McLaren HEALTH CARE

Guidance on CASE REPORTS and CASE SERIES

General Guidance: Clinical education activities sometimes involve creating a Case Reports or Case Series of an interesting clinical situation or medical condition. It is important that use and disclosure of PHI for these activities is done in a HIPAA compliant manner.

MHC physicians, staff and medical residents have I.T. credentials to access patient records for the work/patient care purposes only. Data mining or searching MHC data bases or EMR **is not allowed** to find interesting trends or potential case study subjects. Anyone seeking to review records of patients not under their care, should contact the HIPAA Privacy Officer for approval of the request first.

CASE REPORT: External reporting (i.e. publication or poster/verbal presentation) of an interesting clinical situation or medical condition on **1-2 patients**.

- The patient information used in the report must have been collected solely for non-research purposes as the result of a clinical experience
- Case Reports do not have to be reviewed and approved by the Institutional Review Board, as they are not considered research
- Case Reports should contain only de-identified information or pictures that conceal the identity of the individual whenever possible.
    - **NOTE:** Consultation with a HIPAA Privacy Officer **is required** to confirm that the data and pictures are de-identified. The Privacy Officer does have the authority to make this final determination.
- A HIPAA Authorization is not required if the information in the case report does not allow the reader to identify the person
- If the data or pictures are not de-identified, written permission must be obtained from the individual using the McLaren Authorization Release of Information Form.

CASE SERIES: External reporting (e.g. publication or poster/verbal presentation) of an interesting clinical situation or medical condition in a series of **3 or more patients**. In general, an anecdotal report on a series of patients seen in one's own practice and a comparison of those patients to existing reports and literature do not require IRB approval. If it involves cases seen by other clinicians, however, it may be considered research requiring IRB review, particularly when the author is attempting to prove or disprove a hypothesis.

- The IRB must review a case series of 3 or more patients to determine whether it meets the definition of human subject research.
- All case series should be submitted to the McLaren IRB via a "Non-Human Subject Research Determination" form.
- If a case series is determined to be human subject research, the investigator must submit to the IRB for further review by completing an application via the eProtocol electronic submission system.
- If the IRB determines that a case series is NOT human subject research, no further IRB review is required. However, you need to contact your institution's Privacy Officer regarding accessing patient records.

If you have questions regarding this guidance please (248) 484-4950.