PHA6935: Principles of Peer-Reviewed Biomedical Publications
3 credit hours

Note: The final syllabus posted in the course Canvas site is the most current and supersedes the syllabus posted on the internet.

Class Meeting Times
This is a 12-week, asynchronous course beginning Sunday May 12, 2024. There are no synchronous class meetings.

Class Meeting Location
Modules are accessed online via UF's e-learning system, Canvas. If you are having trouble accessing the course Canvas site, please contact Distance Education Support Services at ahc-dess@ufl.edu.

Instructors
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Course Description
Students will learn principles fundamental to the ethical and responsible publication of peer-reviewed biomedical content. Skills gained will relate to the purpose and importance of best practices and ethical standards in the conduct and reporting of research, the roles and responsibilities involved in peer-reviewed

publishing, and the principles and practices of sound publication planning, development, publication, and post-publication.

Course Objectives

Upon successful completion of this course, the student will be able to:

1. Explain the rationale for best practices and ethical standards in the conduct and reporting of research and other material published in peer-reviewed biomedical journals.
2. Recall the scope and general principles of key best practice guidelines related to peer-reviewed biomedical publishing, including publication planning and publication development.
3. Differentiate the roles and responsibilities of authors, contributors, and others involved in peer-reviewed biomedical publishing, as well as common types of biomedical publications.
4. Recall the elements of a publication plan and develop components of a plan based on sound ethics and planning principles.
5. Evaluate manuscripts for compliance with research reporting guidelines.
6. Analyze the quality of data visualization and storytelling in manuscripts.
7. Identify the procedures for publishing a manuscript, inclusive of journal process, copyright assignment, and post-publication activities.
8. Articulate the importance of transparency and inclusivity in peer-reviewed biomedical publishing and how certain practices can promote and support these.
9. Analyze case studies for adherence to appropriate best practices and ethical standards and justify applicable corrective action when necessary.

Relationship to Program-level Student Learning Outcomes

This course pertains to the following program-level student learning outcomes:

1. Assess the value of a pharmaceutical product using systematic reviews, meta-analyses, and value messaging practices.
2. Create evidence-based communications that are compliant with regulations and convey the value story of a pharmaceutical product that uses data-driven visuals.

Required Textbooks and/or Software

There is no textbook or special software required for this course.

Throughout this course, students will utilize Canvas to navigate module activities including but not limited to, reviewing recorded lectures, completing reading assignments, participating in discussion boards, and demonstrating learnings through various assessments.

Online POP Course Syllabus

Recommended Materials
None

Course Pre-Requisites
None

Structure and Organization
This course is organized into five modules through which students will advance on their own. The assigned work (e.g., lectures, readings, discussion boards, and assessments) for each module can be accessed via the corresponding link on the course home page in Canvas. It is recommended that students proceed through the material in the order in which it appears, as later topics may build on previous ones.

Due dates for assigned work will also be listed in Canvas and students can easily view these using the calendar from the main Canvas menu. While students are required to submit all assigned work by the due date, work may also be submitted any time prior to the due date. Please note that early submissions may not be graded until after the due date.

Course Schedule

Module	Topics	Learning activities/Assessments

1: Introduction	1. Standards in the conduct and reporting of research
	2. Publication guidelines
	3. Publication terminology
	4. Publication professional roles
	5. Publication types
		Pre-recorded lectures
		• Best Practices and Ethical Standards in the Conduct and Reporting of Peer-reviewed Biomedical Research
		• The Belmont Report
		• Common Terms in Peer-reviewed Publishing
		• Article Types in Biomedical Journals
		Required readings
		• The Belmont Report
		• What have we learnt from Vioxx?
		• Good Publication Practices
		  o Glossary
		  o Supplement A: Publication Types (except subsection on Secondary Publications)
		  o Supplement B: Publication Professional Roles and Development (sections on Professional Roles, Professional Development, and Sharing Best Practices)
		Assessments – **Due May 26**
		• Quiz 1
		• Short essays

