



Case Reports Using Existing Data - Author Worksheet

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The UMCIRB does not require review of case reports that do not meet the definition of human subject research. Information gathered for the a priori intent to conduct research is considered research and such studies must be submitted to the IRB for review. Use this form to help determine whether submission to the IRB is required.

	TRUE	FALSE
The case report includes three records or less (if more than three, call the IRB office).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Nothing was done to the patient(s) with prior research intent.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The case report does not contain elements of a systematic investigation (e.g. statistical methods, qualitative research, structured interviews, etc.).	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The case report describes an interesting treatment, presentation, or outcome.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
The published article will not contain any identifiable information ¹ , or authorization ² has been obtained.	<input checked="" type="checkbox"/>	<input type="checkbox"/>

SUBMISSION IS NOT REQUIRED IF: All of the questions are answered "TRUE".

- You must read and agree to the statement of assurance.
- Print a copy of this checklist, sign, and date.
- Save a copy for your records.

SUBMISSION IS REQUIRED IF: Any of the questions are "FALSE".

- Submit a new study application to the IRB.

Statement of Assurance

I agree to the following:

- I will take specific measures to protect the confidentiality of information obtained retrospectively about existing data studied in this review.
- I will record data in such a way that individuals will not be identifiable in any public communication unless specific permission, documented in writing, to do so is granted by the individual(s) involved.
- I will submit a separate new study application, as required by the IRB, if further studies involving human subjects are desired in this project.

I accept and agree to the terms set forth as it pertains to this checklist.

Narasimha Gollol Raju [Signature] 7.1.15
 Printed Name Signature Date

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. This also includes the description of a case so rare that an individual could be identified.

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.



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252-744-3224 fax
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To whom it may concern

7/1/14

I, Ms Recia McNair, allow Dr Narasimha Swamy Gollol Raju and the medical team to utilize my clinical information related to side effects from contrast media for the purpose of publication in a medical journal.

Recia McNair