



DEPARTMENT OF PUBLIC HEALTH SCIENCES

DIVISION OF BIOSTATISTICS

Biostatistics

Collaboration and

Consulting Core (BCCC)

Mission Statement

The Aim of the Biostatistics Collaboration and Consulting Core (BCCC) is to ensure that the appropriate use of statistical methodology is incorporated in research. BCCC statisticians are available for ongoing statistical collaborations and short term consulting support to faculty, staff, and students in the University of Miami Miller School of Medicine, and throughout the University of Miami. The BCCC will provide fee based support at all stages of research, including but not limited to preparation of grants and contracts, data analysis, abstracts, and manuscript preparation. We strongly encourage obtaining biostatistical collaboration as early as possible. Early collaboration in development of research ideas increases the quality of research, the likelihood of meeting study objectives, and success in obtaining extramural funds.

The BCCC provides high quality statistical support for clinical and translational research. The objective is to enhance the University's scientific mission by assuring appropriate planning for and use of statistical methodology. The ways in which this can benefit research programs and investigators include:

- Developing study and experimental designs that maximize efficiency, increase interpretability and generalizability, and enhance the ethical conduct of research;
- Formulating hypotheses in a manner which addresses the research questions of interest and are scientifically and statistically testable;
- Translating and applying robust and efficient analytic methods to estimate effects precisely and efficiently test significance;
- Refining measurements to increase precision and sensitivity;
- Developing grant proposals and increasing the likelihood of funding;
- Assisting with manuscript writing, increasing the likelihood of publication and improving the quality of the results.

BCCC Support

The BCCC operates as a cost center, offering support activities to faculty, staff, and students. The BCCC statisticians are available for collaboration at all stages of research, including but not limited to those described below:

- **Study Design:** The BCCC statisticians can help you turn your research questions into hypotheses that are scientifically testable. They can help you determine the most appropriate and efficient design for your study whether it be a simple two-group comparison, a cross-over study, a factorial experiment, or a sequential clinical trial.

- **Randomization Schemes:** The BCCC statisticians can produce randomization schemes for sampling designs and group assignment. These could be simple randomization for two groups, a stratified randomization, or more complex design.
- **Statistical Analysis Plan (SAP):** The statistical analysis plan is an important component of every study. The types of independent (predictor) variables and dependent (outcome) variables determine the type of statistical analyses that need to be performed, and the type of analysis determines how the sample size and power are calculated. The BCCC statisticians can design the appropriate statistical analysis plan for your data before the study begins.
- **Sample Size Estimation or Power Analysis:** One of the most important questions in the design of a study is, “How many participants do I need?” Or, on the other hand, if only feasible to recruit n patients for a study, you want to know “Do I have sufficient power to detect the hypothesized effect size”, the BCCC statisticians can determine the appropriate sample size for your study so that you will have sufficient statistical power to detect a clinically meaningful effect, or can estimate how likely your statistical test will be to detect a specific effect with a given sample size.
- **Statistical Analysis:** The BCCC statisticians can perform statistical analyses, using statistical software such as SAS and R. Our experience ranges from basic statistics to more complex analyses including longitudinal data analysis, multivariate techniques, survival analysis and more.
- **Survey/Questionnaire Design:** The BCCC can collaborate in the process of instrument development and perform statistical analyses for reliability and validity.
- **Abstract/Manuscript Preparation:** The BCCC statisticians can contribute to manuscript preparation by writing the statistical methods, analyses, results, and assisting with discussion sections (authorship policy applies). We can also produce appropriate tables and graphs.
- **Grant Preparation:** The BCCC statisticians have experience in assisting with grant preparation from crafting research hypotheses and aim to identifying endpoints, developing the study design, the statistical analyses plan, and calculating appropriate sample sizes for desired statistical power.
- **Protocol Review:** The BCCC statisticians are available for protocol review to see whether the design, statistical analyses, sample size and power are appropriate for the study. The BCCC can also make recommendations to help ensure that your research questions are answered.
- **Consulting Statistician for Staff and Professional Meetings:** The BCCC statisticians are available to attend staff and research meetings to help your team discuss new research projects, evaluate the progress of existing studies, and design new studies.

Safety Committee: Many Data Safety and Monitoring Boards (DSMB) require a statistician to serve on the board. The BCCC statisticians are available for monitoring for safety as well as usefulness or uselessness.

The BCCC offers different support options, depending on the research needs of the investigator or research team. Support can either be in the form of short term consulting on specific activities, or ongoing collaborative relationships.

Short Term Support Activities:

- **Support:** Statistical support on a short term, per hour basis. Short term consultations work best when investigators have well defined questions with relatively small datasets. Fees are based on the estimated number of hours required for the specific support activities requested. Situations for which short term support is available include but are not limited to:
 - Developing research proposals;
 - Defining and framing hypothesis;
 - Selecting variable and measurement techniques;
 - Developing a statistical Analysis Plan;
 - Calculating sample size/power;
 - Performing statistical analysis on a prepared data set;
 - Preparing abstract or other presentations;
 - Preparing manuscripts (either initial or for a resubmission, authorship policy applies);
 - Developing pilot study designs;

- **Policies/Billing:** Investigators will initially contact the BCCC, and set up an initial meeting to describe a specific project. The BCCC will then estimate the workload needed to complete the project, and determine the associated fee for this support based on our hourly rate. This would be a one-time fee, requiring a signed IDR or approval on the Ariba system, at the time when an agreement is made between the BCCC and investigator/research team for BCCC support. This must be completed before any work will begin.

