IOWA SCHOLARS IN CLINICAL INVESTIGATION

AND

THE UNIVERSITY OF IOWA COLLEGE OF PUBLIC HEALTH

CLINICAL RESEARCH ETHICS

(EPID:6950:0001)

SYLLABUS, SPRING 2022

Course Website: http://icon.uiowa.edu/
(EPID:6950:0001 Spr22 Clinical Research Ethics)

Course meets Tuesdays, 12:00pm-1:50pm
By Zoom or, if in-person, in the ICTS Conference Room (C44-A GH)

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1. Purpose of Course

Clinical Research Ethics is a semester-long, 2-credit course with a 3-credit option (see Course Requirements on pages 5-6). The course introduces students to some of the key ethical, legal, and policy issues that investigators encounter as they conduct clinical research. In this course we take for granted that clinical research ethics matters to investigators, and we do so because clinical research is at heart a *moral* undertaking due both to its participants (human beings) and its goals (human health). This means that in clinical research, science and ethics are inseparable. We also recognize that clinical research is a *public* undertaking and therefore requires a vocabulary to articulate ethical justifications for research decisions so that their moral basis can be transparent to study subjects, Institutional Review Boards, and society. This course introduces you to topics, values, and policies you need to understand to design and conduct clinical research that is ethically justifiable.

2. Overall Objectives

1. Appreciate the inseparable relationship between science and ethics in clinical research.
2. Recognize common ethical challenges in clinical research.
3. Recognize the ethical aspects of the design and conduct of clinical research that require explicit assessment and justification.
4. Understand key regulations that govern clinical research.
5. Understand the ethical values that guide the regulation of clinical research.
6. Apply principles of clinical research ethics to student's own clinical research interests.

3. Format

The course will meet **once each week, on Tuesdays from 12:00pm-1:50pm, by Zoom or, if in-person, in the ICTS Conference Room (C44-A GH)**. Attendance at all class sessions is required. The first hour of class will be reserved for student-led discussions. The second hour of class will be more didactic and led by the course director or one of the guest lecturers.

4. Accessing Assigned Readings and Cases

The assigned readings and case for each week are posted as URL links or PDF files on the ICON course website (http://icon.uiowa.edu/). If for some reason a URL link does not function properly, please email the course coordinator at laura-shinkunas@uiowa.edu.

5. LECTURERS

• Lauris Kaldjian, MD, PhD
Professor, Department of Internal Medicine
Director, Program in Bioethics and Humanities
Richard M. Caplan Chair in Biomedical Ethics and Medical Humanities
Week 1: *Course Overview and Introduction to Clinical Research Ethics*
Week 2: *What Makes Clinical Research Ethical?*
Week 3: *Philosophical Foundations*
Week 7: *Integrity and Good Practice in Clinical Research, Part I*
Week 8: *Integrity and Good Practice in Clinical Research, Part II*
Week 14: *Conflicts of Interest*
Week 15: *Clinical Research Ethics in Developing Countries*

• Michele Countryman, CIP
Director, Human Subjects Office
Week 4: *IRB Review*
Week 5: *Special Emphases in IRB Review*

• Anya Prince, JD, MPP
Associate Professor, College of Law
Member, University of Iowa Genetics Cluster
Affiliate Faculty Member, Program in Bioethics and Humanities
Week 6: *Informed Consent in Human Subjects Research*
Week 11: *Ethics of Genetic and Genomic Research*

• J. Andrew Bertolatus, MD
Professor Emeritus, Department of Internal Medicine (Nephrology)
Primary IRB Chair
Week 9: *Phase I & Placebo-Controlled Trials*

• Christie Thomas, MBBS
Professor, Department of Internal Medicine (Nephrology)
Director, Renal Genetics Clinic
Nephrologist, Kidney Transplant Program
Week 10: *Gene Editing and Stem Cell Research*

• David Moser, PhD
Professor, Department of Psychiatry
Vice Chair, Faculty Development
Affiliate Faculty Member, Program in Bioethics and Humanities
Week 12: *Vulnerable Populations and Special Circumstances*

• Erica Carlisle, MD
Assistant Professor, Department of Surgery (Pediatric Surgery)
Affiliate Faculty Member, Program in Bioethics and Humanities
Week 13: *Ethical Issues in Research Involving Children*

6. COURSE REQUIREMENTS

6.1. **Attendance, Preparation, and Participation (40 grading points):** Consistent class attendance, preparation, and participation are critical to getting the most out of this course. Preparation is demonstrated by reviewing each week's assigned readings and case (pp. 7-14 in Syllabus) and contributing knowledgeably on the readings and case during class discussions.

