VALUATION AND RESEARCH REVIEW COMMITTEE

1.0 POLICY TITLE: EVALUATION AND RESEARCH REVIEW COMMITTEE

2.0 EFFECTIVE DATE: April 14, 2003

2.0 PURPOSE: To define the purpose and goals of the King County Mental Health, Chemical Abuse and Dependency Services Division (MHCADSD) Evaluation and Research Committee and the legal requirements to be met by the review process.

3.0 REFERENCES:

Washington State Laws and Regulations

WAC[1] 388-04	Protection of Human Research Subjects
WAC 388-865[2]	Community Mental Health and Involuntary Treatment Programs
RCW[3] 10.77	Criminal Procedure – Criminally Insane
RCW 42.48	Release of Records for Research
RCW Title 70	Public Health & Safety
RCW 70-02	Medical Records – Health Care Information Access and Disclosure[4]
RCW 70.96A	Treatment for Alcoholism, Intoxication, and Drug Addiction[5]
RCW Title 71	Mental Illness
RCW 71.05	Mental Illness[6]
RCW 71.24	Community Mental Health Services Act
RCW 71.34	Mental Health Services for Minors[7]

Federal Regulations

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].

45 CFR Parts 160 and 164 – Standards for Privacy of Individually Identifiable Health Information

[1] WAC is the abbreviation for Washington Administrative Code
[2] See 388-865-0410 Consumer Rights
[3] RCW is the abbreviation for Revised Code of Washington
[4] See 70.02.050
[5] See 70.96A.150
[6] See 71.05.390 Confidential information and records – disclosures and 71.05.630 Treatment records – Confidential – Release.
[7] See 71.34.200 Information concerning treatment of minors confidential – Disclosure – Admissible as evidence with written consent.
[8] See 45 CFR 164.512(i)

4.0 RESPONSIBILITIES:

4.1 The Mental Health, Chemical Abuse and Dependency Services Division is responsible for maintaining and supporting the Evaluation and Research Committee.

4.2 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.

4.3 The Privacy Committee is responsible for review and approval of oaths of confidentiality and applications for access to the MHCADSD electronic client information.

4.4 Institutional Review Boards (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).

4.5 Researchers who intend to access MHCADSD data or use an MHCADSD database to identify or recruit clients for their research study are responsible for following this policy.

5.0 POLICIES AND PROCEDURES

5.1 MHCADSD 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 MHCADSD.

5.2 MHCADSD, 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.

5.3 Any research and/or evaluation activities that involves data from MHCADSD information systems or any data collected and maintained by MHCADSD must be reviewed and acted upon by the Evaluation and Research Committee prior to the initiation of such activity.

5.4 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.

5.5 The MHCADSD Evaluation and Research Committee will :

5.5.1 Review all evaluation and research proposals involving data and/or staff resources obtained or supported by MHCADSD funds to assure that activities are consistent with the policies outlined in this manual.

5.5.2 For approved proposals, facilitate fulfillment of the MHCADSD responsibilities as specified in the proposal.

5.5.3 Work with the involved IRB(s) to coordinate and facilitate the approval process

5.5.4 Work with the Privacy Committee to monitor researchers' electronic access to MHCADSD data.

5.5.5 Review submitted proposals.

5.5.6 Monitor completion of approved projects.

5.5.7 Monitor and track all disclosures of protected health information (except limited data sets, see Appendix C)[9] approved by the Evaluation and Research Committee so that this information is available if a client requests an accounting of all such disclosuress. This disclosure tracking shall extend for 6 years after each release of information that takes place on or after April 14, 2003, the compliance date of 45 CFR Part 164. The information required in appendix D from the researcher must be provided to a client who requests such an accounting:[10]

5.5.8 If MHCADSD provides an accounting for research disclosures, and it is reasonably likely that the protected health information of the individual was disclosed for such research protocol or activity, MHCADSD will, at the request of the individual, assist in contacting the entity that sponsored the research and the researcher.

5.6 Requests to the Evaluation and Research Committee for review of evaluation and research activities will be conducted as follows:

5.6.1 Researchers proposing studies utilizing MHCADSD data must submit a the Evaluation and Research Proposal Checklist (Appendix A) and all required materials. The Evaluation and Research Committee will retain records of all reviewed studies for a period of 7 years.

