Retrospective Chart Review Guidance

When medical record data (paper, electronic, or databases created from a medical record) are being used for research, one of two review processes are used by WSU’s IRBs.

1) **Exemption**: When the proposed research fits exemption category 4 [45 CFR 46.101(b)(4); see exemption categories at: [http://irb.wayne.edu/exemptcat.php](http://irb.wayne.edu/exemptcat.php)], the following steps should be used to prepare the submission. Please note that for a chart review to receive concurrence of exemption from the IRB, it means that a **master list with a code number and identifiers cannot be kept**.

1. Complete a Medical Exemption Protocol Form
2. Complete a HIPAA Summary Form and request a waiver of authorization-
3. Submit a protocol- background, significance, research questions, inclusion/exclusion, methodology
4. Submit a list of variables to be collected from the record (data collection sheet)
5. Follow directions on the back page of the form

2) **Expedited Review**: When the proposed research fits expedited category 5 (45 CFR 46.110), the following steps should be used to prepare the submission. Please note that when a chart review is appropriate for expedited review, a **master list can be kept** with identifiers and a code number throughout the research study. Expedited Categories can be found on the IRB website at: [http://irb.wayne.edu/expeditecat.php](http://irb.wayne.edu/expeditecat.php)

1. Submit a Medical-Behavioral Protocol Summary Form
   a. Most of the questions about recruitment and consent are NA, except for the request for a waiver of consent (see section c.).
   b. Protecting confidentiality is the most important issue for a chart review-usually the only potential risk.
   c. You must request a request for a waiver of consent to conduct this retrospective review of records. Be sure to justify your request carefully.
2. Submit a HIPAA Summary form requesting a waiver of authorization-provide justification.
3. Submit a protocol-background, significance, research questions, inclusion/exclusion, methodology
4. Submit a list of variables to be collected from the record (data collection sheet)
5. Follow directions on the front of the form