Unavoidable, expected absences from class should be preceded by an email or other communication to the course director and coordinator explaining the reason for the absence.

> *Gaps in Attendance, Preparation, and Participation* (GAPP): GAPP notices will be provided to students whose attendance, preparation, or participation is cause for concern. If students continue to lag after receiving these notices, deductions will be made from their Attendance, Preparation, and Participation grading points.
>
> *Absences:* If a student misses *more than two* class sessions, 1 point will be deducted from his or her Attendance, Preparation, and Participation grade for each additional class session missed (e.g., a student who misses 4 class sessions will lose 2 points).
>
> *Make-Up Work*: When a student misses a class session, he or she will write a 2-page, single-spaced reflection that engages all of the assigned readings for the session missed. These reflections should be emailed to the course director and coordinator no more than one week following the missed session.

6.2. **Leading or Co-Leading Discussions (30 grading points):** Students will lead or co-lead (depending on the size of the class) the first half (i.e., 45-60 mins) of each week's class session. Each student will choose a particular week or weeks (depending on the size of the class) and its associated topic; a sign-up sheet will be circulated at the semester's first meeting. Discussion (co)-leaders are expected to (1) generate and pose to the class an engaging series of questions that cover the readings for their week, and then (2) lead a discussion of the case assigned for their week. They are expected to steer the discussion with support from the instructor.

6.3. **Final Paper (30 grading points):** Students must write a short final paper reflecting on a particular research practice or policy that does or may present ethical challenges in their own work. Students should describe why an issue is ethically problematic and how it could be avoided or better managed. Papers should be 3-4 double-spaced pages for 2-credit students. Referencing is not necessary. Papers should be uploaded to ICON by noon on **May 5, 2021.**

Directions for the 2-Credit Option:

1. **Opening Paragraph**
    a. A brief description of the research ethics dilemma/problem of interest.
    b. A brief note on the context, environment, etc. in which the problem arose (e.g., lab, field, clinic, or other).
2. **Body**
    a. Why (from a research ethics perspective) is this a problem/dilemma?
    b. Identify the ethical/moral principles at stake.
3. **Conclusion**
    a. Suggest possible solutions(s).
    b. What could be done to avoid/address this sort of problem in the future?

3-Credit Option: *Students enrolled for 3-credits must write an in-depth final paper of 8-10 double-spaced pages with supporting references, on a research ethics topic of their choice. Prior consultation with the course director on the focus and direction of the paper is recommended. See Appendix at the end of the syllabus for further guidance.*

7. GRADING

Requirements	**Points Allocated**
Attendance, Preparation, Participation	40 points
Leading/Co-Leading Discussion	30 points
Final Paper	30 points
Point totals:	**100 points**

Final letter grades will be determined using the following point ranges: 90-100 (A), 80-89 (B), 70-79 (C), 60-69 (D), less than 60 (fail).

8. COURSE SCHEDULE AND CONTENT

Date **Topics, Objectives, Readings, and Case**

Week 1: Jan 18 ***Course Overview and Introduction to Clinical Research Ethics*** **(Lauris Kaldjian)**

Learning Objectives
Through this week's readings and class discussion, we will aim to identify and understand:

- The inherent ethical and moral tensions in scientific experimentation involving human participants.
- The historical context for current ethical considerations, law and guidance.
- The key place of the Nuremberg Code in protecting human research participants.

Readings (on ICON)

- Beecher HK. (1966). Ethics and clinical research. *N Engl J Med, 274*(24), 1354-1360.
- Jones DS, Grady C, Lederer SE. (2016). 'Ethics and clinical research' – The 50th anniversary of Beecher's bombshell. *N Engl J Med, 374*(24), 2393-2398.
- The Nuremberg Code. (1949).
- Alexander L. (1949). Medical science under dictatorship. *New Engl J Med*, 241(2), 39-47.

