

INFORMATION SHEET

Capacity Building in Ethics for Scientists across the Translational Spectrum

Principal Investigator: Jonathan Herington, PhD

This form describes a research study that is being conducted by Jonathan Herington from the University of Rochester's Department of Health Humanities and Bioethics. The purpose of this study is to pilot and evaluate a course on the ethics of translational research for emerging translational researchers.

If you decide to take part in this study, you will be asked to participate in a course on the ethics of translational research targeted at trainee translational scientists. You will also be asked to complete a survey instrument pre- and post-course to assess your ethical decision-making capacity, as well as participate in a focus group at the conclusion of the course. We estimate that approximately 15 subjects will take part in this study.

Your participation will last for approximately 10 weeks, with (i) 8 x 2-hour classroom sessions, (ii) a 90-minute focus group session at the conclusion of the course, and (iii) the completion of two survey instruments online (of approximately 30-45 minutes each). The classroom sessions will involve eight in-person, classroom discussions of ethical questions in translational research with the other subjects in this study. All sessions will be conducted by a study team member in a private conference room within the School of Medicine and Dentistry. These classes will require some pre-reading of material. They will not be recorded or involve formal assessment beyond the pre- and post-survey. The pre- and post-survey instruments will be collected online. You will be emailed a unique link to both the pre-survey and post-survey that will associate your answers at the beginning and end of the study. Finally, at the conclusion of the study you will be assigned to one of two focus groups, which will involve discussions with up to 8 other subjects about your attitudes towards the course and translational research ethics more generally.

You will receive communications about this study via email. Messages will be limited to class session and focus group scheduling, session reminders, distribution of readings and the distribution of the survey. Email communications between you and the study team may be filed in your research record. You will not be expected to reply to these emails and the content of emails will not be used as part of the research data.

Email communications may be sent or received in an unencrypted (unprotected) manner. Therefore, there is a risk that the content of the communication, including your personal information, could be shared beyond you and the study team. Your participation in the study indicates that you understand this risk. The University of

Rochester is not responsible for any interception of messages sent through email or texting.

Participating in this study offers no direct benefit and poses no more than minimal risks. The focus group meeting will be video recorded and thus will result in identifiable data collection. This could expose you to the risk of some reputational loss if (i) you disclosed breaches of professional ethics within the focus group, and (ii) there were a breach of confidentiality. To mitigate the risk of a confidentiality breach, all focus groups will be conducted by a study team member in a private conference room within the School of Medicine and Dentistry. At the conclusion of the discussion, the audio from the video recordings will be extracted and transcribed using a secure transcription service. PI Herington will remove your name, roles, and other identifying information from the transcripts of the interviews. The de-identified transcripts will be stored separate to the video/audio recordings on a secure University of Rochester server. The original audio and video will be stored separately, accessible only to PI Herington, and will be destroyed at the conclusion of the study.

There is also a small chance that some of the class or focus group discussions may make you feel uncomfortable. This could expose you to the risk of some reputational loss if (i) you disclosed breaches of professional ethics within the classroom session, and (ii) there was a breach of confidentiality. To mitigate the risk of a confidentiality breach, all subjects will be instructed that the discussions in this course are confidential and are not to be shared outside of the classroom. You may leave any session at any time. There is also a small possibility that some of the questions from the surveys may make you feel uncomfortable. You may skip any questions you don't want to answer. There are no other expected risks to you for participating in the study.

The University of Rochester is receiving payment from National Center for Advancing Translational Science (NCATS) for conducting this research study. You will be paid \$1000 for participating in this study. There will be no cost to you to participate in this study. You are free to decline to participate in the study or withdraw your data at any time before the publication of the work, and your payment will be pro-rated according to the following schedule.

Completion of...	Incentive (\$)	Total incentive (\$)
Pre-survey	50	50
Week 1	50	100
Week 2	100	200
Week 3	100	300
Week 4	100	400
Week 5	100	500
Week 6	100	600
Week 7	100	700
Week 8	100	800
Focus Group and Post-Survey	200	1,000

Payment received for taking part in research is considered taxable income. If you receive payment for your taking part in studies at the University of Rochester of \$600.00 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. You may be asked to submit a W-9 form, which includes your Social Security Number. If you are asked to complete a W-9 form and we find that you are not a US citizen or permanent resident, we may need to withhold 30% of your payment for taxes consistent with tax requirements.

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, only de-identified transcripts will be made available to the study team beyond PI Herington and co-I Ross. Audio and video recordings of interviews, alongside a subject enrollment key, will be stored separately (accessible only to PI Herington and co-I Ross). Sometimes, however, researchers need to share information that may identify you with people that work for the University, or the National Institutes of Health. If this does happen we will take precautions to protect the information you have provided. Deidentified results of the research may be presented at meetings or in publications. Your name or other identifiable information will not be used.

The National Institutes of Health (NIH) issued a Certificate of Confidentiality (CoC) for this study. A Certificate of Confidentiality provides extra protection for you and any information and/or samples (blood, tissue, etc.) collected from you as part of this study because it prevents us from disclosing this information in a lawsuit or legal proceeding. We cannot release your study information in a lawsuit or legal proceeding unless you provide your consent for us to do so. This is an extra layer of protection above the already existing protections in place for you and any information and/or samples (blood, tissue, etc.) collected from you as part of this study. However, these protections do not apply in some situations. For example, we may have to release your information if a law requires us to do so, the Agency funding this study requests the information, or if the FDA tells us to release this information. You should visit the NIH website at <https://grants.nih.gov/policy/humansubjects/coc.htm> to learn more.

Your participation in this study is completely voluntary. You are free not to participate or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefits to which you are otherwise entitled.

If you are a student at the University of Rochester, you should note that participating in this study will not affect your class standing or grades at the University of Rochester. You will not be offered or receive any special consideration if you take part in this research.

If you are an employee of the University of Rochester, you should note that taking part in this research is not a part of your University duties, and refusing will not affect your

job. You will not be offered or receive any special job-related consideration if you take part in this research.

For more information or questions about this research you may call Jonathan Herington at (585) 275-5800. Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.