The estimate, and corresponding fees, will be revised if the investigator adds work, or if there are unexpected complications not disclosed originally (like messy data, additional data, design complexities, or complex hypotheses not initially discussed). It is very common for analysis projects to expand beyond the initial estimate of workload. If this is the case, the BCCC will communicate the need to expand the time devoted to the study, and additional fees will be requested in order to accommodate the changes to the original agreement.

Ongoing Collaboration Plan:

Support: The BCCC provides support for collaborations that are ongoing. This might be in the form of long term projects or a Dept/Center/Research group that wants to have a “retainer” on biostatistics support. The collaboration plan will be supported by Core & Matched by CTSI. (Collaboration Plan Agreement and Authorization for Use of Existing Collaboration Plan [Authorization form](#) (*Appendix 6 and 7). For example, a certain Department may want to have the equivalent of .25 FTE (520

hours/year) of biostatistics support available to them for whatever they need. This can be protocol development, manuscript writing, data analysis, etc. An ongoing collaboration plan agreement would be established with the BCCC for this type of ongoing support, and fees would correspond to $.25 \times 2080$ hours/year=520 hours/year. This support can be utilized for proposal development, manuscript writing (authorship policy applies), statistical analysis, presentations within the department by biostatistical staff, presence at departmental research meetings, assistance with journal clubs (methodological review), assistance with research conference presentations, and K-award mentoring.

Policies: The collaboration plan does not cover work funded by grants other than K awards. Biostatistical support should be built into grant budgets as described below during submission:

- As grant proposals arising from this arrangement are funded, grant funds will supplement rather than replace the ongoing collaboration funding arrangement;
- Collaboration plan owner will prioritize usage of the resource by her or his faculty; The time agreed upon needs to be honored within the fiscal year.
- The plan will be used to support abstract preparation on a first-come first-serve basis for fellows, other trainees, and junior faculty as part of their first research project. The intent of the abstract must be to produce a subsequent manuscript for peer review. Normally advance notice of at least one month is required.

Billing: Billing for this plan would be monthly, and based on our rate structure. This, for ongoing biostatistical support equivalent to 0.20 FTE, we would charge 0.20×2080 hours/year=520 hours/year, and bill on a monthly basis. This plan usually requires a one-year commitment, to allow for appropriate resource allocation and planning but the level of support can be adjusted when deemed appropriate upon agreement between the collaboration plan holder and the BCCC Director. This would need to be determined and agreed upon PRIOR to the month in which the adjustment would take place. Research groups investing in the Biostatistical collaboration plan will be responsible for utilizing the support they are retaining. Grant proposals developed under this plan are expected to include BCCC support in the proposal budget for ongoing additional BCCC support to the specific investigation.

Grants:

Biostatisticians in the BCCC are available to participate in grant development in various ways including:

- Assisting with the formation and operation of a proposal development team;
- Assisting the investigators in refining study questions and measurement methods;
- Developing study and experimental designs;
- Writing statistical analysis plans;
- Computing precision, power, and sample sizes necessary to achieve a given precision of estimation or a given power.

In our experience, it is not uncommon for statisticians to uncover design issues that must be addressed, prior to conducting analyses. For example, a study design may need to be improved

prior to estimating power. We reserve the right to require these types of remediation before analyses are done.

BCCC Support with CTSI Funding

The mission of the Research Design and Biostatistics Component of the Miami CTSI is to lead, advise, educate, and train the next generation of clinical/translational (C/T) researchers in the design and analysis of their studies. The allocation of the Miami CTSI resources has guidelines in which the consideration for each study is taken. Priority is given to junior investigators preparing NIH grants, senior investigators focusing on new approaches and investigators with NIH and intramurally funded studies that require supplements to achieve major interdisciplinary breakthroughs. See below for more detailed information regarding prioritization for CTSI resources.

Educational opportunities such as biostatistics clinics and roundtables will continue to be offered. These will be announced as they become available. Initial Meetings for investigators seeking to obtain support for research will continue to be available by appointment as well as office hours for quick walk-in consultation. The forms for these requests can be found on our website www.biostat.med.miami.edu/core.

It is strongly encouraged that investigators requesting biostatistical support in developing NIH grant submissions for the approaching January deadline contact our office as soon as possible, in order to allow adequate time for quality support. See page 7 for a description of appropriate timelines for requesting biostatistical support.

All research proposals and requests for these CTSI services and resources should incorporate ideas and approaches from multiple disciplines and/or propose innovative research initiatives that have the potential to translate into improved health.

CTSI research priorities:

1. K-awardees
2. Institutionally-funded pilot studies

Priority among the above Investigators will be given to those whose proposed studies, in order of preference:

1. Address health disparities/minority health/medically underserved communities or elucidate/tease effects of racial/ethnic minority status
2. Propose the creation of new fields of study at the intersection between existing fields
3. Are translational, and interdisciplinary (e.g. co-investigators) from at least two schools/disciplines
4. Are collaborative (e.g. co-investigators) from different scientific/clinical fields/subspecialties
5. Are multifaceted in research support demands, e.g. requires use of more than one CTSI component's services/resources or resources from another NIH-funded program grant (e.g. P-awards, U-awards, R-awards, T-awards, etc.)