No Case for this session

Week 2: Jan 25 ***What Makes Clinical Research Ethical?*** **(Lauris Kaldjian)**

Learning Objectives
Through this week's readings, case, and class discussion, we will aim to identify and understand:

- The different benchmarks for determining whether a clinical trial is ethical.
- The (nuanced) differences between clinical research and practice.
- The ethical principles for the protection of human subjects research.

Readings (on ICON)

- Emanuel EJ, Wendler D, Grady C. (2000). What makes clinical research ethical? *JAMA, 283*(20), 2701-2711.
- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. (1979).
- WMA Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects. (2013).
- Prasad V. (2018). Non-inferiority trials in medicine: Practice changing or a self-fulfilling prophecy? *J Gen Intern Med*, *33*, 3-5.
- Agich G. (2019). Knowing one's way around: The challenge of identifying and overseeing innovations in patient care. Am J Bioethics 19(6),1-3.

Case (on ICON)

- Higgins WC, Rogers WA, Ballantyne A, et al. Against the use and publication of contemporary unethical research: The case of Chinese transplant research. J Med Ethics. 2020 Oct; 46: 678-684.
- Caplan AL. The ethics of the unmentionable. J Med Ethics. 2020 Oct 1;46(10):687-8.

Week 3: Feb 1 ***Philosophical Foundations*** **(Lauris Kaldjian)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- The relevance of philosophy to human subjects research and research protections.
- The concept of moral reasoning.
- The different ethical theories that can help organize thinking about research ethics.

Readings (on ICON)

- Frankena WK. (1973). Morality and moral philosophy. In: *Ethics* (pp. 1-11). Upper Saddle River, NJ: Prentice-Hall.
- Pellegrino ED. Toward a virtue-based normative ethics for the health professions. Kennedy Institute of Ethics Journal 1995;5:253-277.

Case (on ICON)

- Paul C, Brookes B. The rationalization of unethical research: Revisionist accounts of the Tuskegee Syphilis Study and the New Zealand "Unfortunate Experiment". Am J Public Health. 2015 Oct;105(10):e12-9.

Week 4: Feb 8 ***IRB Review*** **(Michele Countryman)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Application of the Belmont Report's principles in IRB review.
- IRB review criteria.
- Variations between institutions in the IRB review process.
- Potential challenges regarding investigators attitudes toward IRBs.
- Human subjects research determination form.
- Criteria for 'exempt status' (exempt from full IRB review).

Readings (on ICON)

- Pech C, Cob N, Cejka JT. (2007). Understanding institutional review boards: Practical guidance to the IRB review process. *Nutr Clin Pract, 22*(6), 618-628.
- Dziak K, Anderson R, Sevick MA, Weisman CS, Levine DW, Scholle SH. (2005). Variations among institutional review board reviews in a multisite health services research study. *Health Serv Res, 40*(1), 279-290.

- Klitzman R. et al. (2019). Local knowledge and single IRBs for multisite studies: Challenges and solutions. *Ethics & Hum Res, 41*(1), 22-31.
- Do I need IRB review? Is this human subjects research? A guide for investigators. Prepared by the University of Iowa Human Subjects Office/IRB.
- Code of Federal Regulations (§46.104) Exempt research.

Case (on ICON)

- Savulescu J, Spriggs M. The hexamethonium asthma study and the death of a normal volunteer in research. J Med Ethics. 2002 Feb;28(1):3-4.

Week 5: Feb 15 ***Special Emphases in IRB Review*** **(Michele Countryman)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Privacy concerns posed by use of social media in research.
- Adaptive clinical trials and informed consent.
- Understand the ethical concerns regarding financial incentives in research.

