

**HRM 742 DRAFT**  
**Ethical Issues in Research Involving Human Subjects**  
(Winter 2024)

**Instructor**

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*Sessions will be held in person. This class schedule is based upon current university and public health guidelines and may be subject to changes during the term. Any changes to the schedule or course delivery will be communicated on the course announcements section on Avenue to Learn. Please check the announcements prior to attending class.*

**Text**

- There is no book assigned for this course. Papers are identified for each session with web-links.
- Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2) is available on line <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epc2/Default/>
- For tips on paper writing: Pryor J. How to write a philosophy paper. 2006 Sep 7. Available from: <http://www.jimpryor.net/teaching/guidelines/writing.html>

**Assessment**

Mock REB	15%	Feb 5
<a href="#">TCPS Certificate</a>	5%	Feb 26 (certificate must be no more than 4 years old)
Paper outline	10%	March 4
Presentations	15%	March 18 – April 1
Paper	45%	April 8
Participation	10%	Discussion

**Schedule and Location (N.B: Subject to change at the discretion of the course leader)**

Date	Week	Content	Instructor(s)	Room
Jan 08	1	Overview / History / Theory	Lisa	HSC-2A3
Jan 15	2	Consent & Risk	Lisa	HSC-2A3
Jan 22	3	Privacy & Confidentiality Collecting equity-oriented data	Lisa Fatima Sheikh	HSC-2A3
Jan 29	4	Clinical trials	Lisa	HSC-2A3
Feb 05	5	Pediatric & emergency research <b>Mock REB;</b>	Melissa Parker	HSC-2A3
Feb 12	6	Qualitative Research Reflexivity and Positionality	Lisa	HSC-2A3
Feb 19	7	Family day – no classes		
Feb 26	8	A: Research Integrity B: Big Data & Public Health	Lisa Jennifer Salerno	HSC-2A3
Mar 04	9	Participatory Research <b>Outlines due</b>	TBD	HSC-2A3
Mar 11	10	Indigenous Research Global & Disaster Research	Chelsea Gabel Lisa	HSC-2A3
Mar 18	11	<b>Presentations</b>		HSC-2A3
Mar 25	12	<b>Presentations</b>		HSC-2A3
Apr 1	13	<b>Presentations</b>		HSC-2A3

Apr 8	14	Open class; <b>Papers due Apr 8</b>	Lisa	HSC-2A3 Email papers
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**Sessions will be held in person**

**Session 1** (Jan 08, 2024)

**Lecturers:** Lisa Schwartz

**Course Overview / History / Theoretical Foundations**

**Aims of the session:**

Using historical case examples, we will explore the dimensions of research ethics and the concepts and principles which underlie statements that guide ethics in research practice.

**Key questions to be addressed in this session are:**

- What is research ethics?
- What are principles and theories that underpin research ethics?
- How are these principles and theories applied and enacted?
- Why are they particularly relevant today?
- How can I be sure my research does not undermine justice?
- What is the scope of research requiring review?
- How does the governance of research ethics differ between Canada and the USA?

**Readings**

1. Emanuel E. J., Wendler D., & Grady C. (2000). What makes clinical research ethical? *JAMA*, 283(20), 2701-2711. <http://jamanetwork.com/journals/jama/article-abstract/192740>
2. Ashcroft, R. E. (2004). Current epistemological problems in evidence-based medicine. *Journal of Medical Ethics*, 30(2), 131-135. <http://jme.bmj.com/content/30/2/131>
3. Read S, Parfitt A, Bush T (2020) How do we know our research is 'inclusive'? *LSE Impact Blog* <https://blogs.lse.ac.uk/impactofsocialsciences/2020/10/27/how-do-we-know-that-our-research-is-inclusive/>
4. Pratt, B., Wild, V., Barasa, E., Kamuya, D., Gilson, L., Hendl, T., & Molyneux, S. (2020). Justice: a key consideration in health policy and systems research ethics. *BMJ Global Health*, 5(4), e001942. <https://gh.bmj.com/content/5/4/e001942.abstract>
5. TCPS2 ch 1, 2 & 4 (no need to read in detail, but please visit the website) <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

## Consent and Risk

### Aims of the session:

To review ethical principles and familiarize students with the Tri-Council Policy Statement and governance of human research in Canada.

