

Biostatistics information for grant applications

There are 3 options for inclusion of CTSC biostatistics support in grant applications:

Option A: For individual grants (eg R01) where a specific biostatistician is included as key personnel, **with fractional effort** for this named individual is included in the budget.

This can be a good option for investigators who have developed research programs with a specific biostatistician, and have room in their budgets to include salary support for a named individual.

It is important to note that some CTSC biostatisticians are unable to commit additional effort to grants in this way, because of other commitments and/or caps on effort due to impact on retirement benefits.

Option B: For individual grants (eg R01) where the **CTSC core** is identified for use, **with hourly rates for core** use included in the budget.

This is a good option for investigators who wish to use a biostatistician from the CTSC core who does not have % effort available to commit to a new grant (e.g. Drs Schrader or Qualls).

It is also a good option for some investigators who do not yet have well-developed plans for biostatistical support, or for whom needs may change depending on outcomes throughout the study. This option can include description of the full CTSC resources available to the investigator throughout the project, and potential costs projected from the hourly rate.

If this option is used, it is strongly recommended that the investigator still complete an initial consultation about the project with the core. This has many advantages, including the ability to name (in the Resources description) the biostatistician that has contributed to the design of the project. This consultation is usually free (depending on what prior work has been done for the investigator).

Option C: For program or center-type grants (eg P series NIH grants) where the CTSC biostats core is included as a complete package to serve needs of multiple investigators in the grant.

Being able to identify a functional core, with comprehensive services and support already available can be a real strength for some types of program/center grants. This option can be very good for center-type grants that have a group of investigators with diverse needs. Describing the full capabilities and access to the CTSC core can then be a strength to the application.

Care should be taken with this option if sophisticated and/or novel biostatistical approaches are a central component of the application. Depending on the type of grant, identification of personnel (or group of personnel) with appropriate expertise, and inclusion of their CVs as key personnel can have advantages.

It is strongly encouraged that program/center grant PIs discuss their plans with the core director well in advance of the grant deadline, to give the core the opportunity to help as much as possible.

SAMPLES

Option A: For individual grants (eg R01) where a specific biostatistician is included as key personnel, with fractional effort for this named individual is included in the budget.

This can be a good option for investigators who have developed research programs with a specific biostatistician, and have room in their budgets to include salary support for a named individual.

A.1. Personnel:

It is important to note that some CTSC biostatisticians are unable to commit additional effort to grants in this way, because of other commitments and/or caps on effort due to impact on retirement benefits. **The following biostatisticians currently can commit fractional effort to new grant proposals:**

Biostatistician	Expertise
Li Luo, PhD	Statistical genetics, bioinformatics, analysis of high-dimensional data, next-gen sequencing
Cristina Murray-Krezan, MS	Clinical trials design, general data analysis
Orrin Myers, PhD	Environmental and ecological modeling, spatial modeling
Hal Nelson, MS	Analysis of SEER and Medicare databases
Betty Skipper, PhD	Epidemiology, community-based studies, general data analysis

A.2. Example of Language for Resources Page:

Core Description:

Biostatistical support for this project will be provided by XXXXXX, as described in section XXX. XXXX is a member of the Design, Biostatistics, and Clinical Research Ethics (DBE) Component of the UNM HSC Clinical and Translational Science Center (CTSC), which provides centralized support for clinical and translational researchers in the areas of study design, biostatistics and ethics issues. DBE faculty have office space in the Multidisciplinary Research Facility, providing a centralized point of access to these services. The core also includes a service unit with comprehensive tracking and billing functions. Support is typically provided to investigators through direct consultations in one- or two-hour onsite appointments, and longer term collaborative support is also provided. These activities include, but are not limited to assistance with (1) the statistical design of clinical trials and biomedical studies, including sample size/power calculations; (2) the formulation of hypotheses and the preparation of the statistical methodology or analysis sections of proposals, abstracts and manuscripts; (4) database design and data analysis; and (5) responding to critiques, and planning new projects. The DBE Component also offers short courses and hour-long discussions on topics in research ethics, biostatistics and study design. These sessions are available to all CTSC investigators and students. The highest priority for support from the DBE Component is given to investigator-initiated protocols, grant proposals, and projects involving new clinical and translational researchers.

