SAN MATEO COUNTY HEALTH SYSTEM
BEHAVIORAL HEALTH AND RECOVERY SERVICES

DATE: February 17, 1995

BHRS POLICY: 95-02

SUBJECT: Research Policies and Procedures

AUTHORITY: 45 CFR Part 160, HIPAA Privacy Regulations; California Code of Regulations, Title 9, Sections 774 -780; CA Welfare &Institutions code 5328 and 95 HHS Office of Research Integrity

AMENDED: February 25, 2003, December 16, 2015

ATTACHMENTS:

A. Institutional Review Board (IRB)
B. Health Care Operations
C. Checklist for Research Involving Behavioral Health & Recovery Services (BHRS) Clients
D. Proposal Face Sheet
E. Oath of Confidentiality for Persons Engaged in Research Involving BHRS Clients
F. Informed Consent for Participation as a Research Subject
G. Authorization for Use or Disclosure of Health Information for Research Purposes
H. Sample (of completed) Authorization for Use or Disclosure of Health Information for Research Purposes
I. Procedures for Developing Informed Consent Protocol and for Communicating Complaint/Grievance Procedure to Clients Participating in Research.

POLICY

San Mateo County BHRS encourages and supports applied and theoretical research within the practical constraints of client service responsibilities. Since properly conducted research contributes to both the professional development of staff and the validation and improvement of care and treatment services, it is essential to support a research program.

The BHRS Director has established an Institutional Review Board (IRB) which is responsible for review and approval of research involving BHRS facilities, programs, clients/consumers, and staff. The IRB may, at its discretion, designate a Research Sub-Committee for initial review of proposals. The IRB shall meet all legal standards including membership, expertise and impartiality required of an IRB (Attachment A).

Research is not considered a "routine" health service under federal regulation, except for certain studies related to health care operations, such as quality assurance and utilization management activities (Attachment B). Because research is not routine, special regulations govern its application within health systems. Researchers will use the Checklist for Research Involving BHRS Clients (Attachment C) in their applications.

Any person or agency wishing to undertake research within San Mateo County BHRS must first submit a research proposal, including an Oath of Confidentiality (Attachment E), to the IRB. For purposes of this policy, a research study may be initiated within or outside BHRS, with the broad intent of furthering general or specific knowledge regarding behavioral health treatment, services and/or trends.

Treatment is defined by federal regulation to include all "preventative, diagnostic, therapeutic, rehabilitation, maintenance and palliative care provided to an individual" (partial definition). In general, research differs from treatment in that the end goals of treatment are to benefit the individual being treated, while research is performed for the benefit of obtaining general knowledge.

When a research inquiry is combined with treatment, for example in drug trials or in structured group situations, consent for participation and the use and disclosure of information obtained must meet standards that apply to both situations.

Excluded Research

- San Mateo County BHRS will not approve any pharmaceutical study involving minors, except in the rare circumstance where the BHRS Director has pre-screened the proposal and presents it to the IRB for its consideration.
- San Mateo County BHRS will not approve any pharmaceutical study for adults involving the use of placebo.

PROCEDURES

All projects must adhere to the following procedures. The procedures are listed in the order in which they must be done.

1. The Principal Investigator secures approval of his or her sponsoring agency or institution. (Example: A graduate level trainee documents approval from an appropriate faculty advisor.)

2. Approval must be secured from the BHRS Unit Chief, Program Manager, and/or other appropriate administrators responsible for the units or sites to be involved.

3. One copy of the research proposal is submitted to the Chairperson of the IRB. The format to be followed is contained in the "Research Proposal Guidelines" below. With the exception of the Face Sheet (Attachment D), other formats may be used as long as the content is substantially equivalent. The BHRS Face Sheet must always be used.

4. The Chairperson of the IRB submits the proposal to the committee for consideration. The committee

reviews the proposal for scientific merit, resources required, demands on clients/subjects, cultural competency and conformity with guidelines for confidentiality and informed consent. The committee recommends approval or disapproval according to the following process: The members may vote to approve the proposal, or disapprove the proposal. Approval requires a two-thirds vote. The exact number of votes to approve or disapprove shall be recorded in the IRB Committee minutes. The IRB chair will forward the outcome of the voting to the QM Manager, principal investigator and BHRS Medical Director.

