PSYCHOLOGICAL BEHAVIORAL SERVICES PROVIDER MANUAL

Chapter Fifteen of the Medicaid Services Manual

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State of Louisiana
Bureau of Health Services Financing

CHAPTER 15

PSYCHOLOGICAL BEHVIORAL SERVICES

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OVERVIEW

The Psychological and Behavioral Services Program (PBS) is designed for children and youth, ages 0-20 years, who require psychological and/or behavioral services. These services include necessary assessments and evaluations, psychological testing, clinical interventions, including individual and family psychotherapy (with the recipient present), periodic follow up and linkages to emergency mental health services in crisis situations. Services are provided by a licensed psychologist.

RECIPIENT ELIGIBILITY CRITERIA

In order to be eligible for PBS, a Medicaid recipient must be under the age of 21 and meet one of the following criteria:

- Have a current version Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis in the spectrum of Pervasive Developmental Disorder (PDD) according to a clinically appropriate diagnostic screening tool or other assessment; or
- Have an impaired functional status that can be addressed by psychological treatment on an instrument or other assessment of individual functioning that is appropriate for individuals with developmental disabilities; or
- Engage in behaviors so disruptive or dangerous that harm to others is likely (e.g., hurts or attempts to hurt others, such as hitting, biting, throwing things at others, using or threatening to use a weapon or dangerous object). Behaviors must be recurrent, not a single instance; or
- Engage in behaviors that have resulted in actual physical harm to the child himself/herself, such as bruising, lacerations or other tissue damage, or would result in physical harm if the child was not physically restrained. Behaviors must be recurrent, not a single instance. Behaviors are not the result of clinically suicidal intent.

COVERED SERVICES

Psychological services are for obtaining, integrating, and interpreting information about child behavior, and child and family conditions related to learning, mental health, and development. These services include:

- Psychological assessment/evaluations
- Psychological testing
- Family psychotherapy (with the patient present)
- Individual psychotherapy

Psychological Evaluation

The psychological evaluation includes a battery of tests, interviews, and behavioral evaluations that appraise cognitive, motor, sensory, emotional, social, and behavioral functioning and self-concept. Providers performing evaluations for this population should follow the best practice guidelines offered through the American Academy of Child and Adolescent Psychiatry, the American Academy of Neurology and Child Neurology Society and Academy of Pediatrics. Providers should include standardized, reliable, and valid psychological testing that is consistent with best practice standards for the population with pervasive developmental disorders.

NOTE: Please refer to the EPSDT PBS fee schedule located on the Louisiana Medicaid website (see Appendix A for website) for currently covered procedure codes and maximum fees reimbursed by Medicaid.

PROVIDER REQUIREMENTS

In order to receive reimbursement as a Medicaid provider of EPSDT psychological and behavioral services, a psychologist must provide verification that he or she meets all of the following qualifications:

- Have a doctorate in psychology from an accredited university or college (all college degrees must be from a nationally accredited institution of higher education as defined in Section 102(b) of the Higher Education Act of 1965, as amended);
- Be licensed to practice within the state of Louisiana under the provisions of R.S. 37:2351– 2367; and
- Be professionally qualified to treat children, or to treat children and/or adults with PDD, including autism and/or developmental disorders.

RECORD KEEPING

Providers must maintain records in an organized and standardized format at the enrolled office site. Original records shall not be kept in off-site service delivery locations. The provider must have adequate space, facilities, and supplies to ensure effective record keeping.

Retention of Records

The provider must retain administrative, personnel and recipient records for five years from the date of the last payment. However, if the provider is being audited, records must be retained until the audit is complete, even if the five years is exceeded.

In the event records are destroyed or partially destroyed in a disaster, such as a fire, flood or hurricane and rendered unreadable and unusable, such records must be properly disposed of in a manner, which protects recipients' confidentiality.

NOTE: Upon practice closure, all provider records must be maintained according to applicable laws, regulations and the above record retention requirements. The Bureau must be notified of the location of the records.

Destruction of Records

After the required record retention period has expired, records may be destroyed. Confidential records must be incinerated or shredded to protect sensitive information.

