**Clinical Case Report Guidance**

**HIPAA Compliance Review**

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 and/or poster does not require IRB review, the author(s) of a **case report** must comply with **HIPAA**.

If all HIPAA identifiers (including unique patient characteristics) have been removed but the publication is requesting patient consent there is a template available on the WMed Website under [Forms and Templates](https://med.wmich.edu/node/723) for your use.

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 may constitute “research”.

The purpose of this checklist is to provide support for clinicians in the review of case reports. This form does not need to be reviewed by the IRB; however, the IRB recommends you maintain a copy of the completed form for your records.

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| Document attending provider approval here: The attending provider       from       (healthcare system) has knowledge of this clinical case report and has granted permission to utilize the patient and agrees this is an accurate representation of the case. | |
| Yes  No | Does the report cover more than 3 cases? If **yes**, a protocol must be submitted to the IRB for review. Contact the WMed IRB at 269-337-4345 or visit <https://med.wmich.edu/irb> for guidance. |
| Yes  No | Report does not contain HIPAA identifiers AND does not contain other uniquely identifying information or image(s)?   * If HIPAA identifiers OR photo/video images ARE to be included in the report, a HIPAA-compliant authorization form must be signed by the patient(s) involved. Contact WMed IRB to obtain the appropriate authorization form. IRB review on the form is not required; however, the signedrelease form must be scanned into the patient’s medical record prior to any presentation of the case report. * If no HIPAA identifiers or images are to be included, but the case report includes a “unique characteristic” that might suggest the patient’s identity OR if the author has actual knowledge that the information presented in the case report could be used alone or in combination with other information to identify the patient, then the author must contact the HIPAA Privacy Officer\* to discuss steps to be taken to protect the patient’s identity prior to presentation or publication of the case report. |

I have reviewed the content of the proposed clinical case report and attest the proposed data being presented by       has been stripped of HIPAA identifiers or proper permissions have been obtained as per the above instruction and covered entity policy.

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| **Faculty Signature** | **Date** |

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