IRB Guidance for Case Reports

Federal regulations and university policies require Institutional Review Board (IRB) approval for research with human subjects. This applies whether the research is conducted by faculty or students. *Failure to obtain proper approval in advance may prevent you from publishing the results and place you and the institution in violation of federal regulations.* This guidance will help you determine whether you need to get approval from the IRB before conducting a given activity. Please note that IRB does not have the option of granting “retroactive” approval after research is done; you should err on the side of submitting or consulting with the IRB at 912-350-6866 if there is any doubt. All forms and additional guidance are available by contacting Jean Wiggins at wiggije1@memorialhealth.com.

Case reports for publication must be prepared in accord with the requirements of the HIPAA privacy regulations. This guidance applies to retrospective reviews. It does not apply to prospective interactions or interventions with patients. The IRB may only waive authorization for research purposes. Therefore, a waiver cannot be granted for a case report that does not meet the definition of research. Publication of a case report may be a disclosure of PHI.

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| Activity  | IRB Approval  | HIPAA Authorization  |
| Case report or retrospective chart review with three (3) or fewer (an *n* < 3) patients not presented as a systematic investigation designed to contribute to generalizable knowledge.  | IRB approval not required.  | If the case report will include one or more of the 18 PHI data elements, including “any other unique identifying number, characteristic, or code,” an authorization must be obtained for disclosure of the PHI in the case report. This includes a case so unique that individuals with personal knowledge of the incident could identify the patient. Investigators will be referred to Patrick Cross for assistance with HIPAA questions and the appropriate authorization for a case report. It is required that patients provide written HIPAA authorization to allow information on their case to be published, if it is not de-identified in accordance with 45 CFR 164.514(a). In the case of patients who are deceased, HIPAA authorization is required from the patients’ family, with the exception of persons who have been deceased for more than 50 years. |
| Case report or retrospective chart review of more than three (3) patients (an *n* > 3).  | IRB review and approval required. Submit appropriate IRB application.  | See IRB policy on the Memorial Health Intranet, Policy MS1005.  Written HIPAA authorization must be obtained unless the IRB has granted a waiver of authorization and/or documentation of informed consent.  |

**NOTE: Investigators asked by a journal to provide documentation of IRB approval prior to publication for a case report of three (3) or less patients must submit a written request to the IRB describing the case report to be published.**