Non-paper files, such as computer files, require a special means of destruction. Disks or drives can be erased and reused, but care must be taken to ensure all data is removed prior to reuse. Commercially available software programs can be used to ensure all confidential data is removed.

Confidentiality and Protection of Records

Administrative and recipient records are the property of the provider. Records must be secured against loss, tampering, destruction or unauthorized use in accordance with Health Insurance Portability and Accountability Act (HIPAA) regulations.

The provider must safeguard the confidentiality of any information, which may identify the recipients or their families. The information may be released only under the following conditions:

- By a court order,
- By the recipient's written, informed consent for release of information,
- If the recipient has been declared legally incompetent, his/her legal representative must provide written consent, or
- If the recipient is a minor, the parent or legal guardian must provide written consent, or
- Upon request, a provider must make available information in the recipient records to the recipient, legally responsible guardian, or other service providers including another PBS provider in the case of a recipient transfer. If, in the professional judgment of the provider, information contained in the record would be harmful to the recipient, that information may be withheld from him/her except under court order.

A provider may use material from recipient records for educational purposes if names are deleted and other identifying information is removed. For research purposes, providers must comply with the Bureau's research policy (refer to Appendix B).

NOTE: Under no circumstances should providers allow staff to remove recipient records from the provider's site.

Review by State and Federal Agencies

Providers must make all administrative, personnel and recipient records available to the Bureau and appropriate state and federal personnel upon request. Failure to allow access to records in a timely manner may result in a sanction.

Administrative and Personnel Records

The provider's administrative files must have critical program information including but not limited to documentation of Medicaid enrollment, insurance policies, minutes of formal meetings, bylaws of the governing body, if applicable, training and supervision documentation, and required policies and procedures.

Personnel records shall be maintained for all staff, subcontractors, volunteers and interns. An employee must have reasonable access to his/her personnel file and must be allowed to include any written statement he/she wishes in the file.

A provider must not release a personnel file without the employee's written permission except according to state law.

Recipient Records

Records must be maintained in chronological order. Documentation shall be sufficient to verify that services conform to the Bureau policy as stated below and that the reimbursement amount is correct.

The organization of individual records and location of documents must be uniform. Records must be appropriately thinned so that current material can be easily located. Records must contain at least six months of current pertinent information relating to services provided. Records older than six months must be kept on-site and be available for review upon the request of the Bureau.

All entries and forms completed by staff in recipient records must be:

- In ink, in a color other than black,
- Legible,
- Fully dated,
- Legibly signed, and
- Include the functional title of the individual making the entry.

Any error in a recipient's record must be corrected using the legal method, which is to draw a line through the incorrect information, write "error" by it and initial the correction. **Correction fluid must never be used in a recipient's records.** If information is typed, signatures must be in ink, in a color other than black.

Components of Recipient Records

The recipient's record must consist of the active recipient record and stored files or folders. The active record must contain the following current information unless a recipient refuses disclosure, which may include race, ethnic origin, sex, or marital status.

Identifying information recorded on a standardized form including the following:

- Name,
- Home address,
- Home telephone number,
- Date of birth,
- Sex,
- Race or ethnic origin,
- Living arrangements,
- Closest living relative/guardian,
- Education,
- Marital status,
- Name, address, and telephone number of employer or school,
- Date of initial contact,
- Court and/or legal status, including relevant legal documents,
- Names, addresses, and telephone numbers of others involved with the recipient's treatment plan,
- Date this information was gathered,
- Required signatures on all forms,
- Signed release of information form,
- Documentation verifying that the recipient meets medical necessity criteria including copies of required professional evaluations, past treatment records, LOCUS/CALOUS rating, and other reports and information concerning the recipient's medical, social, familial, cultural, developmental, legal, educational, vocational, psychiatric and economic status,
- Electronic clinical data inquiry printout,
- Medicaid eligibility information for Medicaid recipients,
- A completed and signed treatment plan including the crisis plan and discharge plan.

Reason for case closure and any agreements with the recipient at closure.