Within the above schema, applications are encouraged in the following scientific foci:

1. Obesity-related issues, substance abuse, sexually transmitted diseases, or low-birth weight babies (priorities established by the CTSI Community Advisory Board)
2. Therapeutic development

Timing: Grant proposals require intellectual contribution from teams with unique areas of expertise, biostatistics being one of them. It is optimal that biostatistical expertise be included as early as possible in the proposal development. The BCCC should be contacted at least two months before a grant submission deadline in order to provide assistance with proposals. If not, the BCCC will provide support only if we have resources available.

Development: The BCCC will collaborate in proposal development, and will charge for this support activity as a short term activity. If the proposal development is with a Dept/center/research team that is engaged in an ongoing collaboration plan with the BCCC, time for grant development will be provided under collaboration plan, but funding for BCCC support within the grant budget for the funded investigation will be expected. The initial pre-award work will be billed depending on the estimated workload needed for proposal development. For a specific proposal development, an initial meeting will be scheduled, and there will be no cost incurred. After the meeting, the workload will be estimated and associated fees will be determined.

Initial Estimate of Workload: It is often difficult to make accurate estimates of the future effort required for a specific project. Factors that determine increased complexity thus greater effort include:

- Many variables (measurements) per subject or animal;
- Repeated (serial, longitudinal) measurements per animal or subject;
- A significant number of subjects dropping out before the planned termination of their follow-up;
- Other types of missing data;
- Plans for sequential monitoring of treatment effects or safety with an eye to possible early termination of the study;
- Data and safety monitoring committees;
- Data from other sources where the data must undergo major transformations or cleaning to be analyzable;
- Data from multiple clinical sites;
- Measurements that are only partially observable (e.g., when concentrations may be below the lower limit of detectability).

Budgets: Grant proposals may include statistical support provided by the BCCC in the grant budget

for a line item amount of support each year. Statistical support under this structure will be designed to ensure available support to an investigator or department/center that makes this agreement (Grant Submission [Agreement form](#) (*Appendix 4)) with the BCCC. Once funded, a collaborative arrangement between the BCCC and Principal Investigator is created for the duration of the grant to be billed monthly. Funding for BCCC support included in the grant proposal budget will need to be agreed upon by the Core Director, and based on the estimated workload for BCCC support per year of the grant.

Changes to Budget: Grants that include biostatistical collaboration provided by the Core will need to have funding built into the proposal budget for Core support. Any changes to the budget at any time involving the Biostatistical Core support on grants must be approved by the Core Director. An Agreement of Support must be signed between the PI and the Core Director concerning the support activities and Core Funding described in the grant proposal, and will go into effect upon award of funding.

Quick Consulting/Office Hours

The BCCC offers office hours to address simple biostatistical questions or providing short consultations at no charge. [Office Hours Appointment Form](#) (*Appendix 5). This is limited to very quick questions or statistical advice which can be resolved within a short meeting.

If the question is not quick and/or requires comprehensive analysis or support, the BCCC representative will refer you to fill out a request form for statistical support.

Project Initiation and Agreement

Investigators who wish to request support must fill out a BCCC request form (Appendix 2) to provide a brief summary of the objectives and study design for the project. An initial meeting to ascertain the scope of work will then be scheduled, usually within 10 business days, depending upon BCCC resource availability. Principal Investigators and Senior mentors, when applicable, are required to attend the initial meeting.

- The initial meeting with a Biostatistician to discuss needs/project scope is free of charge. The purpose of the meeting will be to review the research needs and study design issues, to estimate workload, and to plan a realistic timetable. If BCCC support is desired by the Investigator, an Agreement Form (Appendix 3) will be developed by the BCCC, and presented to the Principal Investigator with estimated workload and associated fees.
- After the initial meeting, upon a signed Agreement between the BCCC and Principal Investigator, all subsequent support will be charged according to our *rate structure*, unless investigator's home department is enrolled in our collaboration plan.
- No work can begin until a project agreement form has been completed; this includes our fees based on the estimated workload, a University of Miami account number to be billed, and the signature of a person authorized to expend funds from the account. (Projects external to the University of Miami (non-UM) must provide other acceptable billing information, and paid in advance, prior to the start of the work.) Initial fees established after the initial meeting will not be exceeded without prior notification and approval.
- For more information or to arrange meetings to discuss biostatistical support contact Maria Jimenez-Rodriguez, Division of Biostatistics, Biostatistics Collaboration and Consulting Core

at mjrodriguez@biostat.med.miami.edu or 305-243-4465.

Biostatistics Clinic and Roundtable

Biostatistics Clinic – Monthly

The Biostatistics Clinics offers education regarding statistical considerations in clinical and translational research, and is open to the entire research community at UM. Example topics presented include Experimental Design, Sample Size and Power Considerations in Clinical and Translational Research, Statistics 101, Statistical Considerations in Grant Development, Missing Data, An Introduction to R, and others. This series is meant to enhance breadth of knowledge of statistical methodology and its application to clinical and translational research.

Biostatistics Roundtable – Weekly

The Biostatistics Roundtable provides an informal question and answer session about general statistical issues in regards to research. A specific topic or short talk will be presented with time to discuss issues as a group and/or their individual issues. Investigators are welcome to describe their projects and ask questions for discussion relating to the topic presented. This fosters communication among investigators from different disciplines, and teaches both biostatisticians and scientists how to work together as an interdisciplinary team.

Timelines

Advance contact is necessary to allow sufficient time to address your needs before deadline. Below are minimum times required:

Protocol Development/ Grant application – two months. It is most advantageous that biostatistical expertise be obtained as early as possible in the proposal development.

