GMS 6806: Security and Privacy in Clinical Research (3 credit hours)

LOCATION: TBD

CLASS HOURS: TBD

INSTRUCTORS:
Jiang Bian, PhD, MS
Clinical and Translational Research Building (CTRB) 3228
Phone: (352) 273-8878
Email: bianjiang@ufl.edu

COURSE OVERVIEW:
GMS 6806 provides students with an introduction to a wide range of concepts, policies, and techniques in security and privacy (S&P) as they apply to biomedical and clinical research. Information security and data privacy are essential components of biomedical and clinical research. It is imperative for students to understand S&P rules and guidelines (e.g., the Health Insurance Portability and Accountability Act (HIPAA) but also gain practical experience with technologies, tools, and approaches in dealing S&P issues thought out the life cycle of a research project, from experimental design and data collection to data analysis to the dissemination and archiving of valuable results. In this course, students are introduced to the broad landscape of information security and data privacy for biomedical and clinical research: S&P related regulations and guidelines in clinical research; basic concepts of computer security; security analysis of a study's security plan; best practices in secure data management (e.g., de-identification and encryption); and state-of-the-art tools, methods, and approaches for the protection of information security and data privacy.

COURSE OBJECTIVES:
Teaching methods include lecture, discussion, and hands-on data assessment, analysis, and presentation. The goals of the course are:

- To provide basic understanding of role of information security and data privacy in biomedical and clinical research.
- To familiarize students with basic principles of computer security (e.g., confidentiality, integrity, and availability).
- To deepen students' understanding of security principles in research data management.
- To help students understand ethical and legal issues with dealing with biomedical and clinical data.
- To introduce the concepts of the Institutional Review Board (IRB) and its function in protecting human subjects.
- To give students access to state-of-the-art tools, methods, and approaches for the protection of information security and data privacy.

TEXTBOOKS/READING MATERIALS:
The following are suggested reading materials, however, they are not required. The instructor will distribute lecture handouts when necessary.

References:
- Department of Health and Human Services Summary of the Privacy Rule of the Health Information Portability and Accountability Act (HIPAA)

- D. McGraw, J. Dempsey, L. Haris, and J. Goldman. Privacy as an enabler, not an impediment: building trust into health information exchange. Health Affairs. 2009; 28(2): 416-427
- Samuel Warren and Louis Brandeis. The right to privacy. Harvard Law Review. 1890; V. IV, No. 5.
- L. Sweeney. Simple demographics often identify people. Working Paper 3, Data Privacy Laboratory, Carnegie Mellon University. 2000.
- P. Golle. Revisiting the uniqueness of simple demographics in the US population. Proceedings of the 5th ACM Workshop on Privacy in Electronic Society. 2006: 77-80.
- K. Benitez & B. Malin. Evaluating re-identification risks with respect to the HIPAA Privacy Rule. Journal of the American Medical Informatics Association. 2010; 17(2): 169-177.
- Martin Kuhlmann, Dalia Shohat, and Gerhard Schimpf. Role mining – revealing business roles for security administration using data mining technology. Proceedings of the 8th ACM Symposium on Access Control Models and Technologies. 2003: 179-186.
- L. Røstad and Ø. Nytrø. Access control and integration of health care systems: an experience report and future challenges. Proceedings of the 2nd International Conference on Availability, Reliability and Security (ARES). 2007: 871-878.
- A. Boxwala, J. Kim, J. Grillo, and L. Ohno-Machado. Using statistical and machine learning to help institutions detect suspicious access to electronic health records. Journal of the American Medical Informatics Association. 2011; 18: 498-505.
- Michael Goodrich, Roberto Tamassia. Introduction to Computer Security. Pearson. 2010.

OFFICE HOURS:

Office hour is by request. Please email the instructors for an appointment in advance. It is likely that we can address the questions over email. However if this is not possible please make an appointment.