### Key questions to be addressed in this session are:

- How can we respect the autonomy of the individual in research?
- What are the theoretical concepts supporting the idea of autonomy and consent?
- What are the limitations of consent?
- What are the best practices that can be applied to informed consent in research?
- What is “therapeutic misconception” and how is it relevant to autonomy & consent?
- How does one balance benefits and risks in research?
- How ought risk be communicated to research participant?
- Is there room for paternalism in respect for the autonomy of research participants?
- Do these concepts differ when dealing with therapeutic vs. non-therapeutic research?

### Readings

1. Emanuel E. J., Wendler D., & Grady C. (2000). What makes clinical research ethical? *Jama*, 283(20), 2701-2711. <http://jamanetwork.com/journals/jama/article-abstract/192740>
2. Hasnain-Wynia, R., & Baker, D. W. (2006). Obtaining data on patient race, ethnicity, and primary language in health care organizations: current challenges and proposed solutions. *Health services research*, 41(4 Pt 1), 1501-1518. <https://doi.org/10.1111/j.1475-6773.2006.00552.x>
3. Euzebiusz Jamrozik, Michael J Selgelid (2020) COVID-19 human challenge studies: ethical issues. *Lancet Infect Dis*; 20: e198-203 [https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30438-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30438-2/fulltext)
4. Witness History (2013) The Tuskegee Syphilis Study (9 min). *BBC World News Service*. Last aired on Sunday 20 Jan 2013. <https://www.bbc.co.uk/programmes/p013281q>
5. *BBC medical editor Fergus Walsh speaks to people volunteering to be infected with coronavirus to help find a vaccine.* <https://www.bbc.com/news/health-53862413>
6. *OPTIONAL: McHugh J. (2007 Apr 24). Drug Test Cowboys: The Secret World of Pharmaceutical Trial Subjects. WIRED Magazine, 15(5). Retrieved 18 May 2007 from* <https://www.wired.com/2007/04/feat-drugtest/>
7. TCPS ch 3 (no need to read in detail, but please visit the website)

### Assignment

If you have not already done so, complete the introductory tutorial for the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. Found at <https://tcps2core.ca/welcome>.

### Cases

We will be referring to the cases mentioned in the Spriggs and Edwards papers. For more information about these cases you may be interested in reviewing the following:

- Risk

- S2 E5 Human guinea pigs <https://www.cbc.ca/listen/shows/on-drugs/episode/15527493>
- Jesse Gelsinger
  - Bioethics: Gene therapy business: the tragic case of Jesse Gelsinger. News Weekly. 2000 Aug 12; [cited 2007 Apr 24]. Available from: [http://www.newsweekly.com.au/articles/2000aug12\\_bio.html](http://www.newsweekly.com.au/articles/2000aug12_bio.html)
  - Wikipedia contributors. Jesse Gelsinger. Wikipedia, The Free Encyclopedia. 2007 Apr 9; [cited 2007 Apr 24]. Available from: [http://en.wikipedia.org/w/index.php?title=Jesse\\_Gelsinger&oldid=121551802](http://en.wikipedia.org/w/index.php?title=Jesse_Gelsinger&oldid=121551802)
  - The Story of Jesse Gelsinger told by his father at US Congress on C-SPAN February 2, 2000. <https://www.c-span.org/video/?c4655135/story-jesse-gelsinger>
- Ellen Roche
  - John Hopkins Medicine. Report of Johns Hopkins internal investigation. 2001. [\[http://www.hopkinsmedicine.org/press/2001/JULY/report\\_of\\_internal\\_investigation.htm\]](http://www.hopkinsmedicine.org/press/2001/JULY/report_of_internal_investigation.htm)
  - Alliance for Human Research Protection. Johns Hopkins Admits Fault in Fatal Experiment. 2001 Jul 17; [cited 2007 Apr 24]. Available from: <http://www.ahrp.org/infomail/0701/17.php>
- Stanley Milgram
  - The Milgram Experiment 1962 <https://www.youtube.com/watch?v=rdrKCilEhC0>
  - Experimenter, 2015 (if available)

## Privacy and Confidentiality

### **Aims of the session:**

To introduce students to the “fair information principles” underlying most laws internationally, and to the CIHR’s Best Practices for Protecting Privacy in Health Research (2005).

### **Key questions to be addressed in this session are:**

- Why have privacy and confidentiality taken on such a high profile in recent years?
- The role of consent in “minimal risk” health research
- What are the challenges associated with research using registries and biobanks?
- How does Big Data affect privacy and how can it be used responsibly in research?

