

April 26, 2023

Good Morning,

We trust you have had a fun filled teaching semester and now have some time planned off to enjoy the warming weather. Before we truly finish the academic term off, we are very excited to announce our second speaker in *The Road to Reproducible and Translatable Pre-clinical Research* seminar series – a new initiative of the SSMD Office of Research and Innovation, Pre-clinical Research – which spotlights new and innovative methodologies in pre-clinical research as well as the latest thinking underlying best practices in *in vivo* and *ex vivo* pre-clinical research programs. You might remember, Dr Joe Garner from Stanford was able to be our inaugural lecturer in 2021. This year we are very privileged to host Dr. Jonathan Kimmelman of McGill University as our guest lecturer.

Lectures by Professor Jonathan Kimmelman

Professor Jonathan Kimmelman will present two lectures in person** in **DSB 1002** on May 11th and 12th, 2023:

1. **Thursday, May 11th, 3:30 – 4:30 pm** – ‘The Reproducibility Crisis, Preclinical Research and Ethics’
2. **Friday, May 12th, 10:00 – 11:00 am** – ‘Justifying First-in-Human Trials of New Drugs: The PATH Approach’

Additionally, Dr. Kimmelman will be hosting a lunch with graduate students on the **Friday, May 12th at 12 noon**. If you know of graduate students who might be interested in joining the lunch program, please ask that they complete the sign-up form (<https://forms.gle/z3qSvn6LraF3ssiG9>). **Please note that spots are limited and only the first 15 will be accommodated.**

Further information will be released shortly, and in the meantime, we encourage you to disseminate this information to your research groups and to place a hold in your calendars to attend what promises to be an exciting information sharing opportunity.

Should you have any questions and or wish to meet with Dr Kimmelman on the afternoon of May 12th, please don't hesitate to contact me at your convenience.

Best,



Tim Regnault PhD
Assistant Dean - Preclinical research, SSMD
Professor - Departments of Obstetrics and Gynaecology and Physiology and Pharmacology
Scientist - Children's Health Research Institute

Brief Bio of Jonathan Kimmelman

Jonathan Kimmelman, PhD, is the James McGill Professor of Biomedical Ethics at McGill University, runs his own research group, STREAM (Studies in Translation, Ethics and Medicine) and was formally director of the Biomedical Ethics Unit. Dr. Kimmelman's research centers on ethical, policy, and scientific dimensions of clinical development. He received the Maud Menten New Investigator Prize (2006), a CIHR New Investigator Award (2008), a Humboldt Bessel Award (2014), and was elected a Hastings Center Fellow (2018). He has sat on various advisory bodies within the U.S. NHLBI and NIAID, served for four tours of duty on U.S. National Academies of Medicine committees, and chaired the International Society of Stem Cell Research Guidelines for Stem Cell Research and Clinical Translation revision task force (2015-16). His research has been covered in major media outlets, including NPR's All Things Considered, STATNews, and Nature. Dr. Kimmelman is deputy editor at Clinical Trials, and associate editor at Med.

For the most up-to-date information about Dr. Kimmelman, including recent publications, lab members and press clips, please visit: <http://www.translationalethics.com/>

Lectures **

Lecture 1 - 'The Reproducibility Crisis, Preclinical Research and Ethics

Thursday, May 11th
3:30 – 4:30 pm

Learning Objectives:

- Understand how reproducibility and translation crises affect harm: benefit when it comes to ethical approval
- Identify key issues, and simple solutions in experimental design that should be enforced
- Identify appropriate methods of power calculation and numbers justification

Lecture 2 - 'Justifying First-in-Human Trials of New Drugs: The PATH Approach'

Friday, May 12th
10:00 – 11:00 am

Learning Objectives:

- Understand the relationship between a trial's expected value and the basic and preclinical science supporting it
- Recognize problems with how basic and preclinical supporting evidence is currently assessed in clinical trial submissions
- Understand the basic structure of basic and preclinical evidence supporting an early phase clinical trial
- Learn some basic methods for assessing the strength of a basic and preclinical evidence supporting early phase trials of new drugs

One-on-one Meetings

Please contact Tim Regnault (tim.regnault@uwo.ca) to arrange.

****Zoom will be available upon request**

Please reach out to stacey.bastien@schulich.uwo.ca