



Course Code & Title	LISS328 Ethics of Clinical Research				
Convenor(s)	Dr Silvia Camporesi, Department of Global Health & Social Medicine				
Institution	King's College London	Department	LISS DTP		
Academic Year	2020-21	Term	Summer		
Number of sessions	8	Research Platform	Social Theory & Epistemology	Length of Session(s)	Various
Day, Date		Start : End		Room Location	
Monday 17 May 2021		9:30 – 17:00		Microsoft Teams and KEATS – link to be sent after enrolment via Skillsforge	
Tuesday 18 May 2021		9:30 – 17:00			
Wednesday 19 May 2021		9:30 – 17:00			
Thursday 20 May 2021		9:30 – 17:00			
Friday 21 May 2021		9:30 – 17:00			
Tuesday 1 June 2021		9:30 – 13:00			
Wednesday 2 June 2021		9:30 – 13:00			
Thursday 3 June 2021		9:30 – 13:00			
Enrolment Links:	https://bit.ly/LISS328 You will be prompted to log into SkillsForge				

Course Description:

This module aims to provide an introduction to the foundations of clinical research ethics. The first half of the course introduces students to fundamental concepts and key frameworks used in research ethics. The second half of the course puts these concepts and frameworks to work by discussing current topics in clinical research ethics, such as genetic research and bio-banking or international research. The closing session invites students to reflect on the extent to which clinical research ethics is “exceptional”, compared to how we reason about ethics in other areas of life, as some commentators have claimed.

On successful completion of the module, students will:

Demonstrate a critical understanding of fundamental concepts and key frameworks in clinical research ethics;

Be familiar with, and able to critically appraise, current topics in clinical research ethics; and

Be able to act as independent and critical learners who manage their own requirements for continuing academic and professional development.

Reading List:

Abadie, R. (2010). *The professional guinea pig: Big Pharma and the risky world of human subjects*. Durham: Duke University Press.



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Danis M, Largent E, Wendler D, Hull SC, Shah S, Millum J, Berkman B, Grady C: Research ethics consultation: a casebook. Oxford University Press: 2012.

Faden, R and Beauchamp T (1986), A History and Theory of Informed Consent, New York: Oxford University Press.

Goldacre B: Bad Pharma: How Medicine is Broken, and How We Can Fix It. Fourth Estate 2013.

Lederer, Susan. 1997. Subjected to science : human experimentation in America before the Second World War. Johns Hopkins Paperbacks ed. Baltimore: Johns Hopkins University Press.

Miller FG: The Ethical Challenges of Human Research: Selected Essays. Oxford University Press 2012.

Petryna, A. (2009). When experiments travel: clinical trials and the global search for human subjects. Princeton University Press.

Richardson, H. (2012). Moral entanglements: The ancillary-care obligations of medical researchers. Oxford University Press.

Skloot, R. (2011). The immortal life of Henrietta Lacks. Broadway Books.

Wendler, D. (2010). The ethics of pediatric research. Oxford University Press.

Emanuel EJ, Grady C, Crouch RA, Lie R, Miller F, Wendler D (Eds.): The Oxford Textbook of Clinical Research Ethics. Oxford University Press 2008.

Fisher J: Medical Research For Hire: The Political Economy of Pharmaceutical Trials. Rutgers University Press 2008.

Kimmelman J: Gene Transfer and the Ethics of First-in-Human Research: Lost in Translation. Cambridge University Press 2009.

Klitzman RL: The Ethics Police? The Struggle to Make Human Research Safe. Oxford University Press 2015.

Hawkins JS, Emanuel EJ (Eds.): Exploitation and Developing Countries: The Ethics of Clinical Research. Princeton University Press 2008.

Wertheimer A: Rethinking the Ethics of Clinical Research: Widening the Lens. Oxford University Press 2010.

Useful websites:

Council for International Organizations of Medical Sciences (CIOMS), International Ethical Guidelines for Biomedical Research Involving Human Subjects. Geneva: CIOMS 2001:

http://cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm

Cash R, Wikler D, Saxena A, Capron A (eds). Casebook on Ethical Issues in International Health Research. Geneva: World Health Organization, 2009:

http://whqlibdoc.who.int/publications/2009/9789241547727_eng.pdf

Nuffield Council on Bioethics, numerous research-related reports: <http://nuffieldbioethics.org>

U.S. Presidential Commission for the study of bioethical issues, numerous research-related reports:

<http://bioethics.gov>



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U.S. National Institutes of Health, Office of Clinical Research and Bioethics Policy:

<http://osp.od.nih.gov/office-clinical-research-and-bioethics-policy>

World Health Organization, Research ethics resources: who.int/rpc/research_ethics/en/

World Health Organization / Global Health Network, Research Ethics Online Training:

<http://globalhealthtrainingcentre.tghn.org/elearning/research-ethics/>

World Medical Association (WMA), WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. WMA: Fortaleza 2013: <http://wma.net/en/30publications/10policies/b3/>

Pre-course preparation:

You should be contacted shortly before the course with details of pre-course requirements

Number of students: 5