Grand Valley State University Institutional Review Board	
G-3: Guidance on research activities not requiring IRB approval	
Revised: May 21, 2020	Office of Research Compliance and Integrity

Guidance on Research Activities Not Requiring IRB Approval

The federal regulations for the protection of human research subjects define "research" as a *"systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge*." 45 CFR 46.102(l).

Any activity conducted by GVSU students, faculty, or staff that meets this definition requires prior review and approval by the Institutional Review Board (IRB) before the activity may begin.

Students sometimes collect data from or about other persons by using professional research methods as part of academic course activities, even though the student's work is not expected to contribute to generalizable knowledge. Such activities do not meet the federal definition "research" because they are not designed to develop or contribute to generalizable knowledge and therefore do *not* require IRB approval.

To be considered an academic activity that does ***not*** constitute research on living human subjects and therefore does not require IRB review, the following criteria must be met:

- The activity involving research methods is designed as part of a course learning requirement involving the collection and analysis of information from or about living human persons, **and**
- The results of the data analysis are ***not*** designed to develop or contribute to generalizable knowledge.

Clarifications

A. Post-facto Research Conducted on Data Previously Collected from Class Activities

If a student or instructor wishes to conduct research on data previously collected as part of a class activity in order to validate, expand or otherwise enhance generalizable knowledge, a research protocol must be approved by the IRB *before* the data may be used for that purpose. The protocol application should include a description of how the data were initially collected and why IRB approval for research was not sought or required at that time.

In most cases this type of research will be exempt under category #4 (existing data, records or specimens), or if not exempt, then expedited category #5 (data previously collected for non-research purposes). Failure to acquire IRB approval before utilizing data outside of the classroom for which the research activities were assigned is considered conduct of unapproved research and is a form of research non-compliance.

Student education records are covered by the FERPA regulations and the researcher will need to consider if FERPA authorization needs to be obtained. Note that FERPA authorization is separate from research consent. For additional specific information on how FERPA intersects with research, refer to IRB guidance document G-17: *Guidance on FERPA in Human Subjects Research Studies*.

B. Single Case Reports and Case Series

A "single" case report (three or fewer cases) does not require review by the IRB. Investigators do not need to submit a protocol review application form. If an investigator wishes to have the project assessed by the IRB to see if it meets the definition of a single case report, the investigator should submit the IRB Research Determination Form in IRBManager. A formal letter will be issued documenting that the case report does not meet the federal definition of research and IRB oversight is not needed.

Investigators should inform the Office of Research Compliance and Integrity (ORCI) if a journal does not accept the formal determination letter.

A case *series* (more than 3) generally meets the definition of research.

NOTE: Case reports for publication must be prepared in accord with the requirements of the HIPAA privacy regulations. Any use or disclosure of protected health information (PHI) must be done with authorization of the patient, or, if the patient is deceased, authorization of the patient's family. Publication of a case report is a disclosure of PHI. The HIPAA Privacy Office of the institution responsible for the security of the medical record (hospital, clinic, physician practice group, etc.) should be consulted prior to submission of the case report to assure proper authorization was obtained.

Case Report Publication Guidance: IRB Review and HIPAA Compliance

Background: Many journals now require a letter, or other acknowledgement, from an IRB prior to publication of a case report. Specifically, they wish to know whether IRB approval was obtained or was not required for the described case. The IRB has adopted a policy to address the following question and answers.

Q: What constitutes a "case report"?

A case report for IRB purposes is a retrospective analysis of one, two, or three clinical cases. If more than three cases are involved in the analytical activity, the activity will generally constitute "research."

Q: Do faculty who prepare a case report as an article for submission to a journal require IRB approval prior to preparation?

No. A case report is a medical/educational activity that does not meet the federal definition of "research", which is: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Therefore, the activity does not have to be reviewed by the IRB.

Q: Are there HIPAA implications associated with publication of case reports?