Readings (on ICON)

- Azer SA. (2017). Social media channels in health care research and rising ethical issues. AMA J Ethics, 19(11), 1061-1069.
- Tsan MF, Ling B, Feske U, Zickmund S, Stone R, Sonel A, Arnold RM, Fine M, Hall DE. Assessing the Quality and Performance of Institutional Review Boards: Levels of Initial Reviews. J Empir Res Hum Res Ethics. 2020 Sep 11:1556264620956795.
- [OPTIONAL: Chow SC, Chang M. Adaptive design methods in clinical trials - a review. Orphanet J Rare Dis. 2008 May 2;3:11.]
- Halpern SD, Chowdhury M, Bayes B, et al. (2021). Effectiveness and ethics of incentives for research participation: 2 randomized clinical trials. JAMA Intern Med, 181(11), 1479-1488.
- Ngo S, Kim AS, Chiong W. (2021). Evidence for the ethics of incentivizing clinical trial enrollment? JAMA Intern Med, 181(11), 1488-1489.

Case (on ICON)

- Laage T, Loewy JW, Menon S, Miller ER, Pulkstenis E, Kan-Dobrosky N, Coffey C. Ethical considerations in adaptive design clinical trials. Therapeutic innovation & regulatory science. 2017 Mar;51(2):190-9.

Week 6: Feb 22 ***Informed Consent in Human Subjects Research*** **(Anya Prince)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- The ethical and moral principles underlying informed consent.
- The components of informed consent (disclosure, understanding, voluntariness).
- Criticisms and emerging challenges regarding informed consent.

Readings (on ICON)

- Dickert et al. (2017). Reframing consent for clinical research: A function-based approach. *Am J Bioethics*, 17(12):3-11.
- Morain SR, Joffe S, & Largent E. (2019). When is it ethical for physician-investigators to seek consent from their own patients? *Am J Bioethics, 19*(4), 11-18.
- Zhang JZ, Nicholls SG, Carroll K, et al. Informed consent in pragmatic trials: Results from a survey of trials published 2014-2019. J Med Ethics. 2021 Nov 15.

Case (on ICON)

- Rudolph AE, Martinez O, Davison R, Amuchi CB. (2020). Informed consent for HIV phylogenetic research: A case study of urban individuals living with HIV approached for enrollment in an HIV study. EHQUIDAD. 2020(14), 129-143.

Week 7: Mar 1 ***Integrity and Good Practice in Clinical Research, Part I*** **(Lauris Kaldjian)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Values and guidelines for professional self-regulation in research.
- Government and institutional regulations and policies for research integrity.
- Research misconduct definitions and policies.
- Good data management practices.

Readings (on ICON)

- Steneck NH. (2007). Part I: Shared values (pp 1-26) and Part III: Conducting research: Data management practices (pp 83-97). In: *ORI Introduction to the Responsible Conduct of Research* (Updated ed.). Washington DC: Dept. of Health and Human Services, Office of Research Integrity.
- NOT-OD-19-020: Responsibilities of recipient institutions in communicating research misconduct to NIH.

Case (on ICON)

- Couzin-Frankel J. (2010, Jun 28). Scientist turned in by grad students for misconduct pleads guilty. *Science*.
- Federal Bureau of Investigation. (2010, Sept 3). Former UW genetics professor sentenced for making false statements in grant progress report. Milwaukee, WI: U.S. Attorney's Office.

Week 8: Mar 8 ***Integrity and Good Practice in Clinical Research, Part II*** **(Lauris Kaldjian)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Mentor and trainee responsibilities.
- Integrity in collaborative research.

- Authorship roles and responsibilities.
- Integrity in peer review.

Readings (on ICON)

- Steneck NH. (2007). Part III: Conducting research: Mentor and trainee responsibilities (pp. 103-128) and Part IV: Reporting and reviewing research (pp. 129-154). In: *ORI Introduction to the Responsible Conduct of Research* (Updated ed.). Washington DC: Dept. of Health and Human Services, Office of Research Integrity.
- Al-Herz W, Haider H, Al-Bahhar M, et al. (2014). Honorary authorship in biomedical journals: How common is it and why does it exist? *J Med Ethics, 40*, 346-348.
- Mentzelopoulos SD, Zakynthinos SG. (2017). Research integrity, academic promotion, and attribution of authorship and nonauthor contributions. *JAMA, 318*(13), 1221-1222.
- University of Iowa. (2012). Authorship Policy (27.10).

Case (on ICON)

- Steneck NH. (2007). Case study on authorship (p. 133). In: *ORI Introduction to the Responsible Conduct of Research* (Updated ed.). Washington DC: Dept. of Health and Human Services, Office of Research Integrity.

