

NUTR*4330 Applied Nutritional and Nutraceutical Sciences II

Winter 2018 Section(s): C01

Department of Human Health and Nutritional Sciences Credit Weight: 0.75 Version 1.00 - January 05, 2018

1 Course Details

1.1 Calendar Description

In this course 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.

Pre-Requisite(s): NUTR*3330, NUTR*3390, (HK*3810 or HK*3940)

Restriction(s): Registration in B.Sc. NANS major or minor.

1.2 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).
- 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.

1.3 Timetable

Lecture: Monday 12:30 – 3:20 (SCIE 2315)
Lab 1: Wednesday 11:30 – 2:20 (FS 146)

Lab 2: Wednesday 2:30 – 5:20 (FS 146)

1.4 Final Exam

There is no final exam for this course.

2 Instructional Support

2.1 Instructor(s)

Dr. Amy Tucker

Email: aborland@uoguelph.ca

Office: FS 142A

Office Hours: Office hours by appointment only, please email

aborland@uoquelph.ca to make an appointment during the hours

of 8am-4pm.

2.2 Teaching Assistant(s)

Teaching Assistant: Dita Moravek

Email: dmoravek@uoguelph.ca

Office Hours: TAs will be available during the laboratory periods on Wednesdays.

If you require additional support for a project, please email the

corresponding TA for an appointment.

Teaching Assistant: Kate Faughnan

Email: kfaughna@uoguelph.ca

Office Hours: TAs will be available during the laboratory periods on Wednesdays.

If you require additional support for a project, please email the

corresponding TA for an appointment.

3 Learning Resources

3.1 Additional Resources(s)

Readings and/or websites will be provided during the lectures (Readings)

Additional readings of journal articles and/or websites provided in lecture will be for your interest only. There are no formal resources (i.e. textbook, lab manual) required for this course. Lecture presentation slides will be provided on Courselink before the lecture period. You may wish to print a copy of the slides to take notes during the lecture.

4 Learning Outcomes

5 Teaching and Learning Activities

5.1 Schedule of Activities

Week	Date	Lecture	Laboratory
1	January 8	 Welcome and Overview What is the Human Nutraceutical Research Unit? Overview of Project #1- Functional Food Diets 	 Brief tour of the Human Nutraceutical Research Unit (HNRU), University of Guelph Estimating food portions and serving sizes Organization into groups for Project #1 and sign up for presentation time
2	January 15	 Introduction to clinical trials of foods and natural health products Dr. Julie Conquer, RGB Consulting; Natural Health Products Testing and Regulation in Canada – An Introduction to the Regulatory Framework 	 Meet in SCIE 1304 Computer Lab Introduction to diet analysis software/ hypothetical 24 h recall diet entry & analysis/ class discussion Group work for Project #1 - Computer lab (SCIE 1304) is available for use of ESHA Food Processor Software.
3	January 22	 Clinical trials - study design considerations & good clinical practices Clinical trial design activity CONSORT and assessing quality of clinical trials—small group activity 	Meet in SCIE 1304 Computer Lab Group work opportunity for Project #1 – Computer lab (SCIE 1304) is available for use of ESHA Food Processor Software.
4	January 29	 Krista Coventry - Natural health product regulations - An industry perspective Introduce NHP Critical Evaluation Assignment 	 Project #1 Presentations & assignments due Q & A about Individual NHP Critical Evaluation Assignment
5	February 5	Sandra Auld, University of Guelph Research Ethics Officer; Ethics in	Project #1 Presentations & assignments due

Week	Date	Lecture	Laboratory
		 Human Research Facilitated discussion – Ethics in human research case studies Assign online tutorial related to ethics of human participation in studies. Students will need to complete the TCPS tutorial before lab on Wednesday February 14th and submit the completion certificate in lab. 	Q & A about Individual NHP Critical Evaluation Assignment
6	February 12	 Biomarkers and their role in nutrition and health research Overview of Project #2- Biomarkers of chronic disease symposium 	 Demonstration of blood collection and analysis procedures in the HNRU (with Premila Sathasivam) Submit certificate of completed TCPS CORE Tutorial due in lab Wednesday February 14th Organization of groups for Project #2 and sign up for presentation time, discussion of topic
	February 19	Reading Week	Reading Week
7	February 26	 Data analysis and interpretation in clinical trials Working with and presenting datasmall group activity 	 Mini-skill building activity Group work opportunity for Project #2 Individual NHP Critical Evaluation Report assignment due in lab Wednesday February 28
8	March 5	 Dissemination of research findings Translating results for different audiences – small group activity Overview of Project #3- Journal Article and Mock NPN application & distribute data 	 Mini-skill building activity Group work opportunity for Project #2

Week	Date	Lecture	Laboratory
9	March 12	 Disease/Biomarker Symposium: Project #2 Presentations & assignments due *only 11:30am lab section attends 	 Disease/Biomarker Symposium: Project #2 Presentations & assignments due Organization of groups for Project #3
10	March 19	Disease/Biomarker Symposium: Project #2 Presentations & assignments due *only 2:30pm lab section attends	 Group work opportunity for Project #3 Biomarker presentation critiques due in lab Wednesday March 21st
11	March 26	 Graduate student research and experiences What's next?	 Mini-skill building activity Group work opportunity for Project #3
12	April 2	 Functional Food Potluck Lessons Learned and Future Perspectives *Invitation to attend HHNS*6410 Product Showcase on Tuesday April 3rd in FS146, details to follow* 	 Mini-skill building activity Group work opportunity for Project #3 – due by 12 pm (noon) Thursday April 5th.

6 Assessments

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.