At least six weeks. If it is a first submission and we don't have enough time, our contribution will demonstrate statistical involvement but will likely be criticized for being incomplete. If it is a re-submission, we may at least two months to provide quality input.

Protocol review (completed) – 2 weeks. We may find statistical issues, and if it is desired the BCCC support the protocol from that point, more time will be required.

Statistical analysis – 3 weeks, depending on the type of analysis and study design.

Abstracts – 1 month, depending on statistical analysis.

At least one month. If it is less than a month before the deadline, we may be able to help you with some simple summary statistics. There may not be enough time to do anything more complex.

Manuscript preparation-3-4weeks, after statistical analysis is complete.

As the deadline approaches, the likelihood that we can provide helpful statistical support diminishes.

On a case by case basis, we may be able to accommodate requests that are closer to the deadlines than described in the timelines above. In order to provide anything of real quality, appropriate planning for adequate time is essential.

Publication Submission and Authorship Policy

- Co-authorship on scientific journal articles is generally expected on studies where substantive input on design and/or analysis is provided. The contribution of each person needs to be evaluated as a manuscript is prepared. Consideration for authorship should be based on the accepted criteria for most medical journals. These criteria generally cite both study design and statistical analysis as intellectual input sufficient for authorship. It is impossible to define every situation in advance; however, it should be clear that reimbursement for time does not preclude or replace authorship. For more information, please refer to the edicts set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, http://www.icmje.org/ethical_1author.html
- The biostatistician performing the analysis will be a co-author on the publication to acknowledge the intellectual contribution to the work. Statistician co-authors will use their primary appointment affiliation on manuscripts and abstracts.
- To maintain study and statistical integrity, statistical analysis for publication and abstracts will only be analyzed after study completion.
- The BCCC biostatistician performs the analysis, collaborates in the structuring of the presentation of the results and writes the “statistical methods” section of the paper.
- The BCCC biostatistician reviews the final publication prior to submission.
- The biostatistician assists with revisions and reviews the publication prior to resubmission.
- All publications resulting from the utilization of CTSI resources are required to credit the CTSI grant by including the NIH Funding Acknowledgment and must comply with NIH Public Access Policy. Please reference your PMID Number and PMCID Number on all publications the benefited from any resources supported by the UM CTSI.
“The project described was supported by Grant Number 1UL1TR000460, University of Miami Clinical and Translational Science Institute, from the National Center for Advancing Translational Sciences and the National Institute on Minority Health and Health Disparities. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.”

Data

- The time and effort involved in performing statistical analyses can be greatly reduced if the data are entered in the proper format. It is the responsibility of the investigator or research team to provide data sets that are clean and in proper format. If the BCCC needs to invest time in cleaning and formatting data, this will be charged for according to our rate structure. It

is best to consult with BCCC personnel before you begin to collect the data if possible to ensure that proper construction and formatting is used. We recommend the use of the Velos or UChart database systems when it is feasible.

- Requirements and guidelines for proper data set preparation are described in: Database Guidelines for Statistical Analysis Form (*Appendix 1). The BCCC requires that the Investigator provide a separate document defining all variables contained in the data set provided.
- Subject identifiers such as name and social security number, and medical record locator **must** be removed from the dataset before it is given to the BCCC.

In summary Prioritization is:

In general, the priorities for BCCC support resource allocation (from highest to lowest) are:

- Grant preparation;
- Abstracts for national meetings, and other reports with fixed deadlines;
- Protocol design and review;
- Laboratory, animal, and epidemiology study design and review;
- Short term consults;
- Study monitoring, analysis, manuscript preparation, and replies to manuscript reviews;
- Education of users;

Regulatory Considerations

- It is the responsibility of the Principal Investigator to ensure that databases, analysis datasets and other aspects of the study are HIPAA compliant. Datasets received by the BCCC with Protected Health Information (PHI) will be returned to the study investigator for removal of non-compliant fields.
- All projects must have IRB approval for human subject studies and IACUC approval for animal studies. Investigators must be willing to provide approval documents when requested by the BCCC.

Fees

All Fees are based on UM policy B020 for Recharge or Cost Centers (see page 28):

- An hourly rate of \$105.00, for all support activities for University of Miami, and affiliated organizations and institutions;
- An hourly rate of \$152.00, for all support activities for Non-University of Miami, and external non-affiliated organizations and institutions.

For example, the BCCC may be approached by a University of Miami Investigator to provide statistical support for a proposal development/grant application that the BCCC estimates to require 40 hours of work. Thus, we would charge $40 \times \$105 = \4200 for this support.

If you are interested in obtaining BCCC support funded by the Miami CTSI, or to learn more about the available biostatistics support and corresponding procedures and policies, please contact Maria Jimenez-Rodriguez at mjrodriguez@biostat.med.miami.edu. Please indicate on your message the nature of your research and if it falls into the prioritized areas described above.

You may also visit our website at www.biostat.med.miami.edu/core for additional information. We would be happy to meet with you to learn about your specific research needs.

Billing & Procedure

User departments and/or sponsored accounts will be billed via Interdepartmental Requisition Form (IDR) or Ariba System. The BCCC's policy and procedure must be adhered to in order to receive core support. Outstanding bills (past one quarter) will lead to project termination and or denial of future support.