[9] 164.528(a)(1)(viii)
[10] 45 CFR 164.528(b)(4)

5.6.2 Subject to the requirements of 42 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 MHCADSD, but final approval by MHCADSD 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)

5.6.3 The requester shall provide a brief description of the protected health information for which use or access has been determined to be necessary by the IRB[11]. (That is, the minimum necessary information without which the research would not be practical).

5.6.4 All researchers that request access to MHCADSD data shall use and sign a data use agreement that meets the requirements of 46 CFR 164.514 (e)(4). An example of an acceptable data sharing agreement can be found in Appendix B. The specifics of each data sharing agreement will be negotiated between the researcher and MHCADSD.

5.6.5 All researchers requesting access to KCMHDSD client protected health information shall maintain a tracking system in order to provide an accounting of disclosures as provided in 45 CFR 164.528(b)(4)(i).

A. Each researcher shall regularly[12] provide an electronic file containing the name of the Research Protocol, each King County Client Identification Number, the variables accessed for research and the date(s) the protected health information was accessed.

B. All researchers shall complete the form in Appendix D containing the information required in 45 CFR 164.528 (b)(4). A copy of this form will go in the study file.

C. MHCADSD shall maintain an Excel file of research protocols and the clients whose information was disclosed for each protocol. This file shall be used in order to provide an accounting of disclosures (according to 45 CFR part 164) when requested.

5.6.6 A researcher may request a "limited data set" as defined by 45 CFR Part 164.514(e). See Appendix C for requirements of a limited data set. This use shall require a data use agreement and still must be approved by an IRB in order to meet the reqirements of RCW 70.02

[11] 45 CFR 164.512 (i)(2)(ii)(C) and (iv)
[12] Frequency depends upon the design of the research study.

A. A limited data set excludes identifiers as specified. Excluded identifiers include the King County Identification Number (KCID) or any other health identifier number that might be used to re-identify individuals.

B. A data use agreement between MHCADSD and the limited data set recipient must meet the requirements of the law. An example of a data use agreement can be found in Appendix B of this policy.

5.6.7 If a researcher requires data from MHCADSD, the data set will be created by MHCADSD subject to available resources. A proposal may not be approved if the resources are not available.

5.6.8 If a researcher requests access to a specific client's data, provision may be made for MHCADSD personnel to obtain specified information for the researcher subject to resources available. In such cases, the researcher shall provide MHCADSD 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.

5.6.9 The Evaluation and Research Committee will endeavor to review each proposal within a month of when it was received.

5.6.10 The Evaluation and Research Committee Chair will notify the researcher of the Committee's decision. If the project is approved, the Evaluation and Research Committee Chair shall be the primary contact person for the life of the project.

5.6.11 All research approved by the Evaluation and Research Committee shall adhere to the MHCADSD Confidentiality Policy. A copy of this confidentiality policy will be posted on the MHCADSD web page. In accordance with this policy, all persons having access to confidential information – whether electronic or non-electronic - shall have a completed oath of confidentiality on file with MHCADSD and this oath shall be updated annually in accordance with policy.

5.7 While study design and methodology of the project results are the responsibility of the project researcher, MHCADSD requests immediate notification (at the same time that the IRB is notified and before any more data is accessed) in the event of protocol changes or 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.

5.8 When approval is granted, it shall be for one year, renewable annually, unless the IRB approval terminates sooner. Research may not proceed after IRB approval has expired or been rescinded.

5.9 All approvals are conditional based on adherance to this policy and conditions negotiated during the approval process. Approval may be rescinded if all conditions are not met.

5.10 A final research report and a copy of all publications shall be provided to the Evaluation and Research Committee at the conclusion of the project.

5.11 Research results shall be shared with MHCADSD and MHCADSD shall be allowed to use or share with contractors or other government entities any product or information without censure or cost.

