Psychosocial, Behavioral and Health Services Research Committee (PBHSRC) Procedures

Submission and Pre-Review

1. Principal Investigator (PI) and study staff submit protocol via electronic protocol system, Protocol Document On-Line (PDOL).

2. PBHSRC Coordinator will do a quick administrative review to make sure all required information has been submitted and determines which committee should review the protocol.
   a. If there are missing components, the protocol will be rejected back to the PI and study staff.
      i. PI and study staff will need to make the corrections and resubmit the protocol back to the PBHSRC.

Review and Approval Process:

3. PBHSRC Coordinator inputs pertinent data into the electronic database, Clinical Oncology Research system (CORe).

4. Protocol is accepted and Status is changed in the electronic protocol system (PDOL) to PBHSRC Sent to Reviewers.

5. PBHSRC Coordinator will send out a generic memo in the electronic protocol system (PDOL) with pertinent deadline dates for the submission cycle to the PI and study staff.

6. New Protocol List is sent out to the Ancillary Reviewer contact group and access is granted in the electronic protocol system (PDOL).

7. PBHSRC Chair assigns Medical Reviewers and access is granted in the electronic protocol system (PDOL).

8. PI and study staff will start receiving critiques on their newly submitted protocol.
   a. If no issues noted, then the PI and study staff do not need to respond back to the reviewers.
   b. If issues or questions are noted, then the PI and study staff will need to respond.
      i. Reviewer(s) will review the PI’s response and either give their approval to proceed forward or bring up additional concerns.

9. PI and study staff will need to make any agreed upon changes to the protocol documents before proceeding forward to the PBHSRC Meeting.

10. PI or study staff resubmits protocol back to the PBHSRC.

11. PBHSRC Coordinator will review the revised protocol documents to make sure all agreed upon changes have been made.
   a. If ready to proceed forward, the protocol is then accepted and the status is then changed to Pending CRC / PBHSRC Review.
### Meeting Process

12. The PBHSRC Chair sets the upcoming meeting agenda.
13. The PI and study staff are then notified of the protocol presentation time for the upcoming PBHSRC meeting.
14. During the open session of the PBHSRC meeting, the PI will give a brief synopsis of the protocol and reviews received, and answer any questions that the Committee might have regarding the protocol.
   a. 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).
   i. If a delegated individual is presenting, the PI or co-PI must be present in person.
   b. 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.
15. During the closed session, the Committee will discuss, make a motion and vote on the protocol.
16. The PI and study staff will be notified of the Committee’s decision with 48 hours of the PBHSRC meeting.

### Protocol Dispositions:

a. If the protocol is Approved, it will proceed to the Institutional Review Board (IRB).

b. If the protocol is 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.

c. If the protocol is Approved with Major Contingencies – Requires Modification Before IRB –
   i. The PI and study staff must create a generic memo responding to the meeting contingencies via the electronic protocol system, PDOL.
   ii. Protocol documents will need to be revised before resubmitting back to the PBHSRC.
   iii. The PBHSRC meeting coordinator will review the revised documents and send to the PBHSRC Chair for review.
   iv. PBHSRC Chair must give their final approval, prior to the protocol being forwarded to the IRB.

d. If the protocol is Deferred –
   i) The PI and study staff must create a generic memo responding to the meeting contingencies via the electronic protocol system, PDOL.
ii) Protocol documents will need to be revised before resubmitting back to the PBHSRC.

iii) The PBHSRC meeting coordinator will review the revised documents and send to the PBHSRC Chair for review.

iv) PBHSRC Chair will review and provide an administrative sign off before the protocol can be placed on a PBHSRC meeting agenda.

v) The PI will be notified of their presentation date and time.

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

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**Contact Information:**

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