Space:

The CTSC Design, Biostatistics and Ethics Component (DBE) is consolidated in a suite of offices and conference spaces on the first floor of the Multidisciplinary Research Facility (MRF). The area includes three offices (approximately 450 total square feet) and a conference room, and an additional shared workspace (721 square feet) which is used to meet with teams of investigators. Centralized administrative support for the DBE component is located adjacent to the offices. This consolidated location of DBE resources also promotes excellent communication with the Division of Biostatistics and Epidemiology, which is housed in the Research Incubator Building, immediately adjacent to the MRF.

Director:

Edward J. Bedrick, Ph.D, is a Professor of Biostatistics in the UNM Department of Internal Medicine and serves as Director of the Design, Biostatistics and Ethics Component (DBE) of the UNM Clinical and Translational Science Center. Dr. Bedrick has over 25 years experience developing biostatistical methods (primarily for regression models and categorical data) and in the design and analysis of biomedical studies. Dr. Bedrick is a Fellow of the American Statistical Association and oversees the operations of the core, including supervision of XXXXX .

A.3. Example of Language for Budget Justification:

XXXX (Biostatistician) 1.2 calendar months

XXXX will be responsible for

Option B: For individual grants (eg R01) where the CTSC core is identified for use, with hourly rates for core use included in the budget.

This is a good option for investigators who wish to use a biostatistician from the CTSC core who does not have % effort available to commit to a new grant (e.g. Drs Schrader or Qualls).

It is also a good option for some investigators who do not yet have well-developed plans for biostatistical support. This option can include description of the full CTSC resources available to the investigator throughout the project, and potential costs projected from the hourly rate.

If this option is used, it is strongly recommended that the investigator still complete an initial consultation about the project with the core. This has many advantages, including the ability to name (in the Resources description) the biostatistician that has contributed to the design of the project. This consultation is usually free (depending on what prior work has been done for the investigator).

B.1. Example of Language for Resources Page:

Core Description:

The Design, Biostatistics, and Clinical Research Ethics (DBE) Component of the UNM HSC Clinical and Translational Science Center (CTSC) provides support for clinical and translational researchers who need assistance with study design, biostatistics and ethics issues. DBE faculty have office space in the Multidisciplinary Research Facility, providing a centralized point of access to these critical services. Support is typically provided to investigators through direct consultations in one- or two-hour onsite appointments, but longer term collaborative support is also available. These activities include, but are not limited to assistance with (1) the statistical design of clinical trials and biomedical studies, including sample size/power calculations; (2) the formulation of hypotheses and the preparation of the statistical methodology or analysis sections of proposals, abstracts and manuscripts; (4) database design and data analysis; and (5) responding to critiques, and planning new projects. The DBE Component also offers short courses and hour-long discussions on topics in research ethics, biostatistics and study design. These sessions are available to all CTSC investigators and students. The highest priority for support from the DBE Component is given to investigator-initiated protocols, grant proposals, and projects involving new clinical and translational researchers.

Services are provided on an hourly fee-for-service model, and the component also includes a service unit with comprehensive tracking and billing functions.

Space:

The CTSC Design, Biostatistics and Ethics Component (DBE) is consolidated in a suite of offices and conference spaces on the first floor of the Multidisciplinary Research Facility (MRF). The area includes three offices (approximately 450 total square feet) and a conference room, and an additional shared workspace (721 square feet) which is used to meet with teams of investigators. Centralized administrative support for the DBE component is located adjacent to the offices. This consolidated location of DBE resources also promotes

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Director:

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Biostatisticians:

Edward J. Bedrick, Ph.D.	Mixed models, observational data analysis, meta-analysis
Li Luo, PhD	Statistical genetics, bioinformatics, analysis of high-dimensional data, next-gen sequencing
Cristina Murray-Krezan, MS	Clinical trials design, general data analysis
Orrin Myers, PhD	Environmental and ecological modeling, spatial modeling
Hal Nelson, MS	Analysis of SEER and Medicare databases
Clifford Qualls, PhD	Clinical trials design, general data analysis, time series and data modeling
Ronald Schrader, PhD	Clinical trials design, general data analysis, regression modeling
Betty Skipper, PhD	Epidemiology, community-based studies, general data analysis

B.2. Example of Language for Budget Justification:

Biostatistical Support

\$XXXX is requested for services of the UNM CTSC Biostatistics and Design Core. As described in the Resources section, this core facility is led by Dr Edward Bedrick, and includes 7 other biostatisticians with extensive experience in design and analysis of biomedical studies. Initial biostatistical support for the current application was provided by consultation with core member Dr XXXX, an expert in XXXXX (*copy and/or modify from Resources page*). The core includes a service unit for scheduling, tracking and billing core usage. Because of support from CTSC and institution, all service from this core is provided at a subsidized rate of \$75 per hour. Based on discussions with Dr XXXXX (*name the initial consulting biostatistician*) and Dr Bedrick, we estimate that XXXX hours of biostatistical support will be required annually to complete the current project.

