**Module 5 Activity: Case-Based Self-Assessment**

**Outcomes from Orthopedic Implant Surgery**

Select all response options that apply

1. The owner of the data in this case is:
   1. The original research resident
   2. The last research resident
   3. Dr. X
   4. The institution where Dr. X is employed
   5. All of the above
   6. None of the above
2. Ethical issues related to re-use of data in this case might include
   1. Providing a copy of the proprietary software package used to monitor patients walking rate to a researcher who wants to do a follow-on study
   2. One of the residents copying the data for later follow-on research at another institution
   3. Using the data which has been transferred to a public repository as part of a later study at the same institution and publishing a paper citing a publication related to the earlier study
   4. All of the above
   5. None of the above
3. Legal issues related to this case include:
   1. Providing a copy of the proprietary software package used to monitor patients walking rate to a researcher who wants to do a follow-on study
   2. Copying the analytic software for the accelerometer data to other computers outside the lab
   3. Providing the survey questions for re-use outside the institution
   4. All of the above
   5. None of the above
4. Privacy issues related to this case might include:
   1. Giving surgeon notes from physical exams to another researcher for reuse
   2. Sharing structured database of physical exam measures for reuse
   3. Providing patient survey data for re-use
   4. Providing the data generated by the accelerometer for re-use
   5. Use of all of the data for a later study on pain and disability following any kind of orthopedic surgery
   6. All of the above
   7. None of the above

**Answers:**

1. d: The institution where Dr. X is employed owns the data and Dr. X is the steward of the data
2. d: All of the above: a) Proprietary software requires a separate license for each PC on which it is used . b) A resident could not copy the data without permission from the home institution and Dr. X. c) If the data has been published in a public repository, the data should be cited as well as the prior publication
3. a&b: a) Proprietary software requires a separate license for each PC on which it is used. Survey questions, if they are part of a copyright protected survey tool could probably not be re-used without compensating the originator; however, if it is a survey that has been developed in house or has never been given copyright protection, it could be reused with permission of the developers.
4. f: All of the above:

a-d) Use of any of the data sets would require permission from the home institution unless they are published in a public repository. e) Additionally, the informed consent originally signed by the patients would have to have asked them to agree to use of the data for purposes other than the original study. If the data were to be reused, patient data needs to be stripped of personal identifiers.

**Regeneration of Functional Heart Tissue in Rats**

Select all response options that apply

1. The owner of the data in this case is:
   1. The principal investigator
   2. The project director
   3. The senior project staffer
   4. The institution where the principal investigator is employed
   5. All of the above
   6. None of the above
2. Ethical issues related to re-use of data in this case might include
   1. Providing a copy of the custom software used to track particles on the surface of the heart to a researcher at another institution who wants to do a follow-on study
   2. One of the project staff members copying the data for subsequent related research at another institution
   3. Using the data as part of a later study at the same institution and publishing a paper citing a publication related to the earlier study
   4. All of the above
   5. None of the above
3. Legal issues related to this case include:
   1. Providing a copy of the custom software used to track particles on the surface of the heart to a researcher at another institution who wants to do a follow-on study
   2. Copying the custom tracking software to other computers outside the lab within the home institution
   3. Providing the images taken of the rat heart which have been placed in a public repository for re-use outside the institution and publishing a paper citing a publication related to the earlier study
   4. All of the above
   5. None of the above
4. Privacy issues related to this case might include:
   1. Leaving the surgical log in the unlocked lab
   2. Sharing database of left ventricle pressure measures with synchronized images of the living heart for reuse
   3. Providing the images of the slides containing stained heart sections for re-use
   4. All of the above
   5. None of the above

**Answers**

1. d) The institution where the principal investigator is employed owns the data and the PI is the steward of the data
2. d: a) custom software cannot be reused without permission and acknowledgement of the source unless it is available under an open source license. b) a resident could not copy the data without permission from the home institution and PI. c) If the data has been published in a public repository, the data should be cited as well as the prior publication
3. a&c: a) custom software cannot be reused without permission and acknowledgement of the source unless it is available under an open source license. b) since the custom software does not require a proprietary license, being homegrown, it can be used on other computers at the home institution with the developer’s permission. c) If the data has been published in a public repository, the data should be cited as well as the prior publication
4. e: None of the above: None of these are privacy issues since human subjects are not involved as participants in the study; however, there may be security issues with option a) and legal issues with b) and c).