PREREQUISITES:

N/A

GRADE COMPOSITION:

Attendance: 5%

Homework assignments: 30%

Midterm (proposal for the technical report and presentation): 25%

Final (technical report and presentation): 40%

Homework assignments:

Assignments are writing critiques for relevant papers (6) in the field.

Students will be asked to read articles in topics related to security and privacy in clinical research and to write a critique of the paper. Please do not copy and rearrange the sentences in the original paper, which will result in low a grade.

Assignment rules: You are required to compliant with these rules.
- Your assignment must be turned in no later than 11:59 pm on the day that it is due.
- Late homework assignments will NOT be accepted, unless you have a formal proof of the exception (e.g., a written doctor note, a police ticket, etc.).
- No handwritten assignment. All assignments need to be submitted electronically either by email or the online system (will be clarified at the beginning of the course).
- DO NOT COPY OTHERS' HOMEWORK. There is zero-tolerance for academic dishonesty. The one who copies the homework will receive 0 point; and the one who is copied will get only 50% of the points that he/she should have received.

- You can work with others (e.g., discuss, consult, etc.) on a homework assignment. And, if you work on a homework assignment with other students in the course, you are required to list their names when you turn in the assignment. Plagiarism will receive 0 point.
- Searching for a solution on the web—and then submitting it as your answer for a homework assignment—will be considered a violation.

Course project:

The final product of the course is a technical report on topics relevant to the course, which consists of 65% of overall the grade. Each student is required to complete a technical report. You can collaborate with other students as a team. However, each team can have up to two (2) members. Exception can only be made with written explanation and subject to the instructor's approval. And, please clearly delineate roles and responsibilities of each team member. Your final grade of the course project will be adjusted based on your contribution (e.g., merely presenting the project in the final presentation is NOT a contribution).

Students will be asked to conduct a systematical review of papers relevant to specific area of the course (e.g., data privacy with big data in healthcare applications), and write a technical report (or a review paper). You are encouraged to come up novel ideas related to the course (e.g., design a security protocol for secure data management). You will conduct extensive background research (e.g., literature review), and you are expected to write a project proposal and give a presentation during the midterm. Please follow the requirements below for the project proposal and presentation.

Project proposal requirements:
- Cover Page: Include title and list of team members.
- Abstract: Up to 1 page. Explain the motivation for the work to be accomplished.
- Project description: Up to five (5) pages, and please include the following:
  - Specific Aims/Objectives
  - Background and Significance
  - Approach/Research Design (preliminary data and analysis if applicable)
  - Timeline
- Literature cited (no page limit); please follow the Vancouver style.

Proposals must use single column and single spacing; Arial or Times New Roman font; font size no smaller than 11 point; tables and figure labels can be in 10 point; minimum 0.5 inch margins.

Midterm (proposal) presentation:
- Up to fifteen (15) slides and no more than 15 minutes of presentation with 10 minutes Q&A.
- Please send the slides to the instructor at least three (3) days in advance.

Each project team is expected to turn in a final project report, associated code and datasets (or reference to used datasets), and a group presentation.

Project report requirements: the project report can be up to ten (10) pages (including references), and please structure the report to include:
- Title (14 point typeface) and names of each team member
- Abstract: no more than 250 words summarizing the project.
- Introduction: a short background and objective(s) of the study.
- Methods: design, setting, dataset, approaches, and main outcome measurements.
- Results: key findings
- Discussion: key conclusions with direct reference to the implications of the methods and/or results.

- References: please follow the Vancouver style.

<u>Final project presentation:</u>
- Up to fifteen (25) slides and no more than 25 minutes of presentation with 10 minutes Q&A.
- Please send the slides to the instructor at least three (3) days in advance.

<u>Attendance policy:</u>
Class attendance is mandatory. Excused absences follow the criteria of the UF Graduate Catalogue (e.g., illness, serious family emergency, military obligations, religious holidays), and should be communicated to the instructor prior to the missed class day when possible. UF rules require attendance during the first two course sessions. Missing more than three scheduled sessions will result in a failure. Regardless of attendance, students are responsible for all material presented in class and meeting the scheduled due dates for class assignments. Finally, students should read the assigned readings prior to the class meetings, and be prepared to discuss the material for each session.