Step 1: Before work is started: 3 forms need to be completed and signed

1. BCCC Support [Request Form](#) (*Appendix 2), all required fields should be completed, and form should be sent via e-mail to the BCCC contact person, mjrodriguez@biostat.med.miami.edu, before the scheduled initial meeting;
2. BCCC Support Agreement [Agreement form](#) (*Appendix 3) – will be e-mailed, to the investigator, by the BCCC contact person, mjrodriguez@biostat.med.miami.edu, after the initial meeting. This will include a description of the proposed work; the corresponding BCCC time commitment estimated based on the initial meeting, and associated fees.

The BCCC Support Agreement should include an account number, and authorized signature of the client(s), before any type of work can begin.

3. Two different forms of payment, one or the other:
 - **Paper: Interdepartmental Requisition Form (IDR)**
 - [\(IDR\) form](#) (*Appendix 8), and the [Invoice](#) (*Appendix 9) will be sent to the investigator(s), with the approved Agreement for Support,
 - Person responsible for financial responsibility needs to sign the IDR and invoice, then return to BCCC contact person mjrodriguez@biostat.med.miami.edu

- The approved IDR and Invoice will be taken to Medical Finance for payment, at the beginning of the support.

OR

- **Paperless: ARIBA System**

- [Invoice](#) (*Appendix 9) will be sent to the investigator(s), of the work to be performed, for signature;
- Person responsible for financial responsibility needs to sign invoice, then return to BCCC contact person mjrodriguez@biostat.med.miami.edu
- An order will be created in the Ariba system, on behalf of client(s), with the invoice for payment, at the beginning of the support.

BCCC Contact Information

Department of Public Health Sciences Biostatistics Collaboration and Consulting Core (BCCC)

University of Miami Miller School of Medicine
Clinical Research Building, 10th Floor
1120 N.W. 14th Street (R-669)
Miami, FL 33136
Contact person: Maria Jimenez-Rodriguez
Tel: 305-243-4465
E-mail: MJRodriguez@biostat.med.miami.edu
Website: www.biostat.med.miami.edu/core

BCCC Resources and Environment

The BCCC is located within the Division of Biostatistics in the Department of Epidemiology and Public Health. BCCC resources include state-of-the-art research computing equipment to support biostatistical, epidemiologic, basic, clinical and translational health research. All technologies used within the BCCC are production quality and fully supported externally by the respective vendors, ensuring that current technologies are readily available for use on a project, as appropriate.

BCCC Leadership and Personnel

All collaboration and consulting activities involve MS and Ph.D. level BCCC staff statisticians. The members of the BCCC cover a wide range of interests and statistical expertise and have consulting experience in a variety of subject matter areas.

Scientific Core Director: Dr. Shari Messinger Cayetano

Dr. Shari Messinger Ph.D. is an Associate Professor of Biostatistics and Director of the Biostatistics Collaboration and Consulting Core, Division of Biostatistics, Department of Epidemiology and Public Health. She has been a member of the Biostatistics Faculty at the University of Miami Miller School of Medicine since 2002, after earning her Doctorate in Biostatistics from the University of Michigan. She has served as the Director of Biostatistics for the former GCRC, the Director of the Biostatistics Core of the Diabetes Research Institute, and currently serves as Director of the Research Design and Biostatistics Component of the Miami Clinical and Translational Science Institute.

Dr. Messinger's research has focused within two broadly defined areas of islet transplantation research. The first is in determining factors that are associated with improved islet viability and yield, resulting in transplantable islet preparations. This work considers factors that are donor specific, or related to the isolation process. Her collaborations accelerate the translation of these laboratory

investigations into clinical practice of transplantation by identifying factors that are prognostic of eventual graft survival in the host. The extension into clinical practice involves evaluating how different techniques used for the islet transplant procedure affect post-transplant clinical course in islet recipients. Dr. Messinger additionally collaborates in research investigations involving epidemiologic and intervention studies addressing primary and secondary prevention for persons at risk and living with HIV. She has extensive knowledge and experience in application of appropriate statistical methodology.

Dr. Messinger is responsible for directing all operations of the core. She oversees the operations and administrative functions of core staff and/or Faculty, maintains support and quality standards, and promotes the usage and marketing of the core support activities. Her expertise/role and commitment provides scientific direction of the facility.

Tel: 305-243-6230; SMessinger@biostat.med.miami.edu

Assistant Scientist and Biostatistician: Dr. Hua Li

Dr. Hua Li joined University of Miami as a Lead Research Analyst (Biostatistician) in August 2010. He received his M.D. and Ph.D. from Tongji Medical University, a MS in Computer Information Systems and a MS in Applied Statistics from the University of Miami. He has worked in medical (basic and clinical) and healthcare research fields for many years, focusing on immune tolerance, organ transplantation, diabetes, healthcare outcome, and pharmaco-vigilance with more than 40 papers published and more than 10 years of experience in statistical analysis and data management. He is interested in clinical trial, longitudinal studies, epidemiological and health care/service studies, categorical data analysis, survival data analysis, and biostatistical consulting.

Dr. Li provides statistical support to the University community and oversight to staff biostatisticians within the Core. This includes study design and statistical analysis plans, analyzing, evaluating and reporting on complex observation research data, preparing results for progress reports and presentations, preparing results for peer-reviewed publications and being a co-author on peer-reviewed manuscripts, presenting results of statistical analysis to study investigators, collaborating with the study investigators on planning and specifying statistical analysis, and consulting on data collection methods, and quality control.