- Service documentation,
- Copies of all pertinent correspondence,
- If the provider is aware that a recipient has been interdicted, a statement to this effect must be noted and the court appointed guardian named,
- A description of any current treatment or medication necessary for the treatment of any serious or life threatening medical condition or known allergies. This may include documentation from the treating physician.

Service Documentation

Service documentation must document the allowable services billed and must reflect the services delivered.

The following information must be included in the service documentation:

- Name of recipient,
- Name of provider and employee providing the service,
- Date of service contact,
- Begin and end time for service rendered,
- Indication if a crisis occurred during the contact,
- Type of contact,
- Service provided,
- Service participants, and
- Narrative describing the service.

Records must include specific documentation instead of using general terms such as "assisted recipient to" and "supported recipient" do not constitute adequate documentation. When more than one service is provided to a recipient during a contact, service documentation must be completed for each service. For each entry, the goal, objective, and intervention as documented in the treatment plan must be paraphrased. The use of goal, objective, and intervention numbering is not acceptable. For example, "Goal 1, Objective 1, Intervention 1" does not constitute acceptable documentation. All of the following documentation components must be included for each log entry:

- Goals, objectives, and interventions documented in the recipient's current treatment plan. If crisis services are provided, the treatment plan must be updated to reflect the needed services,
- Services are appropriate in terms of frequency and intensity,
- Services are clinically appropriate to the needs of the recipient,
- Specific intervention(s) and training material used during the contact,
- Recipient's response to interventions using observable/behaviors terms,
- Recipient's progress with accomplishing the targeted goal or objective, and
- A plan for the next recipient contact to ensure continuity of services.

Only the staff member providing the services may develop, sign, and make any necessary corrections to the service documentation. Service documentation must be completed at or near the time of service to ensure accuracy.

NOTE: Refer to chapter one (General Information and Administration) for additional information on record keeping.

PROGRAM MONITORING

The Bureau may conduct a monitoring review for reasons including, but not limited to, ensuring compliance with program requirements, reviewing billing practices and investigating complaints and grievances.

A monitoring review may include a review of recipient, personnel and administrative records.

Monitoring interviews may include speaking with a representative sample of recipients, the family, teacher(s) and other school personnel, with the approval of the parent or guardian.

Upon completion of a monitoring review, the Bureau staff may conduct an exit interview to discuss the findings. A written summary of the findings will be sent to the provider, stating whether a plan of correction is required.

Plan of Correction

A plan of correction (POC), if required, must be submitted to the Bureau. If the POC is not submitted within 10 working days, sanctions as described in the Surveillance and Utilization Systems (SURS) rule, LAC 50:1 Chapter 41 (Louisiana Register, Volume 29, Number 4) may be imposed. The POC must address the correction of each deficiency cited. If the POC submitted does not meet Bureau standards, it may be returned to the provider for revision.

All deficiencies must be corrected within 60 days of receipt of the notice. Failure to do so may result in sanctions. A follow-up review may be conducted by the Bureau to ensure that all deficiencies have been corrected.

CLAIMS FILING

Psychological Behavioral Services are billed electronically on the 837P transaction or hardcopy on the current CMS-1500 claim form.

NOTE: Refer to the Psychological and Behavioral Services Fee Schedule located on the Louisiana Medicaid website (see Appendix A).

Items to be completed are either required or situational. Required information must be entered in order for the claim to process. Claims submitted with missing or invalid information in these fields will be returned unprocessed to the provider with a rejection letter listing the reason(s) the claims are being returned. These claims cannot be processed until corrected and resubmitted by the provider.

Situational information may be required (but only in certain circumstances).

Paper claims should be submitted to the Fiscal Intermediary (FI) (see Appendix A for contact information).

NOTE: General claims filing information can be found in chapter one (General Information and Administration).

