CFAR Biometrics Core Policies and Procedures

Services:

1. Service is free for all CFAR investigators for consultation on unfunded activities including advice on development of a Statistical Analysis Plan (SAP) for a publication, statistical support for grant applications or short (1-2 hours) meetings to obtain advice on the use of statistical methods or interpretation of results. For support in preparing a grant application, the relevant criteria for receiving support from the core are that if sufficiently complex analysis are proposed as part of the proposal the grant will include FTE in the budget to support a biostatistician in the Biometrics Core. The amount of FTE requested can be determined based on our *Biostatistics Effort Guidelines* which are included in the Appendix of this document. Note that if support for a statistician is not included, only very limited free support will be available as described above and subject to availability of staff supported by other funded projects. Support without funding may be provided at the discretion of the Core Director when the project benefits both the investigator and member(s) of the core.

The use of the service is on a first come/first serve basis with priority given to junior investigators who have not yet received an R-level NIH grant (or equivalent from another institution). In addition, CFAR investigators can contact the core for short term consultations on analyses they plan to conduct themselves, interpretation of results or database development. The support provided will generally consist of a few hours of the core member's time. All awardees of CFAR funded grants, such as the New Investigator Awards for junior faculty will receive consultations prior to submitting the grant and support without charge for basic statistical support through the duration of the award if funded. If significant or complex support is expected in a CFAR sponsored award, funds for a member of the Biometrics Core should be included in the application.

2. When CFAR investigators require more than a few hours of time from our members they should consult the *Biostatistics Effort Guidelines* (See Appendix) to determine how much support will be required to meet their needs. In general, a discussion between the Core Director and the Investigator will be held to determine the appropriate level of support required based on these guidelines. Funds can either be currently available with a project that requires immediate or near-term support or can be requested in a grant budget for future support. Whenever possible, core members who receive funding will continue to support the project after the funding ends. The amount of time available for this will depend on the other Biometrics Core commitments but in general, approximately one month is our goal for wrapping up a project after funding ends. Requested revisions to manuscripts or similar activities will be supported after grant funding ends.

3. Investigators are encouraged to use the "**Request for Consultation**" link on our web page: https://depts.washington.edu/cfar/discover-cfar/cores/biometrics/consultation. Core members can also be contacted directly, and investigators will be asked to fill out the form as the consultation occurs. The Biometrics Core meets every Tuesday and we determine which core member has time and expertise to handle the request. We try to assign someone to every request that comes in the week before our next Tuesday meeting and notify the investigator who made the request within a day. In most cases our masters level staff handles the requests with supervision as needed from either the Core Director, Dr Sarah Holte, or one of the Associate Directors; Dr Barbra Richardson or Dr Elizabeth Brown. More complex requests are handled by the Core Director, one of the Associate Directors, or in some cases, our colleagues in the Biostatistics Department at UW or the Biostatistics Program at the Fred Hutch.

4. As a general rule, contact the Biometrics Core as soon as possible when support is anticipated. For specific deadlines, such as grant applications, contact the Biometrics Core, via the "**Request for Consultation**" link at least two weeks prior to the submission deadline in order to insure standard support for an application. If specialized or sophisticated methods are required it is likely that more time will be required. Similarly, if an abstract is planned for submission with a specific due date the Biometrics Core should be notified that support is needed a minimum of two weeks prior to the deadline. The two-week window begins on the Tuesday of core staff meetings when we evaluate **Request for Consultation** submissions that have been received in the previous week (see 3) so that the **Request for Consultation** should be completed prior to that time. When these timeframes are not met, the core will do everything possible to provide the required support but cannot guarantee that the support can be provided in a shorter (than two weeks) timeframe. If a last-minute

opportunity arises, contact the core immediately. The most reliable approach is to use the **Request for Consultation** form on our web page, although CFAR investigators are welcome to request support directly from core members, and *if time allows*, core members may be able to support the request immediately.

