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| **Lesson Plan for Module #5: Legal and Ethical Considerations for Research Data** | |
| Learner  Objectives | By participating fully in this class, students will be able to:   1. Explain ownership considerations related to data sharing 2. Explain and evaluate potential legal issues connected to one’s data 3. Explain ethical considerations related to data sharing 4. Recognize the importance of privacy with some forms of data (HIPPA) 5. Understand the importance of removing key identifiers |
| Lecture Content | 1. Who owns research data?  2. How do intellectual property laws and/or copyright protections relate to research data and researchers?  3. Issues related to licensing or charging for reuse of research data  4. What ethical and privacy considerations does one need to be aware of when using another’s data or sharing data?  5. What is the importance of acknowledging the source of data that are used in research?  6. What are the components of a data citation? |
| Activities | 1. Read this Columbia RCR [case](http://library.umassmed.edu/necdmc/necdmc_activity5c.docx). Discuss the ownership issues and answer the questions. 2. Locate, review, and discuss the Intellectual Property (IP) Policy of your local institution. 3. Locate, review, and discuss your local Institutional Review Board (IRB) policies to see what information they have regarding data management (e.g. patient privacy, data retention guidelines, informed consent, etc.). 4. Identify the components of a data citation used in your discipline’s literature. 5. Using one of the research [cases](http://library.umassmed.edu/necdmc/research_cases), examine its legal and ethical issues. (Examples of [case-based ethical and legal questions](http://library.umassmed.edu/necdmc/necdmc_activity5a.docx) and [assessment](http://library.umassmed.edu/necdmc/necdmc_activity5b.docx)). 6. Complete an anonymization/de-identifying [activity](http://library.umassmed.edu/necdmc/necdmc_activity5d.docx). |
| Assessment | Reflect on your own project. What legal and ethical issues and policies have you encountered? Do you know who owns your data? What are your funders’ requirements regarding legal and ethical compliance? What provisions or obstacles, if any, would prevent you from sharing your data? |
| Readings | 1. National Institutes of Health. Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule. <http://privacyruleandresearch.nih.gov/pr_02.asp> 2. Clinical Tools, Inc. Office of Research Integrity. (2006). Guidelines for Responsible Data Management in Scientific Research. <http://ori.hhs.gov/education/products/clinicaltools/data.pdf> pgs. 6-8 3. Columbia University. Responsible Conduct of Research. Who Owns Research Data? [http://ori.dhhs.gov/education/products/columbia\_wbt/rcr\_data/case/index.html#2](http://ori.dhhs.gov/education/products/columbia_wbt/rcr_data/case/index.html%232) 4. University of Oregon Libraries. Constructing Access Permissions. [http://libweb.uoregon.edu/datamanagement/sharingdata.html#three](http://libweb.uoregon.edu/datamanagement/sharingdata.html%23three) |