2: Publication ethics	1. Ethical publication practices
	2. Research integrity in publishing
	3. Transparency and inclusivity in publishing
	4. Research registries
	5. Disclosures
	6. Plain language summaries
	7. Open access
	8. Authors, medical writers, and contributors
		Pre-recorded lectures
		• General Ethical Publication Principles
		• Protecting Research and Data Integrity in Biomedical Publishing
		• Data Transparency and Inclusivity in Biomedical Research and Publishing
		• Open Access Explained
		Required readings
		   Lecture readings
		• General ethical publication principles
		    o GPP General Principles for Ethics and Good Publication Practice (n=8)
		    o Supplement C. Ethical Principles
		• Research integrity in publishing
		    o ICMJE Protection of Research Participants
		    o GPP: Principles for Protecting Research and Data Integrity (n=2)
		• Transparency and inclusivity in publishing
		    o GPP Principles to Support Inclusivity (n=4)
		    o GPP Principles to Promote Transparency (n=5)
		   Disclosures
		• ICMJE: Disclosure of Financial and Non-Financial Relationships and Activities, and Conflicts of Interest
		• ICMJE: Disclosure of Interest Form
		• The sunshine act and medical publications: Guidance from professional medical associations
		   Additional transparency/inclusivity tools
		• ICMJE Publishing & Editorial Issues: Clinical Trials
		• Open Pharma recommendations for PLS
		• ISMPP: A multistakeholder discussion on open access and medical publishing (sections 5-8, pg 11-19)
		   Authors, contributors, and medical writers
		• GPP sections on authors, medical writers, and contributors:
		    o Principles for Authorship, Contributorship, and Accountability (n=4)
		    o Supplement G: Authorship and Contributorship Determination
		    o Supplement H: Publication Process (sections on Working with Professional Medical Writers and Acknowledgements, Disclosures, and Author Statements)
		• ICMJE: Defining the Role of Authors and Contributors
		• AMWA/EMSW/ISMPP Joint Statement on the Role of Professional Medical Writers
		• Ghostwriting in biomedicine

		Additional readings/resources
		• Contributor Roles Taxonomy (CRediT)
		    ○ Wiley Author Services: CRediT
		• ORCiD
		Assessments – **Due June 16***
		• Quiz 2
		• Clinicaltrials.gov search
		• Plain language summary evaluation
		• Disclosure policy activity
		• Case study: Authorship
		• Case study: Culturally offensive content
		• Case study: Research integrity
		• *Discussion board: Challenges to implementing ethics
		    ○ Post 1 – Due June 2
		    ○ Post 2 – Due June 9
		    ○ Post 3 – Due June 15

3: Publication planning	1. Publication planning
	2. Policies and procedures
	3. Publication steering committee
	4. Good publication plan principles
	5. Journal and conference selection
	6. Predatory publishers
	7. Developing a publication plan
		Pre-recorded lectures
		• Practical Publication Planning Principles
		• Good Publication Plan Principles
		• Publication Steering Committees
		• How to Select a Journal
		• Developing the Publication Plan
		Required readings
		• Good Publication Practices
		    ○ Practical Planning Principles
		    ○ Supplement B. Publication Professional Roles and Development (subsection on Developing Publications Policies and Procedures only)
		    ○ Supplement D. Publication Steering Committees
		    ○ Supplement E. Publication Plans
		    ○ Supplement H. Publication Process (section on Journal and Conference Selection only)
		• It Takes a Village: The Value of Publication Planning with Functional Partners and External Stakeholders
		• Think and Act Globally When It Comes to Publication Planning
		• WAME Identifying Predatory or Pseudo-Journals
		• Journal Citation Report
		Additional readings/resources
		• AMWA-EMWA-ISMPP joint position statement on predatory publishing
		• COPE Predatory Publishing
		• Think. Check. Submit.
		• Distinguishing Predatory from Reputable Publishing Practice (by Dr. Happe)