4. The Core Director and Associate Directors are often asked for letters of support or Biosketches to be submitted with grant applications. We are happy to do this but require that when a letter of support or Biosketch is provided a minimum of 5% FTE must be requested for one of our core staff members, or possibly the Core Director or an Associate Director. The amount of support will be discussed by the Core Director and the Investigator submitting the grant and will be based on the ***Biostatistics Effort Guidelines*** (See Appendix).

5. The CFAR Biometrics Core provides a wide range of services generally of a quantitative nature. The most productive use of the core is when a Biometrics Core member is involved in a project from start to finish; Helping develop the study hypothesis, study design so that the correct information is collected, database development including advise on or development of a data dictionary, regular reports on study specifics such as enrollment, QC of incoming data and methods for resolution of data errors, development of an analysis data set and finally analysis of the study data. The above items are typical to many studies and as mentioned, while the most efficient collaborations involve the core from start to finish, requests for support can be made at any stage of a study. The core is open to providing a variety of other types of support such as evaluating data and results for reproducibility. Investigators who are unsure about whether the core supports a specific type of activity should submit a **Request for Consultation** or consult the core director. Our goal is to be as flexible as possible and if Biometrics Core has the experience and expertise to provide support for requests we will work with investigators to determine the most appropriate role the Biometrics Core can play in assisting with any request.

Training:

We are continually posting resources such as SAP templates, data management and analysis examples in different software packages on our web page https://depts.washington.edu/cfar/discover-cfar/cores/biometrics/training. We generally develop analysis examples when we see similar requests from multiple investigators.

The Biometrics Core sponsors a Microbiome Working Group which is designed to be an informal meeting with short presentations and a leader for discussion. The goal is to link researchers using microbiome data with experts in the processing and analysis of microbiome data. In the next series of meetings Metabolomics will be included.

Questions and Answers about the Biometrics Core:

1. *Who gets access?*

Any CFAR investigator, their postdocs, students and in some cases non-CFAR colleagues, can request support from the Biometrics Core. For free service, CFAR investigators who have either previously used the core and have produced papers and grants as a result of support from the Core OR CFAR investigators who have not used the core have priority. Junior Investigators, including students, always have priority, although we are nearly always able to accommodate senior investigators when needed. Service is provided on a “first come, first served” basis. “Productivity” and career stage considerations come into play only when demand exceeds capacity.

2. *I have my own student or post-doc who will conduct most of my analysis. Can I use the free service to write the grant but not write the core statistician into my grant even though he/she helped on the grant application?*

Possibly. If you used the free service to develop the grant application, you may also need to write the core member who assisted in preparing the grant into the budget for the grant if the proposed analysis is complex in nature. Whether support for a core member is required and the level of support will be determined through

discussions with the core director and based on the ***Biostatistics Effort Guidelines*** (See Appendix). In addition, see Section 1. description of services above.

3. *Can I use a core faculty member to help on a grant by providing letters of support or a Biosketch but do the analysis myself or have my students or post-docs conduct the analysis without providing support for Biometric Core staff?*

No. Investigators, students and post-docs often conduct analysis proposed in a grant. However, when a Biometrics Core faculty member provides a letter of support or a Biosketch, it is expected that one of the core staff members will receive support from the grant. If investigators, students or post-docs are conducting most of the analysis the amount of effort required for Biometrics Core staff will be reduced although the minimum of 5% FTE is required. See ***Biostatistics Effort Guideline*** (Appendix). Masters level statisticians do not provide Biosketches or Letters of Support.

4. *Can my postdoc or student request the support?*

Yes. Any CFAR member can request support from the Biometrics Core

5. *Can I use the free service for my funded project work?*

Yes, but only if the amount of support requested is of the type described under free services in Section 1. The free service is specifically designed to support very short term consultations and unfunded research.

APPENDIX

CFAR Biometrics Core
Guidelines for Budgeting Biostatistical Support on New Grants
Adapted from document prepared by the Center for Health Studies

Statisticians should be involved early in the grant submission process and should be included in both the development of the study design, analyses, and sample size determination as well as in budgetary decisions about biostatistician FTE, computer and software purchases, and training and travel. The following guidelines are intended as a starting point for budget discussions with an investigator and the Biometrics Core Director as well as biostatistician-track researchers who may desire support from masters level statisticians. These percentages should be increased for junior biostatisticians and for graduate students. In general, funding for core staff classified as Biostatistician I should not fall below 20% on a single project.

