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-Requisites: NUTR*3330, NUTR*3390, HK*3810
Restrictions: Registration in B.Sc. NANS major or minor.

1.2 Course Description

• This course builds on concepts covered in Applied Nutritional and Nutraceutical Sciences I (NUTR*3390). Together, these laboratory-intensive courses explore and provide experiential learning opportunities in two key aspects surrounding the Nutritional and Nutraceutical Sciences. This includes the development of natural health products (NHP) and functional foods (Part I) and their testing and approval (Part II).
• The primary objective of NUTR*4330 is to provide valuable learning opportunities surrounding food and NHP clinical testing as well as critical analysis and reporting to support evidence based products.
• The major themes of this course will include the design and evaluation 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; quality reporting and dissemination of human study results; and critical review of evidence to support functional foods and NHPs in the Canadian marketplace.
1.3 Timetable

- Synchronous Class Meeting - Mondays 2:30 – 3:30, by Zoom or Virtual Classroom TBD (recorded)
- Asynchronous Lecture Content - Videos posted weekly
- Lab 1: Wednesday 11:30 – 2:20 - Synchronous by Zoom or Virtual Classroom TBD (not recorded)
- Lab 2: Wednesday 2:30 – 5:20 Synchronous Zoom or Virtual Classroom TBD (not recorded)

1.4 Final Exam

There is no final exam for this course.

2 Instructional Support

2.1 Instructional Support Team

Instructor: Amanda Wright PhD
Email: ajwright@uoguelph.ca
Office: HHNS ANNEX-Room 283
Office Hours: Mondays 3:30 - 4:30, by Zoom or Virtual Classroom (TBD). Alternatively, please email to make an appointment.

2.2 Teaching Assistants

Teaching Assistant: To be determined 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 Resources

Readings and/or websites will be provided during the lectures (Readings)
Course materials (e.g. journal article readings, videos, websites, software, etc.) will be provided in lecture, laboratory, and/or referenced in Courselink. There are otherwise no formal resources required.
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 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

Course content will be delivered through a combination of synchronous and asynchronous methods using Courselink and Virtual Classroom or Zoom (TBD). This will include Monday synchronous 1-hr class meetings which will involve lecture and active learning components, as well as video lectures and other curated resources that students will work through asynchronously in advance of weekly class meetings.

To ensure you receive up to date announcements about NUTR4330, please be sure you turn
on notifications in CourseLink. To learn more, visit; https://support.opened.uoguelph.ca/instructors/courselink/tools/content/notifications

### 5.1 Schedule of Course Activities

<table>
<thead>
<tr>
<th>Week</th>
<th>Monday Synchronous Class Meeting Activities</th>
<th>Wednesday Synchronous Laboratory Meetings</th>
<th>Asynchronous Lecture Topics &amp; Other Activities - DRAFT</th>
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</thead>
<tbody>
<tr>
<td>Week 1</td>
<td>Welcome&lt;br&gt;Course overview &amp; housekeeping&lt;br&gt;Introduction to Project #1 - Functional Food Diet Design &amp; Analysis</td>
<td>Introduction to Food Processor diet analysis software&lt;br&gt;Start Project #1</td>
<td>Introduce yourself by posting a short, simple video (see example)&lt;br&gt;Download software to access Food Processor for Project #1&lt;br&gt;Introduction to clinical trials of foods and natural health products</td>
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<tr>
<td><strong>January 11-15</strong></td>
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<tr>
<td>Week 2</td>
<td>Key concepts in human clinical research</td>
<td>Food records and dietary recall&lt;br&gt;Project #1 group work</td>
<td>Clinical trials - Study design considerations&lt;br&gt;Good clinical practices&lt;br&gt;What is the Human Nutraceutical Research Unit? - Interview with Dr. Amy Tucker</td>
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<td><strong>January 18-22</strong></td>
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<tr>
<td>Week 3</td>
<td>Clinical trial design, registration &amp; other best practices</td>
<td>Practice technology and presentation skills</td>
<td>Food and NHP testing to support claims</td>
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<tr>
<td>Date</td>
<td>Topic</td>
<td>Activity</td>
<td>Notes</td>
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<tr>
<td>January 25-29</td>
<td>Project #1 group work</td>
<td>NHP testing and regulation in Canada - an introduction to the regulatory framework &amp; exploring the Health Canada website</td>
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<td>Week 4</td>
<td>Natural health product regulations – An industry perspective - guest lecture TBA</td>
<td>Project #1 Presentations due</td>
<td>Introduction to biomarkers</td>
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<tr>
<td>February 1-5</td>
<td>Introduction to NHP Critical Evaluation Assignment (due Friday March 5th)</td>
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<td>Working together - personality and group dynamics</td>
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<tr>
<td>Week 5</td>
<td>Biomarkers and their role in nutrition and health research</td>
<td>Professional skills in working together</td>
<td>Biosafety in human research</td>
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<td>February 8-12</td>
<td>Introduction to Project 2 – Biomarkers of chronic disease</td>
<td>Project #2 group work</td>
<td>Online biosafety training module – Submit certificate through Dropbox &amp; reflect in Discussion board</td>
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<td>Check in with instructor about topic for NHP Critical Evaluation Assignment</td>
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<tr>
<td>February 15-19</td>
<td>Reading Week</td>
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<td>Week 6</td>
<td>February 22-26</td>
<td>Introduction to human research ethics</td>
<td>Project #2 group work</td>
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<td>Keeping perspective – Centrality of the research participant</td>
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<td>Week 7</td>
<td>March 1-5</td>
<td>Human research ethics case studies – Mock Research Ethics Board (REB) deliberations</td>
<td>Project #2 group work</td>
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<tr>
<td>Week 8</td>
<td>March 8-12</td>
<td>Introduction to Project #3 - Analyzing, reporting, and synthesizing data</td>
<td>Project #2 Presentations; Biomarkers of Disease Symposium – Part A</td>
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<td>(Students will complete anonymous peer evaluations)</td>
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<tr>
<td>Week 9</td>
<td>March 15-19</td>
<td>CONSolidated Standards of Reporting Trials (CONORT) and other best practices</td>
<td>Project #2 Presentations; Biomarkers of Disease Symposium – Part B</td>
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<td></td>
<td></td>
<td>(Students will complete anonymous peer evaluations)</td>
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<tr>
<td>Week 10</td>
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<td>To Be Announced</td>
<td>Team building activity</td>
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</table>
6 Assessments

