

**EPI 6178**  
**Course Schedule**  
**Fall 2008**

**1. September 10**

- 9.00-10.20 Introductions, course objectives and overview  
General introduction to intervention studies
- 10.20-10.40 Break
- 10.40-11.30 General introduction to intervention studies cont'd
- 11.30-11.50 Introduction to Assignment 1
- 11.50-12.00 Preview of next week's topic

**2. September 17**

\*\*\*deadline for Assignment 1\*\*\*

- 9.00-10.20 General anatomy of intervention studies
- 10.20-10.40 Break
- 10.40-11.20 Internal and external validity
- 11.20-11.50 Introduction to Assignments 2 & 3 and Final Assignment
- 11.50-12.00 Preview of next week's topic

**3. September 24**

\*\*\*deadline for Assignment 2\*\*\*

- 9.00-10.20 Basic design issues (1)
- 10.20-10.40 Break
- 10.40-11.50 Discussion of study examples submitted by students
- 11.50-12.00 Preview of next week's topic

**4. October 1**

- 9.00-10.20 Basic design issues (2)
- 10.20-10.40 Refreshment break
- 10.40-11.30 Basic design issues (3)
- 11.30-11.50 Review of protocol topics
- 11.50-12.00 Preview of next week's topic

## **5. October 8**

- 9.00-10.20 Basic design issues (4)
- 10.20-10.40 Break
- 10.40-11.50 Class discussion of protocol topics (1)
- 11.50-12.00 Preview of next's week's topic

## **6. October 15**

- 9.00-10.20 Analyzing intervention study data (to be confirmed)
- 10.20-10.40 Break
- 10.40-11.40 Class discussion of protocol topics (2)
- 11.50-12.00 Preview of next week's topic

## **7. October 22**

\*\*\*Deadline for Assignment 3\*\*\*

- 9.00-10.20 Sample size calculation (to be confirmed)
- 10.20-10.40 Break
- 10.40-11.30 Class discussion of protocol topics (3)
- 11.30-11.50 Introduction to Assignment 4 (sample size exercise)
- 11.50-12.00 Preview of next week's topic

## **8. October 29**

- 9.00-10.20 To be confirmed
- 10.20-10.40 Break
- 10.40-11.50 Class discussion of protocol topics (4)
- 11.50-12.00 Preview of next week's topic

## **9. November 5**

\*\*\*Deadline for Assignment 4\*\*\*

- 9.00-10.20 Non-simple controlled designs
- 10.20-10.40 Break
- 10.40-11.30 Class discussion of protocol topics (5)
- 11.30-11.50 Feedback on Assignment 4
- 11.50-12.00 Preview of next week's topic

## **10. November 12**

- 9.00-10.20 Complex interventions and pragmatic intervention studies  
10.20-10.40 Break  
10.40-11.50 Class discussion of protocol topics (6)  
11.50-12.00 Preview of next week's topic

## **11. November 19**

- 9.00-10.20 Statistics workshop (to be confirmed)  
10.20-10.40 Break  
10.40-11.50 Class discussion of protocol topics (7)  
11.50-12.00 Preview of next week's topic

## **12. November 26**

- 9.00-10.20 Ethical issues in intervention studies  
10.20-10.40 Break  
10.40-12.00 Optional workshop on Final Assignment issues

## **13. December 3**

- 9.00-10.20 Reporting trial findings  
10.20-10.40 Break  
10.40-12.00 Review and wrap up

### **EPI 6178 INTERVENTION STUDIES IN HEALTH RESEARCH**

- Time:** September 10-December 3, 2008, 09.00-12.00  
**Place:** Room 2021  
**Faculty:** Dr Brenda Wilson (professor in charge) [bwilson@uottawa.ca](mailto:bwilson@uottawa.ca)  
Dr David Schramm [dschramm@ottawahospital.on.ca](mailto:dschramm@ottawahospital.on.ca)  
Dr Jonathan Cook [jocook@ohri.ca](mailto:jocook@ohri.ca)  
Dr George Wells [gawells@ottawaheart.ca](mailto:gawells@ottawaheart.ca)  
**Teaching Assistant:** Nadine Enright [nenright@gmail.com](mailto:nenright@gmail.com)