CONTACT/REFERRAL INFORMATION

Name of Contact	Address/Telephone/Website
Fiscal Intermediary: Molina Medicaid Solutions ***(formerly UNISYS Corporation)***	
Electronic Media Claims (EMC) Electronic claims sign up and testing	P.O. Box 91025 Baton Rouge, LA 70898 Phone: 225-216-6000 Fax: 225-216-6335
Pharmacy Point of Sale (POS)	P.O. Box 91019 Baton Rouge, LA 70821 Phone: 800-648-0790 (Toll Free) Phone: 225-216-6381 (Local) **After hours please call REVS line*
Pre-Certification Unit (Hospital) Pre-certification issues and forms	P.O. Box Baton Rouge, LA 708 Phone: 800-877-0666 Fax: 800-717-4329
Prior Authorization Unit (PAU) Prior authorization issues, forms, etc.	P.O. Box 14919 Baton Rouge, LA 70898 Phone: 800-807-1320 ***(Home Health)*** Phone: 866-263-6534 ***(Dental)*** Phone: 800-488-6334 ***(DME & All Other)***
Provider Enrollment Unit (PEU) Provider Enrollment, direct deposit problems, reporting of changes and ownership, NPI	P.O. Box 80159 Baton Rouge, LA 70898 Phone: 225-216-6370 Fax: 225-216-6392
Provider Relations (PR) Billing and training questions	P.O. Box 91024 Baton Rouge, LA 70821 Phone: 225-924-5040 (Local) 800-473-2783 (Toll Free) Fax: 225-216-6334
Recipient Eligibility Verification (REVS)	Phone: 800-776-6323 (Toll Free) Phone: 225-216-7387 (Local)
Web Technical Support	Phone: 877-598-8753 (Toll Free)

Name of Contact	Address/Telephone/Website
Department of Health and Hospitals (DHH)	
Bureau of Appeals	P.O. Box 4183 Baton Rouge, LA 70821-4182 Phone: 225-342-0443 Fax: 225-342-8773
Health Standards Section (HHS)	P.O. Box 3767 Baton Rouge, LA 70821 Phone: 225-342-0138 Fax: 225-342-5292
Louisiana Medicaid Website Provider Web Portal	www.lamedicaid.com
Louisiana's Medicaid and Louisiana Children's Health Insurance Program (LaCHIP) General Medicaid and card questions	General Medicaid Hotline: 888-342-6207 LaCHIP: 225-342-0555 (Local) LaCHIP: 877-252-2447 (Toll Free) http://bhsfweb.dhh.louisiana.gov/LaCHIP/
Office of Aging and Adult Services (OAAS)	P.O. Box 2031 Baton Rouge, LA 70821 Phone: 866-758-5035 Fax: 225-219-0202 E-mail: MedWeb@dhh.la.gov http://www.dhh.louisiana.gov/offices/?ID=105
Office of Citizens with Developmental Disabilities (OCDD)	628 N. Fourth Street Baton Rouge, LA 70802 Phone: 225-342-0095 (Local) Phone: 866-783-5553 (Toll Free) E-mail: ocddinfo@la.gov http://www.dhh.louisiana.gov/offices/?ID=191
Office of Emergency Preparedness (OEP) Required Emergency Preparedness HH Model	http://gohsep.la.gov/modelhmhlthpln.aspx
Office of Management and Finance (Bureau of Health Services Financing – MEDICAID)	P.O. Box 91030 Baton Rouge, LA 70810 http://www.dhh.louisiana.gov/offices/?ID=92

Name of Contact	Address/Telephone/Website
Department of Health and Hospitals (DHH)	
Program Integrity (PI)	P.O. Box 91030 Baton Rouge, LA 70810 Fraud and Abuse Hotline: 800-488-2917 Fax: 225-219-4155 http://www.dhh.louisiana.gov
Rate and Audit (R&A)	P.O. Box 546 Baton Rouge, LA 70821-0546 Phone: 225-342-6116 Fax: 225-342-1834 http://www.dhh.louisiana.gov/offices/?ID=111
Recipient Assistance for Authorized Services	1-888-758-2220
Take Charge (Family Planning Waiver)	P.O. Box 91278 Baton Rouge, LA 70821 Phone: (888) 342-6207 Fax: (877) 523-2987 medweb@la.gov www.takecharge.dhh.louisiana.gov
Third Party Liability (TPL) TPL Recovery, Trauma	453 Spanish Town Road Baton Rouge, LA 70802 Phone: 225-342-8662
Other Helpful Contact Information	
Office of Emergency Preparedness Home Health Emergency Model Plan	http://gohsep.la.gov/plans/modelhmhlthpln.htm
Office of Population Affairs (OPA) Clearinghouse	P.O. Box 30686 Bethesda, MD 20824-0686 Phone: 866-640-7827 Fax: 866-592-3299 www.opaclearinghouse.org

