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CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

DIVISION OF BIOSTATISTICS

Biostatistics Collaboration and Consulting Core (BCCC)

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Department of Public Health Sciences

Biostatistics Collaboration and Consulting Core (BCCC)
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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 Public Health Sciences. 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.

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Lead Research Analyst 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.

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Lead Research Analyst and Biostatistician: Alejandro Mantero

Alejandro Mantero received his PhD in Biostatistics from University of Miami, he received his Masters and Bachelors of Arts in Economics, and Bachelors of Science in Physics, from University of Miami (UM). He has been working with the Biostatistics Collaboration and Consulting Core (BCCC) assisting with research studies, and is the REDCap liaison for the BCCC. He is dedicated to providing statistical support to the UM research community as well as outside of UM. His field of research is unsupervised machine learning utilizing the random forest algorithm.

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Lead Research Analyst and Biostatistician: Tae Kyoung Lee

Dr. Tae Kyoung Lee received his PhD in Human Development and Family Science from the University of Georgia, Athens, GA., his Masters in Child and Family Development and Bachelors in Child Studies.

Biostatistician: Hongyan (Helen) Liu

Hongyan (Helen) Liu joined Biostatistics Collaboration and Consulting Core (BCCC) in 2018. She received her Ph.D. in Veterinary Medicine from The Ohio State University, and a Master in Applied Statistics from the Penn State University. She has worked as a biostatistician on statistical analysis and data management in the Case Western Reserve University. She is very interested in clinical trials from study design, statistical analysis plans, to analyze data, report and interpret results, prepare for presentations and manuscripts.

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Biostatistician: Hang (Agnes) Zhang

Hang (Agnes) Zhang received her Masters of Biostatistics, from University of Florida (UF). She is a Ph.D. candidate in Biostatistics in the Department of Public Health Sciences, Division of Biostatistics. Hang joined the Biostatistics Collaboration and Consulting Core (BCCC) in Jan, 2018 and has been assisting with research studies, and REDCap-related problems. She is dedicated to providing statistical support to the UM research community

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Sr. Project Coordinator / BCCC Administrator: Maria Jimenez-Rodriguez

Maria Jimenez-Rodriguez received a Masters of Arts in Liberal Studies (M.A.L.S.), and a Bachelors of Arts in Sociology, with minors in Business Administration and Management, from University of Miami. She has over twenty 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.

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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/Development:** 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. Biostatistical considerations in the design and analysis of proposed investigations are critical to the procurement of funding and quality of research.

- **Grant Review and Manuscript Review:** The BCCC is available to carefully review the documents and provide feedback and suggestions to the authors/investigative team regarding the design and statistical aspects of the investigation.

- **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.

- **REDCap:** Support and assist users to build and manage online surveys, and databases quickly and securely.

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.

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).

Support Activities:

- **Short Term Support**

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 signing an Agreement for Support Form (Appendix 4) developed by the BCCC, and presented to the Principal Investigator with the estimated workload, and associated fees. Binding agreement between the BCCC and investigator/research team for BCCC support. This must be completed and signed 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. See BCCC Collaboration Plan Agreement form (*Appendix 6) and BCCC Authorization for Use of Existing Collaboration Plan Agreement form (*Appendix 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*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. In many cases, and when resources are available, collaborative plans may receive matched support by CTSI resources, and would provide available hours of support in excess of hours paid for by the collaboration plan holder.

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 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 and is available within the fiscal year of the collaboration plan agreement. 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**

BCCC support is available for externally funded-grant proposals that include our core in the grant budget for a line item amount of support each year. This would fall into the form of an ongoing collaboration described above. Once the PI and the BCCC receives award notice, the BCCC will then establish an ongoing collaborative agreement, for which the BCCC will bill monthly. The dollar amount put into the budget for the grant will need to be agreed upon by the BCCC, and based on the estimated workload per year of the grant.

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 5) 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.

Grant Development

The strongest grants are those that have biostatistical collaboration from the beginning of the design process. Generally, grants are more likely to be funded when there are biostatisticians participating in the development of the proposal.

The research design must be developed to accommodate the scientific questions of interest. The design must be as efficient as possible in order to improve power and increase efficiency (and potentially save money). Each hypothesis proposed under each aim of the investigation must have a thought out and described plan for analysis in order to appropriately assess them.

