Scenarios – People, Tissues, Cells, & Data: Key Ethical Considerations and Resources

Things to think about

A. Would REB clearance be required for Queen's University?
B. Would REB clearance be required at another Institution?
C. Would participant consent be required?
D. Would Queen's affiliated hospital approvals be required through submission of a TRAQ DSS?
E. Would an Agreement be required through the Contracts Unit?
F. Would a Biosafety permit be required through Environmental Health and Safety?
G. Will there be any generation of identifiable information through data linkage?

Scenarios

1. A) Dr. Li is a researcher from the Department of Biomedical and Molecular Sciences working in Botterell Hall at Queen's University. Dr. Li would like to order a human primary dermal fibroblast cell line from the American Tissue Culture Collection (ATCC) called HDFa. What administrative steps would Dr. Li need to take to bring this cell line into their laboratory?

A. Yes, REB clearance is required. Cell lines would be considered non-identifiable information, but not anonymous information. Thus, this research would not meet the criteria for exemption from REB review based on Article 2.4.
B. No, REB review is not required to transfer the sample. The biobank would be required to obtain REB review for the initial collection of the biological material.
C. Participant consent would not be required for this secondary use of non-identifiable biologicals. The biobank would be required to obtain consent for the initial collection.
D. Hospital approval would not be required. Research is not occurring at the hospital or using hospital resources and the location of the lab/PI's office is on Queen's University Campus.
E. No, an agreement is not required by the institution. The biobank may request an agreement for the use of the samples.
F. Yes, a biosafety permit would be required. An amendment would need to be submitted to add the additional cell line.
G. There are no concerns with respect to data linkage, as no identifiers were associated with the cell line.

B) What if Dr. Li's colleague at University of Toronto, Dr. Hernandez, has a primary dermal fibroblast cell line that was isolated from a patient and Dr. Hernandez has agreed to provide an aliquot of the de-identified cells free of charge to Dr. Li?

B. Yes, REB clearance would be required at Queen's. This would be considered a secondary use of non-identifiable biological material. Thus, this research would not meet the criteria for exemption from REB review based on Article 2.4.
C. No, REB clearance would not be required for the transfer of the sample from UofT to Queen's. REB clearance would be required at UofT for the original collection of the biological material.
D. No, participant consent would not be required for the secondary use of biological material at Queen's, as a de-identified sample was provided. UofT would need participant consent for the

original collection of the sample. UofT would also need to confirm that the participant did not decline to participate in future research.

E. Hospital approval would not be required. Research is not occurring at the hospital or using hospital resources.
F. An agreement would be required for the transfer of this material. This agreement would be initiated by UofT, as they are transferring the samples to Queen's.
G. Yes, a biosafety permit would be required. An amendment would need to be submitted to add the additional cell line.
H. There are no concerns with respect to data linkage, as only a de-identified sample was provided.

2. A) Dr. Smith is a bioinformatician from the School of Computing at Queen's University. A local clinician researcher at Kingston Health Sciences Centre (KHSC) – KGH Site, Dr. James, would like Dr. Smith to analyze some de-identified data sets. The data will be from a retrospective chart review study led by Dr. James that will be completed at the Ottawa Hospital Research Institute (OHRI) by a site investigator and at the KHSC-KGH Site by Dr. James. Dr. James has agreed that Dr. Smith will be listed as a co-author on the publication. What administrative steps would Dr. James and Dr. Smith need to take to complete this research project at Queen's University?

A. Yes, REB clearance would be required at Queen's. This would be considered a secondary use of non-identifiable data. Thus, this research would not meet the criteria for exemption from REB review based on Article 2.4.
B. Yes, REB clearance is required at OHRI. Collection of human information is also occurring at this site and so local REB clearance would be required.
C. No, Participant consent is not required for retrospective chart reviews at KHSC. KHSC has an opt-out research policy and all patients are required to opt-out via form request. Each patient record would need to be checked to ensure participants have not opted out of research. The OHRI local hospital policy would need to be followed for chart reviews for research. OHRI may or may not require participant consent depending on their policy.
D. Yes, hospital approval would be required through the submission of a TRAQ DSS. This research is occurring at the hospital and will access patient medical records.
E. Yes, an agreement is required for the transfer of participant information from one institution to another.
F. No, a biosafety permit is not required. There are no biological materials involved.
G. This does involve linking two datasets (KHSC & OHRI). The researcher would need to explain if there would be a possibility of identifiable information being generated through this analysis.

B) What if Dr. James was sending the KHSC data set to a bioinformatician at OHRI for analysis?

A. Yes, REB clearance would be required at Queen's. This would be considered a secondary use of non-identifiable data. Thus, this research would not meet the criteria for exemption from REB review based on Article 2.4.
B. Yes, REB clearance is required at OHRI. Collection of human information is also occurring at this site and so local REB clearance would be required.
C. No, participant consent is not required at Queen's based on the KHSC research opt-out policy. The OHRI local hospital policy would need to be followed for chart reviews for research. OHRI may or may not require participant consent depending on their policy.

D. Yes, hospital approval is required through the submission of a TRAQ DSS. This research is occurring at the hospital and will be accessing patient medical records.
E. Yes, an agreement is required for the transfer of participant information from one institution to another.
F. No, a biosafety permit is not required. There are no biological materials involved.
G. This does involve linking of two datasets. The researcher would need to explain if there would be a possibility of identifiable information being generated through this analysis.

3. A) Dr. Potter is a researcher from the Department of Chemical Engineering studying regenerative medicine. Dr. Potter would like to use discarded non-identifiable adipose tissue from lipo-suction procedures at KHSC – HDH Site. Dr. Potter will use the tissue to isolate cells for analysis in their laboratory at Dupuis Hall. Dr. Potter has a clinician colleague at KHSC, Dr. Wang, that has said they would be able to help Dr. Potter acquire the tissue. What administrative steps would Dr. Potter and Dr. Wang need to take to enable this research project?

A. Yes, REB clearance is required at Queen's. This would be considered a secondary use of non-identifiable biological material.
B. No, REB clearance is not required at another institution, as no other sites are involved.
C. No, participant consent is not required, as these samples are non-identifiable biological material being used for secondary analysis.
D. Yes, hospital approval is required through the submission of a TRAQ DSS. This research is occurring at and potentially using hospital resources.
E. No, an agreement would not be required.
F. Yes, a Biosafety permit would be required. An amendment would need to be submitted to add this additional tissue to the permit.
G. No, there is no indication of multiple datasets.

B) What if Dr. Potter was acquiring discarded adipose tissue from a hospital in Toronto?

A. Yes, REB clearance is required at Queen's. This would be considered a secondary use of non-identifiable biological material.
B. REB clearance is unlikely required from the Toronto Hospital; however this requirement may vary depending on institutional requirements.
C. No, participant consent would not be required by Queen's for the secondary use of biological material.
D. No, local hospital approval would not be required. This research is not occurring at the hospital or using hospital resources.
E. Yes, an agreement would be recommended for the transfer of the biological material.
F. Yes, a Biosafety permit would be required. An amendment would need to be submitted to add this additional tissue to the permit.
G. No, there is no indication of multiple datasets.