POLICY NUMBER:	0021-98	
SUBJECT:	Departmental Research	
CONTENT:	Policy and procedures for the protection of human subjects of research projects conducted in facilities and programs operated or funded by the Department of Health and Hospitals	
EFFECTIVE DATE:	Issued:	March 1, 1991 (Office of Human Services Research Policy)
	Revised:	March 20, 1998
INQUIRIES TO:	Office of Management and Finance Division of Research and Development P.O. Box 2870 Baton Rouge, LA 70821-2870 Telephone: (225) 342-3807 FAX (225) 342-0080	

I. PURPOSE

These policies are designed to assure the protection of the rights of human subjects of research conducted in programs or facilities operated or funded by the Department of Health and Hospitals (DHH).

II. APPLICABILITY

These policies apply to all research conducted in programs/facilities operated or funded by the DHH.

III. DEFINITIONS

Cognitively Impaired - having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgement and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps may also be compromised in their ability to make decisions in their best interests.

Competence - technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. (See also: *Incompetence, Incapacity*.) Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations.

DHH - Department of Health and Hospitals (Louisiana).

DHHS - U.S. Department of Health & Human Services. This Federal agency promulgated 45 CFR, Part 46, *Protection of Human Subjects*, revised June 18, 1991, effective August 19, 1991. DHH's research policies are based upon 45 CFR, Part 46.

Human Subject - a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. data through intervention or interaction with the individual; or

2. identifiable private information.

Identifiable Private Information - private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable (i.e., the identification of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Incapacity - refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.

Incompetence - technically, a legal term meaning inability to manage one's affairs. Often used as a synonym for incapacity.

IRB Approval - the determination of the IRB that the research has been reviewed and may be conducted within the constraints set forth by the IRB and by other State and Federal requirements.

Institutional Review Board (IRB) - the DHH committee with responsibility for reviewing and recommending approval/disapproval of all research proposals.

Interaction - includes communication or interpersonal contact between investigator and subject.

Intervention - includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or his/her environment that are performed for research purposes.

Investigator - the person conducting research.

Minimal Risk - the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Programmatic Offices - the major programmatic offices in DHH are: Bureau of Health Services Financing (BHSF), Office of Alcohol and Drug Abuse (OADA), Office for Citizens with Developmental Disabilities (OCDD), Office of Mental Health (OMH), and Office of Public Health (OPH).

Research - systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

IV. STATEMENT OF PRINCIPLES

A. The DHH believes that research involving human subjects must be based upon the principles of *respect for persons, beneficence, and justice.*

1. *Respect for persons* involves a recognition of personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

2. *Beneficence* entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

3. *Justice* requires that benefits and burdens of research be distributed fairly.

B. DHH also recognizes that many consumers of its services may be cognitively impaired and therefore deserve special consideration as potential research subjects. The predominant ethical concern in research involving persons with psychiatric, cognitive, developmental, or chemical dependency disorders is that their conditions may compromise their capacity to understand the information presented and their ability to make a reasoned decision about participation. Consequently, approval of proposals to use these individuals as research subjects will be conditioned upon the researcher demonstrating that:

1. such individuals comprise the only appropriate subject population;

2. the research question focuses on an issue unique to these subjects;

3. the research involves no more than minimal risk, except when the purpose of the research is therapeutic for these individual subjects and the risk is commensurate with the degree of expected benefit.

