu:** Identification of Causal Genetic Variants of Inherited Ovarian Cancer through Whole Exome Sequencing
  - **Kevin Eng:** Pilot Study of Personalized Treatment Markers in Recurrent Ovarian Cancer
- **Bill Brady** presented a novel Phase II design at the 2013 meeting of the American Statistical Association

- **Greg Wilding** designed studies with Dr. Mohler showing the relevance of RhoA as a mediator of clinically relevant androgen action in prostate cancer.
- **Austin Miller** collaborated with Dr. Odunsi on a study demonstrating improved clinical benefit in ovarian cancer patients that mounted integrated antibody, CD4+ and CD8+ T cell responses to NY-ESO-1 long peptide, and to recombinant vaccinia-NY-ESO-1, and recombinant fowlpox-NY-ESO-1.
- **Bill Brady** designed the first prospective trial in low-grade serous carcinoma of the ovary—published in *The Lancet Oncology* in 2013.

## Software

- SAS® Software
- R
- Mathematica®
- PASS Power Analysis and Sample Size Software
- PERL
- Plink
- GATK

## Hardware

- Microcomputer workstations
- Linux high-performance computing cluster (1,600 processors, 200 TB storage)
- Access to UB's Center for Computational Research's (CCR) Linux cluster with >8,000 processor cores and 600 TB of high-performance storage

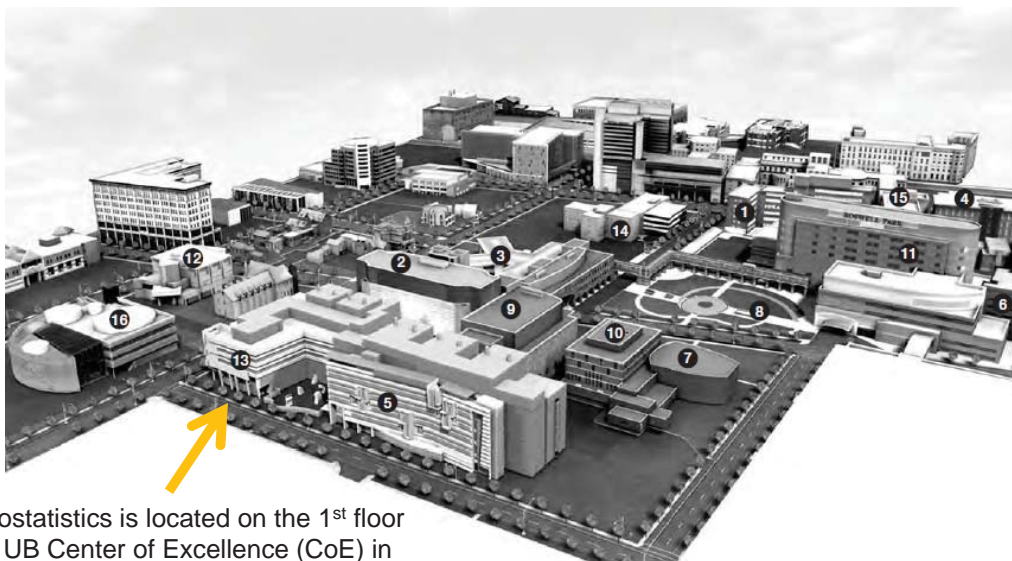
- Biostatistics Core members are on the following committees in the Institute
  - IRBs (all of them)
  - CRPC
  - SRC
  - DSMB
  - Phase I Core
  - CCSG Steering Committee
  - And others...
- Serve on external DSMBs, DMCs, NIH study sections
- Our own methodological research

## How much do we do?

- In past year: 208 requests (in LIMS [more on this later])
- *Current* protocols with Core personnel: 231
  - 118 intervention
  - 102 non-intervention
  - 11 EDR
- Publications with Biostatistics members in 2013:
  - 56 manuscripts

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## Where are we?



Biostatistics is located on the 1<sup>st</sup> floor of UB Center of Excellence (CoE) in Bioinformatics & Life Sciences

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## Why work with our Core?

- Biostatistics is a vital part of the entire scientific process
- Grants typically do not get funded without good statistical input via collaboration
- Studies do not get approved without good statistical input via collaboration
- And in the end, all investigator-initiated studies need to have a statistician assigned to them

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## Cost?

- For internal (RPCI) users, there is **no fee**/chargeback for using the Biostatistics Shared Resource
- On grants, there should be an appropriate percent effort for the biostatistician
  - On grants, unfunded participants are viewed dubiously during review

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- Requests for collaboration/service should be made with **LIMS** at: <https://rpcilims.roswellpark.org/> (which can also be found under our directory listing in *i2*)
- Some notes on using LIMS
  - Must be on campus (or access via Citrix)
  - Must use Internet Explorer (others potentially in the near future...)
  - There are occasional problems with logging in. If so, email me...
  - Put in meaningful *Request Description* and realistic *Due Date*

- i2: search for “biostatistics”
- [www.roswellpark.edu/shared-resources/biostatistics](http://www.roswellpark.edu/shared-resources/biostatistics)
- Questions can be directed to:
  - Bill Brady – Director
    - [William.Brady@RoswellPark.org](mailto:William.Brady@RoswellPark.org)
  - Greg Wilding – Co-Director
    - [Gregory.Wilding@RoswellPark.org](mailto:Gregory.Wilding@RoswellPark.org)
  - Ellen Sanders – Administrator
  - Pam Jarrett – Principal Secretary