This is an introductory course designed to cover the basic elements of intervention study design. It complements the Biostatistics and Epidemiology I courses which are designed to introduce key concepts in statistical inference and epidemiological reasoning and study design, respectively. By the end of the course you should be familiar with the different types of intervention study design and the key elements which influence their validity. You should also be able to develop

and defend a comprehensive scientific protocol for evaluating the effectiveness of an intervention of your choice.

The course is primarily tutorial and problem-based. Its aim is to ensure you develop a firm grasp of conceptual issues and skills in designing intervention studies, and have an idea of how to apply this knowledge in practice. Students in the course come from many different backgrounds, but the course is designed to make the point that the fundamentals of study design are the same, whether the context is clinical medicine, community health, social programs, or health service organization.

Student participation and engagement is key to this course. By the end of the course, you will develop a full scientific protocol for an intervention study, on a topic of your choice. We review the entire class's ideas throughout the course, using them as examples for exploring study design and implementation issues. All discussions are informal, non-judgmental, and serve as a vehicle for learning and problem-solving.

The overall **learning objectives** for the course are:

1. to understand the theoretical basis for the elements of intervention studies in the health field
2. to understand the range of choices in the design of an experimental or quasi-experimental trial and the practical consequences of each alternative
3. to be able to formulate a research question and develop a research proposal addressing the question
4. to develop an understanding of the practical concerns in implementing a research protocol.

Specific learning objectives are provided for each module.

Here are my **expectations** of you during the course:

1. to attend all classes wherever possible
2. to come to class prepared – which means reading any advance material as directed
3. to be ready to participate actively in discussions
4. to actively develop your own research protocol ideas as the course progresses, and be ready to present your ideas and the challenges you encounter in class
5. to submit assignments on time

## **Reading**

The course textbook is

Friedman LM, Furberg CD, DeMets DL. *Fundamentals of clinical trials* (3<sup>rd</sup> edition). St Louis, Mosby, 1996.

While there are many books on the topic of clinical trial design, I have encountered none (so far) which cover the concepts and methods from a non-clinical perspective and are written at the introductory level appropriate for this course. Although this textbook is resolutely clinical in orientation, it covers the majority of issues encountered in any trial and is a generally helpful reference text.

This is supplemented by many further methodological articles, examples of intervention studies, and notes which are currently provided on CD and will be posted on BlackBoard Vista as soon as we can set this up. Further material may be posted as the course progresses.

If you wish to extend your reading further, consider the following book, which is too advanced for an introductory course. It examines the conceptual and philosophical basis for intervention study design and causal inference in health and social settings. It is not for the casual reader!

Shadish WR, Cook TD, Campbell DT. *Experimental and quasi-experimental designs for generalized causal inference*. Boston, Houghton Mifflin, 2002

## **Course evaluation**

The course is graded on an A-E scale. To pass this course, a student must:

1. Maintain a high attendance record
2. Come to class well-prepared
3. Participate actively in the class
4. Submit satisfactory assignments (including any formative assignments which do not attract an individual grade)
5. Submit a final assignment in accordance with the final assignment guidelines.

Further information is in the document named ‘Assignments’.

## **Office hours**

My office hours during fall semester are:

Tuesdays 13.30-14.30 (after the seminars)

Thursdays 13.00-14.00

I will protect these times as much as possible, but like all professors there are sometimes demands on my calendar which are unavoidable. You are welcome to just turn up, but if you want to be sure I am free please email or call Silvia Visentin ([svisenti@uottawa.ca](mailto:svisenti@uottawa.ca), 613-563 5800 x8005). If you have an urgent problem, please call Silvia so she can fit you in quickly.

Brenda Wilson, on behalf of EPI6178 faculty.