Mar 14-18 ***SPRING BREAK***

Week 9: Mar 22 ***Phase I and Placebo-Controlled Trials*** **(J. Andrew Bertolatus)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- The concept of equipoise.
- Ethical issues in phase I trials.
- Ethical issues in placebo-controlled trials.

Readings (on ICON)

- Grunwald HW. (2007). Ethical and design issues of phase I clinical trials in cancer patients. Cancer Investigation. 25, 124-126.
- Miller FG. (2002). What makes placebo-controlled trials unethical? Am J Bioeth. 2(2), 3-9.
- [OPTIONAL: Jansen LA, Mahadevan D, Appelbaum PS, et al. (2018). Perceptions of control and unrealistic optimism in early-phase cancer trials. *J Med Ethics, 44*, 121-127.]

Case (on ICON)

- Rid A, Lipsitch M, Miller FG. The ethics of continuing placebo in SARS-CoV-2 vaccine trials. JAMA. 2020 Dec 14.

Week 10: Mar 29 ***Gene Editing and Stem Cell Research*** **(Christie Thomas)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Ethical issues raised by gene editing and stem cell science.
- Controversies regarding using gene editing and stem cells.
- Research using gene editing and stem cells as an opportunity to clarify the relationship of science and ethics in new technologies.

Readings (on ICON)

- Carvalho AS, Ramalho-Santos J. (2013). How can ethics relate to science? The case of stem cell research. *Eur J Hum Genet, 21*(6), 591-595.
- Hurlbut JB, Jasanoff, S, Saha, K, et al. (2018). Building capacity for a global genome editing observatory: Conceptual challenges. *Trends Biotechnol, 36*(7), 639-641.
- King NMP & Perrin J. (2014). Ethical issues in stem cell research and therapy. *Stem Cell Res Therapy, 5*, 85.

Case (on ICON)

- Solbakk JH, Zoloth L. The tragedy of translation: the case of "first use" in human embryonic stem cell research. Cell Stem Cell. 2011 May 6;8(5):479-81.

Week 11: Apr 5 **Ethical Issues in Research Involving Children (Erica Carlisle)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Research ethics issues specific to pediatric populations.
- How to identify ethically justifiable approaches to research with pediatric subjects.

Readings (on ICON)

- Fleischman, A. R. (2016). Ethical issues in neonatal research involving human subjects. *Semin Perinatol, 40*(4), 247-253.
- Crane, S., & Broome, M. E. (2017). Understanding ethical issues of research participation from the perspective of participating children and adolescents: A systematic review. *Worldviews Evid Based Nurs, 14*(3), 200-209.

Case (on ICON)

- Krugman S. (1986). The Willowbrook hepatitis studies revisited: Ethical aspects. *Reviews Infect Dis, 8*(1), 157-162.

Hepatitis studies at the Willowbrook state school for children with mental retardation. Retrieved from: https://sites.google.com/a/narrativebioethics.com/emhr/contact/hepatitis-studies-at-the-willowbrook-state-school-for-children-with-mental-retardation

Week 12: Apr 12 ***Vulnerable Populations and Special Circumstances*** **(David Moser)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Which populations are considered vulnerable?
- The ethically significant features of some research subject groups that indicate vulnerability.
- Research allowances with prison populations.

Readings (on ICON)

- Coleman CH. (2009). Vulnerability as a regulatory category in human subject research. *J Law Med Ethics*, *37*, 12-8.
- Krubiner CB, Faden RR. (2017). Pregnant women should not be categorized as a 'vulnerable population' in biomedical research studies: Ending a vicious cycle of 'vulnerability.' *J Med Ethics, 43,* 664-665.
- Wieland ML, Njeru JW, Alahdab F, Doubeni CA, Sia IG. Community-engaged approaches for minority recruitment into clinical research: a scoping review of the literature. Mayo Clin Proc. 2020 Sep 28:S0025-6196(20)30317-7.

Case (on ICON)

Moser DJ, Arndt S, Kanz JE, et al. (2004). Coercion and informed consent in research involving prisoners. *Compr Psychiatry, 45*(1), 1-9.

