

NUTR*4330 Applied Nutritional and Nutraceutical Sciences II, Winter 2017

Instructor:

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Class Schedule:

- Lecture: Monday 12:30 – 3:20 (SCIE 231)
- Lab 1: Wednesday 11:30 – 2:20 (FS 146)
- Lab 2: Wednesday 2:30 – 5:20 (FS 146)

University of Guelph Calendar Description:

Laboratory and other investigational techniques are covered, together with their underlying concepts. The course is designed to enhance understanding of the design and use of nutraceuticals for human and animal health. Limited to students in the Nutritional and Nutraceutical Sciences Major, Department of Human Health and Nutritional Sciences. Prerequisite(s): NUTR*3210, NUTR*3330, HK*3940, NUTR*3390

Course Description:

This course is designed to build on concepts covered in Applied Nutritional and Nutraceutical Sciences I (NUTR*3390). Together, these laboratory-intensive courses will explore and provide experiential learning opportunities in two key aspects surrounding the Nutritional and Nutraceutical Sciences. This includes the development of natural health and functional food products (Part I) and testing and approval for safe and efficacious products (Part II). NUTR*3390 will focus on the requirements for product testing and on the analytical techniques which support the development and marketing of functional foods and nutraceuticals (FFN). The primary course objective of NUTR4330 is to provide students with valuable learning opportunities surrounding the clinical testing of natural health products (NHP). To this end, the curriculum includes a clinical trial project in which students may volunteer as participants and are also involved in conducting. This experience is supported by a series of relevant guest lecture presentations and case study type exercises to enhance knowledge and skill development.

In NUTR*3390 (Part I), product development strategies, the regulatory framework, and marketing aspects of FFN were the focus. Students worked in groups to develop novel products with the potential to prevent the development of various chronic diseases. Now, in NUTR*4333 (Part II), students will have unique and valuable opportunities to learn about the clinical testing of NHP. The

major themes of this course will include; the design of dietary interventions to prevent chronic disease, the use of short-term biomarkers to determine the risk of chronic disease progression, safety, ethical and regulatory aspects of designing and conducting human clinical trials, and the process for approval of new NHP in the Canadian marketplace following clinical testing.

Human Ethics Issues:

As part of this course, students will be invited to participate as human participants in a clinical trial project of common FFN. Your participation is completely voluntary and may be withdrawn at any time. Students who do not participate in the project as subjects will have the same opportunities and expectations to analyze and present the data which arises from the project.

NUTR*4330 is unique at the University of Guelph in terms of its learning objectives and outcomes. It also presents unique challenges in terms of ethics issues. However, this will lead to valuable experiential learning opportunities. Students will gain hands-on experience that goes beyond discussing the importance of human ethics. This course will introduce students to many important issues, including the respect surrounding the volunteer nature of participation, safety in the experimental design, and privacy issues associated with human subject participation.

To stress the importance of ethical responsibility in testing, students will complete the online tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans: [TCPS](#) Also, representatives from the Research Ethics Board will be invited to share their perspectives and experiences in ethical issues surrounding clinical testing involving human subjects. For further information about ethical research involving humans, students are referred to the University of Guelph, website: [Office of Research - Procedures, Forms, Regulations and Guidelines](#)

Schedule of Activities:

The course will be built around the following themes. 1) The role of regulations in the development of an effective FFN industry, 2) Regulatory structure in the approval of new NHP and in the clinical testing that leads to market approval (avoiding major overlap with previous course work, 3) Human ethics; concepts, university structures, approval of clinical trials related to FFN, and 4) Use of short-term biomarkers to assess the impact of dietary regimens on long-term health.

Week		Lecture	Laboratory
1	January 9	<p>Welcome and Overview</p> <p>Introduction to class clinical trial project & distribution of informed consent forms & participant identification random numbers</p> <p>Assign online tutorial related to ethics of human participation in studies. Students will need to complete the TCPS tutorial before class on Monday January 18th and submit the completion certificate at that</p>	<p>N.B. The lab this week will be held in the Computer lab (SCIE 1304). Please note that, unless otherwise stated, all Wednesday labs will meet in FS146.</p> <p>Q&A session about class clinical trial project</p> <p>Overview of Project #1- Functional Food Diets</p> <p>Introduction to diet analysis software/ hypothetical 24 h recall diet entry & analysis/ class discussion</p>