5.12 MHCADSD data may be used only for the purposes outlined in the approved project.

Appendix A

King County Mental Health Chemical Abuse and Dependency Services Division

EVALUATION AND RESEARCH COMMITTEE PROPOSAL CHECKLIST

Cover Page for Submitted Proposals

Item to be included with Proposal (Items with page reference box shaded should be filled out in the space below.)	Page Reference
Name of Principal Investigator (PI) _____	
Name of Project Contact Person: **Person to whom all correspondence will be sent.**	
Telephone number for Contact: _____	
Email address of Contact Person: _____	
Mailing address for Contact Person: _____ _____ _____ _____ _____	
Date Submitted to MHCADSD: _____	
Date submitted to IRB (if not yet approved)	
Date of IRB Approval: (Projects may not begin before a copy of the current IRB approval is received by MHCADSD. Leave blank if not yet approved by IRB):_____	
Date Project is to begin:_____	
Date Project is to end (must be within the approval dates of the IRB, or indicate renewal of IRB will be required, and send copies of IRB renewals before continuing past original end date): _____	
Name of Proposal:_____ _____	
An institutional review board (IRB) a**s defined in 45 CFR Part 164.512(i)** shall review and approve research prior to contact with subjects. [70.02.010 RCW, WAC 388-865, and 45 CFR Part 164.512(i)] Submit to MHCADSD Evaluation and Research committee the entire IRB package – all forms -- for review of the Proposal with comments from the IRB committee and supporting documents. Final IRB approval is required before research may begin[13]. **A copy of the final approval should be sent to the Evaluation & Research Committee when it is granted.** [WAC 388-865, 42 CFR Part 2, 45 CFR Part 46, 45 CFR Part 164 and 70.96A.150 RCW]	
MHCADSD Project Number[14] *(Leave this space blank. To be filled in by Committee Chair)*	
Appendix D: One page (or less) summary of proposal in plain language(page number) (Or a second summary in plain language if the initial summary is too technical to be used in an accounting of disclosures to clients)	
For studies requiring a full review, the following	
Copy of the Complete Proposal Including all appendices	
Detailed Budget with respect to MHCADSD services	
If client identifying information is required, a copy of all protocols to be followed in working with clients, including The methodology and administrative costs of contact, the voluntary nature and extent of client participation, and a	

[13] **The Evaluation and Research Committee may review a study prior to final IRB approval and write a letter of support to be included in the IRB package. However, final approval for all research will not be granted by MHCADSD until a copy of the current IRB approval and signature is received.**

[14] Each proposal will be given a MHCADSD Number. This number will define unique studies in our files. Please make note of the number when it is assigned as all files will be kept by that number.

King County Mental Health Chemical Abuse and Dependency Services Division

EVALUATION AND RESEARCH COMMITTEE PROPOSAL CHECKLIST

Cover Page for Submitted Proposals

Item to be included with Proposal (Items with page reference box shaded should be filled out in the space below.)	Page Reference
C**opy of all letters, advertisements, scripts or other mechanisms for contacting and involving client subjects**.	
Copy of all protocols for contacting subcontractors	
Copies of letters of support	
Copies of working agreements	
Specify exactly what **information you will require from MHCADSD**. Do we need to supply the name of the subcontractor and the client ID? How many times does MHCADSD have to provide information for your project?	
IF Human Subjects review is not required, the proposal must be reviewed and approved by a **Privacy Board** as required by 45 CFR 164.512. Please submit a copy of the signed approval from the chairman of the privacy board and (or including) a copy of the submitted proposal including a detailed abstract of the proposed project to include: (1) A brief overview of the proposal (2) Questions which the project will investigate (e.g. each hypothesis to be tested) (3) A description of the project design. [45 CFR 164.512(i), 42.48, 70.02, 71.05.390, 71.05.630 and 71.34 RCW] [Substance Abuse laws include 42 CFR Part 2, 45 CFR Part 46, 70.96A.150 RCW]	
Detailed list of **data required** from MHCADSD IS. (We will provide technical support for creating this list) Data will be limited and **will usually not include personal identification such as name, date of birth or social security number. Because of limited staff time, we may not be able to accommodate requests for research data, or there may be a long delay in obtaining such data. SPECIFY ALL VARIABLES REQUESTED**	
Copies of project timeline as it impacts the MHCADSD. Include date final report of the project is due. Date individual data files are required. (Note that at least 4 weeks notice will be required to change these dates)	
Specify Resources required from MHCADSD. Include all data needs here. Also include staff resources required. Include approximate date county resources will be needed on the timeline or elsewhere.	
Confidentiality Issues. How will confidentiality be protected? What personal information is required and why. Include the protocol on how the data will be kept secure. (Locked file cabinets, encrypted data files, etc.) and the timeline for destruction.	
Agreement to share results of research with MHCADSD and subcontractors.	
Agreement to limit use of MHCADSD data to the above approved proposal only. **A Completed Data Sharing Agreement (Appendix B) must be submitted** and terms may be negotiated with KCMHDSD for ALL research utilizing personal health data on KCMHDSD clients, including de-identified data sets. See Data Sharing Agreement Sample format, and 45 CFR 164.514(e)(4)	
Investigator agrees to give at least 4 weeks notice when requesting any data including lists of eligible clients in order for the IS personnel to schedule this task	

Note: The MHCADSD Evaluation and Research Committee will endeavor to review each proposal within a month of when it was received.

