Universidad de Navarra

Research Methodology (F. Medicina)

Subject guide 2026-27

INTRODUCTION

- **Brief description of the course:**
- The course covers the main methodological aspects of biomedical research. To this end, it will integrate disciplines necessary for the development of biomedical knowledge and the practice of medicine. Among others, concepts of Biostatistics –application of statistics to biomedical problems–, Epidemiology –a method of reasoning that studies, in human populations, the dynamics of health-disease, the factors that influence it, as well as the methods of diagnostic-therapeutic intervention– will be addressed. During the course, the student needs to be familiar with a software for creating data bases and analyzing them, the Stata software is recommended for this purpose.
- The main **handbook needed** to follow the course is BIOESTADISTICA AMIGABLE, **5th EDITION**. [*WARNING: Previous editions are **not** valid for this course*].

amigable_5th_ed.jpg

- **Course's charecter**: Mandatory
- **ECTS**: 9
- **Year and dates**: 2nd year, 31-Aug-2026 to 19-Feb-2027
- **Language**: English
- **Degree**: Medical Degree
- **Module and topic of the course**: II Social Medicine, Communication Skills & Introduction to Research; II.2 Research in Biomedicine
- **Responsible faculty**: Prof. Miguel A. Martínez-González, Full professor. Preventive Medicine and Public Health, (mamartinez@unav.es)
- **Other faculty**:
- Prof. Jokin de Irala, Full professor, Preventive Medicine and Public Health (jdeirala@unav.es)
- Prof. Alvaro Alonso, Full professor, Epidemiology, Emory University/UNAV (alvaro.alonso@emory.edu)
- Prof. Estefanía Toledo, Full professor, Preventive Medicine and Public Health (etoledo@unav.es)
- Prof. Gema Frühbeck, Full professor, Nutrition and Food Science (gfruhbeck@unav.es)
- Dr. Javier Gómez Ambrosi, Associate professor, Nutrition and Food Science (jagomez@unav.es)
- Dr. Amaia Rodríguez, Associate professor, Nutrition and Food Science (arodmur@unav.es)
    - Dr. Javier Pérez de Rojas, MD, Preventive Medicine and Public Health, CUN (Clínica Universidad de Navarra) (jperez.22@unav.es)

- **Schedule and room:** please, click here

LEARNING OUTCOMES (Competencies)

A. BASIC COMPETENCES

CB1 - That students have demonstrated knowledge and understanding in an area of study that builds on the foundation of general secondary education, and is usually at a level that, while relying on advanced textbooks, also includes some aspects that involve knowledge from the cutting edge of their field of study.

CB2 - That students know how to apply their knowledge to their work or vocation in a professional manner and possess the competencies that are usually demonstrated through the development and defense of arguments and problem solving within their field of study.

CB3 - That students have the ability to gather and interpret relevant data (usually within their area of study) to make judgments that include reflection on relevant social, scientific or ethical issues.

CB4 - Students will be able to transmit information, ideas, problems and solutions to both specialized and non-specialized audiences.

CB5 - That students have developed those learning skills necessary to undertake further studies with a high degree of autonomy.

B. GENERAL COMPETENCES

CG28 - Obtain and use epidemiological data and assess trends and risks for health decision making.

CG31 - Know, critically evaluate and know how to use clinical and biomedical information sources to obtain, organize, interpret and communicate scientific and health information.

CG32 - Know how to use information and communication technologies in clinical, therapeutic, preventive and research activities.

CG34 - To have a critical, creative, constructive skeptical and research-oriented point of view in professional activity.

CG35 - Understand the importance and limitations of scientific thinking in the study, prevention and management of diseases.

CG36 - Be able to formulate hypotheses, collect and critically evaluate information for problem solving, following the scientific method.

CG37 - To acquire the basic training for research activity.

CG38 - Be able to function in international scientific and clinical settings to participate in translational research in the field of biomedicine.

C. SPECIFIC COMPETENCES

MORPHOLOGY, FUNCTION AND STRUCTURE OF THE HUMAN BODY

SC37 - Knowing the principles and methods of preventive medicine and public health.

SC38 - Risk factors and disease prevention.

SC39 - Recognize the determinants of health of the population. Health indicators.

SC40 - Planning, programming and evaluation of health programs.

SC41 - Prevention and protection against diseases, injuries and accidents.

SC42 - Evaluation of the quality of care and patient safety strategies.

SC43 - Vaccines.

SD44 - Epidemiology.

SC45 - Demography.

SC51 - Knowing, critically assessing and knowing how to use the technologies and sources of clinical and biomedical information to obtain, organize, interpret and communicate clinical, scientific and health information.

CE52 - Knowing the basic concepts of biostatistics and its application to medical sciences. To be able to design and perform simple statistical studies using computer programs and interpret the results.

