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| **Rutgers NJMS - Retrospective Chart Review/UH Research Plan Checklist** |
| 1. **Pre-IRB submission: Protocol checklist – Assure the following:** |
| * PI or sub-investigator is a Rutgers faculty member with Medical staff privileges * Protocol clearly delineates retrospective study design with exact beginning and end dates for data abstraction and with no prospective aspect * Protocol clearly describes the patient population to be included (i.e. specific inclusion/exclusion criteria listed) * Protocol or IRB application describes the investigator’s plan to acquire the data (i.e. How will the investigator obtain a list of potentially eligible subjects? Is there a database maintained with the PI’s department or must reports be requested through University Hospital Medical Records?) * If reports must be requested through Medical Records, assure that the data is easily obtainable (i.e. reports of ICD-9 codes) Questions regarding the feasibility of medical record reports may be directed to Ms. Irene Szczech, Director, Medical Records, ext. 2-4014 or [szczecir@uhnj.org](mailto:szczecir@uhnj.org) * Protocol or IRB application describes an acceptable plan to protect the confidentiality of study subjects and the security of PHI. Acceptable plans include:   + No retention of name or MRN (i.e. data entered into a de-identified database) OR   + A plan to destroy the link to the subject’s name/MRN at the earliest possible opportunity (i.e. immediately after performing a final data quality check.) |
| 1. **IRB Application Stage**: e-mail the following to [OCRAReview@njms.rutgers.edu](mailto:OCRAReview@njms.rutgers.edu):  * Draft **protocol** version which will be submitted to the IRB * **UH Chart Review Registration form** – completed and signed by PI * **UH Research Plan** – completed and signed by the PI   Both forms are available at: <http://njms.rutgers.edu/research/ocra/forms.cfm> NOTE: ALL FORMS MUST BE COMPLETED ELECTRONICALLY AND **NOT BY HAND**. PRINCIPAL INVESTIGATOR SIGNATURES MAY BE EITHER DIGITAL OR MANUAL.  Once received, you will be provided with an e-mail receipt to upload to eIRB where prompted in section 5.0 of the application |
| **a. UH Chart Review Registration Form** (Version 14) Assure that:   * No personal e-mail addresses are used (i.e. use only ‘Rutgers.edu’ or ‘uhnj.org’ addresses) * Information on the form matches the approved protocol and IRB application (i.e. dates of retrospective data collection, conditions to be studied) * All individuals listed on the form are members of the study team as per the IRB application |
| b. **UH Research plan** – Assure that:   * Title of study matches the title as per IRB application and protocol * Protocol and UH Chart Review form are checked as attachments * For effective date, use the date of the PI’s signature or a date prior |
| 1. **Post-IRB approval**: Forward the notice of IRB approval to [OCRAReview@njms.rutgers.edu](mailto:OCRAReview@njms.rutgers.edu) |
| 1. **UH Research Plan Process:** Please allow 2 weeks from the time the notice of IRB approval is forwarded to NJMS-OCRA for final approval by UH. |
| 1. NJMS OCRA reviews package and forwards to UH Office of Clinical Research for review 2. Once the document package meets UH OCR approval, the Research Plan will be signed by both Rutgers and UH 3. UH OCR will forward a copy of the fully executed UH Research Plan to the PI and corresponding investigator 4. The study may be implemented once the UH Research Plan has been fully executed. |