		• Beall's List • ICMJE Responsibilities in the Submission and Peer-review Process • Web of Science • PubMed • DOAJ • JANE – Journal/Author Name Estimator • Springer – How to choose a target journal • Springer – Journal Suggester • Developing a Strategic Publication Plan: A Visual Survival Kit • Components of a Strategic and Tactical Publication Plan Assessments – **Due July 7** • Quiz 3 • Publication planning policy analysis • Journal Citation Report search • Journal and conference selection activity • Case study: Policy and procedure

4: Publication development	1. Publication working groups
	2. Data sharing
	3. IMRAD
	4. Storytelling in manuscripts
	5. Research reporting guidelines
	6. Data visualization – tables and figures
	7. Overlapping publications
	8. Plagiarism
		Pre-recorded lectures
		• Publication Development
		• Reporting Guidelines
		• The ABT Framework
		• Thread Test
		• Good Tables
		• Good Figures
		Required readings
		   Publication Development
		• Good Publication Practices
		     o Supplement F. Publication Working Groups
		     o Supplement H. Publication Process (sections on Data Sharing, Publication Kick-off, Publication Draft [except subsections], and Review and Approval)
		• ICMJE: Preparing a Manuscript for Submission to a Medical Journal
		   Reporting Guidelines
		• CONSORT 2010 Statement
		• The PRISMA 2020 Statement
		• STROBE statement
		• CHEERS 2022 statement
		   Overlapping publications
		• Good Publication Practices
		     o Supplement A. Publication Types (subsection on Secondary Publications only)

		o Supplement H. Publication Process (subsection on Plagiarism and Plagiarism Detectors) • ICMJE Overlapping Publications (except section on preprints) • Text recycling guidelines • Avoiding plagiarism, self-plagiarism, and other questionable writing practices: A guide to ethical writing (subsection on redundancy, publication overlap and other forms of duplication, pg 18-24) Additional readings/resources • "It was a cold and rainy night": Set the Scene with a Good Introduction • Who, What, When, Where, How, and Why: The Ingredients in the Recipe for a Successful Methods Section • Show Your Cards: The Results Section and the Poker Game • The Discussion Section: Your Closing Argument • The write stuff • Writing a page-turner: how to tell a story in your scientific paper • The Writer's Diet • Describing deprescribing trials better: an elaboration of the CONSORT statement • PRISMA 2020 explanation and elaboration • PRISMA 2020 expanded checklist • STROBE explanation and elaboration • CHEERS explanation and elaboration • Overlapping Publication Terminology List Assessments – **Due July 21** • Quiz 4 • Reporting guidelines evaluation • Writing techniques, tables, and figures critique • Case study: Overlapping publications

5: Journal submission, publication, and beyond	1. Journal submission
	2. Documentation guidelines
	3. Copyright
	4. Letters to the Editor
	5. Corrections
	6. Retractions
	7. Altmetrics
	8. Preprints
	9. Embargos
	10. Enhanced content
		Pre-recorded lectures
		• Journal Submission and Publication
		• Copyrights in Peer-reviewed Publications
		• Post-publication Concerns
		• Altmetrics
		Required readings
		 Lecture Readings
		• Good Publication Practices
		  o Supplement H. Publication Process
		  o Subsection: Permissions for the Use of Copyrighted Materials

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- o Subsection: Plain Language Summaries and Enhanced Content
- o Section: Journal Submission, Peer Review, and Page Proofs [except subsection on Journal Posting of Preprints or Accepted Manuscripts]
- o Section: Post-publication Activities
- o Supplement I. Documentation Guidelines
- ICMJE Sending the Manuscript to the Journal

Preprints and Embargos
- Good Publication Practices
  - o Supplement Table 3 – entries on preprints and embargos (also covered in module 3)
  - o Supplement H. Publication Process – subsection on Journal posting of preprints or accepted manuscripts
- ICMJE Overlapping Publications (section on Preprints only)
- ICMJE Journals and the Media

