

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 university 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 934-3789 if there is any doubt. All forms and additional guidance are available at www.uab.edu/irb.

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, serving as the UAB’s Privacy Board, 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.

Activity	IRB Approval	HIPAA Authorization
Case report or retrospective chart review with three (3) or fewer (an $n \leq 3$) patients not presented as a systematic investigation designed to contribute to generalizable knowledge.	IRB approval <u>not</u> 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 Shelia Searson for assistance with HIPAA questions and the appropriate authorization for a case report. It is required that patients provide <u>written</u> HIPAA authorization to allow information on their case to be published, if <u>it is not de-identified</u> 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. (See UAB HIPAA web site http://www.hipaa.uab.edu/faqs/PatientAuthorization.pdf for more information)
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 at http://www.uab.edu/policies/content/Pages/UAB-RA-POL-0000684.aspx 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. Upon receipt and review of the request the OIRB will issue a formal letter regarding the UAB policy.