PHDB DATA ACCESS COMMITTEE, PROCESS, EVALUATION AND PRIORITIZATION CRITERIA

PHDB Data Access Committee (DAC)

PHDB data are available for investigator use in conducting cancer-related research projects at MD Anderson to further MD Anderson’s research efforts, and to support regulatory and required operational initiatives. The use of data collected throughout the lifespan of PHDB requires approval from the PHDB Data Access Committee (PHDB DAC). In order to ensure the integrity and accuracy of PHDB data, no requests for data intended to develop satellite databases will be approved.

The PHDB DAC is charged with stewardship of the PHDB data resources to advance cancer-related research, and with facilitating access to this resource. The PHDB DAC is charged with the responsibility for 1) establishing and maintaining a process for PHDB data access, 2) establishing and maintaining criteria for evaluation, prioritization and approval of requests for PHDB data, 3) serving as reviewer on an ad hoc basis, and 4) resolving any conflicts that may arise regarding access and use of PHDB data.

The PHDB DAC is comprised of five members and is chaired by the PHDB Executive Sponsor. DAC members include representatives from MD Anderson's clinical and epidemiology departments. As of May 2012, PHDB DAC members: Xifeng Wu, MD, PhD (Chair); John Frenzel, MD; Terry Bevers, MD; Alma Rodriguez, MD; Michelle Hildebrandt, PhD. Additional reviewers with appropriate expertise and area of research will be asked to participate on as needed basis.

Process to Request PHDB Data for Research Use

Investigators planning research studies that would require the use of PHDB data must submit an PHDB Data Request Feasibility Assessment Form for assessment as to 1) the availability of data required to conduct the study, 2) overlap with ongoing or other proposed studies, and 3) identification of an appropriate Epidemiology Faculty Sponsor. Feasibility will be assessed within 5-7 working days. If the request is deemed feasible, the requesting investigator will be asked to meet with a PHDB analyst to conduct an assessment of the request, including estimated time involved and associated fees. After meeting with the analyst, the requestor will submit a formal data request form. No data will be released without an IRB-approved protocol or IRB exemption, a QIAB approval (for quality improvement projects), or a designated Honest Broker responsible for data oversight, if data is for regulatory requirements. The data in the PDHB is a component of the Medical Record, and as such requires compliance with Federal (HIPAA) regulations.

Process and Criteria for Evaluating Requests

Proposals for PHDB data will be evaluated for 1) scientific merit based on the scientific significance/relevance of the project, rationale, potential for further research, and methodology; 2) funding source in the following priority sequence: a) peer-reviewed sponsored projects, b) non peer-reviewed sponsored projects, c) unsponsored projects intending to create preliminary data for sponsored applications, with priority to junior investigators, d) unsponsored projects to be completed independent of funding sources; 3) the project timeline, and 4) PHDB portfolio balance. Evaluation criteria may be revised by the PHDB DAC as needed. Since PHDB is source of clinical data, top priority will be assigned to requests associated with CMS compliance if PHDB data are needed to document compliance with applicable statutory, regulatory and Medicare program requirements. Top priority will also be given to requests associated with data quality issues since it is imperative that PHDB data be accurate. Expedited approvals of PHDB data requests may be granted at the discretion of the PHDB DAC Chair. The PHDB DAC meets as needed to review requests for data. Investigators can expect a response to request for data in 2-4 weeks, assuming no additional information is required or contingencies are identified that will need to be addressed by the investigator.

All data requests from an external party must obtain a Data Use Agreement and follow appropriate MD Anderson institutional policies.
Other Considerations

Data use requests approved by the PHDB DAC are approved for use for the outlined project only. Investigators will be required to complete and sign a PHDB Data Use Agreement. Investigators may not release PHDB data to a third party and may not use data for purposes other than those for which they have been approved. Fees, if any, for data and will be assessed in accordance with the rates set by the PHDB DAC.

Investigators using PHDB data will be asked to submit an annual report to the PHDB DAC to include research results obtained from the PHDB data, with complete confidentiality guaranteed until the date of publication or award of a patent. All publications must appropriately acknowledge the PHDB and its various funding sources as appropriate. (Contact PHDB staff person for assistance with acknowledgement wording.)