### **Readings:**

1. Willison, D. J., Swinton, M., Schwartz, L., Abelson, J., Charles, C., Northrup, D., Abelson J., Charles C., Northrup D., Cheng J. & Thabane, L. (2008). Alternatives to project-specific consent for access to personal information for health research: insights from a public dialogue. *BMC medical ethics*, 9(1), 18. [<https://bmcmethics.biomedcentral.com/articles/10.1186/1472-6939-9-18>]
2. Raquel Benbunan-Fich (2016) The ethics of online research with unsuspecting users: From A/B testing to C/D experimentation. *Research Ethics*. [<http://journals.sagepub.com/doi/abs/10.1177/1747016116680664>]
3. Rothstein M. A. (2013). Ethical research and minorities. *American journal of public health*, 103(12), 2118. <https://doi.org/10.2105/AJPH.2013.301390>
4. Stanbrook, M. & Salami, B. (2023) CMAJ’s new guidance on the reporting of race and ethnicity in research articles. *CMAJ* 2023 February 13;195:E236-8. doi: 10.1503/cmaj.230144 <https://www.cmaj.ca/content/195/6/E236>
5. TCPS2 ch 5

## Randomized Clinical Trials (RCTs)

### Aims of the session:

To clarify the concerns related to placebo controlled trials and the idea of clinical equipoise. Placebo controlled trials in the Canadian context – issues and controversies.

### Key questions to be addressed in this session are:

- What is equipoise?
- What is the ethics of methodological design?
- Are placebo controlled trials ever justified?

### Readings

1. Emmanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701- 2780. [<http://jama.ama-assn.org/cgi/reprint/283/20/2701>]
2. Weijer C, Miller PB. When are research risks reasonable in relation to anticipated benefits? *Nat Med*. 2004;10(6):570-573. [<http://www.nature.com/nm/journal/v10/n6/pdf/nm0604-570.pdf>]
3. Weijer C. Placebo trials and tribulations. *Can Med Assoc J*. 2002 Mar 5;166(5):603-4. [<http://www.cmaj.ca/cgi/content/full/166/5/603>]
4. Freedman, B. (1987). Equipoise and the ethics of clinical research. *N Engl j Med*, 317(3), 141-145. [<http://crystal.lib.buffalo.edu/libraries/reserve/course/phi337/freedman.pdf>]
5. London, A. J., & Kimmelman, J. (2020). Against pandemic research exceptionalism. *Science*, 368(6490), 476-477. <https://www.science.org/doi/full/10.1126/science.abc1731>
6. Euzebiusz Jamrozik, Michael J Selgelid (2020) COVID-19 human challenge studies: ethical issues. *Lancet Infect Dis*; 20: e198–203  
[https://www.thelancet.com/journals/laninf/article/PIIS1473-3099\(20\)30438-2/fulltext](https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30438-2/fulltext)
7. TCPS ch 11

## Pediatric & Emergency Research

### Aims of the session:

To explore factors influencing the evolution of Institutional Review Boards/Research Ethics Boards, their place within the institutional research enterprise, and the internal and external perceptions of Board functioning. Experience the challenges tough research studies impose on research ethics review. How will you respond to the research board applicants?

### Key questions to be addressed in this session are:

- Why is there a need for IRB/REBs?
- How do they do their job?
- What special challenges do they face?
- Building an institutional “culture of ethical integrity”

### Readings:

1. Coleman, C. H., & Bouësseau, M. C. (2008). How do we know that research ethics committees are really working? The neglected role of outcomes assessment in research ethics review. *BMC Medical Ethics*, 9(1), 6. <https://bmcomedethics.biomedcentral.com/articles/10.1186/1472-6939-9-6>
2. Edwards SJK, Kirchin S, Huxtable R. Research Ethics Committees and Paternalism. *J Med Ethics*. 2004;30:88-91. <http://jme.bmj.com/content/medethics/30/1/88.full.pdf>
3. Spriggs M. Canaries in the mines: children, risk, non-therapeutic research and justice. *J Med Ethics*. 2004;30:176-181. [<http://jme.bmj.com/cgi/reprint/30/2/176.pdf>]
4. TCPS2 ch 6

**\*\*The second half of this session will involve\*\***

**The Mock REB**

Please come prepared with your notes

### Ethical Issues in Qualitative

**Aims of the session:**

- To better understand the features of and approaches to qualitative research, including relevant ethical considerations including challenges of privacy, risk and adequate ethics review.
- To consider some of the ethical and social issues related to conducting qualitative research and how to move forward with a research plan even when working on sensitive or risky topics.
- Develop and understanding some of the constrictors that influence qualitative research when assessing risk and when trying negotiate the review process.