Option C: For program or center-type grants (eg P series NIH grants) where the CTSC biostats core is included as a complete package to serve needs of multiple investigators in the grant.

Being able to identify a functional core, with comprehensive services and support already available can be a real strength for some types of program/center grants. This option can be very good for center-type grants that have a group of investigators with diverse needs. Describing the full capabilities and access to the CTSC core can then be a strength to the application.

Care should be taken with this option if sophisticated and/or novel biostatistical approaches are a central component of the application. Depending on the type of grant, identification of personnel (or group of personnel) with appropriate expertise, and inclusion of their CVs as key personnel will be more appropriate.

It is strongly encouraged that program/center grant PIs discuss their plans with the core director well in advance of the grant deadline, to give the core the opportunity to help as much as possible.

C.1. Example of Language for Resources Page:

Core Description:

The Design, Biostatistics, and Clinical Research Ethics (DBE) Component of the UNM HSC Clinical and Translational Science Center (CTSC) provides support for clinical and translational researchers who need assistance with study design, biostatistics and ethics issues. DBE faculty have office space in the Multidisciplinary Research Facility, providing a centralized point of access to these critical services. Support is typically provided to investigators through direct consultations in one- or two-hour onsite appointments, but longer term collaborative support is also available. These activities include, but are not limited to assistance with (1) the statistical design of clinical trials and biomedical studies, including sample size/power calculations; (2) the formulation of hypotheses and the preparation of the statistical methodology or analysis sections of proposals, abstracts and manuscripts; (4) database design and data analysis; and (5) responding to critiques, and planning new projects. The DBE Component also offers short courses and hour-long discussions on topics in research ethics, biostatistics and study design.

Services are provided on an hourly fee-for-service model, and the component also includes a service unit with comprehensive tracking and billing functions. Full access to all functions of this core will be provided to all investigators associated with the current XXXX application.

Space:

The CTSC Design, Biostatistics and Ethics Component (DBE) is consolidated in a suite of offices and conference spaces on the first floor of the Multidisciplinary Research Facility (MRF). The area includes three offices (approximately 450 total square feet) and a conference room, and an additional shared workspace (721 square feet) which is used to meet with teams of investigators. Centralized administrative support for the DBE component is located adjacent to the offices. This consolidated location of DBE resources also promotes excellent communication with the Division of Biostatistics and Epidemiology, which is housed in the Research Incubator Building, immediately adjacent to the MRF.

Director:

Edward J. Bedrick, Ph.D, is a Professor of Biostatistics in the UNM Department of Internal Medicine and serves as Director of the Design, Biostatistics and Ethics Component (DBE) of the UNM Clinical and Translational Science Center. Dr. Bedrick has over 25 years experience developing biostatistical methods (primarily for regression models and categorical data) and in the design and analysis of biomedical studies. Dr. Bedrick is a Fellow of the American Statistical Association.

Biostatisticians:

Edward J. Bedrick, Ph.D.	Mixed models, observational data analysis, meta-analysis
Li Luo, PhD	Statistical genetics, bioinformatics, analysis of high-dimensional data, next-gen sequencing
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Ronald Schrader, PhD	Clinical trials design, general data analysis, regression modeling
Betty Skipper, PhD	Epidemiology, community-based studies, general data analysis

C.2. Example of Language for Budget Justification:**BUDGET JUSTIFICATION****Biostatistical Support**

\$XXXX is requested for services of the UNM CTSC Biostatistics and Design Core. As described in the Resources section, this core facility is led by Dr Edward Bedrick, and includes 7 other biostatisticians with extensive experience in design and analysis of biomedical studies. Initial consultation about the suitability of this model of core use for the needs of the current application was provided by Dr Bedrick. The core includes a service unit for scheduling, tracking and billing core usage. Because of support from CTSC and institution, all service from this core is provided at a subsidized rate of \$75 per hour. Based on discussions with Dr Bedrick, we estimate that XXXX hours of biostatistical support will be required annually to support biostatistical consultation and analysis for the investigators in this XXX grant.