SC53 - Understand and interpret statistical data in the medical literature.

SC54 - Knowing the history of health and disease.

SC57 - Use biomedical information search and retrieval systems.

SC58 - Know and manage clinical documentation procedures.

SC59 - Understand and critically interpret scientific texts.

SC60 - Know the principles of the scientific method, biomedical research and clinical trials.

SC61 - Know the principles of telemedicine.

SC62 - Knowing and managing the principles of (best) evidence-based medicine.

CE66 - Make an oral and written public presentation of scientific work and/or professional reports.

PROGRAM

Introduction to research

Scientific thinking and formulation of hypotheses

Ethical aspects in biomedical research

Causality

Causality: models and criteria

Population and sample

Population and sample: concept and practical implications

Data

Types of variables and description of qualitative traits: measures of frequency

Description of quantitative traits: measures of central tendency, measures of spread, measures of shape

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Probability

Probabily and probability distributions: concept and applications

Decission analysis

Validity of a diagnostic test

Measures of frequency, association and impact

Measures of frequency

Measures of association for risk factors and for protective factors

Measures of impact for risk factors and for protective factors

Inference I: confidence intervals

Central limit theorem. Confidence intervals

Application of a confidence interval for a mean, a proportion and a median

Inference II: Hypothesis testing

Hypothesis testing: selection and interpretation of the results

Study design

Counterfactual model.

General characteristics of epidemiological studies

Descriptive studies I: individual data

One case study, case series, cross-sectional studies

Cross-sectional study design

Comparison of one mean and one proportion to a reference value

Comparison of one mean and one proportion to a reference value

Correlation and simple linear regression model

Pearson’s and Spearman’s correlation



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Simple linear regression model

Descriptive studies I: aggregated data

Ecological study and time series

Observational analytical studies I: prospective cohort studies

Prospective cohort studies

Comparison of two independent means

Comparison of two independent means

Sample size estimation for the comparison of two means

Sample size estimation for the comparison of two means

Observational analytical studies II: retrospective cohort studies

Retrospective cohort studies

Comparison of more than two independent means

One-way ANOVA: estimation and interpretation

Observational analytical studies III: case-control studies

Case-control studies

Comparison of two proportions

z test

Pearson’s chi-squared test

Fisher’s exact test

Sample size estimation for the comparison of two proportions

Sample size estimation for the comparison of two proportions

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Observational analytical studies III: alternative approaches for case-control studies

Matched case-control studies. Case-crossover studies. Nested case-control studies

Matching

Comparison of two paired means and two paired proportions

In vitro and in vivo experimental studies

Basic concepts of in vivo studies

Basic concepts of in vitro studies

Experimental analytical studies I: clinical trials

Phases of clinical trials for drug development

Methodological aspects of randomized clinical trials

ANOVA with repeated measurements and between group comparisons

ANOVA with repeated measurements and between group comparisons

Experimental analytical studies II: factorial and cross-over clinical trial

Factorial trials

Cross-over trials

Two-way ANOVA and interaction

Two-way ANOVA. Introduction to the concept of interaction

Experimental analytical studies III: additional options for designing trials

Equivalence and non-inferiority trials

Survival analysis

Description of survival, Kaplan-Meier curves

Across-group comparisons of survival curves

Bias

Selection bias

Misclassification bias

Confounding

Other biases

Dealing with multiple comparisons

Interaction or effect modification

Interaction: concept, assessment and interpretation

Multivariable models

Multivariable linear regression models

Multivariable logistic regression models

Multivariable Cox regression models

EDUCATIONAL ACTIVITIES

Classroom sessions: 78h

Classroom sessions with the faculty. Some of them will have an important practical content.

Tutoring: 2h

Will include all the informal sessions of personal consultation of doubts about the subject and some planned session of resolution of doubts together with the whole class. The professor will attend to the students' doubts before and after each class. He will be available also in his office at the students' request or by e-mail.

Assessment: 6h, 15 min

The assessment will include **TWO** partial exams of 45 minutes each, and the final exam (pending if "co-design" with students).

The **FINAL EXAM** in the ordinary call (February 19th) will contain **three** sections, two of them will correspond to the contents of each partial exam (only to be answered by those with grades <8 in the respective partial exam), and the third part for ALL, corresponding to the last part of the course.

The first 2 sections will contain 25 questions each, and the last section will contain 50 questions. The total exam time will be 160 minutes (2 hours and 40 minutes). The alloted time will be 40 minutes for each of the 2 partial exams and 80 minutes for the last part (50 questions).