In writing a grant proposal, you are essentially asking a funding agency for money. You must demonstrate that scientifically appropriate methods are in place for analyzing the data collected with the funds provided.

Adequate statistical power needs to be demonstrated in order to detect the primary questions of interest. Statistical power can be described with an analogy to a microscope. You have a given amount of power in your lens and with that there is a limit to how small of an object you can see. In order to see smaller objects, you can increase the power of your lens. Statistical power is like that, but the “object” you want to see are the answers to the question of interest in the investigation. It may be an effect of a treatment, or a difference between groups. The smaller it is, the more power you need to see it. There are many approaches to increasing power. One is to increase the sample size or amount of information we use to estimate the effect. Another is to have a more efficient study design that minimizes variability, or other noise, in the data and allows you to see the effect clearly. A third is to use statistical methods of data analysis that are more efficient, and more precisely estimate the effect of interest.

Statistical collaboration is essential for providing support in these critical areas of grant development. Since the likelihood of funding increases, with adequate statistical considerations, it is a worthwhile investment. More importantly, it increases the quality of research. It is very disappointing to spend many years invested in research only to find out that it had a biased design or was not appropriately powered.

Additionally, provision of statistical support throughout the study duration is also critical in demonstrating the availability of resources to carry out the described investigation and corresponding analysis, and making statistical inference about the populations of interest.

Statistical Support in Grant Development

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 issued 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.

Funding for BCCC support in grant proposal development

The BCCC will collaborate in proposal development, and will charge for this support activity as a short term activity, although some funding may be funded under the Miami CTSI. 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.

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.

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 3). 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 Support form (*Appendix 2-pages1-3) 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 for Support Form (Appendix 4) 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.

BCCC Support Under Miami CTSI

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 are periodically offered. These will be announced as they become available. Initial Meetings for investigators seeking to obtain support for research are 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 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 CTSI support 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

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 – Bi-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.

REDCap Support

- BCCC offers support for your REDCap implementation, as part of the Miami CTSI. This includes:

- Going over your project and helping you to design a database that will ensure all important data has a field and is uniformly coded.

- Setting up field validation and required fields to ensure all important items are filled out when populating.

- Setting up reports to determine state of data population.

- Programming branching logic to ensure that only fields relevant to an instance are displayed and filled out.

- Teaching you how to use other features such as the data exportation tool.

- REDCap is accessible to all UM Faculty, Staff, and Students. External users can also access REDCap if they have a CaneID. No access request form is required to log into this application.

- REDCap is an application that allows users to build and manage online surveys and databases quickly and securely.

Prioritization

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*$105=$4200 for this support.

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.

Forms

1. Database Guidelines for Statistical Analysis form (*Appendix 1), requirement for data set preparations.

2. BCCC Request Support form (*Appendix 2-pages1-3), all required fields should be completed, and form should be sent via e-mail to the BCCC Administrator, before the scheduled initial meeting.

3. BCCC Office Hours Support form (*Appendix 3), all required fields should be completed, and form should be sent via e-mail to the BCCC Administrator, before the scheduled Office Hours meeting.

4. BCCC Agreement Support form (*Appendix 4) – will be e-mailed, to the investigator, by the BCCC Administrator, 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.

5. BCCC Grant Submission Agreement form (*Appendix 5-Non CTSI support and CTSI support) – will be e-mailed, to the investigator, by the BCCC Administrator after the initial support has been completed, and when the investigator is ready to submit the grant.

6. BCCC Collaboration Plan Agreement form (*Appendix 6) – will be e-mailed, to the Chair of the department once an agreement of the hours for the years has been established, by the BCCC Administrator. This agreement should include a department account number, and the authorized signature of the account holder, before any type of work can begin.

7. BCCC Authorization for Use of Existing Collaboration Plan Agreement form (*Appendix 7) – will be e-mailed, to the Chair of the department for anyone in their department that would like biostatistics support, by the BCCC Administrator. Once the approval of the Chair is submitted then the support will begin.

