Part I: Introduction to Biostatistics Resources at NYULH

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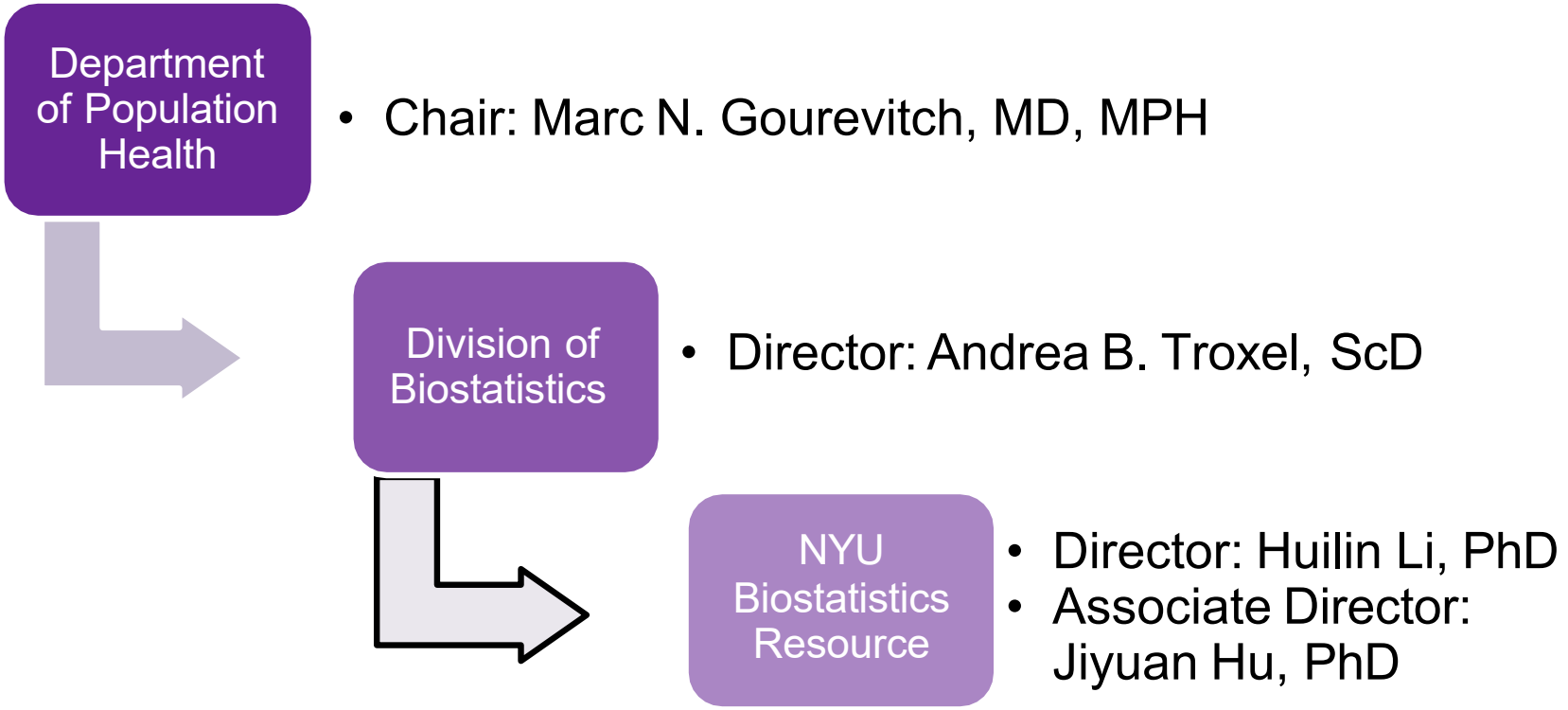
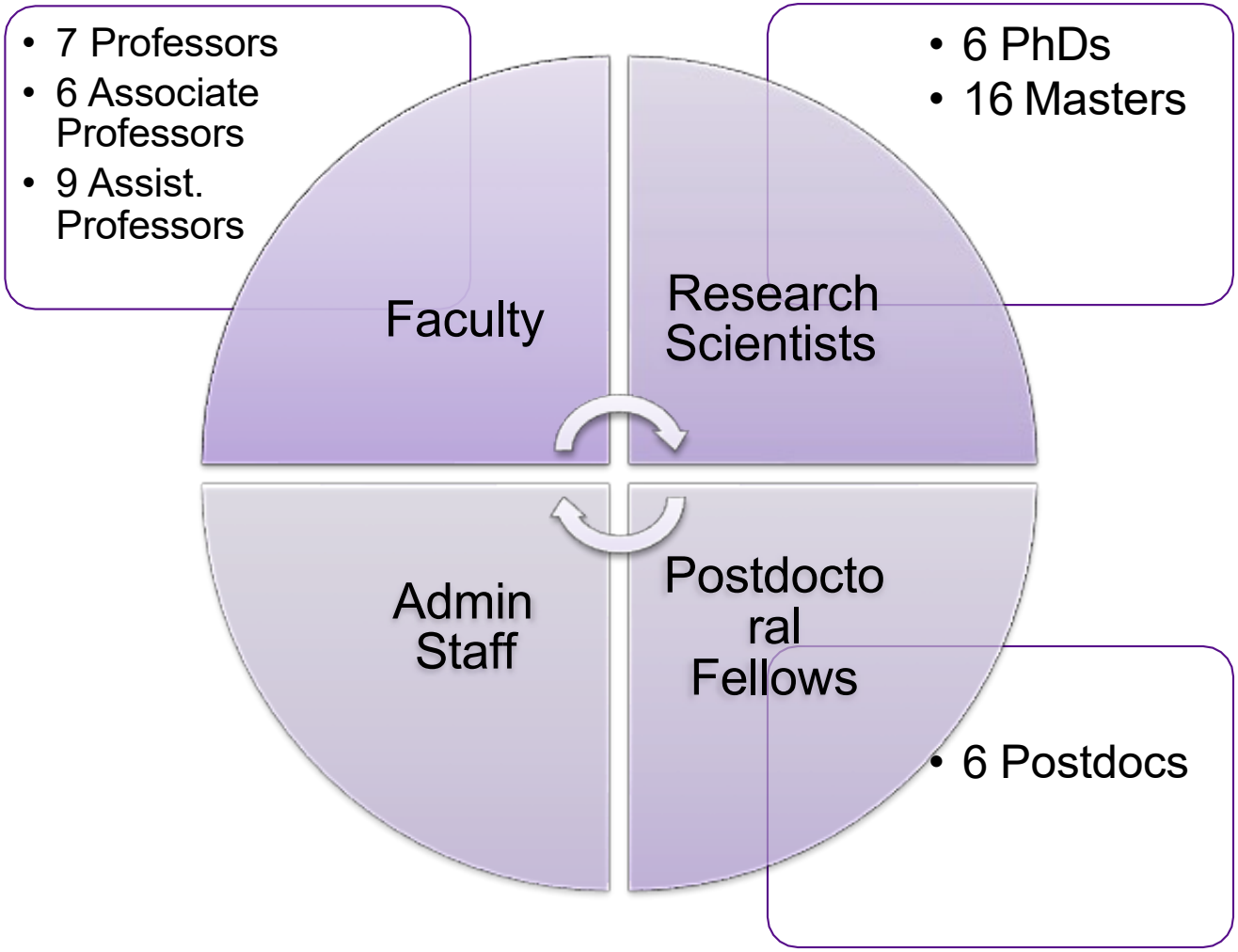
June 16, 2022,

