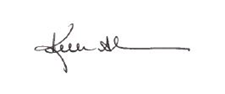
**16B. EVALUATION AND RESEARCH CoMMITTEE**

* 1. POLICY TITLE: Evaluation and Research Committee
     1. Officially Adopted: March 1, 2018
     2. Effective Date: April 1, 2018
     3. Signed:

## Kelli Nomura, Behavioral Health Organization Administrator

* 1. PURPOSE: To define the purpose and goals of the King County Behavioral Health and Recovery Division (BHRD) Evaluation and Research Committee and the legal requirements to be met by the review process.
  2. POLICIES AND PROCEDURES:
     1. BHRD will review and approve research studies in order to promote client confidentiality, informed consent and good research practices that protect clients in research and related activities directed, sponsored or approved by BHRD.
     2. BHRD, through the Evaluation and Research Committee, shall provide oversight to all evaluation and research activities that fall within its purview in order to ensure compliance with the policies and procedures in this manual.
     3. Any research and/or evaluation activities that involves data from BHRD information systems or any data collected and maintained by BHRD must be reviewed and acted upon by the Evaluation and Research Committee prior to the initiation of such activity.
     4. Approval from the Evaluation and Research Committee or a data-sharing agreement does not eliminate the requirement for a consent from the client when it would otherwise be required.
     5. The BHRD Evaluation and Research Committee will:
        1. Review all evaluation and research proposals involving data and/or staff resources obtained or supported by BHRD funds to ensure that activities are consistent with the policies outlined in this manual.
        2. For approved proposals, facilitate fulfillment of the BHRD responsibilities as specified in the proposal.
        3. Work with the involved Institutional Review Board(s) (IRB) to coordinate and facilitate the approval process.
        4. Work with the Privacy and Security Committee to monitor researchers’/evaluators’ electronic access to BHRD data.
        5. Review submitted proposals.
        6. Monitor completion of approved projects.
        7. Monitor annual IRB renewals. The Evaluation and Research Committee may request an annual copy of study modifications submitted to an IRB when the modifications affect how BHRD data is collected, used or disclosed.
        8. Monitor and track all disclosures of protected health information (PHI) approved by the Evaluation and Research Committee so that this information is available if a client requests an accounting of disclosures. The accounting must include disclosures of PHI that occurred during the six years (or such shorter time period at the request of the client) prior to the date of the request for accounting. The following information must be provided to a client who requests such an accounting.[[1]](#footnote-1)
           1. Name of the protocol or the research activity:
           2. A description of the research protocol or other research activity, including the purpose of the research and the criteria for selecting particular records;
           3. A brief description of the type of PHI disclosed;
           4. The date or period of time during which such disclosures occurred, or may have occurred, including the date of the last such disclosure;
           5. The name, address, and telephone number of the entity that sponsored the research/evaluation and of the researcher/evaluator to whom the information was disclosed; and
           6. A statement that the PHI of the client may or may not have been disclosed for a particular protocol or other research activity.
        9. If BHRD provides an accounting for research/evaluation disclosures, and it is reasonably likely that the PHI of the individual was disclosed for such research/evaluation protocol or activity, BHRD will, at the request of the individual, assist in contacting the entity that sponsored the research/evaluation and the researcher/evaluator.
     6. Requests to the Evaluation and Research Committee for review of evaluation and research activities will be conducted as follows:
        1. Researchers/Evaluators proposing studies utilizing BHRD data must submit the Evaluation and Research Proposal Application and Checklist and all required materials. The Evaluation and Research Committee will retain records of all reviewed studies for a period of seven years from study/evaluation completion.
        2. Prior to submitting a proposal, the requester must have a consultation with an Evaluation and Research Committee member. If identified or identifiable data is being requested from BHRD, the requester must also have a consultation with the BHRD Privacy Officer prior to proposal submission.
        3. Subject to the requirements of 42 Code of Federal Regulations (CFR) Part 2 and 45 CFR Part 164, individuals or agencies shall present project materials for Human Research Subject Review (HRSR) at an IRB, if required. Projects may be submitted simultaneously to the IRB and BHRD, but final approval by BHRD will not be given until the IRB or Privacy Board approval or a waiver is obtained. This documentation shall be submitted to the Evaluation and Research Committee prior to final approval of the research. If the IRB has waived the requirement for an authorization or has approved an alteration of the authorization requirement, then the researcher shall present a statement that the IRB has determined that the waiver of authorization satisfies the criteria found in 45 CFR Part 164.512(i).
        4. The requester shall provide a brief description of the PHI for which use or access has been determined to be necessary by the IRB[[2]](#footnote-2). (That is, the minimum necessary information without which the research would not be practical.)
        5. The requester shall provide a description of the purpose(s) for which the data is requested.
        6. All researchers/evaluators that request access to BHRD data shall use and sign a data use agreement that meets the requirements of 45 CFR 164.514 (e)(4). An acceptable data-sharing agreement template can be found on the BHRD Information for Researchers webpage. The specifics of each data-sharing agreement will be developed in collaboration by the researcher/evaluator and BHRD Privacy Officer.
           1. The BHRD Privacy Officer may consult with legal counsel or others, as appropriate, prior to approving the data-sharing agreement.
           2. The data sharing agreement must be signed and executed prior to the release of any data from BHRD to the requester.
           3. A researcher/evaluator may request a “limited data set” as defined by 45 CFR Part 164.514(e). This use shall require a limited data use agreement. An acceptable limited data use agreement template is found on the BHRD Information for Researchers webpage.
        7. If a researcher/evaluator requires data from BHRD, the data set will be created by BHRD subject to available resources. The requester must clearly specify what they expect BHRD staff to do with respect to the data set and what the requester will do. A proposal may not be approved if the resources are not available.
        8. If a researcher/evaluator requests access to a specific client’s data, provision may be made for BHRD personnel to obtain specified information for the researcher/evaluator subject to resources available. In such cases, the researcher/evaluator shall provide BHRD with a copy of the authorization for release of information signed by the client. This copy will be kept in the client’s file or in a central file if there is no paper file for the client.
        9. The Evaluation and Research Committee will endeavor to review each proposal within a month of when it was received. Applications must be received a minimum of one week prior to the next scheduled committee meeting to be reviewed.
        10. The Evaluation and Research Committee Chair will notify the researcher/evaluator of the Committee’s decision. If the project is approved, a designated committee member will be identified as a primary liaison to the researcher/evaluator for the life of the project.
        11. All research/evaluation approved by the Evaluation and Research Committee shall adhere to the fully executed data sharing agreement between the researcher/evaluator and BHRD. In accordance with this agreement, all individuals having access to confidential information – whether electronic or non-electronic – shall have a completed oath of confidentiality on file with BHRD. All individuals accessing confidential information shall submit written verification of Health Insurance Portability and Accountability Act (HIPAA) training, and when relevant, human subjects training.
     7. While study/evaluation design and methodology of the project results are the responsibility of the project researcher/evaluator, BHRD requests immediate notification (at the same time that the IRB is notified and before any more data is accessed) in the event of significant protocol changes, protocol changes that impact how BHRD data is collected, used or disclosed, or any adverse unforeseen events throughout all phases of the project. This specifically refers to any events that would have to be reported to the IRB that approved the protocol.
     8. When approval is granted, it shall be for one year, renewable annually, unless the IRB approval terminates sooner. IRB-approved research may not proceed after IRB approval has expired or been rescinded. Researchers must provide the Evaluation and Research Committee a copy of the annual IRB renewal letter.
     9. All approvals are conditional based on adherence to this policy and conditions negotiated during the approval process. Approval may be rescinded if all conditions are not met.
     10. A final report and a copy of publications shall be provided to the Evaluation and Research Committee at the conclusion of the project.
     11. Research/evaluation results shall be shared with BHRD and BHRD shall be allowed to use or share with contractors or other government entities any product or information without censure or cost.
     12. BHRD data may be used only for the purposes outlined in the approved project.
  3. RESPONSIBILITIES:
     1. BHRD is responsible for maintaining and supporting the Evaluation and Research Committee.
     2. The Evaluation and Research Committee is responsible for preliminary review and waiving, approving or disapproving proposed research and/or evaluation activities in a timely fashion.
     3. The Privacy Officer is responsible for review and approval of oaths of confidentiality and applications for access to the BHRD electronic client information.
     4. IRBs at the researcher’s institution(s) or with jurisdiction over the research are responsible for the human subjects review of all research utilizing human subjects as required in 45 CFR Part 46 and 45 CFR Parts 160 and 164 (HIPAA).
     5. Researchers/evaluators who intend to access BHRD data or use a BHRD database to identify or recruit clients for their research study are responsible for following this policy.
  4. REFERENCES:

