Ethical Challenges and Best Practices for Virtual Biorepositories

June 26, 2017

You are being invited to participate in a research study because you are a professional or other stakeholder working in the area of biorepository research. Your participation involves the completion of a survey, an interview, participation in focus groups, and/or observations during meetings and phone calls. Interviews and focus groups may be audio recorded and should last about 1 hour. The only known risks for your participation in this research study may include some discomfort of expressing you opinion or difficulty of answering some of the questions. The information collected may not benefit you directly. The information learned in this study may be helpful to others. The potential benefit from this study will be to improve how biorepository networks identify and address ethical and regulatory challenges. If you are completing the survey, you can choose to be entered into a drawing to win one of three $100 gift cards to Amazon. The information collected for this study will be stored on a password protected computer and any paper documents will be in a locked file cabinet kept in the research team's office**.**

Individuals from the University of Louisville, Case Western Reserve University, Mayo Clinic, University of North Carolina at Chapel Hill, the Institutional Review Board (IRB), the Human Subjects Protection Program Office (HSPPO), and other regulatory agencies may inspect these records. In all other respects, however, the data will be held in confidence to the extent permitted by law. Should the data be published, your identity will not be disclosed.

Taking part in this study is voluntary. This preamble will be reviewed at the beginning of interviews and focus groups. By completing the survey and/or taking part in the interview, focus group or observations you will be consenting to this study. You can ask the study team questions during this time about the study. This information may be recorded, stored and may be reviewed at a later date for this study. You do not have to answer any questions that make you uncomfortable**.** You may choose not to take part at all. If you decide to be in this study you may stop taking part at any time. If you decide not to be in this study or if you stop taking part at any time, you will not lose any benefits for which you may qualify.

If you have any questions, concerns, or complaints about the research study, please contact Dr. Kyle Brothers at the University of Louisville 502-588-0797 or Aaron Goldenberg at Case Western Reserve University at 216-368-8729.

If you have any questions about your rights as a research subject, you may call the Human Subjects Protection Program Office at (502) 852-5188. You can discuss any questions about your rights as a research subject, in private, with a member of the Institutional Review Board (IRB). You may also call this number if you have other questions about the research, and you cannot reach the study doctor, or want to talk to someone else. The IRB is an independent committee made up of people from the University community, staff of the institutions, as well as people from the community not connected with these institutions. The IRB has reviewed this research study.

If you have concerns or complaints about the research or research staff and you do not wish to give your name, you may call 1-877-852-1167. This is a 24 hour hot line answered by people who do not work at the University of Louisville.

Sincerely,

Kyle Brothers
Assistant Professor of Pediatrics
University of Louisville

Aaron Goldenberg
Associate Professor of Bioethics
Case Western Reserve University