Where is NYUBR?



Location: 180 Madison Ave, the second, fourth and fifth floors
Biostatistics-resource@nyulangone.org

NYUBR Research Team



Our Expertise:

- Study design
- Advanced analytical methods
- Data (clinical) coordinating center creation and implementation
- Core leadership in center grants

Our Expertise: Study Design

"TO CONSULT THE STATISTICIAN AFTER AN EXPERIMENT IS FINISHED IS OFTEN MERELY TO ASK HIM TO CONDUCT A POST MORTEM EXAMINATION. HE CAN PERHAPS SAY WHAT THE EXPERIMENT DIED OF."

Ronald A. Fisher (1890 – 1962)

Our Expertise: Study Design

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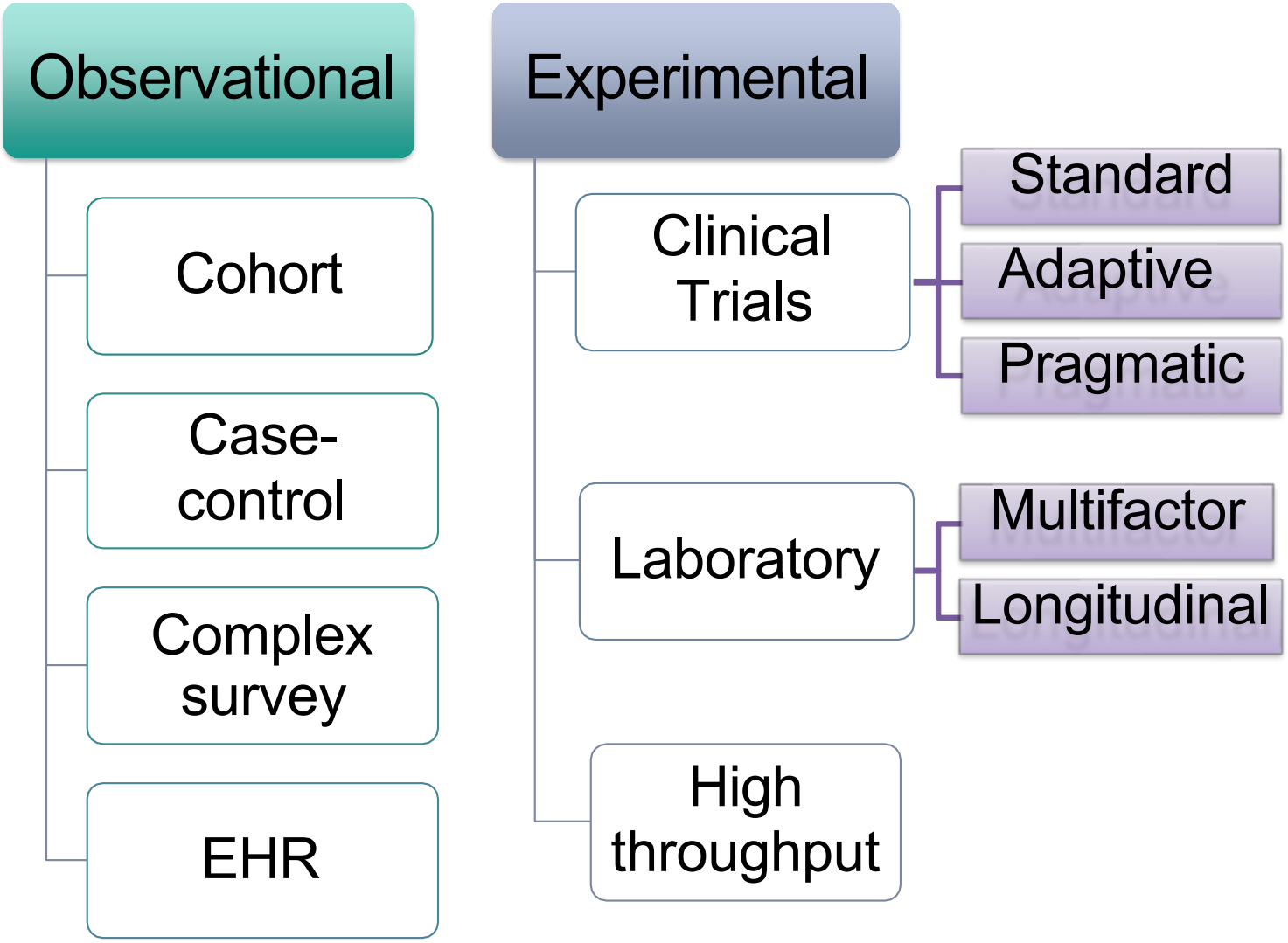
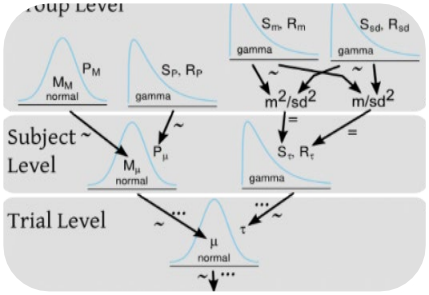
