Discipline **MCP5864**  
**Data Management in Scientific Research**

**Subject area:** 5156  
**Created:** 09/04/2015  
**Active since:** 09/04/2015  
**Number of credits:** 3

**Hours:**

<table>
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<tr>
<th>Theoretical (per week)</th>
<th>Practical (per week)</th>
<th>Self-study (per week)</th>
<th>Duration</th>
<th>Total</th>
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<tr>
<td>8</td>
<td>2</td>
<td>5</td>
<td>3 weeks</td>
<td>45 hours</td>
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**Faculty Members Responsible:**  
Roberto Costa  
Katia Regina da Silva

**Objectives:**

The aim of the course is to present fundamental concepts of the use of electronic systems for collecting and managing data in scientific research, aiming to grant greater security, reliability and quality to the data collected in research projects. Essential principles for the development of an adequate infrastructure for electronic data collection and data management, in accordance with international standards, will be addressed throughout the course in order to subsidize students in the creation of databases to support the information of the research projects carried out with the Postgraduate Program.

**Background:**

Among the various contributions of a research project, the information generated during the study stands out for its undeniable relevance for the production of new knowledge and technologies. Thus, ensuring the quality, reliability, and reproducibility of study data has been a major concern for researchers worldwide. However, in our country, little has been done regarding the incorporation of technological resources for data collection and management, especially if we consider the research carried out in the academic setting. The main goal of this discipline relies on the need to create an adequate infrastructure for data collection and management of the studies carried out in the scope of the Postgraduate Studies. In order to achieve this goal, Postgraduate 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). 1. This system, developed by researchers at Vanderbilt University (Tennessee, USA), is financially supported by the National Institute of Health (NIH), and adequately addresses the privacy and security policies in the Health Insurance Portability and Accountability Act (HIPAA) 2 and the Food and Drug Administration (FDA) 3. Since its inception, REDCap has gained familiarity among researchers from major research centers around the world, and to date this tool is being used in more than 85 countries and features more than 100,000 projects under development. 4 In addition to traditional electronic data capture functionality, REDCap presents tools for data validation and auditing, online reporting, scheduling of patient
evaluations according to the study flow chart, and also allows the creation of a repository of documents related to subjects such as the term of free and informed consent, images of exams, videos, among others. Being a web-based database, that is, accessed through browsers (Chrome, Internet Explorer, Firefox, etc.), it allows the researcher to collect data automatically, that is, using a computer (Laptop or tablets), which streamlines the process, reduces redundancy in information collection and potential typing errors.

Content:

1. Principles of data management in scientific research in health; 2. Fundamental principles for the development of forms and questionnaires (surveys) for data collection; 3. Modalities and tools for data collection in scientific research; 4. Regulatory norms related to the security and privacy of data of research subjects; 5. REDCap - Main functionalities and applications in scientific research; 6. Standardization of variables according to international standards and development of Data Dictionaries; 7. Data management considerations: how to proceed when changes need to be made after the start of a study; 8. Data management considerations: how to proceed when a study is finalized; 9. Interoperability considerations among several systems: how to connect electronic health records, open repositories and research databases; 10. Practical training for the development of forms and application of REDCap tools.

Assessment Method:

1. Assignment of practical exercises at the end of each module. 2. Development of a project in the REDCap system.

Observation:

The projects (databases) developed in the REDCap system will be evaluated regarding the adequate use of the functionalities of this system considering the specific characteristics of each study. The final report should include: Part I - Research Project: (1) Hypothesis of the study; (2) Objectives; (3) Outcomes of interest; (4) Study design; (5) Criteria for eligibility of research subjects; (6) Brief description of the study methodology; Part II - Construction of the Database in the REDCap system: (1) Forms / questionnaires developed for data collection; (2) Tools used for data management; (3) Demonstration that the database was tested for adequacy according to the characteristics of the study; (4) Brief summary of the lessons learned from the course and use of the REDCap system.

Bibliography:

21. Clinical Data Interchange Standards Consortium (CDISC) and Biomedical Research Integrated Domain Group (BRIDG) Model. Available at www.cdisc.org