5. At any stage of the research the IRB may recommend that the BHRS Director revoke approval of the project for violations of patients' rights or confidentiality regulations or for including activities or procedures not specified in the proposal.

6. The project can begin only after approval, and after all research staff members have signed the Oath of Confidentiality for Research (Attachment E). If a proposal is not approved, the principal investigator may resubmit with revisions based on feedback from the IRB.

7. The IRB will conduct ongoing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once a year.

8. A final report of the research findings is submitted to the IRB.

9. Research findings may be presented in classroom situations or in fulfillment of academic requirements. See Section 7 for publication guidelines.

RESEARCH PROPOSAL GUIDELINES

The proposal should be prepared in accordance with the following regulations, should be typewritten and double-spaced, and should not exceed 10 pages in length (not including appropriate appended scales or instruments). Substantially equivalent formats may be used, with the exception of the Face Sheet. Acceptance of such formats is subject to the approval of the committee.

a) Proposal Face Sheet (Attachment D)

b) Research Plan

a. Background
Summarize background and rationale for proposed research and relevant literature and references.

b. Objectives
Provide a concise statement enumerating the specific hypotheses or objectives of the research proposal.

c. Research Design

1. Provide details of the research design, including how the results will be analyzed. For each specific hypothesis or objective, show how it will be addressed by the design.

2. Specify the number and kinds (including ages) of clients/subjects to be involved and the approximate amount of time to be spent with each. Include (as an appendix) detailed protocols for the participation of all clients/subjects.

3. List all psychological, psychiatric or other assessment tests, rating scales, and other instruments that will be employed and attach copies of any tests or scales.

4. Indicate the extent of participation and the amount of time for any staff member(s) to be involved in the research.

c) Client Protection

a. Confidentiality of Client Data

If client identifiable data is to be used, describe what safeguards will be used to protect confidentiality.

b. Authorization for Use or Disclosure of Health Information (Attachment G)

This form is mandated; the form must be maintained for at least six years by the person/entity doing the research. When staff or contract staff of BHRS conducts the research, the form is filed and maintained within the client chart for the lifetime of the chart.

c. Informed Consent for Participation as a Research Subject (See Attachments F and I)

If research directly involves the treatment of individuals, describe how informed consent will be obtained and documented. Signed consents to participate in research related treatment must be maintained for at least six years by the person/entity doing the research. When staff or contract staff of BHRS conducts the research, the form is filed and maintained within the client chart for the lifetime of the chart.

d. Protection of Human Subjects

If research involves human subjects, describe any foreseeable risks to subjects and indicate whether treatment or compensation will be made available. Indicate what possible benefits might result from the research.

4. Inclusions

a) Vitae of principal investigator

b) Signed Oaths of Confidentiality for research staff (Attachment E)

c) Administrative letter(s) of approval

5. Research that Does Not Involve Treatment

There are three types of research that do not involve client treatment:

- Type A - Research that involves gathering aggregate or statistical information from client charts (current or closed), or by using data in the electronic health record or any data otherwise collected.

- Type B - Research that involves review of specific client health information contained in a client chart - for example, to draw conclusions over time about the merits of a possible assessment tool, functional scale or local outcome measure.

- Type C – Research that does not involve clients or medical information such as studies on staffing, workflow, community engagement, etc.

Such research must follow all procedures stated in this policy with the exception that:

- Type A - there is no requirement to obtain signed "Informed Consent for Participation" (Attachment F) nor "Authorization for Use or Disclosure of Health Information" (Attachment G).

- Type B - there is no requirement to obtain signed "Informed Consent for Participation as a Research Subject" (Attachment F). "Authorization for Use or Disclosure of Health Information" (Attachment G) may be required (see Waiver of Authorization for Research That Does Not Include Treatment below).

- Type C – there is no requirement to obtain signed "Informed Consent for Participation as a Research Subject" (Attachment F). "Authorization for Use or Disclosure of Health Information" (Attachment G) may be required (see Waiver of Authorization for Research That Does Not Include Treatment below).

All other instructions in the research proposal guidelines shall apply, including assurances concerning confidentiality of client data and the signed "Oath of Confidentiality for Persons Engaged in Research Concerning BHRS Clients" (Attachment E). BHRS staff members do not need to re-sign the "Oath of Confidentiality," which is a requirement of employment.

