Biomedical Informatics Data Set Request Requirements

The U.S. Office of Civil Rights and Washington State Law together set forth requirements under which an IRB (or privacy board) may approve the research use of patient information from the Electronic Health/Medical Record.

Request for Research Use of a Data Set Obtained Without Consent or HIPAA Authorization
The IRB may approve research uses of patient information without study-specific signed consent and HIPAA Authorization forms. If you'd like to request a patient data set without obtaining individual patient consent and HIPAA Authorization for your research project, here are some suggested processes to comply with federal HIPAA regulations, and Washington State Law that may be helpful in justifying your request for a HIPAA and/or Consent Waiver to the IRB.

1. **Describe the plan to protect the identifiers from improper use and disclosure.**
   Sample process: *We will assign a unique study code to participants, and the link to that unique study code will be kept in a <<locked secure cabinet, password-protected electronic file on a secure server>>. Aggregate de-identified data will be maintained in a password-protected electronic file on a secure server for research analysis.*
   [Source: 45 CFR 164.512 (i) (2) (ii) (A) (1), RCW 70.02.210 (1) (a) (iii), RCW 70.02.210 (1) (a) (iv)]

2. **Describe the plan to destroy identifiers at earliest opportunity consistent with conduct of research.**
   Sample process: *Identifiers will be destroyed by XX/XX/XXXX, when data analysis is complete.*
   [Source: 45 CFR 164.512 (i) (2) (ii) (A) (2) and RCW 70.02.210 (1) (a) (v)]

3. **Adequate written assurances that PHI will not be reused or disclosed to any other party or entity, except as required by law or for authorized oversight of the research.**
   Sample process: *PHI will not be reused or disclosed to any other party outside the research team, except as required by law or for authorized oversight of the research.*
   [Source: 45 CFR 164.512 (i) (2) (ii) (A) (3)]

4. **Explain why the research could not practicably be conducted without the waiver of authorization.**
   Sample process: *The scientific validity of the study requires that we identify all eligible patients over the study interval. We could not identify subjects for this study and collect data necessary to evaluate the study question without first knowing which patients should be included in our data set.*
   [Source: 45 CFR 164.512 (i) (2) (ii) (B)]

5. **Explain why the research could not practicably be conducted without access to and use of the PHI.**
   Sample process: *The electronic medical records of all eligible patients need to be reviewed for this study in order to evaluate the study question.*
   [Source: 45 CFR 164.512 (i) (2) (ii) (C) and RCW 70.02.210 (1) (a) (ii)]

6. **Explain how the research is of sufficient importance to outweigh the intrusion into the privacy of the patient.**
   Sample process: *The invasion of privacy is minimal in this case as we are only reviewing patient information to ascertain study eligibility. The benefit of this study is greater than the minimal risk involved. The study results may be instrumental in guiding more appropriate treatment with improved outcomes.*
   [Source: RCW 70.02.210 (1) (a) (i)]

Request for Research Use of a Data Set about Enrolled Participants

You can request a clinical data set about enrolled participants who have signed a consent form and HIPAA Authorization for your research project. Be sure that your IRB approval and study-specific HIPAA Authorization form are in compliance with the following requirements from the U.S. Office of Civil Rights and Washington State Legislature.

1. **Describe the information to be obtained in a specific, meaningful fashion, and describe the purposes of using the data.**
   To comply with these regulations, your IRB approval and study-specific HIPAA Authorization form should include:
   - ✓ A list of the variables you will include in the data set (*for example: demographics, discharge summary, radiology records/imaging/diagnostics, medical history/treatment, consultation, laboratory tests, EKG or EEG reports, psychological testing, pathology reports, operative report, anesthesia report, dental records*)
   - ✓ Rationale for utilizing these variables in the context of the research.
   - ✓ Procedures to protect identifiable data against breach of confidentiality.
   - ✓ The length of time you will retain identifiers and rationale for this time period.

   [Source: 45 CFR 164.508 (c) (1) (i) and (iv); RCW 70.02.030 (3) (b)]

2. **The name of persons/entities to whom the research data set will be disclosed, and the potential for re-disclosure of information by these parties without federal and state protections.**
   To comply with these regulations, your IRB approval and study-specific HIPAA Authorization form should:
   - ✓ Include a list of the members of the research team who will have access to identifiable data (see UW IRB's Confidentiality Agreement).
   - ✓ Declare whether or not you will share identifiable data with anyone outside the research team. If so, list which identifiers you will share, who these parties are, the reasons for this additional disclosure, and the possibility for re-disclosure by these parties without the same protections.

   [Source: 45 CFR 164.508 (c) (1) (iii), 45 CFR 164.508 (c) (2) (iii), RCW 70.02.030 (3) (c) and (d)]