**Improving End-of-Life Care for African Americans**

Select all response options that apply:

1. The owner of the data in this case is:
   1. The MD who applied for the grant funding the study
   2. The African-American adults who participated in the focus groups
   3. The moderator of the focus groups who was part of the project team
   4. The institution where the MD principal investigator is employed
   5. The qualitative analyst who generated the findings for the study
   6. All of the above
   7. None of the above
2. Ethical issues related to re-use of data in this case might include
   1. Audio-recording the focus groups after informal consent from participants during their recruitment by telephone
   2. Publishing a paper detailing the results of study without having the paper reviewed by the focus group participants
   3. Having focus group participants sign an informed consent form after the focus group
   4. All of the above
   5. None of the above
3. Legal issues related to this case include:
   1. Providing to attendees at a professional conference presentation a pre-publication copy of a manuscript detailing results of the study submitted to a journal that is not open access
   2. Copying the proprietary qualitative data analysis software to a computer at the analysts’ institution
   3. Providing the focus group moderator script for re-use outside the institution
   4. All of the above
   5. None of the above
4. Privacy issues related to this case might include:
   1. Providing a copy of the audiotapes used to record the focus groups to a researcher who wants to do a follow-on study
   2. Providing a copy of the data transcripts for later follow-on research at another institution
   3. Use of all of the data for a later study on comparing end-of-life care considerations across cultures (Anglo, Latino, and African American)
   4. Storing transcripts and analytic data structures with the analyst at another institution
   5. Use of de-identified segments of the transcripts as examples for a qualitative analysis class
   6. All of the above
   7. None of the above

**Answers**

1. d) The institution where the MD principal investigator is employed. The MD is the steward of the data
2. a&c) a written and signed informed consent form is required by most Institutional Review Boards and this document must be signed before recording participants so they know they will be recorded and agree to this. b) part of the informed consent generally states that study results may be published and that no participants will be identified by name, roles, or any other non-generic personal characteristics in any publication
3. a&b) a) Generally pre-publication copies of manuscripts are not to be circulated b) Proprietary software requires a separate license for each PC on which it is used
4. a,b&c) Unless the participant informed consent form explicitly asked for permission to reuse data in other studies, this should not be done. However, if it is de-identified (i.e., participants are not identifiable), project staff may use the data for teaching purposes. d) Storing the data and intermediate results with a staff member at another institution without keeping a backup copy at the home institution could pose a loss of data risk, but all project team members have been generally been certified to do research with human subjects and adhere to privacy constraints.

**Characterizing a Component of a Rocket Engine used to Control Satellites in Orbit**

Select all response options that apply:

1. The researcher has taken the following actions to comply with ITAR restrictions:
   1. He limits use of ITAR restricted equipment to PhD students only.
   2. He does not allow any students who are foreign nationals to have access to ITAR restricted equipment, notebooks or research materials.
   3. He secures the ITAR restricted equipment but is able to share the lab notebooks and any other research documentation.
   4. All of the above
   5. None of the above
2. Intellectual property issues related to this case might include:
   1. Restrictions on publishing research that has been completed for a private company.
   2. Moving raw data from a laptop to an archival CD.
   3. Inability to share MATLAB code that has been created by a student.
   4. All of the above
   5. None of the above
3. Which of the following data is owned or can be reused by the researcher without requesting permission:
   1. The lab notebook
   2. Raw data downloaded from the cathodes onto a student’s laptop
   3. Archival CDs of MATLAB code
   4. All of the above
   5. None of the above
4. The researcher could do which of the following to clarify intellectual property issues related to the MATLAB code:
   1. Continue with current practice. No clarification is needed.
   2. Create two CDs including the code. One would be owned by the student and one by the researcher.
   3. The researcher can request that students sign a form granting reuse right to the researcher prior to graduation.
   4. All of the above
   5. None of the above

**Answers:**

1. b) Foreign nationals may not have access to any part of an ITAR restricted research project.
2. a&c) Information that is owned by a student or a private company may not be shared without permission of the owner.
3. a&b) The lab notebook is the intellectual property of the researcher and raw data is not governed by copyright laws in the United States. The MATLAB code is the intellectual property of the student so permission must be sought in order to reuse or adapt it.
4. c) Option b would not have any impact on who owns the intellectual property contained on the CD. If the student has given consent to the research to use the MATLAB code and adapt it as needed, there would be no need to track down the student later, therefore simplifying the process.