6. Waiver of Authorization for Research that Does Not Include Treatment

When research does not include treatment, BHRS may, under certain conditions, use or disclose PHI without an authorization from the individual about whom the PHI pertains.

a) Approval shall be obtained from the IRB.

b) The IRB must determine that all of the following criteria for waiving individual authorization or altering the requirements of the individual authorization are met:

1) the use or disclosure of Protected Health Information (PHI) will involve no more than minimal risk to the individuals;

2) the alteration or waiver will not adversely affect the privacy rights and welfare of the individual;

3) the research cannot practicably be conducted without access to and use of the PHI;

4) the privacy risks to the individual(s) whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits, if any, to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research;

5) there is an adequate plan to protect the identifiers from improper use of disclosure;

6) there is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research; unless there is a health or research justification for retaining the identifiers or retention is required by law;

7) there are adequate written assurances that the PHI will not be re-used or disclosed to any other person or entity except as required by law, for authorized oversight of the research project, or for other research as permitted by the HIPAA regulations.

c) IRB deliberation and conclusions shall be documented in IRB Committee Minutes and forwarded to the QIC.

7. Publication

Prior to submission for publication, all professional abstracts, reports, and articles resulting from research and/or work experience by staff, interns or students in the BHRS Division (whether or not BHRS is identified by name) shall be submitted for review by the IRB and the QIC.

8.

Research done by BHRS staff involving data from other health system databases, or in collaboration with another county health system may require IRB approval. The researchers will receive the appropriate local approval and will then submit their request for support to the BHRS IRB.

Approved: ___*(Signature on File)*_____
Stephen Kaplan, LCSW
BHRS Director

Approved: ___*(Signature on File)*_____
Robert Cabaj, MD
BHRS Medical Director

San Mateo County Behavioral Health and Recovery Services

Attachment A: INSTITUTIONAL REVIEW BOARD (IRB)

The following excerpts are adapted from the Code of Federal Regulations, Title 45, Public Welfare, Department of Health and Human Services, part 46-Protection of Human Services (45 CFR 46) edition October 1, 1994.

An Institutional Review Board (IRB) is a body established under federal regulations to determine the appropriateness of proposed research within an agency or organization. As described within MH Policy 95-02, review criteria include scientific merit, resources required, demands on clients/subjects, cultural competency and conformity with guidelines for confidentiality and informed consent.

A properly constituted IRB can demonstrate the following:

a. **The Department or Agency Head is provided with a list of IRB members** identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution (for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant). Changes in IRB membership shall be reported to the department or agency head.
b. **Written procedures,** which the IRB will follow (i) for conducting its initial and continuing review of research, and for reporting its findings and actions to the investigator and the institution; (ii) for determining, which projects require review more often than annually, and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subject.
c. **Written procedures** for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head, of (i) any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB, and (ii) any suspension or termination of IRB approval.

§ 46.107 IRB membership.

a.Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB

shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds, and sensitivity to such issues as community attitude to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

b. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
c. Each IRB shall include at least one member whose primary concerns are in scientific areas, and at least one member whose primary concerns are in nonscientific areas.
d. Each IRB shall include at least one member, who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution.
e. No IRB may have a member participate in the IRB's initial or continuing review of any project, in which the member has a conflicting interest, except to provide information requested by the IRB.
f. An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues, which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

§ **46.108 IRB functions and operations.**

In order to fulfill the requirements of this policy, each IRB shall:

a. Follow written procedures in the same detail as described above.
b. Except when an expedited review procedure is used, review proposed research at convened meetings, at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

§ **46.109 IRB review of research.**

a. An IRB shall review, and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
b. An IRB shall require that information given to subjects as part of informed consent is in accordance with §46 .116. The IRB may require that information, in addition to that specifically mentioned in §46.116, be given to the subjects when, in the IRB's judgment, the information would meaningfully add to the protection of the rights and welfare of subjects.
c. An IRB shall require documentation of informed consent, or may waive documentation in accordance with §46.117.

d. An IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision, and give the investigator an opportunity to respond in person or in writing.
e. An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

§ **46.115 IRB records.**

An institution, or when appropriate, an IRB, shall prepare and maintain adequate documentation of IRB activities, including the following:

a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
b. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolution.
c. Records of continuing review activities.
d. Copies of all correspondence between the IRB and the investigators.
e. A list of IRB members, in the same detail as described in §46.103(b)(3).
f. Written procedures for the IRB, in the same detail as described in §46.103(b)(4) and §46.l 03(b)(5).
g. Statements of significant new findings provided to subjects, as required by §46.116(b)(5).