Enhanced Content
- AMWA research study

Additional reading/resources
- Authors' Submission Toolkit: A practical guide to getting your research published

Copyright
- ICMJE Copyright
- Creative Commons
- Copyright (9:03)
- Creative Commons Licensing Explained (4 min)

Post-publication concerns
- ICJME Corrections, Retractions, Republications and Version Control
- ICMJE Scientific Misconduct, Expressions of Concern, and Retraction

Preprints
- COPE Preprints

Social media
- FDA: Using Social Media for Industry

Altmetrics
- Altmetric.com

Assessments – **Due August 4***
- Author guideline activity
- Case study: Post- publication plagiarism detection
- *Discussion board: Course reflections
  - o Post 1 – Due July 28
  - o Post 2 – Due August 4

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| **Final exam** | Comprehensive – multiple choice, timed | **Due August 4** |

Evaluation Methods

Quizzes (20%)

Each module will have a corresponding quiz covering all assigned module content. Questions may be in various formats including but not limited to multiple choice, matching, short answer, and fill-in-the-blank. Refer to individual quizzes for due dates.

Assignments (30%)

Assignments will consist of various formats. For example, these may be short essay topics, or students may be provided with an article and be required to compare it to relevant best practice guidelines. Assignments will relate to topics covered in their corresponding module. Refer to individual assignments for the specific requirements that must be met for each and their due dates.

Case Studies (20%)

Case studies will require students to analyze a given scenario for its adherence to appropriate best practices or ethical standards. Students will be provided with a case description followed by relevant questions to consider. Case study topics will relate to topics covered in their corresponding module. Refer to individual case studies for the specific requirements that must be met for each and their due dates.

Discussion Boards (15%)

Students will participate in discussion boards throughout the course. While discussion board prompts will be associated with a particular module, students may be required to synthesize topics covered throughout the course in their posts. Refer to discussion boards for the specific requirements that must be met for each and their due dates.

Discussion board posts should consist of a substantive comment. This means they should demonstrate understanding of significant ideas relevant to the issue, elaborate with accurate explanations or evidence, provide accurate information, distinguish fact from opinion, stimulate inquiry through thoughtful posts, ask clarifying questions, synthesize points of agreement or disagreement, attempt to motivate the group discussion, and present creative approaches to the topic. Posts should also include citations when appropriate. All citations should be in AMA format.

Final Exam (15%)

There will be a comprehensive final exam due at the end of the 12-week semester covering content from all course modules.

Instructor Feedback Timeline

Grades and feedback from the instructor will be posted within 7 calendar days **of the due date**.

Online POP Course Syllabus

Attendance Policy for Online POP

Students are expected to formally drop or withdraw from the course if they no longer wish to participant. See the program's Academic Calendar for applicable deadlines. In some cases, the University may automatically drop students for inactivity and/or for failure to pay tuition. It is crucial for students to communicate with the DESS (ahc-dess@ufl.edu) about their status in the course, and about any tuition deferments or other special conditions related to their tuition payment. Any student who remains enrolled in the course after the drop/add deadline is considered tuition-liable, unless exempted by University petition. The official UF Attendance Policy can be found here.

Late Assignment/Make-up Policy

Each assignment is posted with a clear due date. **Assignments that are not submitted by the due date will be given a zero.** The instructor will consider extenuating circumstances on a case-by-case basis – if they are contacted by the student in advance of the due date. No other makeup assignments are offered. Contact the instructors for any concerns.

Grading Policy

The only passing grades for graduate students are A, A-, B+, B, B-, C+, C, and S. Grades of B-, C+ or C count toward a graduate degree if an equal number of credits in courses numbered 5000 or higher have been earned with grades of B+, A- and A, respectively. Grade points are not given for S and U grades; S and U grades are not used to calculate grade point averages. All letter-graded courses eligible to count toward the graduate degree, except 1000- and 2000-level courses, are used to calculate the cumulative grade-point average. Letter grades of C-, D+, D, D- or E are not considered passing at the graduate level, although the grade points associated with these letter grades are included in grade point average calculations. See the UF graduate academic regulations for more information.