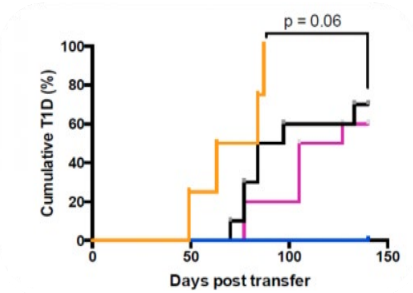


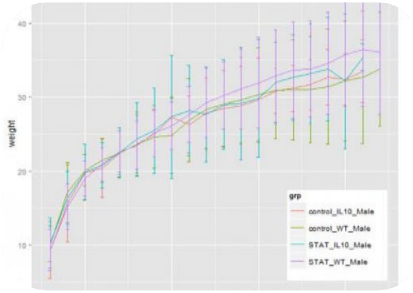
Our Expertise: Advanced Analytical Methods



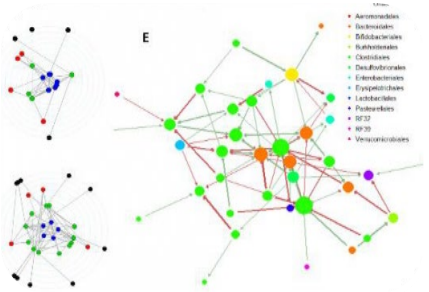
Hierarchical model fitting



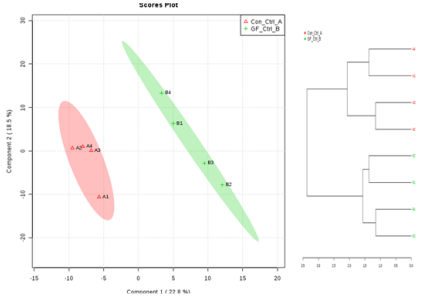
Survival analysis



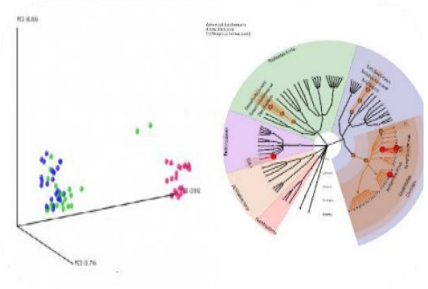
Longitudinal analysis



Network analysis



Clustering, classification, and prediction



High-dimensional omics data analysis

Our Subject Knowledge

Environmental science	Ophthalmology	Orthopedics	Addiction
Geriatric care	Behavioral economics	Cancer	Genetics
Early detection and screening	HIV	Microbiome	Chronic disease
Palliative care	Diabetes	Drug use	Molecular epidemiology

