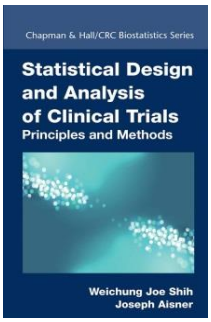
STAT 422/622 **Fall 2025**

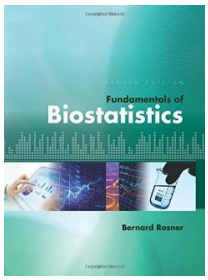
ADVANCED BIOSTATISTICS

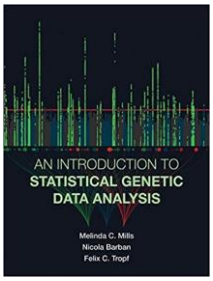
Lectures	Monday and Thursday 4:05 – 5:20 pm	Instructor	Michael Baron
Room	Don Myers room DMTI-109	Office	DMTI 106-D
Course web site	https://dr-baron.github.io/622/	Phone	202-885-3130
Office hours	Monday and Thursday 2^{50}-3^{50} pm in DMTI 106D or by appointment.	Email	baron@american.edu
		Web	https://dr-baron.github.io/

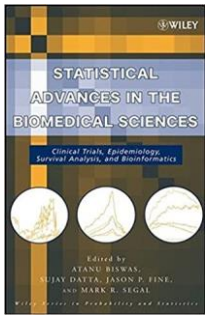
Textbooks

No textbook is required*. The course material will be taught in class, and the instructor will distribute typed and organized* ***lecture notes****, which are based on the following books:*









- *Design and Analysis of Clinical Trials: Principles and Methods*, by W. J. Shih and J. Aisner. Chapman & Hall/CRC Biostatistics Series, 2016. ISBN 1482250497, or 2nd edition, 2021, ISBN 0367772442 [SA].
- *Fundamentals of Biostatistics,* 8th edition, by B. Rosner. Cengage Learning, 2015. ISBN 130526892X [R].
- *An Introduction to Statistical Genetic Data Analysis,* by M. Mills, N. Barban, and F. Tropf. MIT Press, 2020. ISBN 0262538385 [MBT].
- *Group Sequential Methods with Applications in Clinical Trials,* by C. Jennison and B. W. Turnbull. Chapman & Hall/CRC Interdisciplinary Statistics, 2000. ISBN 9780849303166 [JT].
- *Statistical Advances in the Biomedical Sciences: Clinical Trials, Epidemiology, Survival Analysis, and Bioinformatics,* edited by A. Biswas, S. Datta, J. Fine, and M. Segal. Wiley, 2008. ISBN 0471947539 [BDFS].

Course plan [and reference literature]**:**

1. Introduction, overview, motivation, and examples [SA: 1; R: 1]
2. Main concepts and principles of clinical trials. Efficacy, futility, safety, and ethics [SA: 1-2, BDFS: part I]
3. Randomization in clinical trials. [SA: 2.5-2.6]
4. Review of statistical estimation and hypothesis testing. [R: 5.3-5.5, 6.5, 7.1-7.4, 8.1-8.6]
5. Design of clinical trials. Statistical power analysis and sample size calculation. Crossover designs. Optimal allocation. [SA: 3-4, R: 13.12]
6. Survival analysis. Hazard rate. Time-to-event endpoints. Censoring and adjustment. [SA: 4.4, 9; R: 14]
7. Adjustments for multiple comparisons, non-response, missing data, dropouts. [SA: 4.8, 10; R: 13.16]
8. Group sequential clinical trials. Interim analysis. Curtailed experiments. [SA: 6-8, JT: 2-4]
9. Design and analysis of epidemiologic studies. [R: 13]
10. Epidemic models, analysis, estimation, and forecasting. [BDFS: part II]
11. Statistical genetics, terminology and the main concepts. Mendel laws. [MBT: 1, 3, 14]

    If time permits:
12. Design and analysis of genome-wide association studies. [MBT: 4, 12]
13. Polygenic scores and genetic architecture. Modeling and construction. [MBT: 5, 11]

Assignments and Grading:

Weekly homework assignments and mini-projects	20%	Homework will be assigned weekly. A steady effort to work out all the assigned problems is essential for learning statistical methods and for the successful performance in this course. Complete homework solutions will be posted after the homework is submitted. A typical homework will include a few problems to do by hand, to see how things work, and a few realistic problems to do using R software. Late submission may be accepted at a cost of a 10% deduction for each day.
Weekly quizzes	30%	10- to 15-minute quizzes at the end of every Thursday class. Each quiz covers the material of the preceding week and the latest homework. During a quiz, you may use **one cheat sheet**.
Midterm Test	20%	The midterm covers several chapters of the material. Taken in class; **notes and our course materials are allowed**. Time is limited – 1 hour 15 minutes.
Final Test	30%	The final covers the 2nd part of the course, but it is cumulative indirectly because the 2nd part is based on the 1st part. Taken in class during the final week; **notes and our course materials are allowed,** but of course, serious preparation is essential for getting a good grade. Time: 2 hours.

90 – 100 % = A	87 – 90 % = A-	84 – 87 % = B+	80 – 84 % = B
77 – 80 % = B-	74 – 77 = C+	70 – 74 % = C	60 – 70 % = C-

Software

During the course, we'll study statistical machine learning methods and implement them in **R**, including classroom demonstrations and examples. For all computer assignments, use the language of your choice. Advanced programming skills and advanced computer knowledge are *not* required. To use **R**, install it from https://cran.r-project.org/, free of charge.