Appendix B
King County Mental Health, Chemical Abuse and Dependency Services Division

Sample RESEARCH and DATA SHARING AGREEMENT[15]

Agreement made between [Researcher's Name, Affiliation]_____ and members of the research team who will have access to confidential information and who have signed this Agreement (hereinafter referred to as "RESEARCHERS"), and King County Mental Health, Chemical Abuse and Dependency Services Division (hereinafter referred to as "KCMHCADSD").

WHEREAS the RESEARCHERS have submitted a written research proposal entitled [Title of Proposal] "_____" to KCMHCADSD dated _____, a copy of which is annexed hereto and made a part hereof; and

WHEREAS an Institutional Review Board (IRB) or Privacy Board has reviewed said proposal, and has determined that it clearly specifies the purposes of the research and the information sought and is of importance in terms of the agency's program concerns, that the research purposes cannot be reasonably accomplished without disclosure of information in individually identifiable form [and without waiver of the informed consent of the person to whom the record pertains or the person's legally authorized representative], that disclosure risks have been minimized and that remaining risks are outweighed by anticipated health, safety or scientific benefits, and has approved said proposal with respect to scientific merit and the protection of human subjects; and

WHEREAS the RESEARCHERS have declared to be in receipt of the division's Evaluation and Research Review Committee and have had each individual researcher complete and sign an MHCADSD Oath of Confidentiality;

NOW THEREFORE, IT IS AGREED AS FOLLOWS:

Data Requested:

1. The purpose for which the data are requested is: [insert details here].
2. The Period of Agreement. This agreement shall commence on the date of signature (or on: _____) and shall expire on: _____, or if no date is inserted, shall expire one year after the signature date.
3 Description of data shared:
   A. Data file specification (dates, data elements)
   B. Inclusion Criteria (filter variables)
   C. File format (tab delimited, name of file, type of file, diskette or whatever)
   D. File retention: Data Identifiers[16] will be destroyed on ____/____/____ or at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining identifiers[17]. In studies where client authorization is obtained, use and retention of the data must be consistent with the authorization form that the client signed.

[15] This form is to be modified as agreed upon by the researcher and the KCMHCADSD Research Committee to meet the individual requirements of each research study.
[16] Identifiers include names, KCID or medical identification numbers and all other identifiers listed in 45 CFR 164.502(d).
[17] 45 CFR 164.512(i)(2)(ii)(A), RCW 70.02.050(g)(v) and RCW 42.48.020(2)(c)(iii)

E. Researcher shall maintain, document and maintain records of informed consent from each subject or the subject's legally authorized representative s required by law and stipulated by the IRB unless the IRB documented that waiver of some or all of the elements of informed consent has been approved for this research.

Specifications of data disclosed:[Insert details here]: _____

4. Management of Data

A. Storage, privacy protections as follows: _____. The data will be stored in a secure database only accessible to authorized system users and only as necessary as defined below,

B. Access. Database Administration Access: _____ staff whose responsibilities include database administration will have unrestricted views of the data. They are permitted to perform any task with the data as needed to maintain and archive the data. Data administrators must comply with the terms of this agreement and with applicable state and federal confidentiality requirements limiting the release of client identifying information.

5. The RESEARCHERS will:

(a) Uses of data disclosed: [insert details here] _____

(b) Create a master identifier file which links names and direct identifiers with arbitrary study codes, protect this master file with passwords known only to the RESEARCHERS, and maintain all copies of the master file in a secure, locked location at all times when not in use;

(c) Remove names, and other data elements which could identify individuals, from records in the study database, identify records in the database only with arbitrary study codes, and ensure that, without access to the master identifier file or KCMHCADSD records, all database records are unidentifiable;

(d) Maintain all KCMHCADSD records and record information in secure locked locations or in password protected computer files when not in use;

(e) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this agreement.

(f) Restrict access to KCMHCADSD records and record information, including the master identifier file, to persons who have signed this Agreement;

(g) Notify the KCMHCADSD Evaluation and Research Committee if other identifiable data not specified in this Agreement are needed for the study;

(h) Report to KCMHDSD any use or disclosure of the information not provided for by this data use agreement of which RESEARCHER becomes aware.