Tel: 305-243-2206; HLi@biostat.med.miami.edu

Biostatistician: Kaming Lo

Kaming Lo received his Master of Public Health in Biostatistics, from the University of North Texas Health Science Center (UNTHSC), in 2008. He has more than two years of data management experience in both academic and clinical studies involving database development, maintenance, and quality control. Since earning his MPH, Kaming has been actively involved in research activities at the UNTHSC, such as providing statistical support to medical students and faculty, publishing papers, and presenting posters. He joined the University of Miami, BCCC, as a Biostatistician in December 2010 and is dedicated to provide statistical support to the UM research community.

Tel: 305-243-2506; KLo@biostat.med.miami.edu

Biostatistician: Robert O'Brien

Robert O'Brien received his Master of Science in Statistics from the University of California, San Diego. He worked as a statistician at the University of California before joining the University of Miami in 2010. First hired into the Division of Pediatric Clinical Research, Robert has been a member of the Division of Biostatistics since 2012. As of April 2014, he has coauthored six papers.

Robert is also currently pursuing a PhD in Biostatistics at UM. His specific area of interest is the statistical learning method known as random forests but he is broadly interested in survival analysis, longitudinal data, generalized linear models, and clinical trials and he feels competent to consult in these areas.

Sr. Administrative Assistant: Maria Jimenez-Rodriguez

Maria Jimenez-Rodriguez received her Master's degree in Arts and Liberal Studies (M.A.L.S.), a B.S. degree in Sociology, with minors in Business Administration and Management, from University of Miami. She has over seventeen years working at the University. Along with her experience in office procedures, management and administration, her forte is coordinating, organizing, and communicating with persons at all levels.

Maria is the BCCC Administrator, and the initial contact person. She provides support to the Director of the Core, the Core members, and coordinates and manages the scheduling with Faculty, P.I.'s, Departmental Administrators, and other University Administrators. Maria also oversees the tracking, implementing, and invoicing of all BCCC support activities.

Tel: 305-243-4465; MJRodriguez@biostat.med.miami.edu

FORMS:

*Appendix 1



DIVISION OF BIOSTATISTICS

Biostatistics Collaboration and Consulting Core (BCCC) Database Guidelines for Statistical Analysis

HIPAA: Do not communicate any information that can identify patients or subjects.

Use Excel for data entry because it is on all computers. Keep in mind that there is a difference between statistical packages and spreadsheets. Excel is a spreadsheet, not a statistical package. Your statistical consultant will probably use SAS.

Requirements for a successful data set preparation:

- Variable names in the first row only
- One column per variable
- Variables are either numeric or character (a number can be treated as a character, but not vice versa)
- Do not combine character data with numeric data in the same column
 - Do not put "NA", "will get", "<20", or "?" in a numeric column
 - Do not use a dot to represent missing data in a numeric column
- Missing numeric data should have blank cells
- Be sure Excel stores your numeric data as numbers and not as text
- Delete ALL extraneous columns and rows (e.g. summary statistics, notes, coding key)
- Check your date formats. It may look right in excel, but it will be imported according to the internal representation, which may be the wrong century, or worse. As a last resort, you can use three numeric columns for month, day, year
- Give each column a unique, simple, 1-word name, 8 characters or less with no spaces, beginning with a letter, and place this name in the first row.
- Put only one variable in a column. Do not combine variables in the same column.
- Enter each patient at each time point (or unit of analysis) on a separate line, beginning on the second line.
- Give each research participant or patient a unique case number (1, 2, 3, etc.)- in the first column. Delete patient name, SS#, MR#, and any identifying information before sending it to a statistician. Always, save the spreadsheet with a password.

Excel tips that are compatible with importing to SAS:

- Excel is OK to use colors, fonts, and highlighting. They will be ignored.

- It is OK to insert “Comments” into cells from the “Insert” pull-down menu. They will be ignored.
- You can leave your notes, keys, codes, legends on secondary excel sheets. Not on data sheet. Label the sheets.
- Multiple data sheets and/or files are possible, but talk to BCCC statistician first.

Recommendations for efficient data management and analysis:

- One row per case.
- Don’t waste columns combining other columns (e.g. height, weight, BMI)
- Keep variable names short & unique. Start with a letter and use only letters, numbers, & underscore. No spaces. UpperLowerCase is OK
- Be completely and utterly consistent (e.g. M, m, F, f=4 genders)
- For yes/no variables, it is helpful to use 1 for yes and 0 for no
- Missing character and numeric data should have blank cells
- Sort by subjected (preferred) or another sensible scheme like subjectID within DxGroup
- Excel allows 256 columns. SAS can handle more than one row per subject if necessary
- Enter cases and controls in the same spreadsheet. Use one variable to define the control group (TREATED 0=no, 1=yes or GROUP 1=Drug A, 2=Drug B).
- Create a simple guide (or key) using a word processor to explain variables abbreviations, value coding, and how missing values were entered. Be consistent.
- Think through the analysis before collecting any data.
- Have a biostatistician review the coding before data entry and again after the first 10 patients have been entered

- **Subjects measured once:**

SUBJECTID	DXGROUP	SBP	DBP	HR	HEIGHT	WEIGHT
1	1					
2	1					
3	2					
4	2					
5	2					
6	3					

- **Subjects measured repeatedly:**



SUBJECTID	SBP1	DBP1	HR1	SBP2	DBP2	HR2
1						
2						
3						
4						

- Subjects measured repeatedly:

PTID	DXGROUP	DAY1TEMP1	DAY1TEMP2	DAY1TEMP3	DAY2TEMP1	DAY2TEMP2	DAY2TEMP3
1	1						
2	1						
3	2						

- Same data, alternate data entry:

DXGROUP	PTID	DAY	TEMP1	TEMP2	TEMP3		TEMP24
1	1	1	98.8	99.0	99.1		
1	1	2					
1	1	3					
1	2	1					
1	2	2					
1	2	3					
2	3	1					
2	3	2					
2	3	3					

Department of Epidemiology and Public Health

DIVISION OF BIOSTATISTICS
Biostatistics Collaboration and Consulting Core (BCCC)
Support Request Form

Please complete the information below and e-mail to Maria Jimenez-Rodriguez at mirodriguez@biostat.med.miami.edu. The BCCC will contact you as soon as possible to address your needs.

All fields are required Date _____

Principal Investigator First and Last Name: _____

Principal Investigator Id # (C #): _____

Principal Investigator e-mail: _____

Principal Investigator Department, Division, or Institute: _____

Position: Faculty Fellow Resident Student/Post Doc. Other _____

If faculty, please specify position: Assistant Professor Associate Professor Full Professor

eraCommons username: _____ (required for all investigators using services funded by CTSI for federal reporting)

Is this mentored research? Yes No

If Yes, name of Mentor is _____ E-mail of Mentor _____

Seeking support under Miami CTSI: Yes No

If Yes, indicate priority area(s) appropriate to your research

K-Award
 CTSI/Institutionally funded pilot study
 NIH Grant submission

If Yes, Check all that apply to your research:

Health disparities Medically underserved communities
 Minority health
 Obesity Substance abuse Sexually transmitted diseases Low-birth weight babies
 Creation of new fields of study at the intersection between existing fields
 Translational, and interdisciplinary, e.g. co-investigators from at least two schools/discipline
 Collaborative, e.g. co-investigators from different scientific/clinical fields/subspecialties
 Using more than one CTSI Component's services/resources or resources from another NIH-funded program grant

Stage of Research:
 Design (no data collected) Data Collection Analysis (data collected)
 Peer Review Grant Preparation

Check all that apply:

Data analysis
 Power analysis
 Study design
 Hypothesis generation
 New grant application
 Revised grant application
 Manuscript preparation / review
 Presentation / poster / abstract
 Other

Funding source for project: (check all that apply):

National Institute of Health
 National Cancer Institute
 American Cancer Society
 National Science Foundation
 Pharmaceutical Company
 Private foundation
 Institutional
 Not funded
 Other

1



Department of
Epidemiology and Public Health



DIVISION OF BIostatISTICS
Biostatistics Collaboration and Consulting Core (BCCC)
Support Request Form

Project(s) Title(s):

Please provide a brief description of your request:

Please provide a brief description of the data that you have collected if any:

The BCCC is a cost center, and fee for support will be determined based on scope of project and estimated workload. I (we) certify that sufficient funds are, or will be made, available.

I (we) agree that reference to / and acknowledgement of the collaboration in publications or reports will be made in consultation with the BCCC, and that the BCCC will receive a copy of the publication.

Date

Principal Investigator



Department of
Epidemiology and Public Health



DIVISION OF BIostatISTICS
Biostatistics Collaboration and Consulting Core (BCCC)

Agreement for Support

Requested by: _____ Date: _____

Project Title: _____

P.I. Name: _____ P.I. Id # (C#) _____

P.I. Title _____ Dept/Div: _____

Campus Address: _____ Telephone No.: _____

Responsible Entity: P.I. Dept and/or Div Contact (circle one)

*Account Title: _____

*Account No.: _____

*Amount dedicated for statistical support: _____

-NOTE: This form MUST BE SIGNED by the person accepting financial responsibility for the requested work before the project begins.

SIGNATURE APPROVAL:

*by P.I.: _____ Date: _____

or Dept/Div Head: _____ Date: _____

.....
(This portion to be completed by Division of Biostatistics personnel)

Date Received: _____

Biostatistics Support Requested: _____

Estimated workload of Requested Support (Hours/Effort): _____

\$105.00 hourly rate. All Fees are based on UM policy B020 for Recharge or Cost centers

Note: Fee-for service reimbursement for biostatistical support does not alter the contribution to the academic enterprise. It is simply an alternative to salary support as would be provided by serving as a co-investigator on an NIH grant, for example. The contribution of each person needs to be evaluated as a manuscript is prepared. Consideration for authorship should be based on the accepted criteria for most medical journals. These criteria generally cite both study design and statistical analysis as intellectual input sufficient for authorship. It is impossible to define every situation in advance; however, it should be clear that reimbursement for time does not preclude or replace authorship.