8. Forms of payment:
   - Invoice (*Appendix 8) will be created once a signed agreement has been sent to the BCCC Administrator, before entering in Workday for payment, prior to the beginning of the support. OR
   - Invoice (*Appendix 8) will be created, and check, money order, bank check or personal check should me made out to University of Miami, once a signed agreement has been sent to the BCCC Administrator, prior to the beginning of the support.

***Appendix 1**

Department of Public Health Sciences

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 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. Upper Lowercase 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 subject ID 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					

***Appendix 2_page1**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

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 mjrodriguez@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
- ☐ REDCap Support
- ☐ 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
- ☐ REDCap
- ☐ Other

1

***Appendix 2_page2**

Is this project approved by the University of Miami IRB? Yes ☐ No ☐

If Yes, IRB Number: _____

Reason for non-approval: _____

Are you under any deadline(s): Yes ☐ No ☐

If so, what is/are the deadline(s): _____

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 work not supported under the Miami CTSI will be the responsibility of the investigator, and will be determined based on scope of project and estimated workload.

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. Authorship policy accepted by UMMSM and described in BCCC manual applies. Additionally, work supported under the Miami CTSI will include the following acknowledgment:

This work was conducted with support from the Miami Clinical and Translational Sciences Institute (National Center for Advancing Translational Science (GRANT # 1UL1TR000460)). The content is solely the responsibility of the authors and does not necessarily represent the official views of the Miami CTSI, the University of Miami, and its affiliated academic health care centers, or the National Institutes of Health.

_____ _____

Date Principal Investigator

1

***Appendix 2_page3**

Timelines

Advance contact relative to your deadline is necessary to allow sufficient time to address your needs. Below are *minimum* times required after the initial meeting:

- **Protocol Development/ Grant application** – two months (may overlap with study design). It is optimal that biostatistical expertise be obtained as early as possible in the proposal development.

  We need at least six weeks. If it is less than six weeks before the due date, we may be some power calculations and write a few sentences. 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 need at least two months to improve your score.
- **Protocol review (completed)** – 2 weeks. (We may find statistical issues, and if it desired the BCCC work on the protocol from that point more time will be required.)
- **Statistical analysis** – 3 weeks, depending on the type of analysis and study design.
- **Abstracts** – 2-3 weeks, depending on statistical analysis.

  We need 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 will not be enough time to do anything complicated like multiple variable analysis.
- **Manuscript preparation**-1-2 weeks, after statistical analysis is complete. It usually takes more time than abstracts and grants.

As the deadline approaches, the likelihood that we can provide helpful statistical support diminishes. On a case by case basis, we will refuse requests that are too close to the deadline to provide anything useful.

1

***Appendix 3**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

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

Office Hours Consultations

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.

***Appendix 4**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

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): _____

To be invoiced upon signing of this agreement.

$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.

***Appendix 5_Non CTSI support**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

DIVISION OF BIOSTATISTICS
Biostatistics Collaboration and Consulting Core (BCCC)
Grant Submission 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:** _____

Project Title: _____
Project Dates: _____
Funding or Sponsor Agency: _____
Years of Grant: _____ **Proposal No. ("M" #):** _____
Account Title: _____
Grant or Awarded No.: #): _____ ***Account # issued** _____
Grant Amount: _____ **Amount budgeted for statistical support: $6,300.00**

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: _____

Dedicated biostatistics support from BCCC (Hours/Effort), to be budgeted into grant (hours/year of funded grant): _____

Retained support dedicated to this research will be billed monthly, and will initiate upon award of funding. All Fees are based on UM policy B020 for Recharge or Cost centers.

Note: Payment 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. it should be clear that reimbursement for time does not preclude or replace authorship.

***Appendix 5_CTSI support**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

DIVISION OF BIOSTATISTICS
Biostatistics Collaboration and Consulting Core (BCCC)
Grant Submission 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:** _____

Project Title: _____
Project Dates: _____
Funding or Sponsor Agency: _____
Years of Grant: _____ **Proposal No. ("M" #):** _____
Account Title: _____
Grant or Awarded No.: #): _____ ***Account # issued** _____
Grant Amount: _____ **Amount budgeted for statistical support: $6,300.00**

****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: _____

Dedicated biostatistics support from BCCC (Hours/Effort), to be budgeted into grant (hours/year of funded grant): _____

Retained support dedicated to this research will be billed monthly, and will initiate upon award of funding. All Fees are based on UM policy B020 for Recharge or Cost centers.