Definitions:

- Biostatistician I: Masters level Biostatistician with less than 1 year of experience
- Biostatistician II: Masters level Biostatistician with 1-5 years of experience
- Biostatistician III: Masters level Biostatistician with 5 or more years of experience or PhD level Biostatistician

Types of support provided at different funding levels

Extremely limited: 5%: Biostatistician II/III. More effort required for Biostatistician I

- Consult with PI about choice of statistical methods to use, but not enough time to carry out analyses
- Supervise a level I/II biostatistician who is funded at 20% or more FTE
- Meeting attendance will be infrequent and restricted to discussion of statistical issues.

This percentage is often too low to be useful. An important exception occurs when Biostatistician IIII supervises a Biostatistician I or II. This FTE level is too low to guarantee regular meeting attendance, depending on the frequency of meetings and/or one-to-one discussions.

Limited: 10% Biostatistician II/III. More effort required for Biostatistician I.

- Involvement through consultation with the PI about choice of statistical, limited standard statistical analysis and/or database development and maintenance.
- Preparation of regular reports
- Co-author on papers

This percentage is realistic in some cases but is too low if the statistical analysis is at all complicated. Meeting attendance may be infrequent and restricted to discussion of statistical issues.

Regular: 20% Biostatistician II/III, 25%-50% Biostatistician I

- Active participation in publications, with opportunity for first authored paper.
- Involvement in study design, implementation and data collection
- Routine study design and analysis, *e.g.,* analyses carried out using standard statistical software
- Maintenance of an already prepared analysis database.

This percentage is suitable for straightforward projects with uncomplicated analyses.

Extensive: 25% or more Biostatistician II/III, 50% or more for Biostatistician I with supervision from Biostatistician III.

- High involvement in the development and implementation of the research project, which may take many forms, including:
  - development of and/or use and interpretation of new statistical methods
  - development and implementation of complex study design
  - analysis and coordination of multi-center projects
  - development, maintenance, QC and development of a data dictionary of an analysis database.

- Active participation in publications, with opportunity for first authored papers
- Project-related travel and external presentations.
- Not appropriate for Biostatistician I without oversight by a Biostatistician III.

Additional considerations:

1. In a multi-disciplinary research center, investigator-biostatistician responsibilities are two-fold. One is to support the research of other investigators in the center. The other is to stay connected to statistical research through their own work and to stay up-to-date on emerging statistical methods and techniques. The latter is essential for funding and growth in the center. In some cases, new methods will need to be learned or developed when more standard available methods are not appropriate for a given analysis.
2. Any changes in percent support made during proposal writing or after research has been funded must be made jointly between the investigators providing support and the biostatisticians.
3. The guideline percentages can be variable over the lifetime of the grant. For multi-year projects, it might be reasonable to support biostatisticians at a higher level during the design phase, a lower level during data collection periods after design issues have been settled and before analysis database development and analysis have begun, returning to a higher level once analysis database development and statistical analysis begin. This can be accomplished by providing an average level of support over the entire duration of the grant or specifying different levels during different years of the grant.
4. In some cases, investigators have a “portfolio” of related grants. The sum of effort for statistical support from these grants can be combined to reach an appropriate percentage for the type of support desired as described above in the Appendix.
5. In general, Senior Investigators with established research programs who request effort from a Biometrics Core member must make a commitment for funding for at least one year. Exceptions can be made based on discussions with the Core Director. Junior or Early Stage Investigators can make shorter term commitments for providing support.

Guidelines for Authorship on papers:

Authorship on papers should be discussed early. Usually a statistician working 10% or more on a project will have contributed enough to the research to be a co-author on papers. In this situation, the statistician is usually listed as the second, or in some cases the third author. Since different fields have different guidelines for authorship these will be taken into consideration during discussions. Authorship may be merited for supervising statisticians who guide the analyses carried out by more junior researchers.