IRB Policy on Preparation and Publication of Case Reports and Case Series

SCOPE

This policy applies to case reports and case series.

PURPOSE

The purpose of this document is to provide guidance to the IRB and investigators on how to determine if case reports and case series meet the requirements to be classified as research based on human subject protections regulations (45 CFR §46.102(d)(f)) and the Office of Civil Rights regulations (45 CFR §164.501), respectively (Regulations).

PROCEDURE

1) Human Subjects Protections Regulations
   A. Single Case Reports – Limited Case Series (no more than 3 cases)

Regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Generally, a report of a small number of patients does not involve a systematic investigation as it does not include defining a hypothesis that is then investigated prospectively and systematically, to develop or contribute to generalizable knowledge. Therefore, the review of medical records for publication of a single case report or a case series involving data from two or three patients is not considered by the MD Anderson IRB to be research involving human subjects, and does not require IRB review and approval.

Single case reports and limited case series (of 3 or fewer patients) are not required to be submitted to the MD Anderson IRB for review and approval. To the extent that a journal or other publication requests proof of IRB approval prior to publication of single case reports or limited case series of 3 or fewer patients, please contact IRB Help to request documentation (see “IRB Letter” discussion below).

   B. Larger Case Series (more than 3 cases)

When a larger series of patients (more than 3) is being prepared for presentation or publication, a specific research question may have been defined, and a systematic collection of data follows. Such a systematic investigation more closely resembles prospectively designed human subjects research, and thus under the Regulations, a case series involving more than 3 patients may meet the definition of research, and therefore such research is subject to IRB review and approval.
Investigators are required to seek and obtain prospective approval from the IRB prior to conducting a review of the patients’ medical records for preparation of a report of a larger case series involving more than 3 patients.

2) **HIPAA Privacy Rule Requirements**

   **A. Single Case Reports – Limited Case Series Only**

Although IRB approval is not required to write a case report or a limited case series, certain HIPAA Privacy Rule requirements still apply to the use and disclosure of PHI.

MD Anderson regards case report preparation as an internal educational activity. The HIPAA Privacy rule permits a covered entity to use PHI for this purpose, as well as for the purposes of creating de-identified data sets. Therefore, it is permissible for MD Anderson workforce members to use protected health information (PHI) to prepare a de-identified case report without seeking an individual’s written HIPAA authorization. (45 CFR §§ 164.501, 164.502(d), 164.506(c)).

Investigators who submit de-identified case reports for publication do not need to obtain the patient(s)’s HIPAA authorization(s) prior to submission for publication. However, because case reports are usually interesting or unique cases by definition, it is very difficult to completely de-identify a case report. For a case report to be de-identified, it must be both: (1) stripped of the 18 HIPAA identifiers (including name or initials, dates more specific than a year, geographic locations more specific than a state, identifiable images, and many more – see MD Anderson’s Patient Privacy: De-Identification of Protected Health Information Policy (UTMDACC Inst. Policy #ADM1180) for the full list); and (2) unrecognizable to someone who knows the patient, including the patient him or herself. If a case report contains significant details about the patient, their medical history, procedures, etc., it may be possible for someone who knows the patient (or for the patient herself/himself) to know who is being described, and that means that it is not de-identified.

If de-identification is not possible due to the unique nature of the case(s) described or presence of any of the 18 HIPAA identifiers, a written HIPAA authorization must be obtained prior to sharing the case report outside of MD Anderson. It is not necessary to submit the HIPAA authorization form to the IRB for review.

HIPAA authorizations are available in Forms on Demand and in OneConnect among the consents (see “A” for Authorization). Signed HIPAA authorizations must be stored in the patient’s medical record. Signed forms may be submitted to HIM using the HIM collection boxes, or by emailing completed forms to HIM Import. If there is any doubt as to whether a description is “identifiable”, contact the Senior Legal Officer for Privacy Compliance in the Institutional Compliance Office (713-792-6636) at least 10 days prior to your intended submission date.

   **B. Case Series – More Than Three Individuals**

Should an investigator want to prepare publications on a larger series of patients (more than 3), separate IRB approval and HIPAA authorization rules will apply.
3) **IRB Letter for Journal/Publication Requests**

It is the policy of the MD Anderson IRB that a “single case report” or “limited case series” does not require review by the MD Anderson IRB. If an investigator wishes to have the project assessed by the MD Anderson IRB to determine if it meets the IRBs definition of a single case report or limited case series, the investigator may contact the IRB. If the project qualifies as a single case report or limited case series, the MD Anderson IRB will send to the investigator a form letter to share with external entities.

Investigators should inform the IRB if a journal does not accept the IRB’s decision. The issue will then be discussed with the IRB Chair and the Senior Legal Officer for Privacy Compliance to determine a resolution.

**REFERENCES**

Patient Privacy: Authorization for Use and Disclosure of Protected Health Information Policy (UTMDACC Inst. Policy #ADM0396); Patient Privacy: De-Identification of Protected Health Information (PHI) Policy (UTMDACC Inst. Policy #ADM1180)

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Initials</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/25/2018</td>
<td>New</td>
<td>WQ</td>
<td>New IRB3 Policy on Case Reports</td>
</tr>
<tr>
<td>6/27/2019</td>
<td>Rev</td>
<td>JH</td>
<td>Updated department name</td>
</tr>
</tbody>
</table>