NUTR4330 involves several individual and group assessments, in a variety of formats.

6.1 Assessment Details

**Introduce Yourself (1%)**

*Date:* Wednesday January 13th

Students will upload a very short, simple video to introduce themselves, following the example provided.

**Project 1: Functional food diet design and analysis (20%)**

*Due:* Wednesday February 3rd, Presentations during laboratory sections, uploaded materials to Courselink

*Learning Outcome:* 1, 5, 7

Working with a partner, students will focus 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 1 day diet plan that could be used as an alternative to supplementation with a NHP, as well be discussed for Project #3. 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 15 minute presentation (plus 5 minutes for questions). A summary report will also be submitted, in the form of
presentations slides with notes.

**Biosafety Online Tutorial (5%)**

**Date:** Friday February 12th, Courselink Dropbox & Discussion

**Learning Outcome:** 2, 3, 8

Students will complete a Biosafety Online Tutorial and submit the completion certificate through Dropbox (4 marks) and contribute a brief (2-3 sentences) post to a Discussion Board reflecting on how the experience and/or knowledge gained can be used to demonstrate relevant professional skills, in a future scenario (e.g. resume or job interview) (1 mark).

**Human Research Ethics Online Tutorial (5%)**

**Date:** Monday March 1st, Courselink Dropbox and Discussion Board

**Learning Outcome:** 3, 6, 8

Students will complete a Human Research Ethics Online Tutorial and submit the completion certificate through Dropbox (4 marks) and contribute a brief (2-3 sentences) post to a Discussion Board reflecting on how the experience and/or knowledge gained can be used to demonstrate relevant professional skills, in a future scenario (e.g. resume or job interview) (1 mark).

**NHP critical evaluation report (10%)**

**Due:** Friday March 5th, Courselink

**Learning Outcome:** 4

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.

**Project 2: Biomarkers of chronic disease (20%)**

**Due:** Wednesday March 10th & 17th, Presentations during laboratory sections, uploaded materials to Courselink

**Learning Outcome:** 2, 5, 6, 7

Students will work in small groups, 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 (15 minute presentation plus 5 minutes for questions) as part of class Biomarkers of Chronic Disease Symposium. A summary report will also be submitted, in the form of presentation slides with notes.

**Individual Study Design Applying Project #2 Biomarker Knowledge (10%)**

**Date:** Wednesday March 10th & 17th, Courselink

**Learning Outcome:** 2, 3

Individually, students will propose a human clinical trial to investigate the efficacy of a functional food or natural health product based on the foundational knowledge gained about a particular chronic disease and its biomarkers in Project 2.

