GMS 6806: Security and Privacy in Clinical Research (3 credit hours)
Fall 2023

LOCATION: HPNP G-105

CLASS HOURS: Mondays, 12:50pm to 3:50 pm

INSTRUCTORS:
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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:
The goals of the course are:

- To provide basic understanding of the 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:

Additional readings will be assigned each week, as specified in course schedule below.

OFFICE HOURS:
Office hours are 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

CLASS STRUCTURE:
Generally, we will start each class period with a lecture led by the instructors or a guest speaker. The second part of the class will be a student-led discussion by an assigned discussion leader.

GRADE COMPOSITION:
Attendance and Participation: 5%
Discussion lead: 30%
Midterm (proposal and presentation): 25%
Final (report and presentation): 40%

Course project: During the course, you will choose one of the following options and will complete a proposal, midterm presentation, technical report, and final presentation. You can complete this individually or collaborate with other students as a team. However, each team can have up to two (2) members. Exceptions 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)

OPTION 1: Practical project: Propose a study that uses at least two of the following activities as part of your Methods. You are welcome to do this activity related to your research in your lab, but make sure it is something you have not already done in the lab and new for this course, and you must not leverage work your PI or a labmate does.

Choose at least one of the following Methods for each subsection below to include in your project (and to complete during the semester as part of your project):

Do at least one of the following:
- Run an i2b2 query on your intended study sample
- Develop an informed consent and an authorization for PHI use/disclosure

AND
Also do at least one of the following:

- Submit an IDR data request (including the full process of obtaining IRB approval, and including the information needed by IDR in the request portal; may include consulting with IDR if needed)
- Complete a UF risk assessment using the UF Integrated Risk Management System including a workflow diagram that you develop (https://security.ufl.edu/resources/risk-assessment/)
- Run a model for federated learning/differential privacy

**OPTION 2: Review paper:** Students will be asked to conduct a systematic 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.

**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 if not able to share), completed documents (e.g., i2b2 report, informed consent and authorization for HIPAA documents, IRB protocol/approval letter and IDR request correspondence, risk assessment correspondence, model output, etc.) 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 Vancouver style.
- Appendices: Completed materials listed in “completed documents” above

**Final project presentation:**
- 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.

**Student led discussion:** Students will be required to select a class for which they will act as the discussion leader on the assigned topic for that day. Discussion leaders have the responsibility of facilitating discussion by helping to summarize, compare/contrast, integrate, and consider the practical or research implications of the assigned readings. Discussion leaders should plan ahead by forming their own questions and creating activities, debates, and so forth to facilitate meaningful class discussion. Discussion leaders should also find and discuss a recent news article on the topic (ex: [https://www.nytimes.com/2023/02/01/business/goodrx-user-data-facebook-google.html](https://www.nytimes.com/2023/02/01/business/goodrx-user-data-facebook-google.html)) in order to inform the class of things that are relevant current events or “hot off the press.” The overarching goal of class discussion should be to enhance knowledge of the subject, as well as skill in communication and conceptualization.

You are not limited to any particular media outlet for identifying a relevant news article. However, please recall that UF provides free subscriptions to The New York Times, The Economist, and Wall Street Journal to students, if you choose to use one of these sources: [https://businesslibrary.uflib.ufl.edu/wsj-nyt-economist](https://businesslibrary.uflib.ufl.edu/wsj-nyt-economist)

**Participation:** Students are expected to attend all classes. Students are expected to read all required materials before class, having thoughtfully considered the implications and contributions of each reading individually and collectively. Both the quantity and quality of student contributions will be evaluated. Recommendations for effective class participation include (but are not limited to) the following: (1) participate constructively by listening and posing questions or comments that elicit discussion; and (2) contribute additional value to discussions by integrating material and playing devil’s advocate.

**Attendance policy:**
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. 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.

This course is in person with limited support for virtual and hybrid options. Occasional exceptions may be made on a case-by-case basis in consultation with the instructors. Please contact the instructors at least one business day in advance of class (unless an emergency) if you have an extenuating circumstance that prohibits you from being able to attend class in person on a given date.

**Statement on the Use of ChatGPT**
ChatGPT is a conversational artificial intelligence (AI) that uses a natural language processing (NLP) model by OpenAI. ChatGPT’s language model was trained using billions of words and phrases collected from the internet, and it can generate responses in a conversational “thread” and take previous prompts or instructions into account. However, ChatGPT is far from perfect, and is not an effective tool for certain types of tasks. We highly encourage you to read more about how ChatGPT works and the strengths and

In this course, ChatGPT or other AI language models may be used for brainstorming, but not for writing of any type. If you are in doubt as to whether you are using AI language models appropriately in this course, we encourage you to discuss your situation with us. You are responsible for fact checking statements composed by AI language models, and for ensuring content does not violate intellectual property laws, or contain misinformation or unethical content.

How to cite ChatGPT: https://www.scribbr.com/ai-tools/chatgpt-citations/

Grading Scale:
A 93-100%
A- 90-92%
B+ 87-89%
B 83-86%
B- 80-82%
C+ 77-79%
C 73-76%
C- 70-72%
D+ 67-69%
D 63-66%
D- 60-62%
Failure 0-59%

University policy on accommodation students with disabilities: Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, www.dso.ufl.edu/drc/) by providing appropriate documentation. Once registered, students will receive an accommodation letter which must be presented to the instructor when requesting accommodation. Students with disabilities should follow this procedure as early as possible in the semester.