Remember to cite the University of Miami CTSI in your publications and posters:
"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."

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.

Note: Payment 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. it should be clear that reimbursement for time does not preclude or replace authorship.

***Appendix 6**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENCES

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):
Dept. of _____ **=** ____**hrs** **= $**_____
CTSI Match = ____hrs)
A total of ____hours of support.

Check all that apply to the research that will be supported by this plan:

- ☐ Institutionally funded pilot study
- ☐ NIH Grant submission
- ☐ Abstract Preparation
- ☐ Manuscript Preparation
- ☐ 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

To be billed at the beginning of the month ($_____), on a monthly basis, to Dept. of _____.

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 mirodriguez@biostat.med.miami.edu.**

***Appendix 7**

UNIVERSITY OF MIAMI
CLINICAL & TRANSLATIONAL SCIENCE INSTITUTE

DEPARTMENT OF PUBLIC HEALTH SCIENSES

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 _____

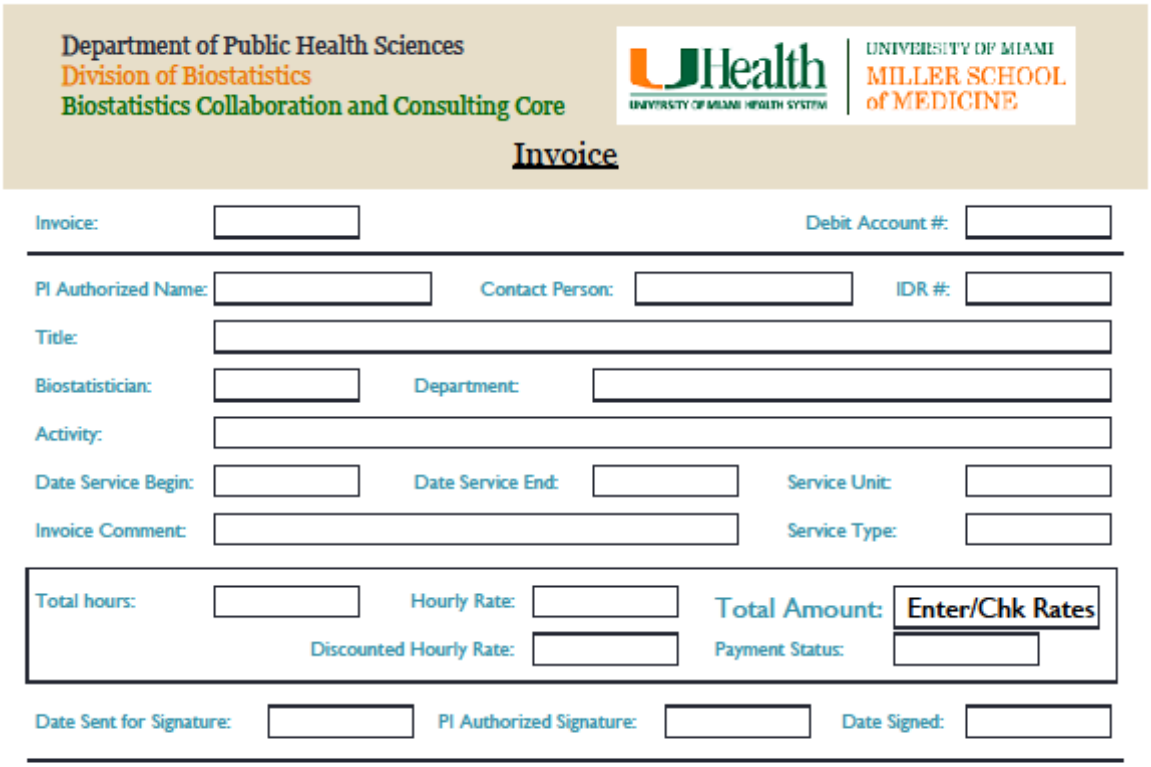
Dept/Div: _____

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 mjrodriguez@biostat.med.miami.edu.**

***Appendix 8**



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

UHealth | UNIVERSITY OF MIAMI MILLER SCHOOL of MEDICINE

Invoice

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