INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

Case Reports Using Existing Data – Author Worksheet

Author Name and Affiliation:	
Department:	**Campus Address:**
Office Phone:	**E-mail Address:**
Co-author name(s) and affiliation(s):	
Title:	

The University of Utah IRB does not require review of case reports which do not meet the definition of human subject research. Use this form to determine whether submission to the IRB is required.

	TRUE	FALSE
The case report includes three records or less.		
Nothing was done to the patient(s) with prior research intent.		
The case report does not contain elements of a systematic investigation (e.g. statistical methods).		
The case report describes an interesting treatment, presentation or outcome.		
The published article will not contain any identifiable information[1] **or** authorization has been obtained[2].		

SUBMISSION IS NOT REQUIRED IF: All of the questions are "true". You must read and agree to the statement of assurance. Print a copy of this checklist, sign, date and save for your records.

SUBMISSION IS REQUIRED IF: Any of the questions are "false". Submit a new study application to the IRB.

Guidelines for Authors Submitting Case Reports

1. Many journals now require documentation of consent by the patient for case reports. Check with your intended journal before submitting your case report.
2. Take measures to protect the confidentiality of information obtained retrospectively about existing data studied in this review.
3. Record any data in a way that individuals will not be identifiable unless specific permission, documented in writing, to do so is granted by the individual(s) involved. Be sure to remove direct identifiers such as names, social security numbers, addresses and telephone numbers or any of the 18 protected health information identifiers noted in HIPAA regulations.
4. If the case study originates at Primary Children's Hospital (PCH), and the author seeks to identify a patient to write about in a case study but was not actually involved in the treatment, a waiver of authorization must be obtained from the PCH Privacy Office.
5. Submit a New Study Application, as required by the IRB, if further studies involving humans result from this report.
6. **Keep a copy of this checklist with all publication records for the report**

[1] Direct identifiers such as names, social security numbers, addresses, and telephone numbers or, any of the 18 protected health information identifiers noted in the HIPAA regulations.
[2] Signed authorization to disclose this information should be obtained from the individual(s) whose information is being disclosed. If the patient is deceased, authorization should be obtained from the next of kin or personal representative of the estate.