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.

**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.

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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.