The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

Attachment B: HEALTH CARE OPERATIONS

Contributed to a HIPAA information website by attorneys Marty Baxter and Gretchen McBeath at Bricker and Eckler, LLP (http:www.bricker.com) and The Quality Management Consulting Group, Ltd (http://www.gmcg.com). E-mail: mbaxter@bricker.com or gmcbeath@bricker.com.

Health Care Operations include any of the following activities:

1. Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities

2. Population-based activities relating to improving health or reducing health care costs

3. Protocol development

4. Case management and care coordination

5. Contacting of health care providers and patients with information about treatment alternatives

6. Reviewing the competence or qualifications of health care professionals

7. Evaluating practitioner, provider, and health plan performance.

8. Conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities

9. Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits

10. Ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance), provided that the requirements of Sections 164.514 (g) of the privacy rule are met, if applicable

11. Conducting or arranging for medical review, legal services, and auditing functions, including fraud and abuse detection and compliance programs

12. Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development or improvement of methods of payment or coverage policies

13. Business management and general administrative activities of the entity, including, but not limited to:

    - Management activities relating to implementation of and compliance with the regulations

    - Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer

    - Resolution of internal grievances

    - Due diligence in connections with the sale, transfer, merger, or consolidation of all or part of a covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity

    - Creating de-identified health information, fundraising for the benefit of the covered entity, and marketing activities

Attachment C: CHECKLIST FOR RESEARCH INVOLVING BHRS CLIENTS/CONSUMERS

Working Title	Applicant

☐ Obtain signed approval by Sponsoring Educational Institution, (if academic proposal).

☐ Obtain signed approval of BHRS Unit Chief, (if clinic/team is site of research).

☐ Obtain signed approval by the Director of a community mental health agency, (if agency is site of research).

☐ Assemble packet containing proposal Face Sheet, full copy of the research proposal including subject consent forms, required signatures and Oath of Confidentiality of researchers.

RESEARCH PROPOSAL MUST MEET ALL SPECIFICATIONS IN BHRS POLICY 95-02

☐ Send packet to Quality Management - IRB (1950 Alameda de las Pulgas Suite 157, San Mateo, CA 94403; Pony MLH327; Telephone 650-573-3431).

☐ If changes are requested by the IRB or the research sub-committee of the IRB, submit changes to the committee chair at the address above.

RESEARCH MAY NOT START UNTIL THE STUDY AND ANY REQUESTED CHANGES ARE APPROVED.

☐ Send copy of completed study to the IRB Committee Chair at the address above.

IF STUDY IS INTENDED FOR PUBLICATION, THE IRB MUST REVIEW THE SUBMISSION PRIOR TO PUBLICATION.

Attachment D: PROPOSAL FACE SHEET

Date Received _____

TO: QUALITY IMPROVEMENT - IRB COMMITTEE

WORKING TITLE _____

PRINICIPAL INVESTIGATOR _____

ADDRESS _____ PHONE _____

_____ E-MAlL _____

SPONSORING INSTITUTION OR AGENCY _____

BHRS UNIT OR CONTRACTOR INVOLVED _____

DATE OF SUBMISSION	DATE STUDY TO START	DATE STUDY TO END

ABSTRACT (50 - 100 WORDS)

Attachment E: Oath of Confidentiality for Persons Engaged in Research Involving BHRS Clients/Consumers

As a condition of doing research concerning persons who have received services from

_____ (facility, agency or person),

I, _____,
agree to obtain the prior informed consent of such persons who have received services to the maximum degree possible as determined by the appropriate institutional review board or boards for the protection of human subjects reviewing my research. I further agree not to divulge any information obtained in the course of such research to unauthorized persons, and not to publish or otherwise make public any information regarding persons who have received services such that the person who received services is identifiable, except as required by law.