Self-assessments and mutual feedback: 6h

In each Learning Unit some self-evaluation questions in order to have appriopriate feedback (mutual feedback) will be made available. Students should answer them once they have worked on the corresponding topic. At the end of the self-evaluation, the student will receive the explained solutions to learn from the mistakes and consolidate the correct answers.

Directed work: 10h

It is mandatory that students solve problems with Stata and exercises proposed during the lectures.

Personal work: 120h

The student's personal work consists of preparing the face-to-face sessions by working on the recommended readings for the specific sessions. In addition, the students will have to study the recommended bibliography to complement their theoretical and practical learning.

ASSESSMENT

ORDINARY CALL

The final grade of the course will be the best grade obtained from the THREE following options.

1. Weighted average between:

- Midterm exams (25% for the average of the midterm exams).

- Final exam (75%).

2. Weighted average between:

- Midterm exams (15% for the average of the midterm exams).

- Final exam (85%).

3. Weighted average between:

- Midterm exams (20% for the average of the midterm exams).

- Class quizzes (20% for the average of them).

- Final exam (60%).

In the final exam the theoretical concepts or practical exercises explained in class could be included for those students not achieving at least 8 points over 10 in the midterm exams .

Therefore, the teachings included each midterm exam will be considered as passed if the student achieves 8 over 10 in the corresponding midterm exam.

In order to average the grades, it is necessary to obtain a score of at least 4.5 in the final exam.

With a score less than 4.5 in the final exam, students cannot pass the course, regardless of their grades in the other assessments conducted during the course .

Mode of evaluation:

Evaluations consisting of multiple-choice questions will have 4 choices, with a penalty of –0.33 for each failed question.

In order to facilitate the student's improvement during the course, the solutions of the Midterm exam will be made available and their review will be facilitated. In addition, students will have self-evaluations of each didactic unit in order to prepare for the evaluations.

EXTRAORDINARY EXAM

The extraordinary examen will consist of a WRITTEN multiple-choice test of 50 questions similar to the ordinary final exam. It will comprise the full course.

STUDENTS IN OTHER SITUATIONS

Students in special situations will have to talk to the person in charge of the course, who will evaluate their case individually.

OFFICE HOURS

Students may request a meeting with the course coordinator (Prof. MA Martínez-González, mamartinez@unav.es) or with any other faculty member by email.

If you wish to speak to Prof. De Irala, please, choose a day and a time from the following schedule of available days: jdeirala.medpreventiva.es. Once you chose a date I will receive a notice. You do not need to do anything else. The appointments will be at his office 0-310 "Edificio Los Castaños". You can also write to Prof. De Irala at: jdeirala@unav.es

BIBLIOGRAPHY AND RESOURCES

(1) Basic bibliography:

Universidad de Navarra

- **Bioestadística Amigable**. **5ª Ed**. Martínez González MA, et al. Elsevier, 2025. Find it in the Library (eBook). **(IMPORTANT: Only the FIFTH edition of this book is valid)**
- **Epidemiología aplicada**. De Irala J, et al. Ed. Ariel. 2ªed. Find it in the Library.

- "Simple and Stupid Stata Summary" 4S. Martínez-González MA. Amazon Books, 2017. (only on-line)
- Videos and other teaching resources prepared by the Dpt. of Preventive Medicine & Public Health.

(2) Resources:

Videos and other teaching resources (mainly about Stata) prepared by the Department of Preventive Medicine

Stata for dummies: beginning from scratch

Stata tutorials in English

(3) Supplementary bibliography:

- "Epidemiology". Leon Gordis. Philadelphia [etc.]: Elsevier. 2024; 7th. ed.
- "A dictionary of Epidemiology". Edited for the International Epidemiological Association by John M. Last; Associate Editors, Robert A. Spasoff...[et al.]; New York: Oxford University Press, cop. 2026. 7th. Ed. Find it in the Library.
- "Epidemiology": an introduction". Kenneth J. Rothman. Publicac New York, N.Y.: Oxford University Press, 2024, 3rd ed. Find it in the Library.
- Altman DG. "Practical statistics for medical research". Londres: Chapman and Hall /CRC, 1991. Reprint: 1999. Find it in the Library.
- Motulsky H. "Intuitive Biostatistics". Oxford University Press, USA; 4th edition (November 15, 2017). Find it in the Library.
- Bailar JC, Hoaglin DC. Medical Uses of Statistics, 3rd Ed. N Engl J Med Books, 2009. Find it in the Library.
- Acock AC. A Gentle Introduction to Stata, Revised 5th Ed. College Station, TX: Stata Press, 2016. Find it in the Library.
- Vittinghoff E, Glidden DV, Shiboski SC and McCulloch CE. Regression Methods in Biostatistics: Linear, Logistic, Survival, and Repeated Measures Models, 2nd ed. New York: Springer, 2012. Find it in the Library.