Week 13: Apr 19 ***Ethics of Genetic and Genomic Research*** **(Anya Prince)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Key ethical, legal, and social issues surrounding genetic and genomic research.
- Informed consent challenges surrounding biobanking.
- Policy needs for new genetic and genomic research.

Readings (on ICON)

- Parens E, Appelbaum P, Chung W. (2013). Incidental findings in the era of whole genome sequencing? *Hastings Cent Rep, 43*(4), 6-19.
- Elger BS, De Clercq E. (2017). Returning results: Let's be honest! *Genet Test Mol Biomarkers, 21*(3), 134-139.
- Ploug T, Holm S. The 'expiry problem' of broad consent for biobank research - and why a meta consent model solves it. J Med Ethics. 2020 Feb 25. [Epub ahead of print]
- Skloot R. (2010). Afterword. In: *The Immortal Life of Henrietta Lacks* (pp. 315-328). New York: Broadway Books.
- Wolinetz CD, Collins FS. Recognition of research participants' need for autonomy: remembering the legacy of Henrietta Lacks. JAMA. 2020; 324.

Case (on ICON)

- Sterling RL. (2011). Genetic research among the Havasupai – a cautionary tale. Virtual Mentor, 13(2), 113-117.

Week 14: Apr 26 ***Conflicts of Interest*** **(Lauris Kaldjian)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Definitions of conflict of interest (COI).
- Typical situations involving COI in research.
- Regulations and strategies for avoiding COI.

Readings (on ICON)

- Rodwin, Marc A., Attempts to Redefine Conflicts of Interest (2017). *Accountability in Research: Policies in Quality Assurance* (December 6).
- University of Iowa. (2012). Conflict of Interest in Research.
- Haque W et al. (2018). Conflicts of interest of editors of medical journals. *PLoS One, 13*(5), e0197141.
- Carr D, Welch HG. (2019). Industry payments to physician directors of National Cancer Institute-designated cancer centers, 2015-2017. JAMA Intern Med, Aug 5, 2019.
- Kanter GP, Loewenstein G. (2019). Evaluating Open Payments. JAMA, July 1, 2019.
- Mitchell AP, Trivedi NU, Gennarelli RL, et al. Are financial payments from the pharmaceutical industry associated with physician prescribing? Ann Intern Med. 2020.

Case (on ICON)

- UI Conflict of Interest in Research: Scenarios and Sample Management Plans (Scenario Four – Dr. Wilma Gilbert & Welkers Pharma-A). Retrieved from: https://coi.research.uiowa.edu/researchers/scenarios-and-sample-management-plans

Week 15: May 3 ***Clinical Research Ethics in Developing Countries*** **(Lauris Kaldjian)**

Learning Objectives

Through this week's readings, case, and class discussion, we will aim to identify and understand:

- Vulnerable populations in international research.
- The "double-standards" argument and counter-argument.
- What international researchers can do to enhance subject protection.

Readings (on ICON)

- Angell M. (2000). Investigators' responsibilities for human subjects in developing countries. *N Engl J Med, 342*(13), 967-969. *{Note: you only need to read the first editorial by Angell.}*
- Garner SA, Anude CJ, Adams E, Dawson L. (2014). Ethical considerations in HIV prevention and vaccine research in resource-limited settings. *J Acquir Immune Defic Syndr, 67*(1), 77-83.
- Chi PC, Owino EA, Jao, I, et al. (2021). Understanding the benefits and burdens associated with a malaria human infection study in Kenya: Experiences of study volunteers and other stakeholders. Trials, 22(1), 494.

Case (on ICON)

- Cohen J, Kupferschmidt K. (2014). Ebola vaccine trials raise ethical issues. *Science*, *346*(6207):289-290.

9. Communication with the Course Instructor and Course Coordinator

Please feel free to contact the course instructor or course coordinator as needed by email. You should expect to receive replies by email within 24-48 hours. As needed, office meetings can be arranged to discuss questions in person.

10. Departmental Administrative Contact Information

If needed, the Departmental Executive Officer in the College of Public Health relevant to this course is Prof. James Torner, Chair, Department of Epidemiology (Office: C21P-1 GH, Phone: 384-5001).