Department of
Epidemiology and Public Health



DIVISION OF BIOSTATISTICS
Biostatistics Collaboration and Consulting Core (BCCC)
Grant Support Agreement

Requested by: _____ Date: _____
P.I. Name: _____ P.I. Id # (C #): _____
P.I. Title: _____
Dept/Div: _____
P.I. Telephone No: _____
P.I. Address: _____
P.I. E-mail: _____
P.I. Fax No.: _____

*Project Title: _____
*Project Dates: _____
*Funding or Sponsor Agency: _____
*Proposal No. ("M" #): _____
*Years of Grant: _____
*Account Title: _____
*Grant or Awarded No.: #): _____ *Account # issued _____
*Amount budgeted for statistical support: _____

**NOTE: This form MUST BE SIGNED by the person accepting financial responsibility for the requested work before the project begins.*

Responsible Entity: P.I. Dept and/or Div Contact (circle one)

***SIGNATURE APPROVAL:**

by P.I.: _____ Date: _____
or Dept/Div Head: _____ Date: _____

.....
(This portion to be completed by Division of Biostatistics personnel)

Date Received: _____

*Biostatistics Support Requested: _____

Preliminary Estimate of Requested Support with or without (select one) Proposal Development (Hours/Effort):

_____ \$152.00 hourly rate. All Fees are based on UM policy B020 for Recharge or Cost centers

Note: Fee-for service reimbursement for biostatistical support does not alter the contribution to the academic enterprise. It is simply an alternative to salary support as would be provided by serving as a co-investigator on an NIH grant, for example. The contribution of each person needs to be evaluated as a manuscript is prepared. Consideration for authorship should be based on the accepted criteria for most medical journals. These criteria generally cite both study design and statistical analysis as intellectual input sufficient for authorship. It is impossible to define every situation in advance; however, it should be clear that reimbursement for time does not preclude or replace authorship.



DIVISION OF BIOSTATISTICS
Biostatistics Collaboration and Consulting Core (BCCC)
Part 1 – Investigator or Contact

Office Hours: Tuesdays, Wednesdays & Fridays 10 am – 12 noon; Wednesdays & Fridays 2 – 4 pm

All fields are required

Date _____

Principal Investigator First and Last Name:

Principal Investigator Id# (C#):

Principal Investigator e-mail:

Principal Investigator Department, Division, or Institute:

Position:

Faculty

Fellow

Resident

Student/Post Doc.

Other

Contact/Requestor First and Last Name:

Contact/Request or E-mail:

Contact/Requestor Phone:

Please provide a detail description of the statistical issues you would like to discuss:

Interested in BCCC Support

Not interested in BCCC Support

Yes or No Will you be able to obtain funding for support if the research requires more comprehensive biostatistical support?

\$105.00 hourly rate. All Fees are based on UM policy B020 for Recharge or Cost centers.



DIVISION OF BIostatISTICS
Biostatistics Collaboration and Consulting Core (BCCC)

Collaboration Plan Agreement

Requested by: _____ Date: _____

FY _____

Name of Responsible Person for Plan: _____

Id # of Responsible Person for Plan (C#) _____ *

Title: _____ Dept/Div: _____

Campus Address: _____ Telephone No.: _____

*Collaboration Account Title: _____

*Collaboration Account No.: _____

*Amount dedicated for statistical support (hours/year): _____

To be billed at the beginning of each month.

***NOTE: This form MUST BE SIGNED by the person accepting financial responsibility for the Collaboration Plan.**

SIGNATURE APPROVAL:

Responsible Person for Plan:

* _____ Date: _____

Person who can authorize use of this support, by specific investigator(s) and project(s):

* _____

*For each project that will be covered under this plan, a Authorization for Use of Collaboration Plan needs to be completed, signed and submit to Maria Jimenez-Rodriguez, prior to use of the plan. Her e-mail is mjrodriguez@biostat.med.miami.edu.



Department of
Epidemiology and Public Health



DIVISION OF BIostatISTICS
Biostatistics Collaboration and Consulting Core (BCCC)

Authorization for Use of Existing Collaboration Plan

Requested by: _____ Date: _____

Existing Collaboration Plan:

Collaboration ID. #: _____

Name of Responsible Person for Plan: _____

Id # of Responsible Person for Plan (C#) _____

Title _____

Dept/Div: _____

Campus Address: _____

Telephone No.: _____

**NOTE: This form MUST BE SIGNED by the person accepting financial responsibility for the requested work before the project begins.*

SIGNATURE APPROVAL:

by Responsible Person for Plan: _____ Date: _____

or Administrator: _____ Date: _____

Project:

Project Title: _____

P.I. Name: _____ P.I. Id # (C#) _____

P.I. Title _____

Dept/Div: _____

Campus Address: _____ Telephone No.: _____

Description or Purpose for the Project: _____

**Time used for this work will be taken from available support in the existing collaboration plan.*

**Sign and submit to Maria Jimenez-Rodriguez, prior to use of the plan. Her e-mail is*

mirodriguez@biostat.med.miami.edu.

Department of Epidemiology and Public Health
Division of Biostatistics
Biostatistics Collaboration and Consulting Core



Invoice

Invoice:	<input type="text"/>	Debit Account #:	<input type="text"/>		
PI Authorized Name:	<input type="text"/>	Contact Person:	<input type="text"/>	IDR #:	<input type="text"/>
Title:	<input type="text"/>				
Biostatistician:	<input type="text"/>	Department:	<input type="text"/>		
Activity:	<input type="text"/>				
Date Service Begin:	<input type="text"/>	Date Service End:	<input type="text"/>	Service Unit:	<input type="text"/>
Invoice Comment:	<input type="text"/>			Service Type:	<input type="text"/>
Total hours:	<input type="text"/>	Hourly Rate:	<input type="text"/>	Total Amount:	<input type="text" value="Enter/Chk Rates"/>
		Discounted Hourly Rate:	<input type="text"/>	Payment Status:	<input type="text"/>
Date Sent for Signature:	<input type="text"/>	PI Authorized Signature:	<input type="text"/>	Date Signed:	<input type="text"/>