



NUTR*4330 Applied Nutritional and Nutraceutical Sciences II - DRAFT

Winter 2019

Section(s): C01

Department of Human Health and Nutritional Sciences

Credit Weight: 0.75

Version 1.00 - October 25, 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)

Amanda Wright PhD

Email: ajwright@uoguelph.ca
Office: HHNS ANNEX-Room 282
Office Hours: Please email to make an appointment.

2.2 Teaching Assistant(s)

Teaching Assistant: TBD TBD
Office Hours: The TA will be available during the laboratory periods on Wednesdays. If you require additional support for a project, please email the TA for an appointment.

3 Learning Resources

3.1 Additional Resource(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. Whenever possible, 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

NUTR*4330 couples with NUTR*3390 as a capstone experience for students in the NANS major. Activities and assessments are intended to reinforce and enable mastery of program learning outcomes, including the general skills; Problem Solving & Critical Thinking, Communication, Professional & Ethical Behaviour and the degree-related skills & knowledge; Scientific Method, Breadth & Depth of Understanding in a Particular Scientific Discipline, and Scientific Technology & Techniques in a Scientific Discipline.

4.1 Course Learning Outcomes

By the end of this course, you should be able to:

1. Understand how functional foods and natural health products fit within the context of the diverse dietary needs, using diet analysis software tools and integrating degree knowledge.
2. Appreciate the key role of biomarkers in the development of evidence-based strategies for diet-related diseases and conditions and be able to apply this knowledge, integrating the concepts of research ethics, safety, and rigor, to design a human study that would determine efficacy of a product.
3. Explain the approval requirements and key study design considerations related to conducting human clinical nutrition research.
4. Critically assess the claims made for natural health products. This includes the ability to critically evaluate the quality of scientific reports, with respect to Health Canada product licensing and claims.
5. Analyze, interpret and communicate study data to a scientific audience, in written format.
6. Apply knowledge of ethics in human research, including the central role of study participants, to discuss best practices with peers.
7. Collaborate effectively to condense scientific information in oral presentation format and demonstrate knowledge of effective communication practices by others.
8. Explain how course activities relate to the development of professional skills and work readiness.

5 Teaching and Learning Activities

5.1 Schedule of Activities

Week	Date	Lecture	Laboratory
1	January 7	<ul style="list-style-type: none"> • Welcome and overview • What is the Human Nutraceutical Research Unit? • Overview of class clinical trial project • Overview of Project #1- Functional Food Diets • Assign online tutorial related to ethics of human participation in studies. Students will need to complete the TCPS tutorial before class on Monday January 14th and submit the completion certificate & reflection in class. 	<ul style="list-style-type: none"> • Meet in SCIE 1306 Computer Lab • Introduction to diet analysis software/ hypothetical 24 h recall diet entry & analysis/ class discussion • Estimating food portions and serving sizes • Organization into groups for Project #1 and sign up for presentation time
2	January 14	<ul style="list-style-type: none"> • Sandra Auld, Director of Research 	<ul style="list-style-type: none"> • Meet in FS146 HNRU

Week	Date	Lecture	Laboratory
		<p>Ethics, University of Guelph; Ethics in Human Research</p> <ul style="list-style-type: none"> Facilitated discussion - Ethics in human research case studies Submit TCPS certificate of completion & reflection in class 	<ul style="list-style-type: none"> Demonstration of blood collection and analysis procedures in the HNRU (with Premila Sathasivam) Group work for Project #1 - Computer lab (SCIE 1306) is available for use of ESHA Food Processor Software.
3	January 21	<ul style="list-style-type: none"> Introduction to clinical trials of foods and natural health products Clinical trial design activity Introduce Individual NHP Critical Evaluation Assignment 	<ul style="list-style-type: none"> Meet in SCIE 1306 Computer Lab Group work for Project #1 – Computer lab (SCIE 1306) is available for use of ESHA Food Processor Software. (Class clinical trial begins with baseline fasting fingerprick blood collection & analysis Monday, Tuesday, Wednesday, by appointment)
4	January 28	<ul style="list-style-type: none"> Clinical trials of foods and natural health products CONSORT and assessing quality of clinical trial reporting—small group activity Q & A about Individual NHP Critical Evaluation Assignment 	<ul style="list-style-type: none"> Project #1 Presentations & assignments due (Class clinical trial project - intervention period, Week 2)
5	February 4	<ul style="list-style-type: none"> Biomarkers and their role in nutrition and health research Biosafety considerations in human research Overview of Project #2- Biomarkers of chronic disease symposium Assign online WHMIS training module. Students will need to complete the WHMIS tutorial & reflection before class on Wednesday February 13th and submit the certificate of 	<ul style="list-style-type: none"> Project #1 Presentations & assignments due (Class clinical trial project - intervention period, Week 3)