A	>92.500%
A-	89.500–92.499%
B+	86.500–89.499%
B	82.500–86.499%
B-	79.500–82.499%
C+	76.500–79.499%
C	72.500–76.499%

C-	69.500–72.499%
D+	66.500–69.499%
D	62.500–66.499%
D-	59.500–62.499%
E	<59.499%

Course Technology Support

Your instructor is not able to handle technological issues or answer questions related to computer issues.

- **Assistance accessing course Canvas page:** Contact Distance Education Support Services at ahc-dess@ufl.edu
- **IT Support:** Contact UF Computing Help Desk at 352-392-HELP (4357) or helpdesk@ufl.edu or submit an online request form. If a technical problem causes you to miss an assignment, you must report the problem to the Help Desk and then email your instructor your Help Desk ticket number to the instructor in order to receive an extension.

Students Requiring Academic Accommodations

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

Course technologies meet online learning accessibility standards for sight and hearing-impaired learners. Likewise, course materials are developed in accordance with accessibility standards. Course documents and webpages are formatted for screen-reader accessibility with the use of headings, styles, or alternative text tagging for images. Accessibility design tools in Microsoft Office products and in Canvas are used to evaluate and update accessibility issues detected in the instructional materials. Synchronous class sessions in Zoom are recorded. These recordings are posted to the course site to accommodate students unable to attend.

- Canvas Accessibility
- Zoom Accessibility

Course Evaluations

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Click here for guidance on how to give

<u>feedback in a professional and respectful manner</u>. Students will be notified when the evaluation period opens and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <u>ufl.bluera.com/ufl/</u>.

University Honesty Policy and Academic Integrity

UF students are bound by The Honor Pledge which states, "We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: "On my honor, I have neither given nor received unauthorized aid in doing this assignment." <u>The Honor Code</u> specifies a number of behaviors that are in violation of this code and the possible sanctions. Furthermore, you are obligated to report any condition that facilitates academic misconduct to appropriate personnel. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Regarding academic integrity, students in the program are strongly encouraged to be mindful of what constitutes plagiarism. Written assignments that contain the research or other original published work of someone else must be properly quoted, cited, paraphrased, or referenced appropriately. A software (TurnItIn) that is integrated with Canvas Assignments may be utilized to help students determine if a written submission meets the criteria for a properly referenced research paper. Please ask for help, utilize resource materials and take advantage of opportunities like creating a draft of your paper to test, ensuring you have addressed any errors prior to the final submission.

Please watch these short videos about this topic:
- <u>Understanding and Avoiding Plagiarism: Types of Plagiarism</u>
- <u>Avoiding Plagiarism</u>

Software Use and Course Technology

All faculty, staff, and students of the University are required and expected to obey the laws and legal agreements governing software use. Failure to do so can lead to monetary damages and/or criminal penalties for the individual violator. Because such violations are also against University policies and rules, disciplinary action will be taken as appropriate. We, the members of the University of Florida community, pledge to uphold ourselves and our peers to the highest standards of honesty and integrity.

The University policy on use of ChatGPT is available <u>here</u>.

Educational technology in the program is primarily the Canvas Learning Management System (LMS) and Zoom web conferencing software. These tools firmly support learning objectives and course goals. Writing with

communication tools, reading articles from digital collections, and viewing video presentations in high-quality, accessible formats are essential to facilitate meaningful learning experiences. These experiences expand knowledge and influence professional work habits and skills such as information-gathering techniques and evidence-based practice. Synchronous class sessions in Zoom provide learners with opportunities to gain confidence and practice how they interact and collaborate in online meetings.