Types of Biostatistics Collaborations

Short-term support

- developing pilot study designs
- performing statistical analysis on a prepared dataset
- preparing abstracts or other presentations
- preparing manuscripts (either initial or for a revision)

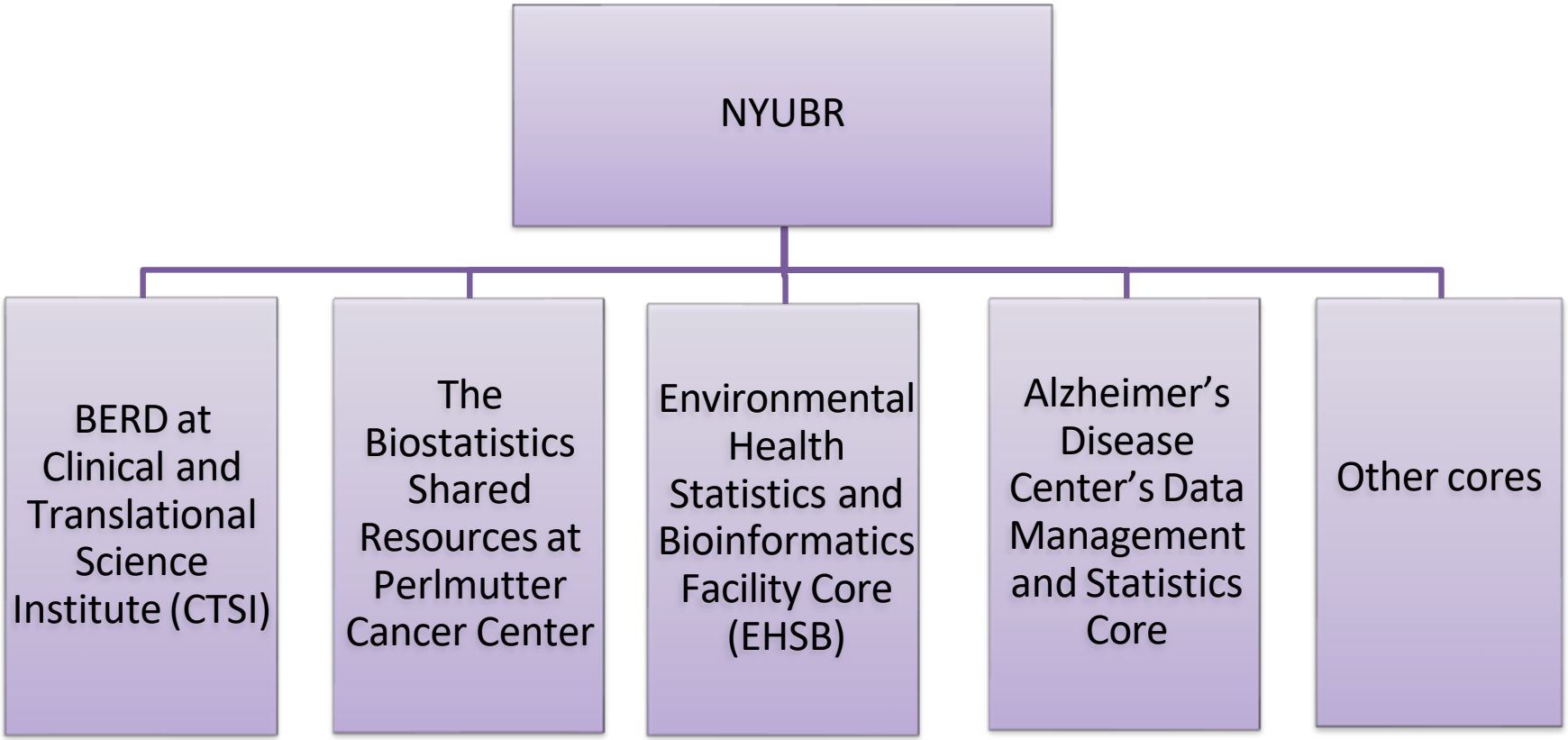
Grant proposals

- assisting in refining study questions and measurement methods
- developing study and experimental designs
- writing statistical analysis plans
- computing precision, power, and sample sizes

