



AN EMERGING TECHNOLOGIES, ETHICS, AND RESEARCH DATA CASE STUDY

MAINTAINING SENSITIVE AND NON-SENSITIVE DATA

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OVERVIEW

The Emerging Technologies, Ethics, and Research Data case studies provide education and guidance on how to identify, assess, and review research data security issues. These studies may be used by IRB administrators and investigators to identify key issues, considerations, and decision criteria when reviewing and designing research studies that involve data collection and sharing components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) contractual, regulatory, ethical, and technical issues, 3) stakeholder considerations to identify, assess, and mitigate risks, and 4) resolution and points for discussion.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining options, the case studies can be used in a variety of ways, which include: 1) as an educational tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

Scenario/Fact pattern:

Researchers at a local university want to study the impact of workplace conditions on health and happiness. They receive IRB approval to conduct a mixed methods study, consisting of both surveys and focus groups, at a local manufacturing plant. The researchers implement their survey with 350 participants. The survey asks questions about salary satisfaction, benefits and health insurance, interpersonal relationships at work, skills training opportunities, workload satisfaction, stressors in the workplace, leadership and management, and health and safety at work. The researchers then take a random sample of survey responses and ask 20 participants

to attend a focus group. The purpose of the focus group is to facilitate a more in-depth discussion of the survey topics that are most important to the group. After conducting five separate focus groups, the researchers begin to notice a trend in the focus group results: participants are very eager to talk about how company policies impact their day-to-day work and wellbeing. One common theme is the lack of a sexual harassment policy. The researchers decide this topic is one that could be significant in supporting the aims of their study, and obtain IRB approval to update their survey and focus group guide to ask questions about sexual harassment at work. The specific questions added include whether participants have been sexually harassed at work and by whom, if they have been offered special treatment or opportunities at work in exchange for sexual favors, who at work asked for these favors, how they reacted to the incident, and how they felt Human Resources at the plant responded to any reports they may have made.

Because the study will now collect sensitive data, in addition to the non-sensitive data collected after initial IRB approval, what kinds of data security measures and protections do the researchers need to put in place? Do the researchers need to manage their data sets differently based on the nature of the data included?

CONSIDERATIONS

Researcher Considerations:

- Do you have the resources to adequately protect the new study data on workplace sexual harassment?
- Have you spoken to your local IT security officer to ensure you have the appropriate data security and confidentiality solutions in place to protect the study data?
- How long do you plan to retain sensitive, identifiable data? When is the soonest it can be destroyed?

IRB Considerations:

- Does the addition of survey/focus group questions about sexual harassment add or increase risk to participants?
- Are the added questions essential? Are there any that can be removed? (e.g. names of harassers)?
- Does the addition of survey/focus group questions about sexual harassment impact the regulatory criteria for approval with respect to establishing adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data in place?
- Does the addition of survey/focus group questions about sexual harassment change the scope of the funding or the purview/involvement of the sponsor?
- How will the researchers update the research protocol to make adequate provisions for monitoring the data collected to ensure the safety of subjects?
- Is it clear to participants that answering questions about sexual harassment, and participation in general, is voluntary?

- Could the study data collected, if disclosed outside of the research, reasonably place the participant at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, or reputation?
- Does the identification of who may have been the perpetrator trigger any additional legal or mandatory reporting on the part of the researcher? How may that impact the participant?
- Should there be any additional provisions in place to protect the rights and welfare for employees who may be vulnerable to coercion or undue influence from their supervisors, coworkers, etc. to participate in this study?

IT Considerations:

- Does the researcher need to be educated on how/why sensitive and non-sensitive study data need to be stored and maintained in different ways?
- How do the data security methods in place for the non-sensitive study data need to change now with the collection of sensitive study data?
- What resources will the researchers need to fulfill IT recommendations to secure the sensitive study data?

DISCUSSION AND RESOLUTION

IRB review will not likely differentiate between how sensitive vs. non-sensitive data is managed. IRBs will generally review human subjects research at the level providing the maximum level of oversight and protection, per the regulations. As a result, the sensitive data will be adequately stored, managed, and monitored, and the non-sensitive data will consequently benefit as well.

REFERENCES

45 CFR 46 - §46.111 Criteria for IRB approval of research:

<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.111>