- Canvas Student Guide
- Zoom Resources

A minimum number of other technical skills are required for success in the online courses. These include accessing course webpages to read text and listen to recorded videos, using word processing tools (MS Word, PowerPoint), downloading/uploading content, submitting online assignments and using a variety of communication tools (Canvas Inbox, Discussions, Zoom Conferences).

Course Communication

Canvas (Inbox tool) will be used as the primary communication tool between the instructor and students. Check daily for new announcements or notifications about course updates. UF email will also be used occasionally for mass communication to the class, so please check your email at least once a day as well. All emails sent out to the entire class will also be posted as an Announcement on Canvas. The instructor will generally respond to student messages within 48 hours.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the course discussion board. We expect students to help each other track down answers as best as possible. Read through all the other posts in the discussion board first before posting to make sure your question has not been addressed/answered already. Please include a clear subject title for your topics to make it clear what your post pertains to. The instructor will generally respond to questions posted on the course discussion board within 48 hours.

Emotions can easily be misinterpreted on a discussion board/emails, so make sure your message is clear before sending it since there are no physical gestures or voice inflections that accompany posts/emails. Any posts/emails deemed inappropriate by the faculty will be dealt with on a case-by-case basis with either the faculty directly or they will be sent on to the Associate Dean for Professional Affairs.

For personal issues/questions, please email your instructor. Be sure to include in your subject line the course listing and then a quick subject (e.g., PHAXXXX – Your Name -). This will allow instructors to quickly identify emails related to the course amongst the many emails that are received each day. Emails not correctly addressed may get lost in the shuffle and unintentionally deleted or ignored so be sure to follow the

guidelines exactly.

Student Privacy
There are federal laws protecting your privacy in terms of grades earned in courses and on individual assignments. For more information, please see the <u>Notification to Students of FERPA Rights</u>.
Recordings of weekly class sessions in Zoom are created for the purpose of course teaching and learning, as well as for use as a resource for students who miss a class session.

The use of video (or web camera) feature in Zoom is not a requirement, but rather is voluntary for meeting participants. For both the audio and video features in Zoom, you will have the option to Start or Stop these functions.

Students who participate with their camera engaged or who utilize a profile image are agreeing to have their video or image recorded. If you are unwilling to consent to have your profile or video image recorded, be sure to keep your camera off and do not use a profile image. Likewise, students who un-mute during class and participate orally are agreeing to have their voices recorded. If you are not willing to consent to have your voice recorded during class, you will need to keep your mute button activated and communicate exclusively using the "chat" feature, which allows students to type questions and comments live. As in all courses, unauthorized recording and unauthorized sharing of recorded materials is prohibited.

- <u>Zoom Software Privacy Statement</u>
- <u>Canvas (by Instructure) Privacy Policies</u>

Security
Online activity in Canvas requires an active UF GatorLink account to log in, as well as enrollment in courses. The Zoom Conference meetings for weekly classes are accessed within Canvas. These meetings have a pass code applied as an additional security setting. Students in the class do not need to enter the passcode, however anyone not enrolled in the course cannot join the meeting without it.

Library Resources
For remote access to UF library resources such as e-journals or other digital collections, use the <u>UF VPN or proxy server to connect</u>.

Additional University Resources

- **U Matter, We Care:** If you or a friend is in distress, please contact umatter@ufl.edu or 352 392-1575 so that a team member can reach out to the student.
- **Counseling and Wellness Center**
- **Sexual Assault Recovery Services (SARS):** Student Health Care Center, 392-1161.
- **University Police Department** at 392-1111 (or 9-1-1 for emergencies), or police.ufl.edu
- **E-learning technical support**: 352-392-4357 (select option 2) or e-mail to Learning-support@ufl.edu.
- **Teaching Center**: Broward Hall, 392-2010 or 392-6420. General study skills and tutoring.
- **Writing Studio**: 302 Tigert Hall, 846-1138. Help brainstorming, formatting, and writing papers.
- **Student Complaints**