Long-term support

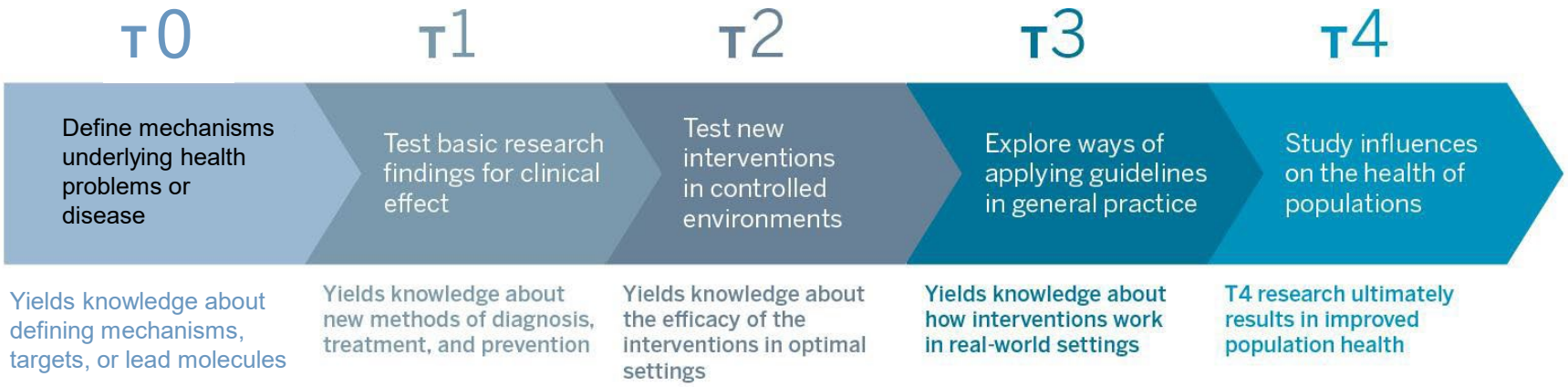
- proposal development
- manuscript writing
- statistical analysis
- presence at departmental research meetings
- participation in journal clubs (methodological review)
- assistance with research conference presentations, and K-award mentoring

Core Resources



Biostatistics, Epidemiology and Research Design Program (BERD) in NYU-H+H Clinical & Translational Science Institute (CTSI)

Translational research transforms basic science discoveries into practical applications that can improve health, such as new diagnostic techniques, therapies, and interventions.



BERD provides biostatistical, epidemiological, and study design collaborations for projects with translational research component

- Consultations
- Grant developments and data analyses (vouchers can be applied)
- Studios (multidisciplinary project reviews)
- IRB scientific reviews
- Trainings

Self-service Tool Page and K-award Resource Repository

Biostatistics Tool

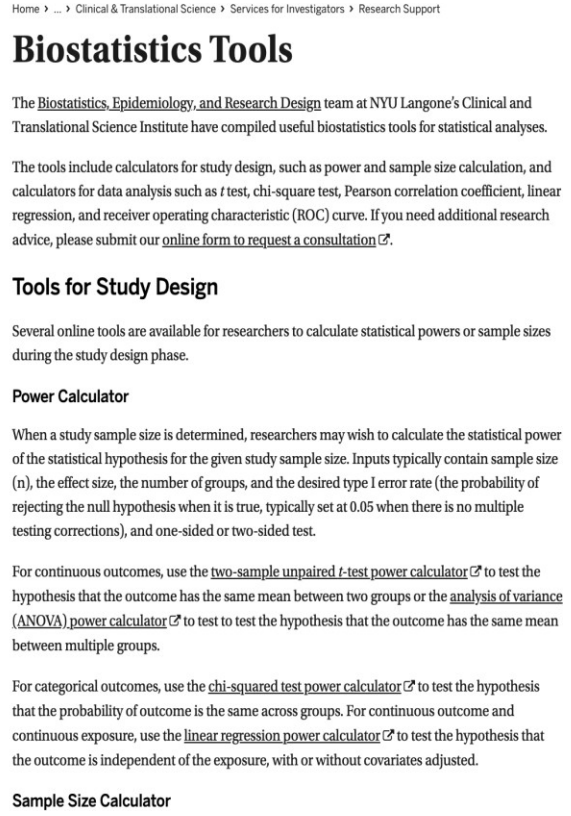
Enable investigators independently implement relatively straightforward tasks:

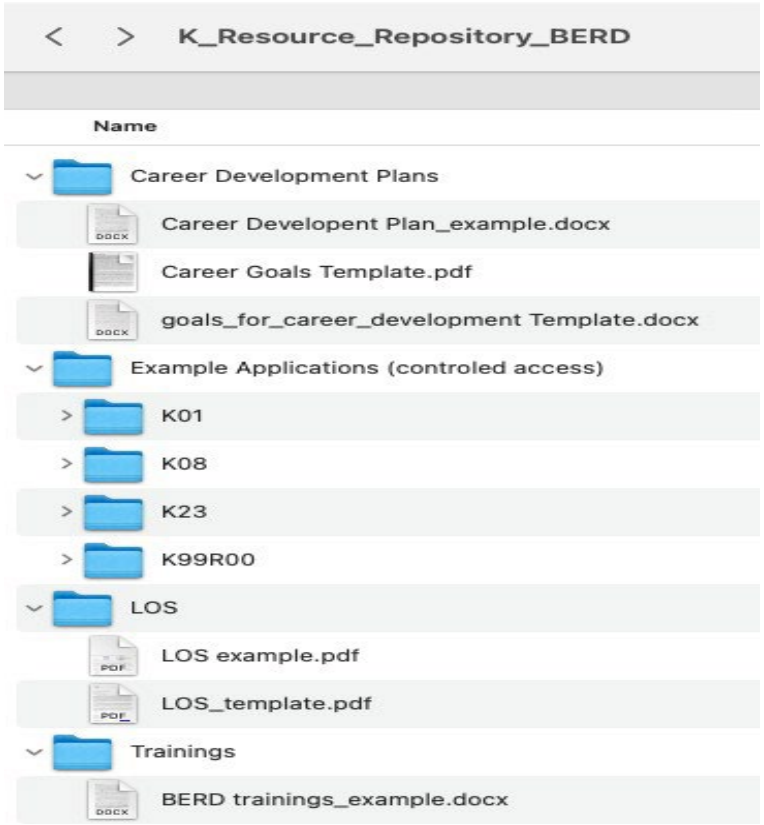
- Power calculators
- Sample size calculators
- Data analysis calculators (t-test, correlations, linear regressions, ROCs etc.)

K Application Resource Repository

Enable efficient mentoring with shared resources on

- successful grant writing and summary statements examples
- career development templates and examples
- biostatistics resources and training catalogs
- letter of support templates





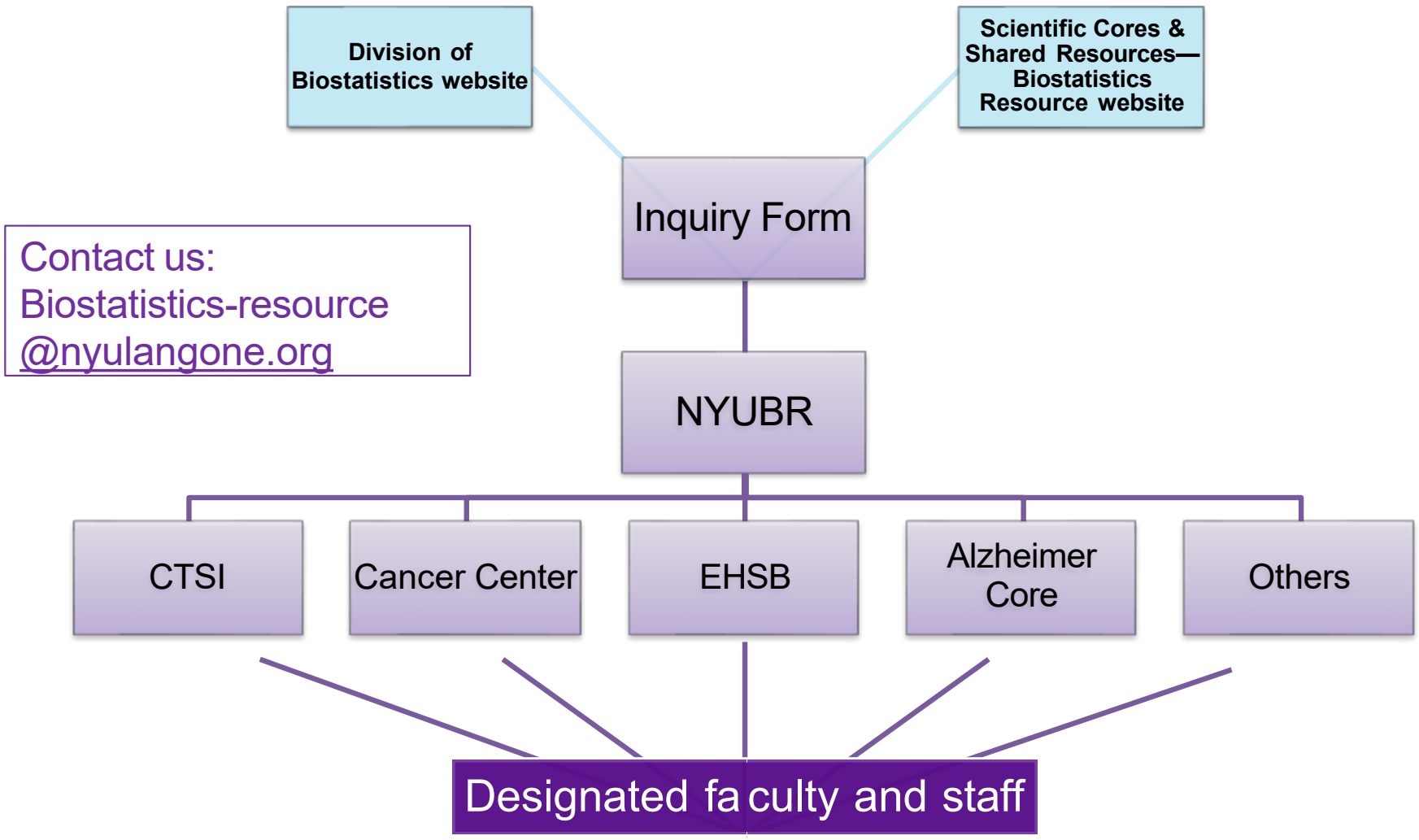
Biostatistics Shared Resource–Perlmutter Comprehensive Cancer Center (PCC)