I recognize that the unauthorized release of confidential information may make me subject to a civil action under provisions of the California Welfare and Institutions Code, and Federal HIP AA Regulation.

_____
Signature

_____
Date

Attachment F: INFORMED CONSENT FOR PARTICIPATION AS A RESEARCH SUBJECT

NAME OF RESEARCH PROJECT _____

DATE _____

I understand that I am free to participate or not to participate in this project. I am also free to withdraw my consent and to discontinue participation in the project at any time without any adverse consequence. I understand also that my treatment at this facility will be provided regardless of whether or not I participate in this project. I understand that I will not be identified in any way in anything published or communicated as a result of this project, except to authorized professional persons treating me or other research personnel on this project. I have been given a written statement explaining this project.

With these assurances, I consent to participate.

Client's Signature _____

Print Name _____
First Middle Last

Parent's, Guardian's, or Conservator's Signature _____

Print Name _____
First Middle Last

Witness's Signature _____

Print Name _____
First Middle Last

CONFIDENTIAL PATIENT INFORMATION: See California Welfare and Institutions Code Section 5328

San Mateo County Behavioral Health and Recovery Services

Authorization for Use or Disclosure of Health Information for Research Purposes

Completion of this document authorizes the disclosure and/or use of individually identifiable health information, as set forth below, consistent with California and Federal law concerning the privacy of such information. **Failure to provide *all* information requested may invalidate this Authorization.**

USE AND DISCLOSURE OF HEALTH INFORMATION

I hereby authorize the use or disclosure of my health information as follows:

Client Name _____

Persons/Organizations authorized to *use* or disclose the information _____

Persons/Organizations authorized to *receive* the information _____

This authorization applies to the following information (select *only one* of the following).

- ☐ All health information pertaining to any medical history, mental or physical condition, including substance use/abuse, and treatment received.
- ☐ Only the following records or types of health information (including any dates):

  _____

EXPIRATION

This Authorization expires at conclusion of the research study.

RESTRICTIONS

California law prohibits the Requestor from making further disclosure of my health information unless the Requestor obtains another authorization from me or unless such disclosure is specifically required or permitted by law.

YOUR RIGHTS

I may refuse to sign this Authorization.

I may revoke this authorization at any time. My revocation must be in writing, signed by me or on my behalf, and delivered to the following address: _____

_____

My revocation will be effective upon receipt, but will not be effective to the extent that the Requestor or others have acted in reliance upon this Authorization.

I have a right to receive a copy of this authorization.[1]

IF REQUESTOR SEEKS THIS AUTHORIZATION

My health information will be used for the following purpose(s):_____

_____

I may inspect or obtain a copy of the health information that I am being asked to use or disclose.

If this box is ☐ checked, the Requestor will receive compensation for the use or disclosure of my information.

SIGNATURE

Date _____ Time _____AM/PM

Signature (client/legal representative) _____

(If you have authorized the disclosure of your health information to someone who is not legally required to keep if confidential, it may be re-disclosed and may no longer be protected. California law prohibits recipients of your health information from re-disclosing such information except with your written authorization or as specifically required or permitted by law.)

If signed by someone other than the client, state your legal relationship to the patient:

_____

Witness _____

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1 Under HIPAA, the individual must be provided with a copy of the authorization when it has been requested by a covered entity for its own uses and disclosures *(see* 45 *CFR* & *164.508 (d)* (1), *(e) (2)).*

CONFIDENTIAL PATIENT INFORMATION: See California Welfare and Institutions Code Section 5328

San Mateo Behavioral Health and Recovery Services

Sample
Authorization for Use or Disclosure of Health Information for Research Purposes

Completion of this document authorizes the disclosure and/or use of individually identifiable health information, as set forth below, consistent with California and Federal law concerning the privacy of such information. **Failure to provide *all* information requested may invalidate this Authorization.**

USE AND DISCLOSURE OF HEALTH INFORMATION

I hereby authorize the use or disclosure of my health information as follows:

Client Name ***Jane Doe***

Persons/Organizations authorized to *use* or disclose the information *San Mateo County*

Behavioral Health and Recovery Services

Persons/Organizations authorized to *receive* the information *Researcher's Name*

This authorization applies to the following information (select *only one* of the following).

