

Grand Valley State University Human Research Review Committee	
G-10: HRRC Guidance on Single Case Reports and Case Series	
Issued: January 29, 2013	Office of Research Compliance and Integrity

## **HRRC Guidance on Single Case Reports and Case Series**

Policy: A “single” case report (three or fewer cases) do not require review by the HRRC. Investigators do not need to submit a protocol review application form. If an investigator wishes to have the project assessed by the HRRC to see if it meets the definition of a single case report, the investigator should contact the HRRC office. If the project qualifies as a single case report, the HRRC will send to the investigator a form letter that states:

“The HRRC received your request (dated ‘x’), concerning a single case report you wish to publish. The HRRC has determined that a case report does not produce generalizable knowledge, nor is it an investigation of an FDA regulated product. HRRC review is not required for this activity.”

Investigators should inform the HRRC if a journal does not accept the HRRC decision. The issue will then be brought to an HRRC meeting for resolution.

A case series (more than 3) 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 PHI must be done with authorization of the patient, or, if the patient is deceased, authorization of the patients family. Publication of a case report is a disclosure of protected health information (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 HRRC 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 constitute “research.”

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

No. A case report is a medical/educational activity that does not meet the DHHS 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 HRRC.

**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 HRRC 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.
- 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 HRRC for review. The appropriate authorization form for use with a single case report may be found on at: \_\_\_\_\_
- 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**

- (i) 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.