**Key questions to be addressed in this session are:**

- What are some of the problems qualitative researchers encounter in their work?
- Identifying and assessing participant risk?
- Creating strategies for proactively addressing potential risk especially with vulnerable populations?

### Readings

1. Hadjistavropoulos, Thomas and Smythe, W.E. (2001) Elements of risk in qualitative research. *Ethics & Behavior*, 11(2) 163-174  
[\[http://www.tandfonline.com/doi/abs/10.1207/S15327019EB1102\\_4\]](http://www.tandfonline.com/doi/abs/10.1207/S15327019EB1102_4)
2. Richards HM, Schwartz LJ. (2002) Ethics of qualitative research: are there special issues for health services research? *BJGP*.  
[\[https://academic.oup.com/fampra/article/19/2/135/490936/Ethics-of-qualitative-research-are-there-special\]](https://academic.oup.com/fampra/article/19/2/135/490936/Ethics-of-qualitative-research-are-there-special)
3. E Nouvet, C Abu-Sada, S de Laat, C Wang, L Schwartz (2016) Opportunities, limits and challenges of perceptions studies for humanitarian contexts. *Canadian Journal of Development Studies*. 37(3):358-377.  
[\[http://www.tandfonline.com/doi/abs/10.1080/02255189.2015.1120659\]](http://www.tandfonline.com/doi/abs/10.1080/02255189.2015.1120659)
4. Langford DR. Pearls, pith, and provocation. Developing a safety protocol in qualitative research involving battered women. *Qual Health Res*. 2000;10(1):133-142. [\[http://qhr.sagepub.com/cgi/reprint/10/1/133\]](http://qhr.sagepub.com/cgi/reprint/10/1/133)
5. *OPTIONAL*: Dyregrov K. Bereaved parents' experience of research participation. *Soc Sci Med*. 2004;58:391-400. [\[http://scholarsportal.info/pdflinks/06032409194527410.pdf\]](http://scholarsportal.info/pdflinks/06032409194527410.pdf)
6. TCPS2 ch 10

**Case** Consider Langford's study on safety protocols and spousal abuse.

1. Put yourself in the shoes of the researchers; what would be some of your concerns? What questions do you have about conducting this type and other types of qualitative research that could be clarified by the guest lecturer?
2. What direction does the TCPS provide the researchers? What does it leave uncovered?
3. Imagine you sit on the REB that reviewed this study's protocol. What privacy, confidentiality and data security issues present themselves to you? Would you permit this research to go forward? Why or why not? What advice would you give the researchers to assist them in preparing to carry out such research?



**Session 7** (Feb 19, 2024)

**Lecturer:** Lisa Schwartz

**Family Day – No class**

➤ **Have a good break!**

## Part A: Big Data & Public Health Research Ethics

### Aims of the session:

After the discussion of privacy in the previous week, we will explore the responsible sharing of data on a bigger scale and examine the tensions with surveillance. This session to questions about use of routinely collected data, and values that drive data sharing.

### Key questions to be addressed in this session are:

- How does Big Data affect privacy and how can it be used responsibly in research?
- What values should drive data sharing and use?
- What is public health ethics and is it different from research ethics?
- What are the tensions between public health surveillance and research?

### Readings:

1. Ienca, M., Ferretti, A., Hurst, S., Puhan, M., Lovis, C., & Vayena, E. (2018). Considerations for ethics review of big data health research: A scoping review. *PloS one*, 13(10), e0204937. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0204937>
2. Salerno, J., Knoppers, B. M., Lee, L. M., Hlaing, W. M., & Goodman, K. W. (2017). Ethics, big data and computing in epidemiology and public health. *Annals of epidemiology*, 27(5), 297-301. <https://www.sciencedirect.com/science/article/abs/pii/S1047279717300017#!>
3. OPTIONAL: WHO guidelines on ethical issues in public health surveillance <https://www.who.int/ethics/publications/public-health-surveillance/en/>
4. TCPS2 ch 5

## Part B: Research Integrity, Falsification, Fabrication and Plagiarism

### Aims of the session:

Now infamous scholar Diederik Alexander Stapel Dutch former professor of social psychology at Tilburg University has said *“When the results are just not quite what you’d so badly hoped for; when you know that that hope is based on a thorough analysis of the literature; when this is your third experiment on this subject and the first two worked great; when you know that there are other people doing similar research elsewhere who are getting good results; then, surely, you’re entitled to adjust the results just a little?”* Is he right?