- ☐ All health information pertaining to any medical history, mental or physical condition, including substance use/abuse, and treatment received.
- ☐ Only the following records or types of health information (including any dates):

_____

EXPIRATION

This Authorization expires at conclusion of the research study.

RESTRICTIONS

California law prohibits the Requestor from making further disclosure of my health information unless the Requestor obtains another authorization from me or unless such disclosure is specifically required or permitted by law.

YOUR RIGHTS

I may refuse to sign this Authorization.

I may revoke this authorization at any time. My revocation must be in writing, signed by me or on my behalf, and delivered to the following address: *Researcher's address*

My revocation will be effective upon receipt, but will not be effective to the extent that the Requestor or others have acted in reliance upon this Authorization.

IF REQUESTOR SEEKS THIS AUTHORIZATION

I have a right to receive a copy of this authorization.[1]

My health information will be used for the following purpose(s): *To see if art therapy in a group helps reduce post-partum depression.*

I may inspect or obtain a copy of the health information that I am being asked to use or disclose.

If this box is ☐ checked, the Requestor will receive compensation for the use or disclosure of my information.

SIGNATURE

Date _____ Time _____AM/PM

Signature (client/legal representative) *Jane Doe*

(If you have authorized the disclosure of your health information to someone who is not legally required to keep if confidential, it may be re-disclosed and may no longer be protected. California law prohibits recipients of your health information from re-disclosing such information except with your written authorization or as specifically required or permitted by law.)

If signed by someone other than the client, state your legal relationship to the patient:

Witness *Researcher*

[1] Under HIPAA, the individual must be provided with a copy of the authorization when it has been requested by a covered entity for its own uses and disclosures *(see* 45 *CFR* & *164.508 (d)* (1), *(e) (2)).*

Attachment I: Procedures for Developing Informed Consent Protocol and for Communicating Complaint/Grievance Procedure to Clients Participating in Research

I. INFORMED CONSENT

Any client who participates as a subject in an approved research project shall give informed consent regarding his or her participation. The burden of proof regarding informed consent rests with the principal investigator.

Informed consent is insured by at least the following:

A. A statement by the principal investigator or his/her designee to each potential subject prior to any participation, which includes at least the following elements:

1. A complete non-technical explanation of the project and the procedures to be followed.

2. An identification of those procedures that are experimental.

3. A description of the potential discomforts or risks including those that are expected and those that are remote.

4. A description of the benefits expected from the project.

5. An assurance that a subject who is placed in a control group will have access to any therapy/treatment which is found to be effective as a result of the project where such therapy could reasonably be offered to the client.

6. An offer to answer any questions concerning the procedures or project.

7. An acknowledgment that the principal investigator assumes responsibility for any harm done to the research subject as a result of experimental procedures.

8. A guarantee that the subject is free to withdraw his/her consent and to discontinue participation in the project at any time without any adverse consequence.

9. An assurance that all information obtained will be kept confidential.

10. A signed "Informed Consent" (Attachment F) obtained from the subject.
11. A written statement to be given to the potential subject which contains at least the following information:

NAME OF PROJECT

Any questions, complaints or other concerns about this project or your participation in it may be addressed to any or all of the following persons:

- Name of Principal Investigator _____
  Address _____
  City _____
  Phone _____

- Quality Management (QM) Manager
  San Mateo County Behavioral Health & Recovery Services
  1950 Alameda de las Pulgas, Suite 157
  San Mateo, CA 94403
  650-573-3431

B. In the event a potential subject is not capable of giving informed consent, the consent procedure must be followed with the guardian or conservator.

C. Review of all research projects relative to Patients' Rights Issues will be the responsibility of the office responsible for consumer protection.

II. COMPLAINT/GRIEVANCE PROCEDURE

When a complaint or grievance is received by the Principal Investigator, QM Manager, or the Office of Consumer and Family Affairs (OCFA), the following actions will be taken:

A. The IRB will be informed and will submit the complaint/documentation to the BHRS Medical Director.

B. The QM Manager along with the OCFA will investigate the complaint within two weeks.

C. Once investigation of the complaint is completed, a special meeting of the IRB may be called if deemed necessary by the QM Manager or the OCFA.

D. Findings and actions taken or recommended as a result of investigation of the complaint will be reported back to the complainant and the BHRS Medical Director within one month.