11. Availability of Accommodations for Students with Disabilities

The Course Director would like to hear from anyone who has a disability which may require seating modifications or testing accommodations or accommodations of other class requirements, so that appropriate arrangements may be made. Please contact the Course Director by email.

12. Procedures for Student Complaints

It is the policy of The University of Iowa that each student shall be guaranteed certain rights and freedoms. A list of these rights and the procedures for complaints against faculty can be found at: http://www.uiowa.edu/~vpss/policies/i/d.shtml#main[Instructors

13. Collegiate Policy on Plagiarism

Plagiarism is the unacknowledged use of another's ideas expressed in either the author's original words or in a manner similar to the original form. It is the student's responsibility to seek clarification of any situation in which he/she is uncertain whether plagiarism is/has been involved. Policies governing plagiarism can be found at http://www.grad.uiowa.edu/Pubs/ManualRulesRegs.asp

14. University Nondiscrimination Policy

The University of Iowa prohibits discrimination and affirms its commitment to providing equal opportunities and equal access to university facilities. For additional information, contact:oie-ui@uiowa.edu.

15. ADDITIONAL READINGS/RESOURCES (NOT REQUIRED)

Introduction to Clinical Research Ethics

- Blustein J. (2007). The history and moral foundations of human-subject research. *Am J Phys Med Rehabil, 86*(2), 82-85.
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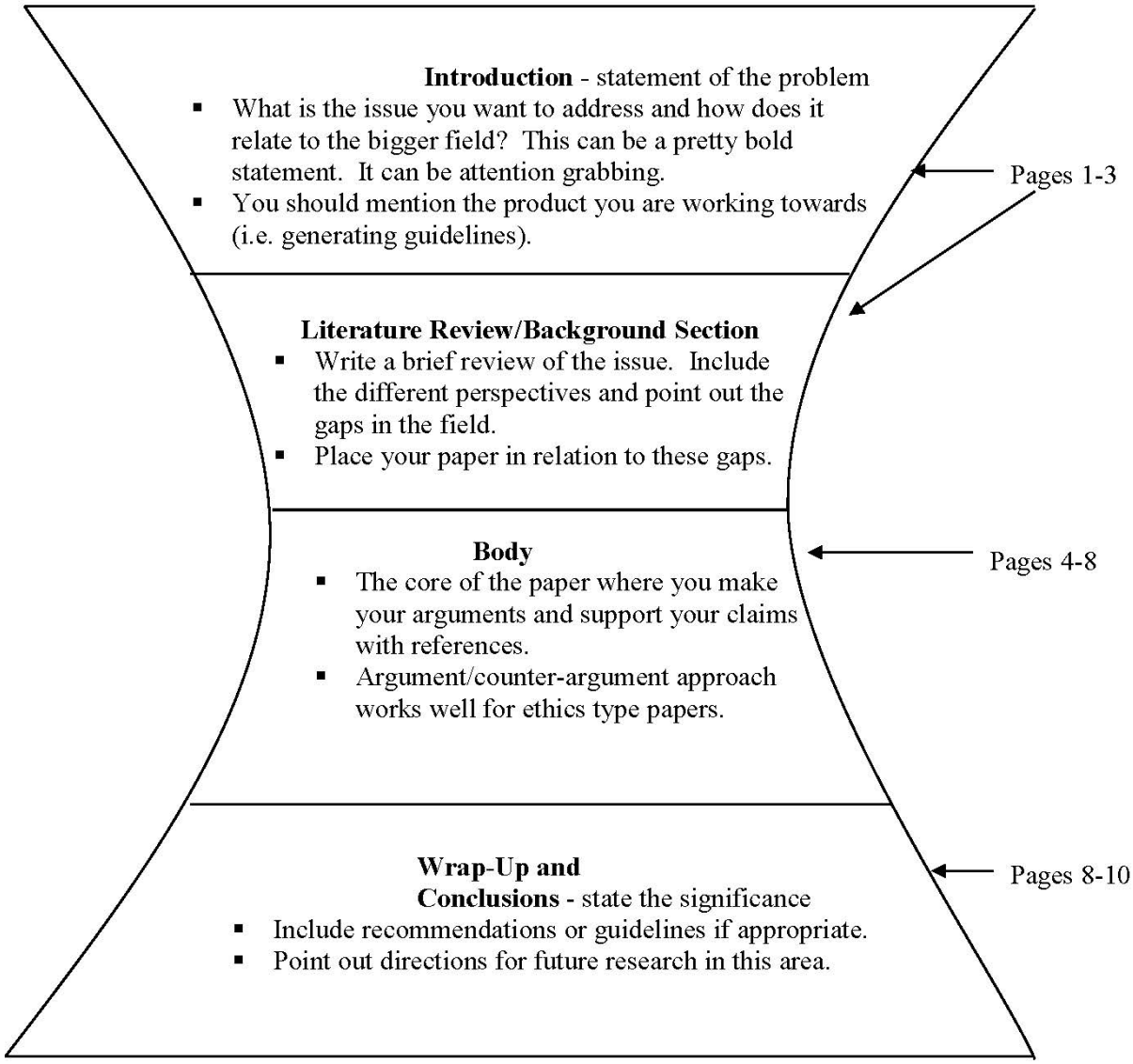
APPENDIX. RESEARCH ETHICS PAPER GUIDELINES & RESOURCES (FOR 3-CREDIT OPTION)