Yes. Under HIPAA, a case report is an activity to develop information to be shared for medical/educational purposes. Although the use of protected health information to prepare the paper does not require IRB review, the author of a case report must comply with HIPAA. Ideally, the author of the article will obtain the signed authorization of the subject, or the subject's legally authorized representative if the subject is deceased, to use the subject's information in the article. If it is not possible to obtain authorization, the author should be aware that one of the identifiers described by HIPAA as requiring written authorization is, "Any other unique identifying number, characteristic, or code…." Moreover, HIPAA requires that, at the time of publication, "[t]he covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information." (See: Definition of De-Identified Data below.)

- Authors who remove HIPAA identifiers (including unique patient characteristics) from the data prior to submission and publication of the article do not need to obtain a signed privacy authorization as long as they have access to the health information for other purposes, such as providing routine clinical care.
- Investigators who wish to publish case report data with HIPAA identifiers will need to obtain from the patient a signed HIPAA compliant authorization. This authorization does not need to be submitted to the IRB for review. The appropriate authorization form for use with a single case report may be found on the GVSU IRB website or obtained from the Covered Entity that holds the PHI.
- If the author strips off all HIPAA identifiers, but the information associated with the subject of the article includes a "unique characteristic" which would make it identifiable to the subject, or the author has actual knowledge that the information about the subject could be used alone or in combination with other information to identify the subject, the author must contact the HIPAA Privacy Officer to discuss the required steps to take prior to publication.

DEFINITION OF DE-IDENTIFIED DATA

Identifiers That Must Be Removed to Make Health Information De-Identified

The following identifiers of the individual or of relatives, employers or household members of the individual must be removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

C. Internship and work activities and advanced degrees from non-GVSU institutions

Research activities that meet the federal regulations definition of research and that are conducted by GVSU students or employees as partial completion of advanced degrees for theses (Masters level) and dissertations (doctorate level) always require approval from an IRB. If the student conducting the research is affiliated with GVSU, but the advanced degree is to be awarded by another institution, consultation with the Office of Research Compliance and Integrity to determine which IRB approval is required is strongly recommended.

GVSU employees (including part-time employees, teaching adjuncts and lecturers) and students may conduct research that is part of a research requirement at another institution, a job responsibility for another employer (including self-employment), or as part of an internship experience. This research does not require IRB approval as long as the researcher does not engage in any of the following activities:

1. Disclose their GVSU affiliation to the potential research participants; or
2. Use any GVSU owned or maintained resources including compensated professional time; or
3. Conduct the research as part of his/her GVSU employment contract.

Procedures

1. If the researcher engages in *any* of the above three conditions, the IRB must review and approve the research project and will require evidence of approval from the IRB at the other institution, when applicable.

2. Research activities for another entity may take place without IRB involvement only if ***all*** of the following conditions are met:

    a. There is no mention in the research consent form, recruiting flyers, spoken or written dialogue exchanges, or other communication with potential participants that the investigator is employed by or otherwise affiliated with GVSU, and

    b. The investigator does not use GVSU logo, letterhead, affiliation, facilities, equipment, or other GVSU owned resources in any aspect of conducting the research including but not limited to GVSU phone numbers, campus facilities, e-mail, web sites, or other institutional mediated communication methodology, and

    c. There is no evidence or suggestion that the research was authorized or approved by GVSU.

D. Instructor Responsibility

It is the instructor's purview to allow the student classroom activities involving research methodologies to occur as part of the coursework. However, instructors have an obligation to ensure that their students understand their ethical responsibilities in carrying out their assignments. Instructors should provide guidance to students collecting information in order to minimize potential harm to individuals, especially if students will collect personally identifiable private information.

E. Training

The IRB strongly encourages but currently does not require specific training for students in research protections, confidentiality, privacy protections, data security, or other research areas in order to engage in research methodologies as part of classroom activities. However, instructors should be aware of any requirements their governing department may have concerning the proper conduct of such activities.

F. Intent to Publish or disseminate study results

The intent to publish, present, post to the internet, or otherwise make publicly available the results of research activities is not determinative of whether the activity meets the definition of research. The proper focus for these purposes is whether the activity (i) involves a systematic investigation ***and*** (ii) the activity is designed to create or contribute to generalizable knowledge.