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], 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

   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