Washington State Laws, Regulations, and Policy including any successor, amended, or replacement laws, regulations, or policies

* Chapter 388-04 Washington Administrative Code (WAC) – Protection of Human Research Subjects
* Chapter 388-877[[3]](#footnote-3) WAC – Community Mental Health and Involuntary Treatment Programs
* Chapter 10.77 Revised Code of Washington (RCW) – Criminal Procedure – Criminally Insane
* Chapter 42.48 RCW – Release of Records for Research
* Title 70 RCW – Public Health & Safety
* Chapter 70.02 RCW – Medical Records – Health Care Information Access and Disclosure[[4]](#footnote-4)
* Chapter 70.96A RCW – Treatment for Alcoholism, Intoxication, and Drug Addiction[[5]](#footnote-5)
* Title 71 RCW – Mental Illness
* Chapter 71.05 RCW – Mental Illness[[6]](#footnote-6)
* Chapter 71.24 RCW – Community Mental Health Services Act
* Chapter 71.34 RCW – Mental Health Services for Minors[[7]](#footnote-7)

Federal Law, Regulations, and Policy including any successor, amended, or replacement laws, regulations, or policies

* 42 CFR Part 2 – Public Health Service, Department of Health and Human Services, Confidentiality of Alcohol and Drug Abuse Patient Records
* 45 CFR Part 46 – Protection of Human Subjects. The Public Health Act as Amended by the Health Research Extension Act of 1985[[8]](#footnote-8)
* 45 CFR Parts 160 and 164 – Standards for Privacy of Individually Identifiable Health Information

1. 45 CFR 164.528(b)(4) [↑](#footnote-ref-1)
2. 45 CFR 164.512 (i)(2)(ii)(C) and (iv) [↑](#footnote-ref-2)
3. See 388-877-0600 Individual Rights [↑](#footnote-ref-3)
4. See 70.02.050 [↑](#footnote-ref-4)
5. See 70.96A.150 [↑](#footnote-ref-5)
6. See 71.05.390 Confidential information and records – disclosures and 71.05.630 Treatment records – Confidential – Release. [↑](#footnote-ref-6)
7. See 71.34.200 Information concerning treatment of minors confidential – Disclosure – Admissible as evidence with written consent. [↑](#footnote-ref-7)
8. See 45 CFR 164.512(i) [↑](#footnote-ref-8)