Week	Date	Lecture	Laboratory
		completion & reflection in lab.	
6	February 11	<ul style="list-style-type: none"> • Dr. Julie Conquer, RGB Consulting & Brescia University College - Natural Health Products Testing and Regulation in Canada – An Introduction to the Regulatory Framework • Work on online WHMIS training. 	<ul style="list-style-type: none"> • Organization of groups for Project #2 and sign up for presentation time, discussion of topic • Skill building - basic library search strategies • Submit WHMIS certificate of completion & reflection in lab • (Class clinical trial ends with baseline fasting fingerprick blood collection & analysis Monday, Tuesday, Wednesday, by appointment)
	February 18	<ul style="list-style-type: none"> • <i>Reading Week</i> 	<ul style="list-style-type: none"> • <i>Reading Week</i>
7	February 25	<ul style="list-style-type: none"> • Data analysis and interpretation in clinical trials • Working with and presenting data- small group activity • Introduce Project #3 (Journal article and mock NPN application) and distribute data from class clinical trial project 	<ul style="list-style-type: none"> • Mini-skill building activity • Group work opportunity for Project #2 • Individual NHP Critical Evaluation Report assignment due through Courselink using Turnitin by end of Wednesday February 27
8	March 4	<ul style="list-style-type: none"> • Dissemination of research findings • Translating results for different audiences – small group activity • To be confirmed: Natural health product regulations - An industry professional perspective 	<ul style="list-style-type: none"> • Mini-skill building activity • Group work opportunity for Project #2
9	March 11	<ul style="list-style-type: none"> • Only 11:30am lab section attends • Disease/Biomarker Symposium: <ul style="list-style-type: none"> ◦ Project #2 Presentations & 	<ul style="list-style-type: none"> • Disease/Biomarker Symposium: <ul style="list-style-type: none"> ◦ Project #2 Presentations &

Week	Date	Lecture	Laboratory
		assignments due	assignments due <ul style="list-style-type: none"> • Organization of groups for Project #3
10	March 18	<ul style="list-style-type: none"> • Only 2:30pm lab section attends • Disease/Biomarker Symposium: <ul style="list-style-type: none"> ◦ Project #2 Presentations & assignments due 	<ul style="list-style-type: none"> • Mini-skill building activity • Group work opportunity for Project #3 • Peer reviews of Disease/Biomarker presentations & reflection due in lab Wednesday March 20th
11	March 25	<ul style="list-style-type: none"> • Graduate student research and experiences in human clinical nutrition studies • Keeping the human in human research: Reflecting on the participant experience 	<ul style="list-style-type: none"> • Mini-skill building activity • Group work opportunity for Project #3
12	April 1	<ul style="list-style-type: none"> • Functional Food Potluck • Lessons learned and future perspectives • <i>*Invitation to attend HHNS*6410 Product Showcase, details to follow*</i> 	<ul style="list-style-type: none"> • Group work opportunity for Project #3 – due by 12 pm (noon) Thursday April 4th.

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. 25% 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

Name	Scheme A (%)
NHP Critical evaluation report	10
Project 2: Biomarkers of chronic disease symposium	25
Project 3: Journal article and mock NPN application	25
Individual skills development & reflections	15
Total	100

6.2 Assessment Details

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

Due: January 30th & February 6th, Presentations 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 management of cardiovascular disease risk. 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. The diet should meet the nutritional requirements of a hypothetical individual whom students will uniquely consider. Students are encouraged to include a diversity of possible factors that might influence dietary needs and choices, i.e. age, health status, religion, food intolerances, food security, etc. Each group will present their dietary program in a 20 minute presentation (plus 5 minutes for questions). A summary report will also 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%)

Due: Wednesday February 27th, Courselink - Turnitin
 NUTR*4330 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 claims. 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. This assignment will be submitted through Courselink using Turnitin.

Project 2: Biomarkers of chronic disease symposium (25%)

Due: March 11th, 13th & 18th, Presentations 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 a critical evaluation of their mechanistic basis and predictive value. Each group will present their project (20 minute presentation plus 5 minutes for questions). A summary report will also be submitted, in the form of PowerPoint slides with notes.

Project 3: Journal article and mock NPN application (25%)

Due: Thursday April 4th - by noon
 Based on class clinical trial project. Students will work in groups of 3. The results of the class-based blood lipid project will be written up as a final scientific 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. This will include critically evaluating and integrating the group's article, as well as published manuscripts, in terms of

their quality and the level of evidence provide to support licensing the omega 3 supplement as an NPN.

Individual Skills Development & Reflections (15%)

Your participation throughout the semester is expected. However, additional marks will be assigned for your individual completion of the online TCPS ethics' tutorial (due in class - Monday January 14th--5%), online WHMIS tutorial (due in lab - Wednesday February 13th -- 5%), and peer review of the disease-biomarker symposium presentations (due in lab Wednesday March 20th --5%). For each activity, you will also submit three to five sentences, reflecting on how you can use the experience and/or knowledge gained to demonstrate relevant professional skills, in a future scenario (e.g. resume or job interview).

7 Course Statements

7.1 Human Ethics Issues

- This course will introduce students to many important ethical issues, including the respect surrounding the volunteer nature of participation, safety in the experimental design, and privacy issues associated with human participation in research.
- 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.
- Students will be invited to participate as human participants in a class 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. All students will reflect, broadly, on the participant experience, in terms of motivations to get involved in research through course content and external accounts of study 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>
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7.2 Use of Turnitin for NHP Critical Evaluation Assignment

In this course, your instructor will be using Turnitin, integrated with the CourseLink Dropbox tool, to detect possible plagiarism, unauthorized collaboration or copying as part of the ongoing efforts to maintain academic integrity at the University of Guelph.

Any submitted assignments will be included as source documents in the Turnitin.com reference

database solely for the purpose of detecting plagiarism of such papers. Use of the Turnitin.com service is subject to the Usage Policy posted on the Turnitin.com site.

A major benefit of using Turnitin is that students will be able to educate and empower themselves in preventing academic misconduct. In this course, you may screen your own assignments through Turnitin as many times as you wish before the due date. You will be able to see and print reports that show you exactly where you have properly and improperly referenced the outside sources and materials in your assignment.

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. [B.Sc. Academic Advising](#) or [Program Counsellors](#)

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/>
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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 [Academic Consideration](#) 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; two-semester courses must be dropped by the last day of the add period in the second semester. The regulations and procedures for [Dropping Courses](#) 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.

More information: www.uoguelph.ca/sas

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 [Academic Misconduct Policy](#) 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 [Academic Calendars](#) 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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