Week		Lecture	Laboratory
		time.	<p>Organization into groups for Project #1 <i>Start of 2 week washout period for class clinical trial project volunteers</i></p>
2	January 16	<p>Sandra Auld, University of Guelph Research Ethics Officer; Ethics in Human Research</p> <p>What is the Human Nutraceutical Research Unit?</p> <p>Introduction to clinical trials of foods and natural health products</p>	<p>Meet in FS146</p> <p>Tour of the Human Nutraceutical Research Unit, University of Guelph</p> <p>Demonstration of blood collection and analysis procedures to be used in class clinical trial project</p> <p>Group work for Project #1 - Computer lab (SCIE 1304) is available for use of ESHA Food Processor Software.</p>
3	January 23	<p>Facilitated discussion – Ethics’ in human research case studies</p> <p>Discussion of ongoing clinical trial</p>	<p>Group work opportunity for Project #1 – Meet in computer lab (SCIE 1304) is available for use of ESHA Food Processor Software.</p> <p><i>Class clinical trial project begins –Week1 Fasting baseline blood sampling and analysis to be done by appointment (January 23,24,25).</i></p>
4	January 30	<p>Dr. Julie Conquer, RGB Consulting; Natural Health Products Testing and Regulation in Canada – An Introduction to the Regulatory Framework</p> <p>Introduce NHP Critical Evaluation Assignment</p>	<p>Project #1 Presentations & assignments due</p> <p><i>Class clinical trial project - Week 2</i></p>
5	February 6	<p>Clinical trials - study design considerations & good clinical practices</p> <p>Small group – clinical trial design activity</p>	<p>Project #1 Presentations & assignments due</p> <p><i>Class clinical trial project - Week 3</i></p>
6	February 13	<p>Biomarkers and their role in nutrition and health research</p> <p>Overview of Project #2</p>	<p>Group work opportunity for Project #2</p> <p><i>Class clinical trial project ends: Fasting 3 week intervention blood sampling and analysis to be done by appointment (February 13, 14, 15).</i></p>
	February 20	Reading Week	
7	February 27	Krista Coventry - Natural health product regulations - An industry perspective	Group work opportunity for Project #2

Week		Lecture	Laboratory
			Individual NHP Critical Evaluation Report assignment due in lab Wednesday March 1
8	March 6	Data analysis, interpretation and dissemination of research findings CONSORT Overview of Project #3 & distribute data from class clinical trial project	Group work opportunity for Project #2
9	March 13	Disease/Biomarker Symposium: Project #2 Presentations & assignments due * 11:30 Lab Section only	Disease/Biomarker Symposium: Project #2 Presentations & assignments due
10	March 20	Disease/Biomarker Symposium: Project #2 Presentations & assignments due * 2:30 Lab Section only	Group work opportunity for Project #3
11	March 27	Functional Food Potluck * Please note we will meet in FS146. Biomarker presentation critiques due	Group work opportunity for Project #3
12	April 3	Lessons learned & future perspectives Attend NUTR3390 Product Showcase	Group work opportunity for Project #3 – due by 12 pm (noon) Thursday April 6th.

Course Evaluation

Throughout the semester, NUTR*4330 students will work in small groups (3 students each) on 3 projects. These are related to the design of a functional food diet vs. supplementation, the use of biomarkers in clinical testing, and the preparation of a scientific article and mock Natural Product Number (NPN) application based on the results of the class clinical trial project. 20% of the final grade is assigned to individually completed tasks.

Project 1: Functional food diet for increased omega 3 and soluble fiber intake (25%)

Students will work in groups of 3, each focused on the use of functional foods (containing either long chain omega-3 fatty acids or soluble fiber) for the treatment of cardiovascular disease. Students will devise a 2 day dietary program that could be used as an alternative to the nutraceutical supplementation that will be used in the class-based blood lipid project. Each group will present their dietary program in a 15 minute presentation (plus 5 minutes for questions). A summary report will be submitted, in the form of PowerPoint slides with notes. Each group will also prepare a dish that effectively incorporates either soluble fibre or long chain omega-3 fats and provide accurate nutrient analysis. The dishes can be shared with the class during the scheduled potluck.

Due date: February 1st and 8th (presentations to be made during laboratory sections)

Project 2: Biomarkers of chronic disease symposium (30%)

Students will work in groups of 3, each focused on a particular chronic disease and the use of biomarkers to assess the impact of functional foods and nutraceuticals on the disease risk. The etiology of the disease will be described, followed by the list of potential short-term biomarkers, including their mechanistic basis and predictive value. Each group will present their project (20 minute presentation plus 5 minutes for questions). A summary report will be submitted, in the form of PowerPoint slides with notes.

Due date: March 13th, 15th and 20th (presentations to be made during class & laboratory sections).

Project 3: Journal article and mock NPN application (based on class clinical project) (25%)

Students will work in groups of 3. The results of the class-based blood lipid project will be written up as a final report (in the format of a brief journal article). Students will then prepare a mock application to Health Canada for a Natural Product Number which permits the sale of NHP in Canada.

Due date: Thursday April 6th at noon.

NHP Critical Evaluation Report (10%)

NUTR4330 emphasizes the importance of an evidence-based approach to functional foods and NHP, particularly within the Canadian context. However, is this a marketplace reality? Students will, individually, select a food or NHP which is sold online and marketed using implied and/or explicitly stated health benefits. In 750 words or less, students will summarize details about their product of choice, identify what are the health claims being made, and, in relation to the claims, discuss the quality of evidence which is provided and exists to support that the product is efficacious and effective.

Due date: In laboratory Wednesday March 1st.

Class Participation (10%)

Your participation throughout the semester is expected. However, additional marks will be assigned for your completion of the TCPS ethics' tutorial (5%) and for your individual critiques of the biomarker symposium (i.e. Project #2) presentations (5%).