Tips

- Collaboration on homework is ok. Even encouraged! Quizzes and exams are to be done individually.
- On quizzes and exams, *show your work*. I will grade your solutions, not your answers.
- *No late assignments*. However, it is possible to take an exam or quiz early, for a good reason, for example, a business trip or a religious holiday. So, plan ahead.
- A steady effort to review material and work out all the assigned problems is your best chance to succeed in this course. Always *keep up* with the course because material is built upon the previously covered concepts.
- Use your absolute right to ask questions in class and during office hours. For example, any homework problem can be discussed.
- For each exam and quiz, review all the new concepts, methods, formulas, etc. Try to understand the methods rather than to memorize them.
- For each quiz, it may be useful to prepare a brief *summary* of important formulas and methods that you may need. Arrange it on a sheet of paper in the most convenient way. Do the same for the final exam! Such summaries will help you use your exam time efficiently.

Learning Outcomes

By the end of the course, students will demonstrate competence in the main concepts and statistical methods used in the design and analysis of clinical trials, analysis of survival data, epidemic modeling, and genome studies. They will apply suitable statistical tools to conduct power analysis and calculate required sample sizes for popular modern clinical trial designs and make the necessary adjustments. Students will be able to model, forecast, and explain the dynamic of epidemics and use appropriate statistical techniques to understand and analyze gene expression data and genome-wide association studies.

Pre-requisites

STAT 302 “Intermediate Statistics”, STAT 320 “Biostatistics”, or STAT 614 “Statistical Methods”.

Support Services

If you experience difficulty in this course for any reason, please do not hesitate to consult with me. In addition to the resources within our department, a wide range of services is available to support you in your efforts to meet course requirements.

Mathematics & Statistics Tutoring Lab. Tutors should be able to help you with Calculus, Algebra, and basic Statistics, may be statistical software, but you should not count on getting homework solutions for advanced Statistics courses! The Math & Stats Lab offers both one-on-one and drop-in tutoring on Monday through Thursday 11^{00} am-8^{00} pm; Friday: 11^{00} am-3^{00} pm; and Sunday: 3^{00}–8^{00} pm in DMTI room 103 (subject to schedule changes in 2025-26). Online tutoring is available on https://american.mywconline.net/. Visit the Quantitative Support page or email tutoring@american.edu for more information. This service is *free* for all our students.

Software support with R - CTRL Connect, ctrl@american.edu, 202-885-2117

Academic Support & Access Center MGC 243, 202-885-3360 supports the academic development and educational goals of all AU students while also providing support to students with disabilities. We offer workshops on topics of interest to all students such as managing the college workload, stress management, time management note taking, critical thinking, memory skills, and test taking. Additional support includes free private and group tutoring in many subjects, supplemental instruction, The Math Lab and The Writing Lab are also available.

Counseling Center MGC 214, 202-885-3500 is here to help students make the most of your university experience, both personally and academically. We offer individual and group counseling, urgent care, self-help resources, referrals to private care, as well as programming to help you gain the skills and insights needed to overcome adversity and thrive while you are in college. Contact the Counseling Center to make an appointment in person or by telephone, or visit the Counseling Center page on the AU website for additional information.

Religious Holidays. Students may receive accommodation in the course for the observance of a religious and/or cultural holiday. The student should notify the professor as soon as possible should such a need exist. More information about accommodations for religious and/or cultural holidays can be found at www.american.edu/ocl/kay/request-for-religious-accommodation.cfm.

***Emergency Preparedness*.** In the event of an emergency, students should refer to the AU Web site (http://www.american.edu/emergency) and the AU information line at (202) 885-1100 for general university-wide information. In case of a prolonged closure of the University, I send updates to you by email and will post all announcements on the course web site.

Center for Student Belonging MGC 201 and 202, 202-885-3651 serves as a principal leader, resource and support in fostering a campus environment where students feel a profound sense of belonging, connection, and the ability to thrive.

American University expressly prohibits any form of discriminatory harassment including sexual harassment, dating and domestic violence, sexual assault, and stalking. The university is an equal opportunity institution that operates in compliance with applicable laws and regulations, and does not discriminate on the basis of race, color, national origin, religion, sex (including pregnancy), age, sexual orientation, disability, marital status, personal appearance, gender identity and expression, family responsibilities, political affiliation, source of income, veteran status, an individual's genetic information or any other bases under federal or local laws in its programs and activities.

If you experience any of the above, you have the option of filing a report with the AU Department of Public Safety (202-885-2527) or the Office of the Dean of Students 202-885-3300 dos@american.edu. Please keep in mind that all faculty and staff – with the exception of counselors in the Counseling Center, victim advocates in the Wellness Center, medical providers in the Student Health Center, and ordained clergy in the Kay Spiritual Life Center – who are aware of or witness this conduct are required to report this information to the university, regardless of the location of the incident.

The Writing Center, First floor of Bender Library, offers free, individual coaching sessions to all AU students. In your 45-minute session, a student writing consultant can help you address your assignments, understand the conventions of academic writing, and learn how to revise and edit your own work. Hours: 11 a.m. to 9 p.m. Monday through Thursday; 11 a.m. to 6 p.m. Friday. Call 202-885-2991 to arrange a session. Meanwhile find handouts, information, and a weekly writer's blog at the Writing Center website and on Facebook.

International Student & Scholar Services, Batelle 4th Butler Pavilion, Rm. 410. Resources to support academic success and participation in campus life including academic counseling, support for second language learners response to questions about visas, immigration status and employment and intercultural programs, clubs and resources.