<u>Grading scale:</u>

Letter Grade	Grade Points	Grade Percentage
A	4.0	95-100
A-	3.67	90-94
B+	3.33	87-89
B	3.0	83-86
B-	2.67	80-82
C+	2.33	77-79
C	2.0	73-76
C-	1.67	70-72
D+	1.33	67-69
D	1.0	63-66
D-	.67	60-62
E	0	< 59

For more detail on letter grades and related University of Florida policies, please see the Grades and Grading Policies at http://gradcatalog.ufl.edu/content.php?catoid=6&navoid=1219#grades.

<u>Make-up policy:</u> Students are allowed to make up work only as the result of illness or other unanticipated circumstances. In the event of such emergency, documentation will be required in conformance with University policy. Work missed for any other reason will earn a grade of zero.

<u>UF POLICIES:</u>

<u>University policy on accommodation students with disabilities:</u> Students requesting accommodation for disabilities must first register with the Dean of Students Office (http://www.dso.ufl.edu/drc/). The Dean of Students Office will provide documentation to the student who must then provide this documentation to the instructor when requesting accommodation. You must submit this documentation prior to submitting assignments or taking the quizzes or exams. Accommodations are not retroactive, therefore, students should contact the office as soon as possible in the term for which they are seeking accommodations.

University policy on academic misconduct: Academic honesty and integrity are fundamental values of the University community. Students should be sure that they understand the UF Student Honor Code at http://www.dso.ufl.edu/students.php. You are expected and required to comply with the University's academic honesty policy (University of Florida Rules 6C1-4.017 Student Affairs: Academic Honesty Guidelines, available at http://regulations.ufl.edu/chapter4/4017.pdf). Cheating, plagiarism, and other forms of academic dishonesty will not be tolerated. Note that misrepresentation of the truth for academic gain (e.g., misrepresenting your personal circumstances to get special consideration) constitutes cheating under the University of Florida Academic Honesty Guidelines

Netiquette – communication courtesy: All members of the class are expected to follow rules of common courtesy in all email messages, threaded discussions, and chats. The first instance of clearly rude and/or inappropriate behavior will result in a warning. The second instance will result in a deduction of five percentage points from your overall grade. The third instance will result in a drop of a letter grade (A to B, A- to B-, and so on).

GETTING HELP:
For issues with technical difficulties for E-learning in Sakai, please contact the UF Help Desk at:
- learning-support@ufl.edu
- (352) 392-HELP - select option 2
- https://lss.at.ufl.edu/help.shtml

COURSE SCHEDULE (TENTATIVE):
The course schedule is subjected to change according to students' background and interests based on the survey conducted at the beginning of the class.

Week	Topic	Instructor
1	Introduction and course overview: information security and data privacy articulated, history and context, examples, technology landscape	
2	Intro to Computer Security – Part 1 - Confidentiality, integrity and availability (CIA)	
3	Intro to Computer Security – Part 2 - Access Control Models - Auditing	
4	S&P Rules, Policies, Regulations and Guidelines in Clinical Research – Part 1	
5	S&P Rules, Policies, Regulations and Guidelines in Clinical Research – Part 2	
6	Case Study 1: IDR	
7	Secure Data Management: tools, technologies and policies	
8	De-identification, Re-identification, and Inference	
9	Case Study 2: OneFlorida Data Trust	
10	Midterm presentation	
11	Technologies, tools, and approaches in protecting information security and data privacy – Part 1	
12	Technologies, tools, and approaches in protecting information security and data privacy – Part 2	

13	Security Analysis, Threat Modeling, Risk Assessment – Part 1	
14	Security Analysis, Threat Modeling, Risk Assessment – Part 2	
15	Case Study 3: Privacy Preserving Record Linkage	
16	Course project presentations	