6.1 Marking Schemes & Distributions

Name	Scheme A (%)
Project 1: Functional food diet for increased omega 3 and soluble fiber intake	25.00
NHP Critical Evaluation Report	10.00
Project 2: Biomarkers of chronic disease symposium	30.00
Project 3: Journal article and mock NPN application	25.00

Name	Scheme A (%)
Class Participation	10.00
Total	100.00

6.2 Assessment Details

Project 1: Functional food diet for increased omega 3 and soluble fiber intake (25.00%)

Due: January 31st & February 7thPresentations to be made during laboratory sections 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.

NHP Critical Evaluation Report (10.00%)

Due: Wed, Feb 28, In laboratory

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.

Project 2: Biomarkers of chronic disease symposium (30.00%)

Due: March 12th, 14th & 19thPresentations to be made during class & laboratory sections 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.

Project 3: Journal article and mock NPN application (25.00%)

Due: Thu, Apr 5, 12:00 PM

Based on class clinical project. 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.

Class Participation (10.00%)

Your participation throughout the semester is expected. However, additional marks will be assigned for your completion of the TCPS ethics' tutorial (due in lab- Wednesday February 14th---5%) and for your individual critiques of the biomarker symposium (i.e. Project #2) presentations (due in lab Wednesday March 21st---5%).

7 Course Statements

7.1 Human Ethics Issues

- 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: https://tcps2core.ca/welcome
- Also, a representative from the Research Ethics Board will be invited to share their
 perspectives and experiences in ethical issues surrounding clinical testing involving
 human participants. For further information about ethical research involving humans,
 students are referred to the University of Guelph, website:
 https://www.uoguelph.ca/research/services-divisions/ethics

8 Department of Human Health and Nutritional Sciences Statements

8.1 Academic Advisors

If you are concerned about any aspect of your academic program:

Make an appointment with a program counsellor in your degree program. <u>B.Sc. Academic Advising</u> or <u>Program Counsellors</u>

8.2 Academic Support

If you are struggling to succeed academically:

- Learning Commons: There are numerous academic resources offered by the Learning Commons including, Supported Learning Groups for a variety of courses, workshops related to time management, taking multiple choice exams, and general study skills. You can also set up individualized appointments with a learning specialist. http://www.learningcommons.uoguelph.ca/
- Science Commons: Located in the library, the Science Commons provides support for physics, mathematic/statistics, and chemistry. Details on their hours of operations can be found at: http://www.lib.uoguelph.ca/get-assistance/studying/chemistry-physics-help and http://www.lib.uoguelph.ca/get-assistance/studying/math-stats-help

8.3 Wellness

If you are struggling with personal or health issues:

- Counselling services offers individualized appointments to help students work through personal struggles that may be impacting their academic performance. https://www.uoguelph.ca/counselling/
- Student Health Services is located on campus and is available to provide medical attention. https://www.uoguelph.ca/studenthealthservices/clinic
- For support related to stress and anxiety, besides Health Services and Counselling Services, Kathy Somers runs training workshops and one-on-one sessions related to stress management and high performance situations. http://www.uoguelph.ca/~ksomers/

9 University Statements

9.1 Email Communication

As per university regulations, all students are required to check their e-mail account regularly: e-mail is the official route of communication between the University and its students.

9.2 When You Cannot Meet a Course Requirement

When you find yourself unable to meet an in-course requirement because of illness or compassionate reasons please advise the course instructor (or designated person, such as a teaching assistant) in writing, with your name, id#, and e-mail contact. The regulations and procedures for <u>Academic Consideration</u> are detailed in the Undergraduate Calendar.

9.3 Drop Date

Courses that are one semester long must be dropped by the end of the fortieth class day; twosemester courses must be dropped by the last day of the add period in the second semester. The regulations and procedures for <u>Dropping Courses</u> are available in the Undergraduate Calendar.

9.4 Copies of Out-of-class Assignments

Keep paper and/or other reliable back-up copies of all out-of-class assignments: you may be asked to resubmit work at any time.

9.5 Accessibility

The University promotes the full participation of students who experience disabilities in their academic programs. To that end, the provision of academic accommodation is a shared responsibility between the University and the student.

When accommodations are needed, the student is required to first register with Student Accessibility Services (SAS). Documentation to substantiate the existence of a disability is required, however, interim accommodations may be possible while that process is underway.

Accommodations are available for both permanent and temporary disabilities. It should be noted that common illnesses such as a cold or the flu do not constitute a disability.

Use of the SAS Exam Centre requires students to book their exams at least 7 days in advance, and not later than the 40th Class Day.

9.6 Academic Misconduct

The University of Guelph is committed to upholding the highest standards of academic integrity and it is the responsibility of all members of the University community – faculty, staff, and students – to be aware of what constitutes academic misconduct and to do as much as possible to prevent academic offences from occurring. University of Guelph students have the responsibility of abiding by the University's policy on academic misconduct regardless of their location of study; faculty, staff and students have the responsibility of supporting an environment that discourages misconduct. Students need to remain aware that instructors have access to and the right to use electronic and other means of detection.

Please note: Whether or not a student intended to commit academic misconduct is not relevant for a finding of guilt. Hurried or careless submission of assignments does not excuse students from responsibility for verifying the academic integrity of their work before submitting it. Students who are in any doubt as to whether an action on their part could be construed as an academic offence should consult with a faculty member or faculty advisor.

The <u>Academic Misconduct Policy</u> is detailed in the Undergraduate Calendar.

9.7 Recording of Materials

Presentations which are made in relation to course work—including lectures—cannot be recorded or copied without the permission of the presenter, whether the instructor, a classmate or guest lecturer. Material recorded with permission is restricted to use for that course unless further permission is granted.

9.8 Resources

The <u>Academic Calendars</u> are the source of information about the University of Guelph's procedures, policies and regulations which apply to undergraduate, graduate and diploma programs.

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