V. POLICIES AND PROCEDURES

A. Policy Basis

Research conducted and authorized by the DHH will meet all applicable federal and state laws and regulations, accreditation standards, and professional codes of ethics. These policies derive primarily from 45 CFR, Part 46, *Protection of Human Subjects* and are also consonant with 21 CFR, Parts 50 and 56, adopted by the Food and Drug Administration. (Both sets of regulations were effective on August 19, 1991.) 45 CFR, Part 46 is applicable to other DHHS components, including the Health Care Financing Authority (Medical Assistance Programs).

B. Establishment of Institutional Review Board (IRB)

There is hereby established a DHH IRB to review and evaluate all proposed research projects.

1. Twenty-four hour facilities may either utilize these policies as written or amend them to provide for an in-house IRB for initial assessment of research projects prior to submission to the DHH IRB for final review.

2. All research involving DHH consumers, employees, or services in the community and in institutions will be reviewed by the DHH IRB before it is submitted to the Secretary or designee for final approval.

3. The IRB is a permanent standing committee which meets quarterly or as needed.

4. The membership shall consist of at least seven members, appointed by the Secretary, partly from recommendations by the assistant secretaries and the director of the BHSF:

    a. The director of Research and Development or his/her designee shall serve as permanent chairperson of the IRB. In the event of an extended absence from duty of the permanent chair, the Secretary shall appoint a temporary replacement to serve during that period;

    b. each office and the BHSF shall have at least one member;

    c. relevant professional disciplines shall be represented in the membership;

    d. at least one member shall be a direct service provider;

e. one member shall not be employed by the DHH. If possible, this member should be an ethicist (specialist in ethics) or an attorney;

f. at least one member shall be either a primary consumer, or a family member, or an advocate;

g. at least one member's primary concerns shall be in science areas and at least one member's primary concerns shall be in non scientific areas. If not selected under Section V.B.4.e., an attorney or ethicist should fill the latter slot.

5. The 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 to the IRB. Such individuals shall not vote with the IRB.

6. IRB members should have appropriate research training, experience or interest. Membership should also represent sufficiently the cultural, ethnic, and gender diversity of the State and be sensitive to diverse community attitudes.

7. Except for the chair, members shall be appointed for one-year terms and may be reappointed.

8. No IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

9. Once constituted, the IRB shall adopt written by-laws and guidelines/application materials for conducting research in DHH operated/funded programs or facilities.

10. Research approved by the Office of Public Health's (OPH) IRB prior to the adoption of these policies does not require DHH IRB approval. However, copies of proposals approved by the OPH IRB shall be provided to the chair of the DHH IRB.

C. IRB Review Process

Prior to authorization and initiation of research, an IRB meeting shall be convened to conduct a detailed review of the project in order to determine that all of the following requirements are met.

1. Proposal incorporates procedures designed to minimize the risk to participants. Risks to subjects are minimized by using procedures which are consistent with sound research design and do not unnecessarily expose subjects to risk and,

whenever appropriate, by using procedures already being performed on subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits and the importance of any knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research, as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research. The IRB should not consider possible long-range effects of applying knowledge gained in the research (e.g., possible effects of research on public policy) as among those research risks that fall within its purview.

3. Selection of subjects is equitable. In making this assessment, the IRB should take into account the purposes and setting of the research. It should be particularly cognizant of special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Research design minimizes possible disruptive effects of project on organizational operation.

5. Research design is in compliance with accepted ethical standards.

6. Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required in Section V.E. of this document.

7. Informed consent will be appropriately documented, in accordance with and to the extent required by Section V.E.1 - E.5 of this policy.

8. When appropriate, the research plan provides monitoring of the data collected to ensure subjects' safety.

9. Research proposal contains requisite safeguards to protect the privacy of subjects and to maintain the confidentiality of data.

10. Research proposal has been approved at the appropriate program administrative level, beginning with the program/facility.

D. IRB Recommendations and Notification

1. Researchers should be either present at the IRB meeting which considers their proposals or available for questioning at an indicated phone number during that time.

2. Following detailed review, the IRB by majority vote approves (fully or provisionally) or disapproves the research proposal.

   a. Provisional approval means that minor modifications, specified in writing by the IRB, must be received by the chair within 30 days in order to recommend full approval.

   b. Proposals receiving full approval are sent to the Secretary or designee for authorization to begin research.