### Key questions to be addressed in this session are:

- What is research integrity and why does it matter?
- What are the three great trespasses in research integrity?
- How should breaches of research integrity be managed?
- What are the tensions between hyper-vigilance and academic freedom in research?

### Readings:

8. Hampson L.A., Agrawal M., Joffe S., Gross C.P., Verter J., & Ezekiel J. Emanuel E. (2006). Patients' Views on Financial Conflicts of Interest in Cancer Research Trials N Engl J Med 2006; 355:2330-2337 November 30, 2006 DOI: 10.1056/NEJMsa064160  
<http://www.nejm.org/toc/nejm/355/22/>
9. Please watch this video, especially 13:00 – to the end Toespraak Diederik Stapel in TEDx Braintrain (lange versie) <https://www.youtube.com/watch?v=WUGh2VWR4JA>
10. Academic Integrity <https://www.cbc.ca/news/community-members-say-they-are-displeased-at-carrie-bourassa-1.6234213>

## Participatory Research & Engagement

### Aims of the session:

Understand the significance of engaging with communities and including them in research development and practice. Discuss 'good participatory practices' in research and how engagement and inclusion can support better research and outcomes.

### Key questions to be addressed in this session are:

- What is community engagement in research, and why is it important?
- What ethical concerns may engagement raise?
- How can we apply engagement practices in research?

### Readings

1. TBD
2. WHO (2020) R&D Good Participatory Practice for COVID-19 clinical trials: a toolbox  
<https://www.who.int/publications/m/item/r-d-good-participatory-practice-for-covid-19-clinical-trials-a-toolbox>
3. WHO (2020) Working with Community Advisory Boards for COVID-19 related clinical studies  
<https://www.who.int/publications/m/item/working-with-community-advisory-boards-for-covid-19-related-clinical-studies>
4. TCPS ch 9

## Research Involving Indigenous Communities

### Aims of the session:

To explore the unique research relationship that exists between academic researchers and Indigenous communities, particularly with respect to how these relationships must be guided by a shared understanding of ethical research behaviour in Indigenous communities.

### Key questions to be addressed in this session are:

- How to foster respectful research relationships between Indigenous communities and researchers, and how the ethical 'needs' of both communities and researchers can be met.
- Exploration of research methods for Indigenous research

## Readings

1. Brant Castellano, M., Reading, J. (2010). Policy Writing as Dialogue: Drafting an Aboriginal Chapter for Canada's Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans. *The International Indigenous Policy Journal*, 1(2). Retrieved from: <http://ir.lib.uwo.ca/iipj/vol1/iss2/1> DOI:10.18584/iipj.2010.1.2.1  
[\[http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1010&context=iipj\]](http://ir.lib.uwo.ca/cgi/viewcontent.cgi?article=1010&context=iipj)
2. Hyett, S., Marjerrison, S., & Gabel, C. (2018). Improving health research among Indigenous Peoples in Canada. *CMAJ*, 190(20), E616-E621.
3. Smith, L. T. (1999). *Decolonizing methodologies: Research and indigenous peoples*. Zed books. Chapter 6.
4. TCPS2 Ch 9 and CORE Module 9 if you have time  
[\[http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/\]](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)
5. *OPTIONAL*: Ninomiya, M. E. M., & Pollock, N. J. (2017). Reconciling community-based Indigenous research and academic practices: Knowing principles is not always enough. *Social Science & Medicine*, 172, 28-36.  
[\[http://www.sciencedirect.com/science/article/pii/S0277953616306062\]](http://www.sciencedirect.com/science/article/pii/S0277953616306062)

**Session 12 & 13** (March 25 & April 1, 2024)

**Lecturer:** Lisa Schwartz

### **Student Presentations**

**Aims of the session:**

Students will present outlines of their final papers for comment from the class.

**Key questions to be addressed in this session are:**

- What is the core ethical issue of your paper?
- What is at stake and for whom?
- Who stands to benefit from this research?
- Who may be harmed?
- How are matters of justice approached in this analysis?

## Global & disaster health research

### Aims of the session:

Cultural differences across communities may have an impact on how research is conducted with individuals in those communities. In this session, we will address challenges in conducting research outside of Canada, the USA, and Western Europe, where human subject protections may be less stringent. Justice, obligation, responsiveness & responsibility in global health research will be examined.

### Key questions to be addressed in this session are:

- How to avoid exploitation of human subjects in global health research.