(i) Ensure that any agents, including a subcontractor, to whom RESEARCHER provides the individually identified personal health data or limited data set agrees to the same restrictions and conditions that apply to the RESEARCHER with respect to such information

(j) Report or publish findings in a manner that does not permit identification of persons whose records are used in the research;

(k) Destroy the master identifier file, and all individual identifiers associated with the KCMHCADSD records or record information when study purposes have been accomplished and provide written certification to the KCMHCADSD Evaluation and Research Committee that this requirement has been fulfilled.

6. The RESEARCHERS will **not**:

(a) Link KCMHCADSD records or record information, or study database records, with information obtained from sources other than those identified in their proposal to KCMHCADSD without the express written permission of the KCMHCADSD Evaluation and Research Committee;

(b) Identify the information in a de-identified limited data set.

(c) Contact or attempt to contact any person identified in records provided by KCMHCADSD without the express written permission of the KCMHCADSD Evaluation and Research Committee;

(d) Disclose, publish, provide access to, or otherwise make known any individually identifiable information in KCMHCADSD records or de-identified limited data set released under this Agreement, or in study database records created under this Agreement, except as provided in RCW 42.48.040;

(e) Copy, duplicate or otherwise retain individually identifiable information provided or created under this Agreement for any use after study purposes have been accomplished.

(f) Transmit any KCMHCADSD/DOH record or record information across any electronic network or medium unless the individual records have been securely encrypted.

7. The RESEARCHERS agree to use the information provided by KCMHCADSD for no purposes other than those described in their proposal to KCMHCADSD. Substantial changes in study design and methods, changes that may affect approved study purposes, and/or use of this record information of thesis, dissertation, or other educational purposes that are not described in the RESEARCHERS' proposal to KCMHCADSD, will be subject to prior review and approved by the KCMHCADSD Evaluation and Research Committee.

8. KCMHCADSD assumes no responsibility for the accuracy or integrity of data derived or created from the source data provided under this Agreement, or for the accuracy or integrity of the source data once the RESEARCHERS have altered or modified the data, or linked the data with other data files.

9. KCMHCADSD assumes no responsibility for the accuracy or validity of published or unpublished conclusions based in whole or in part on analyses of data provided to the RESEARCHERS.

10. The RESEARCHERS agree that KCMHCADSD shall have the right, at any time, to monitor, audit, and review activities and methods in implementing this Agreement in order to assure compliance therewith.

11. In the event the RESEARCHERS fail to comply with any terms of this Agreement, KCMHCADSD shall have the right to take such action, as it deems appropriate, including termination of this Agreement. If the Agreement is terminated, the RESEARCHERS will forthwith return all information provided by KCMHCADSD, including all materials derived from this information, or

make such alternative disposition of provided and derived information as directed by KCMHCADSD. The exercise of remedies pursuant to this paragraph shall be in addition to all sanctions provided by law, and to legal remedies available to parties injured by unauthorized disclosure.

12. The RESEARCHERS will hold KCMHCADSD harmless from any damage or other liability, which might be assessed against KCMHCADSD as a result of any information received pursuant to this Agreement.

13. Unauthorized disclosure of any identifiable information provided under this Agreement is a gross misdemeanor and may also result in a civil penalty of not more than ten thousand dollars for each violation, under the provisions of RCW 42.48.050. Federal requirements of 42 CFR Part 2.32 requires any disclosure of protected substance abuse information made with written patient consent to be accompanied by a written statement that the information disclosed is protected by federal law and that the recipient cannot make any further disclosure of it unless permitted by the regulations. Further, under federal law, any RESEARCHER that receives a limited data set and violates the data use agreement will be in noncompliance with the standards, implementation specifications and requirements of 45 CFR 164.514(e). Penalties for noncompliance may result in a fine of up to $250,000, imprisonment of up to 10 years or both.

14. This Agreement becomes effective on the date it is signed by the KCMHCADSD official authorized to approve disclosure of identifiable records or record information for research purposes. This Agreement remains in effect until the date specified in the Agreement, or until the RESEARCHERS provide written certification to the KCMHCADSD Evaluation and Research Committee that all KCMHCADSD records and record information, and all study databases created in whole or in part from KCMHCADSD records or record information, provided under this Agreement have been destroyed or returned to KCMHCADSD.