3. The Secretary or the director of Research and Development will notify the researcher in writing of the IRB's decision to approve or disapprove the proposed research within 10 working days.

   a. If the proposal is not approved, the letter will indicate reasons for disapproval and give the researcher an opportunity to respond in writing to the IRB.

   b. There are no appeals for research proposals disapproved on the basis of ethical shortcomings or potential harm to subjects.

   c. No research, subject to IRB review, can begin until written authorization from the Secretary or designee is received.

   d. Research approved by the IRB may be subject to further administrative review and approval or disapproval. However, no administrator can approve research which has not been approved by the IRB.

   e. After approval, the IRB shall review the research in progress at appropriate intervals, but not less than once per year.

   f. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval shall be in writing, include the reasons for this action, and be reported promptly to the investigator, appropriate agency officials, and the Secretary.

g. Cooperative research refers to those projects covered by this policy which involve more than one institution or agency. In the conduct of cooperative research projects, each institution or agency is responsible for safeguarding the rights and welfare of human subjects and for complying with 45 CFR, Part 46. With the approval of the DHH or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

4. Expedited Review Procedure

a. Research that involves no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through an expedited review procedure. Under this procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chair from among IRB members. In reviewing the research, the reviewers may exercise all of the authority of the IRB except that they may not disapprove the research. Research may be disapproved only after review in accordance with the non-expedited procedures set forth in Section V.C. A report of all research approved by expedited review will be presented by the chair to the full IRB at its next regularly scheduled meeting. Categories of research which may qualify for expedited review include:

i. research conducted in established or commonly accepted educational settings, involving normal educational practices (e.g., research on special education instructional strategies);

ii. research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior if such research does not record information or identifiers which can be linked to individual human subjects;

iii. research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;

iv. research and demonstration projects which are conducted by or subject to the approval of the Secretary or heads of programmatic

offices and are designed to study, evaluate, or otherwise examine public benefit of services or programs.

v. research conducted by faculty or students at colleges/universities if all of the following conditions are met:

(a). a copy of the university's IRB policies is on file with the DHH IRB;

(b). university IRB's approval of the research is documented;

(c). a copy of the full research proposal is included;

(d). for student research, written approval of the project by both a faculty advisor and a DHH staff sponsor must be provided;

vi. research approved by an IRB in 24-hour facilities if requested via the chief executive officer of the facility to the DHH IRB chair;

vii. requests from investigators for minor changes in research approved less than one year prior to such request;

viii. cooperative research which has been approved by the IRB and head of an agency outside of DHH.

b. The Secretary or agency heads may restrict, suspend, terminate, or choose not to authorize use of the expedited review procedure.

E. Informed Consent of Research Subjects

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research unless the investigator obtains the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or representative shall be in language easily understandable to the subject or representative. No informed consent document may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the

subject's legal rights or the investigator, the sponsor, or the agency and its agents are/appear to be released from liability for negligence.

1. Basic Elements of Informed Consent

Except as provided below, the investigator shall provide each subject the following information:

a. a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

b. a description of any reasonably foreseeable risks or discomforts to the subject;

c. a description of any benefits to the subject or to others which may reasonably be expected from the research;

d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

f. for research involving more than minimal risk, explanations as to whether any compensation and medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

g. an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject;

h. a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. a statement that the particular treatment or procedure may involve risk that is currently unforeseeable;

b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. any additional costs to the subject that may result from research participation;

d. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;

f. the approximate number of subjects involved in the study.

3. Waiver of Informed Consent

The IRB may waive the requirement to obtain informed consent provided that the IRB finds and documents that:

a. the research or demonstration project is to be conducted by or subject to the approval of state government officials and is designed to study or evaluate public benefit of services provided or funded by DHH;

b. such project deals with improving procedures for obtaining benefits/services under those programs and/or suggesting possible changes in or alternatives to those programs/procedures or in the methods/levels of payment for benefits or services under those programs; and

c. such research or projects shall not involve identifying individual recipients of services/benefits.

