Human Subject Research at Dalton State

An Overview of Exemptions to the Common Rule

The update to the Common Rule, §46.104(d), which took effect on January 21, 2019, changes the type of research considered exempt from on-going IRB review and exempt from the informed consent requirements that normally apply to human subject research. Nevertheless, even when informed consent is not required by the Common Rule, researchers at Dalton State are encouraged to seek either informed consent or prospective participant agreement from their subjects. And, as always, basic ethical standards regarding the collection and storage of data (outlined in the PRHP or DSC training courses) apply to exempt research.

Category 1: Research in Established or Commonly Accepted Educational Settings

Investigators may claim this exemption when their research involves normal educational practices so long as the research does not affect the students' opportunity to learn the material and it does not affect the performance assessment of teachers using the instructional techniques, curricula or classroom management tools. Educational settings include classrooms at the primary, secondary, and post-secondary level but may also include after-school programs, tutoring centers, libraries, museums, and workplaces. Investigators seeking this type of exemption should be sure to explain how the research will not interfere with learning or performance assessment.

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior

Investigators may claim this exemption when their research involves the use of educational tests, surveys, interviews, focus groups, or observations of public behavior (i.e., those occurring in public places where there is no expectation of privacy). One of the following criteria must be met for the research to be exempt: (1) the information recorded is not identifiable; (2) any disclosure of the subjects' responses would not reasonably place the subjects at risk or criminal or civil liability; or (3) the identity of the subject can be ascertained from the information collected but the IRB conducts a limited review to ensure the protection of privacy and confidentiality. Investigators seeking this type of exemption should describe what type of information they intend to collect, and if the data includes sensitive and/or identifiable information, they should explain how their will protect the welfare and privacy of the participants.

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects

Investigators may claim this exemption when their research involves behavioral interventions with adults that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. The intervention could include a cognitive, intellectual, educational, or behavioral task or a manipulation of the subject's environment (such as a sensory manipulation). The data also cannot be collected through physical procedures (such as using activity trackers).

Investigators must seek a prospective participant agreement in which the subject agrees to the intervention and the information collection. Additionally, one of the following criteria must be met for

the research to be exempt: (1) the information is collected in such a way that the identity of the subjects cannot be readily ascertained; (2) any disclosure of the subjects' responses would not reasonably place the subjects at risk or criminal or civil liability; or (3) the identity of the subject can be ascertained from the information collected but the IRB conducts a limited review to ensure the protection of privacy and confidentiality. If researchers choose to use deception as a part of their protocol, they must let those subjects know they may be unaware or misled about the nature or purpose of the research as part of the prospective participant agreement. Investigators seeking this exemption should address the nature of the intervention and the mechanism for information collection; they should also indicate whether they intend to collect sensitive and/or identifiable information and how they will obtain participant agreement.

Category 4: Secondary Research for Which Consent is Not Required

Investigators may claim this exemption when their research involves the secondary use of identifiable private information or identifiable biospecimens if the data was not collected for research purposes or the data was collected for research not related to the proposed study. One of the following criteria must be met for the research to be exempt: (1) the information or biospecimens is publicly available; (2) the information is recorded by the investigator in a way that the identity of the subject cannot not be easily ascertained, the investigator does not contact the subject, and the investigator will not reidentify the subject; (3) the research involves only information collection and analysis involving the investigator's use of identifiable health information regulated by 45 CFR 160 and 164; or (4) the research is conducted by or on behalf of a federal agency using government collected data obtained for non-research purposes.

Category 5: Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency

Investigators may claim this exemption when their research is supported by a federal agency. Under the old guidelines, the exemption only applied to federal agencies conducting research; however, the new guidelines allow outside investigators to study and evaluate how to improve federal programs so long as the federal government funds the research. Federal agencies will post information on projects eligible for this exemption on their websites. Since research under this category requires a federal grant, researchers should ensure they have followed the college's policy on grant research.

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

Investigators may claim this exemption when their research involves taste tests to determine quality of foods or consumer preference. To qualify, the food must not contain ingredients or additives that exceed levels the FDA considers safe for consumption.

The revised common rule also added two new exemptions (Category 7 and Category 8) relating to the storage, maintenance, and secondary research use of identifiable biospecimens and identifiable private information. These new exemptions deal primary with biomedical research, though they might also cover some social or behavioral research. Due to the regulatory requirements necessary to track whether the researchers obtained "broad consent" at the time of the initial study, the college will require researchers proposing secondary use research of identifiable data to complete an application for non-exempt research.

Information on Completing Exempt Applications

Although the revised Common Rule allows for self-determination for certain exempt categories, Dalton State College will not implement self-determination. All human subjects research must be

presented to the IRB for consideration. Exempt applications should include an overview of the project, including any potential current or future risks to the participants and information on how researchers will maintain the confidentiality of any sensitive or identifiable information collected as part of the study. Researchers must also explain why they believe your research is exempt from the regulatory requirements.

In most cases, exempt applications will undergo a standard exempt review. However, if the research involves the collection of sensitive or identifiable data, exempt applications with undergo a limited review. In either case, the more information provided with the application, the easier it will be for the IRB to process the application.

- Exempt Review: The IRB uses a standard exempt review for all the categories outlined above unless the research involves the collection of sensitive and/or identifiable information. When completing an application, researchers must indicate the exemption category requested as well as explain why the research could be considered exempt and describe the procedures for dealing with potential risk to the participants.

- Limited Review: The IRB uses a limited review for requests for Category 2 and Category 3 exemptions where researchers propose to collect sensitive and/or identifiable information. When completing an application, researchers must indicate the exemption category requested as well as explain why the research could be considered exempt and describe the procedures for dealing with potential risk to the participants. Furthermore, researchers must explain how they will protect the privacy of the subjects and maintain the confidentiality of the data collected.

Some of these exemptions outlined above do not apply when working with vulnerable populations, namely pregnant women, children, and prisoners; in those cases, researchers will need to complete a regular application for review by the full committee. Researchers considering working with vulnerable populations should contact the IRB at irb@daltonstate.edu if they have any questions.