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.

Communication courtesy: Some content and discussion of this class may be around hard topics that can be sensitive, and individual experiences with, and opinions on, topics may be different. We respect diversity of opinion and will not tolerate inappropriate behavior towards or comments at, or about, any individual in this course. All members of the class are expected to follow rules of common courtesy in in-person class.
discussions, 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). If at any time you feel emotional about, or would like to opt out of a discussion, you are welcome to step out of class. You will not be penalized for doing so.

Course Evaluations
Students are expected to provide feedback on the quality of instruction in this course by completing online evaluations at https://evaluations.ufl.edu. Evaluations are typically open during the last two or three weeks of the semester, but students will be given specific times when they are open. Summary results of these assessments are available to students at https://evaluations.ufl.edu/results/.

Diversity and Inclusivity
We consider this classroom to be a place where you will be treated with respect, and we welcome individuals of all ages, backgrounds, beliefs, ethnicities, genders, gender identities, gender expressions, national origins, religious affiliations, sexual orientations, ability – and other visible and nonvisible differences. All members of this class are expected to contribute to a respectful, welcoming and inclusive environment for every other member of the class.

Honesty Policy
UF students are bound by The Honor Pledge which states, “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.” The Conduct Code specifies a number of behaviors that are in violation of this code and the possible sanctions. If you have any questions or concerns, please consult with the instructors.

In-Class Recording Policy
Students are allowed to record video or audio of class lectures. However, the purposes for which these recordings may be used are strictly controlled. The only allowable purposes are (1) for personal educational use, (2) in connection with a complaint to the university, or (3) as evidence in, or in preparation for, a criminal or civil proceeding. All other purposes are prohibited. Specifically, students may not publish recorded lectures without the written consent of the instructor.

A “class lecture” is an educational presentation intended to inform or teach enrolled students about a particular subject, including any instructor-led discussions that form part of the presentation, and delivered by any instructor hired or appointed by the University, or by a guest instructor, as part of a University of Florida course. A class lecture does not include lab sessions, student presentations, clinical presentations such as patient history, academic exercises involving solely student participation, assessments (quizzes, tests, exams), field trips, private conversations between students in the class or between a student and the faculty or lecturer during a class session. Publication without permission of the instructor is prohibited. To “publish” means to share, transmit, circulate, distribute, or provide access to a recording, regardless of format or medium, to another person (or persons), including but not limited to another student within the same class section. Additionally, a recording, or transcript of a recording, is considered published if it is posted on or
uploaded to, in whole or in part, any media platform, including but not limited to social media, book, magazine, newspaper, leaflet, or third party note/tutoring services. A student who publishes a recording without written consent may be subject to a civil cause of action instituted by a person injured by the publication and/or discipline under UF Regulation 4.040 Student Honor Code and Student Conduct Code.

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

Topical Outline/Course Schedule (Tentative)
The course schedule is subject to change.

<table>
<thead>
<tr>
<th>Week</th>
<th>Date</th>
<th>Topic</th>
<th>Readings (Read before class)</th>
<th>Instructor</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Aug 28</td>
<td>Introduction and course overview: information security and data privacy articulated, examples, technology landscape</td>
<td>n/a</td>
<td>Gregory</td>
</tr>
<tr>
<td>2</td>
<td>Sep 4</td>
<td>Labor Day - No class</td>
<td>n/a</td>
<td>n/a</td>
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<tr>
<td>Date</td>
<td>Topic</td>
<td>References</td>
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<tr>
<td>Week</td>
<td>Date</td>
<td>Topic</td>
<td>Guest Speaker</td>
<td>Reading</td>
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<td></td>
<td>Gregory</td>
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<tr>
<td>7</td>
<td>Oct 9</td>
<td>Midterm Presentations</td>
<td>n/a</td>
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Software security and risk assessment at UF:  
https://security.ufl.edu/resources/risk-assessment/  
and https://irm.ufl.edu/fast-path-solutions/ |
<p>|      |        | Guest Lecture                 | Xu/Guest       |         |</p>
<table>
<thead>
<tr>
<th>Date</th>
<th>De-identification Event</th>
<th>Student discussion leader: TBD</th>
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<tbody>
<tr>
<td>Oct 23</td>
<td>Guest Lecture De-identification</td>
<td>TBD</td>
</tr>
<tr>
<td>Oct 30</td>
<td>Re-identification (Khoa Nguyen)</td>
<td>TBD</td>
</tr>
<tr>
<td>Nov 6</td>
<td>Computer Security (Khoa Nguyen)</td>
<td>TBD</td>
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https://software.ufl.edu/software-listings/
https://security.ufl.edu/resources/risk-assessment/creating-an-information-system-data-flow-diagram/

Hospital Discharge Record Case https://hcup-us.ahrq.gov/reports/final_report.pdf

Xu/Guest Lecture (Khoa Nguyen)
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<table>
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<tr>
<th>Date</th>
<th>Topic</th>
<th>Notes</th>
</tr>
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<tbody>
<tr>
<td>12 Nov 13</td>
<td>No class - AMIA</td>
<td>n/a</td>
</tr>
</tbody>
</table>
| 14 Nov 27 | Emerging topics  
-Federated learning  
-Differential privacy  
[https://www.nature.com/articles/s41746-020-00323-1](https://www.nature.com/articles/s41746-020-00323-1)  
Federated learning AI model could lead to healthcare breakthrough  
| 15 Dec 4 | Course final project presentations | n/a | Xu |