TITLE: Institutional Review Board Waiver of Authorization

WA 1005 Case Report or Case Series

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT:
This policy is written to outline the expectations and procedures for review and evaluation of submissions for the use of patient protected health information in a case report or case series.

EXPLANATION:
Federal regulations for the protection of human subjects define research as "A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". A case report does not involve systematic investigation or contribute to generalizable knowledge. Case reports do not require IRB review and approval.

GENERAL PROVISIONS:
The review of a single medical record is considered a case report. A case report is performed as a medical/education activity. A case report does not need to be reviewed by the Mercy Health Regional IRB if it does not include any of the 18 HIPAA identifiers. Although the case report does not require IRB review, the author must still comply with HIPAA.

If the case report contains a "unique characteristic" (i.e., full facial picture or a tattoo) associated with the patient that may make the patient identifiable, or the if that information could be used in combination with other information to make the patient identifiable, the author of the case report must contact the Office of the IRB to discuss the required steps to take prior to conducting the case report.

The review of medical records involving 3 or more patients represents a systematic collection and data that will contribute to generalizable knowledge. This activity is considered a case series. Case series are typically considered research and should follow the Mercy Health Regional IRB research review and submission process. All case series must be reviewed and approved by the Mercy Health Regional IRB.

The HIPAA regulation requires a written HIPAA authorization for the patient or legally authorized representative (LAR) when the review of records involving less than five patients includes one or more of the 18 HIPAA identifiers. If the HIPAA identifiers are removed from the report then there is no need to obtain a signed HIPAA authorization.

The 18 HIPAA identifiers are:
- Name
- Address (all geographic subdivisions smaller than state, including street address, city, county, and zip code)
- All elements (except years) of dates related to an individual (including birthdate, admission date, discharge date, date of death, and exact age if over 89)
- Telephone numbers
- Fax number
- Email address
MERCY HEALTH

- Social Security Number
- Medical record number
- Health plan beneficiary number
- Account number
- Certificate or license number
- Any vehicle or other device serial number
- Web URL
- Internet Protocol (IP) Address
- Finger or voice print
- Photographic image - Photographic images are not limited to images of the face.
- Any other characteristic that could uniquely identify the individual

It is known that some journals require a letter from the IRB before they will publish a case report. If you intend to submit your case report for formal journal publication, please review the journal requirement and determine if the journal you intend to submit to requires an IRB letter. If they do, please submit a request for review of a case report through the IRBManager electronic submission portal.

DEFINITIONS:
Case Report: The collection and presentation of a single medical record for medical/educational purposes.
Case Series: A collection of 3 or more charts of patient information. Usually used to begin deriving specific information to answer a question. This activity typically moves into determining generalizable information which will meet the definition of research.

REFERENCE:
45 CFR 46.101 (b)
45 CFR 46.102 (d)
45 CFR 46.109 (a)
45 CFR 160, 164

PROCEDURE:

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Chairperson or designee</td>
<td>1. Review case report submissions as requested for formal journal publication.</td>
</tr>
<tr>
<td>Office of the IRB Staff</td>
<td>1. Advise individuals performing case reports that they do not require IRB review or approval.</td>
</tr>
<tr>
<td></td>
<td>2. If the individual conducting a case report intends to publish the case report in a formal journal, advise individual to follow journal directions.</td>
</tr>
<tr>
<td></td>
<td>3. Issue IRB approval as needed if a journal requires an IRB letter for case report publication.</td>
</tr>
</tbody>
</table>

CONCURRENT CONSENTS:  

[Signature]
Institutional Official

Version Date 12/04/2017