IN WITNESS WHEREOF, the parties have signed their names hereto on the dates appearing with their signatures.

_____	_____
Administrator, Title KCMHCADSD	Date
_____	_____
Researcher's Name Affiliation	Date

_____	_____	_____
Research Staff Member (Please Type Name)	Signature	Date
_____	_____	_____
Research Staff Member (Please Type Name)	Signature	Date

Add signature lines as necessary for all research staff members to sign this document.

APPENDIX C
Limited Data Set, from 45 CFR Part 164.514(e) HIPAA

(e)…

(1) *Standard: Limited data set*. A covered entity may use or disclose a limited data set that meets the requirements of paragraphs (e)(2) and (e)(3) of this section, if the covered entity enters into a data use agreement with the limited data set recipient, in accordance with paragraph (e)(4) of this section.

(2) *Implementation specification: Limited data set*. A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

(i) Names;

(ii) Postal address information, other than town or city, State, and zip code;

(iii) Telephone numbers;

(iv) Fax numbers;

(v) Electronic mail addresses;

(vi) Social security numbers;

(vii) Medical record numbers;

(viii) Health plan beneficiary numbers;

(ix) Account numbers;

(x) Certificate/license numbers;

(xi) Vehicle identifiers and serial numbers, including license plate numbers;

(xii) Device identifiers and serial numbers;

(xiii) Web Universal Resource Locators (URLs);

(xiv) Internet Protocol (IP) address numbers;

(xv) Biometric identifiers, including finger and voice prints; and

(xvi) Full face photographic images and any comparable images.

(3) *Implementation specification: Permitted purposes for uses and disclosures.*

(i) A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only for the purposes of research, public health, or health care operations[18].

[18] RCW 70.02.050 further limits the use of a limited data set. IRB approval is required for all research disclosures including limited data sets (70.05.050(g)(v). For public health and health care operations, disclosures are limited by 70.02.050(2)(a) and 70.02.050(1)(b) respectively

(ii) A covered entity may use protected health information to create a limited data set that meets the requirements of paragraph (e)(2) of this section, or disclose protected health information only to a business associate for such purpose, whether or not the limited data set is to be used by the covered entity.

(4) *Implementation specifications: Data use agreement.*

(i) *Agreement required*. A covered entity may use or disclose a limited data set under paragraph (e)(1) of this section only if the covered entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of this section, that the limited data set recipient will only use or disclose the protected health information for limited purposes.

(ii) *Contents.* A data use agreement between the covered entity and the limited data set recipient must:

(A) Establish the permitted uses and disclosures of such information by the limited data set recipient, consistent with paragraph (e)(3) of this section. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the covered entity;

(B) Establish who is permitted to use or receive the limited data set; and

(C) Provide that the limited data set recipient will:

(*1*) Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

(*2*) Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

(*3*) Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware;

(*4*) Ensure that any agents, including a subcontractor, to whom it provides the limited data set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information; and

(*5*) Not identify the information or contact the individuals.

(iii) *Compliance.*

(A) A covered entity is not in compliance with the standards in paragraph (e) of this section if the covered entity knew of a pattern of activity or practice of the limited data set recipient that constituted a material breach or violation of the data use agreement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful:

(*1*) Discontinued disclosure of protected health information to the recipient; and

(*2*) Reported the problem to the Secretary.

(B) A covered entity that is a limited data set recipient and violates a data use agreement will be in noncompliance with the standards, implementation specifications, and requirements of paragraph (e) of this section.

Appendix D
The Information for Research Required by 45 CFR 164.528(b)(4)

This form is to be given to Clients who request an accounting of disclosures.
Please write in PLAIN ENGLISH non technical terms!

All researchers shall provide sufficient details in order to provide the accounting required by 45 CFR 164.518(b)(4). This includes[19]:

1) The name of the protocol or other research activity;_____

_____

_____

2) A description , in plain language, 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 protected health information 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; From:____/____/____ to ____/____/____

5) The name, address and telephone number of the entity that sponsored the research and of the researcher to whom the information was disclosed;

Name:_____ Telephone Number:_____

Address: _____

_____

_____

6) Researcher states that the protected health information of the individual may or (may not have been) disclosed for this protocol or research activity: Signature:_____

For each research subject, please note whether the PHI has been disclosed for this protocol (attach list).

[19] 45 CFR 164.528(b)(4)(i)