To provide state-of-the-art statistical collaboration and consultation to members of the Perlmutter Cancer Center (PCC) basic science, clinical and translational research programs and Shared Resources.

BSR provides biostatistical, epidemiological, and study design collaborations provided by dedicated cancer-focused faculty and staff of Biostatistics.

1. Develop new peer-reviewed **grant applications**
2. Develop research designs and **protocols for investigator-initiated interventional treatment clinical trials**
3. Provide ongoing statistical collaboration for **PRMC-approved, PCC investigator-initiated interventional treatment clinical trials**
4. Develop research designs and protocols for new PRMC-approved, investigator initiated clinical trials, **non-interventional, and observational studies**
5. **Training and mentoring of PCC members and staff** in key statistical issues for study design, analysis, and interpretation of cancer research studies

NYUBR Collaboration Process



Contact us:
Biostatistics-resource
@nyulangone.org

Thank you

NYU Biostatistics Resource email:
Biostatistics-resource@nyulangone.org

Division of Biostatistics website:
https://med.nyu.edu/departments-institutes/population-health/divisions-sections-centers/biostatistics/research

Scientific Cores & Shared Resources—Biostatistics Resource website:
https://med.nyu.edu/research/scientific-cores-shared-resources/biostatistics-resource

NYU Langone Health

Part II: Tips for Preparing Grant Proposals from Statistical Reviewers

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Perspectives from a Statistical Reviewer in Study Sections and Grant Review Panels

- Study sections often have a statistical reviewer for applications involving human subjects and basic science projects involving *omics* analysis
- Statistical review emphases:
  - **Significance**
    - Is the proposed hypothesis statistically testable?
  - **Investigators**
    - Does the team have statistical expertise to design, monitor and analyze?
    - Are the budgeted efforts sufficient to implement the scope of work?
  - **Innovation**
    - Innovative design of the trial and analysis of the observational data is especially appreciated
  - **Approach**
    - Is the proposed strategy likely to produce unbiased and interpretable results?
    - Does the study provide adequate power, use an appropriate study population?
    - Does the application appropriately account for sex and relevant biological variables, and potential confounders?

General Tips

- **Initial contact**
  - Translate clearly defined scientific questions into statistical hypotheses
  - Ensure subject enrollment and sample collection address scientific question and enable data analysis
- **Study design**
  - Driven by scientific questions: interventional vs. observational, retrospective vs. prospective, targeted vs. untargeted, fixed vs. adaptive, controlled vs. pragmatic.
  - Determined by projected effect sizes: preliminary studies or literature
  - Constrained by resource: accessibility to study population, funding, compliance factors
- **Preliminary results**
  - Generate hypothesis and provide rationale of the proposed investigation
  - Provide supporting information to plan the project
- **Sample Size and Power**
  - Sample size often determined for primary outcome; show sufficiency for secondary outcomes
  - Projected effect size: clinical meaningful and well supported by preliminary results or literature
  - Account for multiple testing and potential missing
  - Simple models and assumptions for power analysis
- **Statistical analysis plan**
  - Address the scientific questions: clarity is key with proper approaches (not over-complicated)
  - Cover potential questions: missing data, adjusting confounders, nonlinear effects, dimensional reduction
- **Potential pitfalls and solutions**

Specific Tips for Large P or Center Grant

- **Longer preparation time and larger team**
  - Multiple faculty biostatisticians to provide sufficient expertise supports
- **Biostatistics core**
  - Coordinate with the other administrative cores
  - Collaborate with all research projects
- **Statistical plans**
  - Summarize core activities across the entire the core document
  - Specific analysis plans for each research project
  - Show synergy/interactions across projects and cores

Specific Tips for Clinical Trial Grant

- **Clinical Trial**
  - Justification for choice of design
  - Discussion of randomization/masking
  - Clear statement of primary/secondary/exploratory objectives
  - Consideration of interim analyses, monitoring, and DSMB
- **Data & Safety Monitoring Board**
  - General consideration
  - Align Board expertise with trial goals
  - Budget considerations
  - CTSI resource