**Peer Review of Project #2 Presentations (4%)**
Date: Monday March 22nd, Courselink
Learning Outcome: 7
Anonymous peer review of Project #2 group presentations (3 marks).

Project 3: Journal Article and Evidence Summary Report (20%)
Due: Thursday April 8th, Courselink
Learning Outcome: 3, 4, 5
Students will work in small groups to prepare a scientific report (in the format of a brief journal article) that summarizes a mock clinical trial investigating the effects of a long chain omega 3 supplement on cardiovascular disease risk factors. Students will then compile this article with others in a critical evidence summary report which forms the basis of an application to Health Canada for a Natural Product Number. This activity 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 provided to support licensing the omega 3 supplement as a NHP in Canada.

Class Participation (5%)
Date: In class and through Courselink
Learning Outcome: 1, 2, 3, 4, 6, 7
Student participation throughout the semester is expected. However, additional marks will be assigned for participation and completion of certain activities during lecture. Students will be given choice and awarded 1 mark for participation on each of 5 occasions. Evidence of participation will be specific to each activity and provided in-class or through Dropbox submission at the end of class. More details to follow.

7 Course Statements

7.1 Guidelines for Remote Learning Interactions

• Learning in the remote context presents certain challenges, including more limited opportunities for connection. To mitigate this, it will help if all individuals turn their cameras on at the start of class meetings and for smaller group interactions.
• NUTR4330 was designed to provide students in the NANS major with significant opportunities to engage with their peers on class content. Your instructor and TA will do their best to maintain an interactive environment, but are counting on your participation.
• Classroom etiquette is another important consideration and will be discussed at the start of the semester to establish a set of shared principals and practices.
• Lab periods are specifically held each Wednesday so that students can convene at a set time each week to work with group members, and to interact with the teaching team. Students are expected to attend to ensure progress on collaborative work and learning.
• Lastly, technological issues can and will occur sometimes during remote learning. Your
instructor will communicate what to do in certain scenarios so students know, in advance, how to handle.

7.2 Use of Turnitin

- 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.selfregulationskills.ca/

8.4 Personal information

Personal information is collected under the authority of the University of Guelph Act (1964), and in accordance with Ontario's Freedom of Information and Protection of Privacy Act (FIPPA) http://www.e-laws.gov.on.ca/index.html. This information is used by University officials in order to carry out their authorized academic and administrative responsibilities and also to establish a relationship for alumni and development purposes.

For more information regarding the Collection, Use and Disclosure of Personal Information policies please see the Undergraduate Calendar. (https://www.uoguelph.ca/registrar/calendars/undergraduate/current/intro/index.shtml)

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 grounds for Academic Consideration are detailed in the Undergraduate and Graduate Calendars.

Undergraduate Calendar - Academic Consideration and Appeals
https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-ac.shtml
9.3 Drop Date

Students will have until the last day of classes to drop courses without academic penalty. The deadline to drop two-semester courses will be the last day of classes in the second semester. This applies to all students (undergraduate, graduate and diploma) except for Doctor of Veterinary Medicine and Associate Diploma in Veterinary Technology (conventional and alternative delivery) students. The regulations and procedures for course registration are available in their respective Academic Calendars.

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.

For Guelph students, information can be found on the SAS website https://www.uoguelph.ca/sas
For Ridgetown students, information can be found on the Ridgetown SAS website
https://www.ridgetownc.com/services/accessibilityservices.cfm

9.6 Academic Integrity

The University of Guelph is committed to upholding the highest standards of academic完整性, 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 encourages academic integrity. 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.

Undergraduate Calendar - Academic Misconduct
https://www.uoguelph.ca/registrar/calendars/undergraduate/current/c08/c08-amisconduct.shtml

Graduate Calendar - Academic Misconduct
https://www.uoguelph.ca/registrar/calendars/graduate/current/genreg/index.shtml

9.7 Recording of Materials

Presentations that are made in relation to course work - including lectures - cannot be recorded or copied without the permission of the presenter, whether the instructor, a student, 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 that apply to undergraduate, graduate, and diploma programs.

Academic Calendars
https://www.uoguelph.ca/academics/calendars

9.9 Disclaimer

Please note that the ongoing COVID-19 pandemic may necessitate a revision of the format of course offerings and academic schedules. Any such changes will be announced via CourseLink and/or class email. All University-wide decisions will be posted on the COVID-19

9.10 Illness

The University will not normally require verification of illness (doctor’s notes) for fall 2020 or winter 2021 semester courses. However, requests for Academic Consideration may still require medical documentation as appropriate.