### Readings:

1. Canadian Coalition for Global Health Research CCGHR principles <http://www.ccghr.ca/resources/principles-global-health-research/>
2. Tangwa, G. B. (2017). Giving voice to African thought in medical research ethics. *Theoretical Medicine and Bioethics*, 1-10. [http://www.readcube.com/articles/10.1007/s11017-017-9402-3?author\\_access\\_token=USqmTvdaVFo3WcCxI2tCove4RwIQNchNByi7wbcMAY7NaNKq7CFrzEIUfvxzbNotbmNRmy31HnCmaPA1S-3PF5rc1FWiyzuX1bwBh8QyEBYaNiRcVEoVJJ91W11xjzd9NX0lpR\\_SkKdRYfah2b-iw%3D%3D](http://www.readcube.com/articles/10.1007/s11017-017-9402-3?author_access_token=USqmTvdaVFo3WcCxI2tCove4RwIQNchNByi7wbcMAY7NaNKq7CFrzEIUfvxzbNotbmNRmy31HnCmaPA1S-3PF5rc1FWiyzuX1bwBh8QyEBYaNiRcVEoVJJ91W11xjzd9NX0lpR_SkKdRYfah2b-iw%3D%3D)
3. Jumbam, D. T. (2020). How (not) to write about global health. *BMJ Global Health*, 5(7), e003164.
4. Schopper, D., Upshur, R., Matthys, F., Singh, J. A., Bandewar, S. S., Ahmad, A., & van Dongen, E. (2009). Research ethics review in humanitarian contexts: the experience of the independent ethics review board of Médecins Sans Frontières. *PLoS Med*, 6(7), e1000115. <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000115>
5. Carter, S. E., Gobat, N., Zambruni, J. P., Bedford, J., Van Kleef, E., Jombart, T., ... & Ahuka-Mundeke, S. (2020). What questions we should be asking about COVID-19 in humanitarian settings: perspectives from the social sciences analysis cell in the Democratic Republic of the Congo. *BMJ Global Health*, 5(9), e003607. <https://gh.bmj.com/content/5/9/e003607.abstract>
6. TCPS2 ch 8

### Supplemental optional readings:

- a. Calain P, Fiore N, Poncin M, Hurst SA. Research Ethics and International Epidemic Response: The Case of Ebola and Marburg Hemorrhagic Fevers. *Public Health Ethics* 2009;2(1):7–29. <http://phe.oxfordjournals.org/content/2/1/7.abstract>
- b. Lie RK, Emanuel E, Grady C, Wendler D. The standard of care debate: the Declaration of Helsinki versus the international consensus opinion. *J Med Ethics*. 2004;30(2):190-193. <http://jme.bmjournals.com/cgi/reprint/30/2/190.pdf>
- c. Beyer C, Kass NE. Human rights, politics, and reviews of research ethics. *Lancet*. 2002;360(9328):246-251. [http://www.sciencedirect.com/science?\\_ob=MIimg&\\_imagekey=B6T1B-46B6X0Y-11-1&\\_cdi=4886&\\_user=1067350&\\_orig=browse&\\_coverDate=07%2F20%2F2002&\\_sk=996390671&\\_view=c&\\_wchp=dGLbVtb-zSkzk&\\_md5=3bdc49c8e3a01cd3c16e1758e44fa865&\\_ie=/sdarticle.pdf](http://www.sciencedirect.com/science?_ob=MIimg&_imagekey=B6T1B-46B6X0Y-11-1&_cdi=4886&_user=1067350&_orig=browse&_coverDate=07%2F20%2F2002&_sk=996390671&_view=c&_wchp=dGLbVtb-zSkzk&_md5=3bdc49c8e3a01cd3c16e1758e44fa865&_ie=/sdarticle.pdf)

## Disaster Research Ethics

### Aims of the session:

Explore the ethical, methodological and logistical challenges for researchers and research ethics board in research during or after disasters such as public health crises, natural disaster, refugee and conflict settings.

### Key questions to be addressed in this session are:

- Are there changes in approach that need to be considered in disaster research ethics?

### Readings

1. Edward Cox, M.D., M.P.H., Luciana Borio, M.D., and Robert Temple, M.D. (2014). Evaluating Ebola Therapies — The Case for RCTs. *N Engl J Med*; 371:2350-2351 December 18, 2014 DOI: 10.1056/NEJMp1414145 <http://www.nejm.org/doi/full/10.1056/NEJMp1414145#t=article>
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