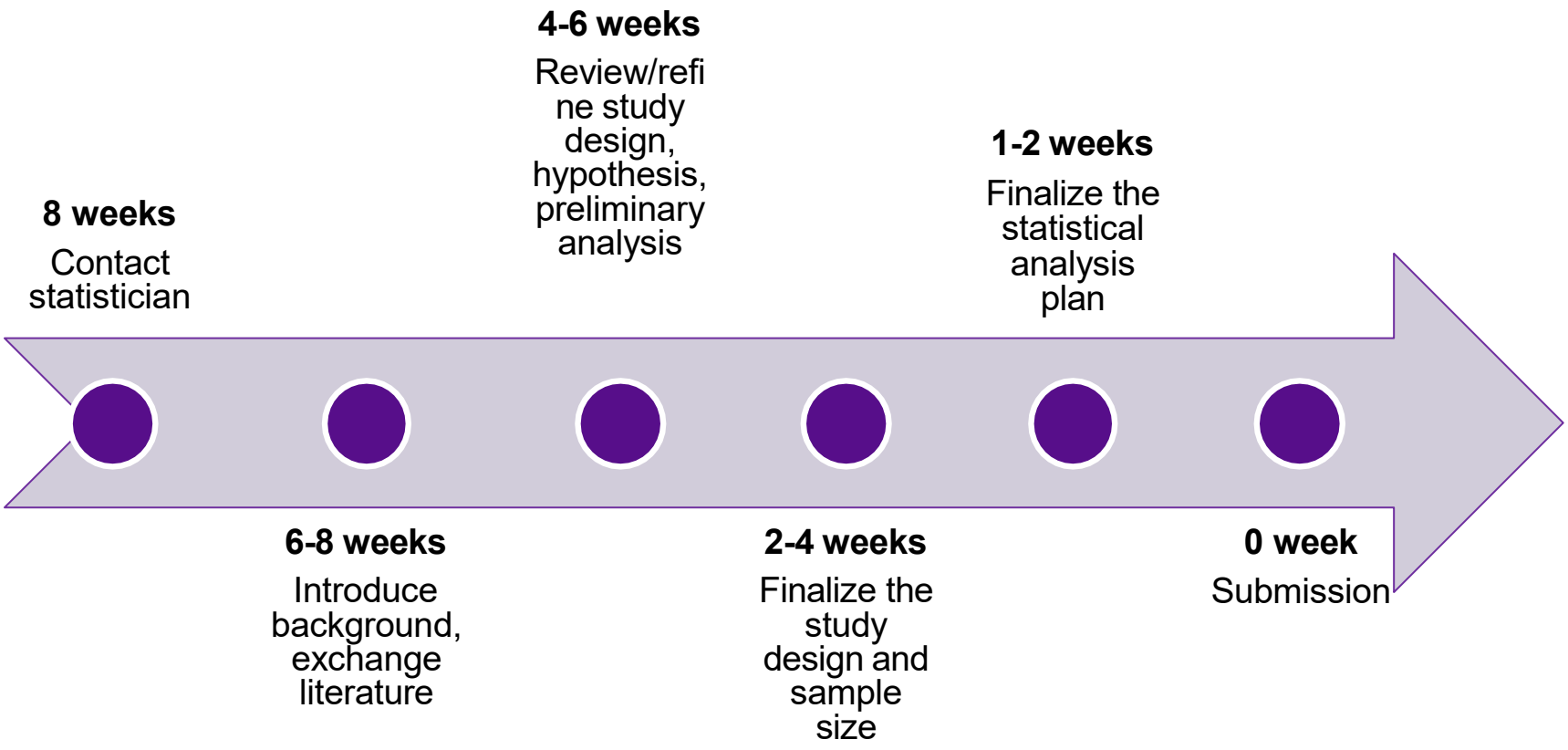
Specific Tips for Other Types of Research Grant

- **Observational Study**
  - Validation cohort is important
  - Ancillary study of the ongoing cohorts
  - Secondary analysis of existing study
- **Molecular Mechanism Study**
  - High dimensional data—multiple testing adjustment
  - Association vs. Prediction
  - Analysis approaches to reflect the updates in modern technology
  - Batch effect
  - Streamlined upstream and downstream data analysis
  - Integrated analysis taking account of study design, omics data, and clinical outcomes

Role of Statisticians by Grant Mechanisms

- **Large P or Center Grant** – Core Director, Co-I, or statistical analyst
- **Two-phase grant UG3/UH3** – MPI, Co-I, or statistical analyst
- **Large research grant: R01/U01** – MPI, Co-I, or statistical analyst
- **Small research grant: R03/R21** – Co-I
- **Training grant** – Mentor

Case Study with the Suggested Timeline



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