I. ORGANIZATION

The Psychosocial, Behavioral & Health Services Research Committee (PBHSRC) is an officially constituted committee of The University of Texas MD Anderson Cancer Center. The PBHSRC reports to the Vice President and Deputy Chief Academic Officer, Clinical and Interdisciplinary, through the Office of the Vice President of Clinical Research Administration.

II. PURPOSE

The purpose of the PBHSRC is to evaluate the scientific content of all research requiring a protocol that addresses areas of investigation related to psychosocial, behavioral & health services research.

These include:

1. Clinical trials in psychosocial, behavioral research, health services research, and pain assessment and management. Study populations will include adult and pediatric patients as well as families, community populations, and individuals at risk for cancer, psychosocial dysfunction, and psychosocial complications of cancer. Examples include pain assessment approaches in acute post-operative and chronic cancer pain and the development of a quality of life instrument. Endpoints of outcomes research, for example, include: quality of life, cost effectiveness, utility and benefit; smoking cessation, dietary change and other behavioral modification interventions.

2. Descriptive studies of psychosocial functioning.

3. Studies of patient and clinician decision making.

A protocol is the instrument establishing the guidelines and rationale for conducting and evaluating the research. This includes all protocols originated by faculty or any other staff members at MD Anderson, all protocols sponsored by external grant-funding agencies (e.g., the National Health Institute), pharmaceutical and biotechnology companies, all large multi-institutional trials and any other clinical investigations requiring a written protocol and approval from the IRB. In this regard, the PBHSRC is a scientific reviewing agent for the IRB for protocols defined by the above scope of committee functions and is a critical component of the Protocol Review and Monitoring System (PRMS) for MD Anderson’s NCI Core Grant. All protocols submitted to the Office of Protocol Review and Reporting must have received departmental approval through the various mechanisms established by their departments and divisions.

III. RESPONSIBILITIES

The PBHSRC has the responsibility of reviewing all aspects for the scientific research that are incorporated into the protocol plan. The protocol plan includes specific aims, background and rationale, methods used to validate the scientific questions being asked,
and the methods of the biostatistical analysis to establish the success or failure of an experiment.

IV. MEMBERSHIP

There is only one PBHSRC committee at MD Anderson. The Chair position is filled by three individuals with expertise in psychosocial, behavioral or health services research, who share the Chair responsibilities on a rotating basis throughout the year. The Chairs are appointed for a 3 year term with one Chair rotating off each year. There will be at least 15 members appointed to the PBHSRC committee with representation from the different Divisions such as Cancer Prevention, Internal Medicine, Cancer Medicine, and Pediatrics. The committee will also have multidisciplinary members from Nursing, and the Quantitative Sciences Division. Members are selected based upon their areas of expertise. Each member of the committee will have one vote. There should be a minimum of 8 voting members present to constitute a quorum for a meeting.

The committee members will be replaced if attendance and participation in protocol reviews is below acceptable limits. Below acceptable limits would be half the number of meetings within a fiscal year. The committee members will be replaced if attendance is below acceptable limits. Below acceptable limits would be half the number of meetings within a fiscal year. The Vice President and Deputy Chief Academic Officer, Clinical and Interdisciplinary along with the Vice President of Clinical Research Administration will annually appoint PBHSRC members at the appropriate time within the academic year and replace vacating members as needed. Membership will be reviewed on a quarterly basis, and members with low attendance will receive warning letters from the PBHSRC Chairs. If attendance does not pick up, the committee member will be replaced.

V. MEETINGS

Meetings of the PBHSRC shall occur on the first Friday of every month at 10:00 A.M. unless otherwise noted. The PBHSRC Chair will set the agenda for the meeting for that month with the PBHSRC Specialist from the Office of Protocol Review and Reporting.

VI. NEW PROTOCOLS

New protocols must be submitted through the on-line system by the designated submission deadlines, as stated on the Office of Protocol Review and Reporting intranet site at MD Anderson. The Office of Protocol Review and Reporting will accept no new protocol until the Principal Investigator submits the required items along with the original protocol for review.

**Required items include:**
- Signature of the relevant Department Chair or Division Head
- Signature of the Principal Investigator (PI) of the newly submitted protocol
- 50% of the Collaborator’s Signatures including the Biostats Collaborator
- Names of Two Nominated Reviewers,
New protocols will be reviewed for scientific merit, biostatistical approach, and for any other aspect deemed appropriate by the PBHSRC Chairs. The reviews will be by two medical reviewers, a biostatistical reviewer, Office of Protocol Support and Management multicenter review, and Office of Protocol Review and reporting (OPR&R) Administrative review and Environmental Health and Safety. The PBHSRC Chair for the month will assign the medical reviewers for that month with the assistance of the PBHSRC Specialist from the Office of Protocol Research.

A protocol cannot be discussed at the PBHSRC Committee unless there has been a written response from the Principal Investigator to the reviewers’ comments, and all of the collaborators’ signatures have been obtained. The PBHSRC Chair shall have discretion to table a discussion or postpone presentation to the committee if in his/her opinion the reviewers’ comments have not been sufficiently addressed by the Principal Investigator.

Meeting Process:
The PBHSRC meeting will consist of an open and closed session. During the open session, the Principal Investigator, will give a brief summary of his/her protocol and respond to specific questions from the PBHSRC members. If the PI is unable to present due to another conflict, a Department Chair, Co-Principal Investigator, or delegated individual (e.g., postdoctoral fellow, graduate student) can present on his/her behalf. If a delegated individual is presenting, the PI or co-PI must be present in person. If a study is a student’s or trainee’s thesis, dissertation, or other academic project, the student’s or trainee’s academic advisor/sponsor for the study must be present in person or by telephone during the presentation of the study to the committee. The members will then have an opportunity to voice their opinions of the protocol and a discussion will follow. Following the discussion, the Principal Investigator will be asked by the Chair to leave the room, and the protocol’s scientific suitability for presentation will be voted on. A simple majority is sufficient to determine the disposition of the protocol.

During the closed session, each committee member will be allowed one vote per protocol. All electronic scoring is done anonymously.

Protocol Dispositions:

**Approved** – Will proceed to the next IRB meeting.

**Approved with Minor Contingencies** – Can Proceed Without Modification. The protocol proceeds to the next IRB meeting, no modifications are made to the protocol until after the IRB meeting. The PBHSRC contingencies become IRB contingencies.
**Approved with Major Contingencies – Requires Modification Before IRB** - The Principal Investigator must resolve the meeting contingencies and the Chair must give their final approval, prior to the protocol being forwarded to the IRB.

**Deferred** – Due to major issues brought up by the committee, the Principal Investigator will need to revise the protocol and all other supporting documents. Once the protocol has been resubmitted, the Chair will review and provide an administrative sign off before the protocol can be placed on a PBHSRC meeting agenda. The PI will be notified of their presentation date and time.

**Rejected** – Protocol cannot be performed at MD Anderson.

**VII. CONFLICT OF INTEREST**

Members of the PBHSRC who are listed as a Co-Principal Investigator or Collaborator on the protocol should recuse themselves from the PBHSRC’s deliberations surrounding the protocol.