Purdue Online Writing Lab (OWL) is a helpful website that provides free writing and referencing resources.

The Biomedical Ethics Library Guide provides an introduction to sources of information having to do with all aspects of ethics in the biosciences and the health sciences. Information provided in this guide includes:

- useful definitions
- web guides to resources
- general references, codes and oaths
- **search indexes and some major periodical titles in the field of bioethics**
- organizations

An alphabetical list of databases/indexes can be found and accessed through the UI Libraries website at http://guides.lib.uiowa.edu/az.php. You will find the following databases/indexes most helpful:

1. PubMed - Provides access to bibliographic information in Medline and other sources. (See the available Help Sheet)
2. Academic Search Elite - This multi-disciplinary database offers full text for nearly 2,000 scholarly journals, including more than 1,500 peer-reviewed titles. Covering virtually every area of academic study, Academic Search Elite offers full text information dating as far back as 1985. This database is updated on a daily basis.
3. Catholic Periodical and Literature Index - Includes indexed citations to articles published in Roman Catholic periodicals, Papal documents, church promulgations, and books about the Catholic faith that are authored by Catholics and/or produced by Catholic publishers.
4. CINAHL Plus - [Help Sheet for Search CINAHL - PDF] CINAHL Plus provides indexing for 3,024 journals from the fields of nursing and allied health, with indexing back to 1937. CINAHL Plus also contains searchable cited references for more than 1,160 journals. Full text material includes more than 80 journals plus legal cases, clinical innovations, critical paths, drug records, research instruments and clinical trials. Offering complete coverage of English-language nursing journals and publications from the National League for Nursing and the American Nurses' Association, CINAHL covers nursing, biomedicine, health sciences librarianship, alternative complementary medicine, consumer health and 17 allied health disciplines.
5. Global Health - Global Health is the definitive international public health database for academics, researchers, NGOs, policy makers, clinicians, healthcare professionals and students.
6. LexisNexis Academic - Provides access to a wide range of news, business, legal research, medical and reference information. The news section provides access to full text of newspapers from the U.S., Europe, Africa, North and South America and Australia in English, as well as some in Dutch, French, German, Italian and Spanish; news wires, television and radio transcripts are also available.
7. Philosopher's Index - Provides indexing and abstracts from books and journals of philosophy and related fields--ethics, aesthetics, social philosophy, political philosophy, epistemology, and metaphysic logic as well as material on the philosophy of law, religion, science, history, education, and language.
8. Web of Science - A citation reference that includes Science Citation Index (1900-present), Social Science Citation Index (1900-present), Arts & Humanities Citation Index (1975-present), Book Citation Index- Science (2005-present), Book Citation Index- Social Sciences & Humanities (2005-present), and Medline, and links to Journal Citation Reports and EndNote web version.

Other helpful resources can be accessed through the Program in Bioethics and Humanities website at: https://medicine.uiowa.edu/bioethics/resources