

Concentration area: 5156

Creation: 14/12/2017

Activation: 14/12/2017

Credits: 3

Workload:

Theory	Practice	Study	Duration	Total
(weekly)	(weekly)	(weekly)		
5	1	3	5 weeks	45 hours

Professors:

Roberto Costa

Katia Regina da Silva

Objectives:

OBJECTIVE: This course aims to present critical concepts and practical methods to support planning, collection, storage, and dissemination of data in clinical research to enhance security, reliability and quality to the data collected for research purposes. Essential principles for implementing a robust infrastructure for electronic data collection and data management, in accordance with international standards, will be addressed throughout the course to support students in creating databases for their research projects that are carried out in the Postgraduate Program.

Rationale:

RATIONALE: Among the various contributions of a research project, the information generated during the study is essential for the development of new knowledge and technologies. Thus, ensuring quality, reliability, and reproducibility of a study's data has been a major concern of researchers worldwide. However, little has been done regarding the incorporation of technological resources for data collection and management, especially considering the studies carried out in the academic settings. The proposal of this course is to create an adequate infrastructure for data collection and management of the studies carried out in the scope of Post-Graduation Program. In order to achieve this goal, students will have access to the world's most widely used system for electronic data collection and data management in scientific research, known as REDCap (Research Electronic Data Capture). This course will provide best practices and real case examples for data management in REDCap.

Content:

CONTENT: Principles of data management in scientific research; Recommended practices for development of questionnaires; Modalities for data collection in scientific research; Privacy, confidentiality and data security requirements of human research data; REDCap – key concepts and applications in scientific research; International data standards and best practices for data dictionaries definitions; Effective data management: reports, data export, graphical visualization and data quality monitoring; Considerations for conducting web-based surveys; Considerations on Interoperability: how to connect electronic health records, open

repositories and research databases; Hands-on training: REDCap projects development (classical and longitudinal) and application of the main REDCap features;

Type of Assessment:

See observation field

Notes/Remarks:

EVALUATION CRITERIA: Hands-on exercises at the end of each module; Development of a database project in REDCap platform, preferably to include data from the research protocols that are being carried out in the Post-Graduation Program. NOTE: Each project will be evaluated in accordance with the following criteria: (1) Best practices for data collection and data management in research; (2) Adequate use of the REDCap features. The final report should include: Part I – Research Project Description: (1) Hypothesis of the study; (2) Objectives; (3) Outcomes measures; (4) Study design; (5) Criteria for eligibility of research subjects; (6) Brief description of the study methodology; Part II – Project developed in REDCap: (1) Adequacy of the forms / questionnaires developed for data collection; (2) Use of REDCap features according to the study characteristics; (3) Summary of the lessons learned throughout the course and using REDCap system. Minimum number of students: 10 Maximum number of students: 25

Bibliography:

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Dunn WD Jr, Cobb J, Levey AI, Gutman DA. REDLetr: Workflow and tools to support the migration of legacy clinical data capture systems to REDCap. Int J Med Inform. 2016;93:103-10

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