4. Documentation of Informed Consent

a. Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

b. The written consent document must embody the elements of informed consent required in Section V.E.1. This form may be read to the subject or the subject's legally authorized representative but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed. An IRB recommended informed consent document will be included in the guidelines/application materials for conducting research in DHH operated/funded programs or facilities.

c. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

i. that the only record linking the subject and the research would be the consent document and the principal risk would be the potential harm resulting from a breach of confidentiality. Each subject will be asked if he/she wants documentation linking him/her with the research, and the subject's wish shall govern; or

ii. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

d. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. The IRB shall demand additional protection and informed consent rights if the research involves fetuses, pregnant women and human in-vitro fertilization (45 CFR 46:201-211), prisoners (45 CFR 46:301-306), or children (45 CFR 46:401-409).

F. Responsibilities of Research Investigators

In addition to all of the requirements detailed above, researchers shall be responsible for the following.

1. Research investigators shall prepare and submit a protocol giving a complete description of the proposed research.

a. The protocol shall include provisions for adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.

b. Samples of proposed informed consent forms shall be included with the protocol.

c. A completed DHH Application To Conduct Research must be submitted with the protocol.

2. Research investigators shall obtain and document appropriate administrative approval (beginning at the program/facility level) to conduct research before the proposal is submitted to the DHH IRB.

3. Prior to the beginning of the research, the investigator shall communicate to impacted staff the purpose and nature of the research.

4. Upon completion of the research, the principal investigator shall attempt to remove any confusion, misinformation, stress, physical discomfort, or other harmful consequences, however unlikely, that may have arisen with respect to subjects as a result of the research.

5. Within 30 working days of the completion of the research, the principal investigator shall communicate the outcome(s) and practical or theoretical implications of the research project to the program administrator and, when appropriate, program staff in a manner that they can understand.

6. The researcher shall submit progress reports as requested by the IRB (at least annually). As soon as practicable after completion of the research, but in no case longer than 90 working days later, the research investigator shall submit to the IRB a written report, which, at a minimum, shall include:

   a. a firm date on which a full, final report of research findings will be submitted;

   b. a succinct exposition of the hypotheses of the research, the research design and methodologies, and main findings of the research;

   c. an estimate of the validity of conclusions reached and some indication of areas requiring additional research; and

   d. specific plans for publishing results of the research.

7. A final report of the research as well as copies of any publications based upon the research will be submitted to the IRB as soon as possible. The State owns the final report, but prior permission of the IRB for the investigator to publish results

of the research is not required. The publication is the property of the researcher and/or the medium in which it is published. However, failure to provide the IRB with required periodic and final reports or publications based on the research shall impact negatively that researcher's future requests to conduct research in DHH operated/funded programs or facilities.

G. Initiation of the Research Review Process

1. The first contact in the process should be by the research investigator with the manager of the program or facility from which subjects will be drawn.

2. If the manager agrees that the research is feasible and desirable, the researcher will obtain his/her written authorization and send the protocol to appropriate staff at headquarters for consideration and approval by the assistant secretaries or the director of BHSF.

3. The assistant secretaries or the director of BHSF, in approving the research proposal, will certify that:

   a. the research design is adequate and meets acceptable scientific standards;

   b. appropriate ethical considerations have been identified and discussed;

   c. the proposal contains provisions to minimize possible disruptive effects of the project on organization's operation;

   d. the research will potentially benefit the participants directly or improve the service system; and

   e. the research topic is compatible with the agency's research agenda.

4. The assistant secretaries or the director of BHSF, after approval of the research, will submit the proposal to the IRB for further consideration.

H. IRB Records

1. The 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 in sufficient detail to show attendance at the meeting; 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 controverted issues and their resolution;

c. records of continuing review activities;

d. copies of all correspondence between the IRB and investigators;

e. a list of IRB members identified by name; earned degrees; representative capacity; indications of experience sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and DHH;

f. written procedures for the IRB and statements of significant new findings provided to subjects.

2. The records required by Section V.H. shall be retained for at least three years, and records relating to research which is conducted shall be retained for at least three years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of DHHS or the agency at reasonable times and in a reasonable manner.