



Site-Based Research Charter

Duke University School of Medicine

Name of CRU: **Psychiatry**

Date: 07-25-2017

CRU Director Signature:

Edward C. Suarez

Unit Head Signature:

[Handwritten Signature]

1. Scope of Research within the CRU :

The Psychiatry CRU will include twelve subgroups: Behavioral Medicine, Biological and Adult Psychiatry, Geriatric Psychiatry, Child and Adolescent Psychiatry and Psychology, Schizophrenia, Epidemiology and Health Services, Cognitive Behavioral Psychology, Nicotine Research, Sleep Disorders, Brain Stimulation and Neurophysiology, Veterans Administration Group, and the Duke Addictions Program. Overlap areas include Duke Integrative Medicine, Neurology, and the Center for Aging.

Research Mission The Department of Psychiatry and Behavioral Sciences is actively involved in three major areas of research: 1) the understanding of the biological, social and behavioral mechanisms of psychiatric disorders 2) the role of behavior and the central nervous system in somatic disease, 3) clinical trials aimed at the design and implementation of new therapies for psychiatric disorders as well as for diseases mediated by the central nervous system and behavior. Investigators in the Department are actively involved in both clinical and basic research studies in all three areas of investigation. Major topics currently being addressed by Departmental investigators include mood disorders, schizophrenia, anxiety disorders, attention-deficit disorders, memory disorders, cardiovascular disease, diabetes mellitus and eating disorders.

2. Key Personnel:

Director : Edward Suarez, PhD, MA

Research Practices Manager: Ana Garcia-Turner, MSHS, CCRP

Assistant Research Practices Manager: Sharikia Burt, MS

Financial Practices Manger: Renee Vaughan, MDiv, MA, CRA

3. Define Clusters & Leadership within Clusters;

Twelve major research groups have been identified. They include: Behavioral Medicine, Biological and Adult Psychiatry, Geriatric Psychiatry, Child and Adolescent Psychiatry and Psychology, Schizophrenia, Epidemiology and Health Services, Cognitive Behavioral Psychology, Sleep Disorders, Brain Stimulation and Neurophysiology, Duke Addictions, Veterans Administration Group, and Nicotine Research.

4. Faculty Advisory Board

Composition:

The following individuals will be members of the committee: Jeanne Beckham, PhD (Behavioral Medicine), , John Beyer, MD (Gerontology), Nicole Heilbron, PhD (Child & Family Mental Health), Christine Marx, MD (Translational), F. Joseph McClernon, PhD (Addictions), Marvin Swartz, MD (Social and Community Psychiatry) and Richard Weiner, PhD, MD (Brain Stimulation).

Function:

The Advisory Board will meet quarterly and be chaired by the Medical Director of the Psychiatry and Behavioral Sciences CRU. The Medical Director may consult or call more frequent meetings of the Advisory Board related to the review of specific proposals or ongoing clinical research projects. Faculty members may raise issues/concerns regarding the conduct of clinical research to the CRU Medical Director that can be brought to the attention of the Advisory Board for discussion and review.

The CRU Advisory Board is an all-volunteer panel. CRU leadership will take reasonable measures to ensure that there is broad representation of the divisions. The board members include faculty, coordinators, financial and administrative staff.

Members of the board will serve for two years. Appointment to the Board is suggested by the CRU leadership to the Department Chair on an annual basis. The Department Chair will have final approval over board members

The role of the Advisory Board is to assist the CRU leadership carrying out its mission. The Advisory Board is charged with reviewing and providing recommendations regarding departmental standards and systems for the conduct of site based research, which includes:

- Review of all standard operating procedures (SOP) for the Psychiatry and Behavioral Sciences CRU.
- Assisting in the development of process-oriented systems that will provide standardized methodologies to track study progress from inception to completion.
- Advising CRU and the Department of Psychiatry and Behavioral Sciences leadership regarding the appropriate establishment of CRU and divisional administrative fees to support clinical research administration as well as the appropriate distribution of margin or loss from sponsored clinical research studies.

5. CRU Governance and Financial Plan:

The Director of the CRU will work with the Department administrator, the Financial Practice Manager, and the Chairman of the Department to develop an annual budget for the CRU activities.

6. CRU Stakeholders:

Brain Imaging and Analysis Center (BIAC) Duke Aging Center, Duke Integrative Medicine, Neurology, John Umstead Hospital (JUH) Central Regional Hospital, Duke Diet and Fitness Center, Behavioral Medicine Research Center, Division of Endocrinology in the Department of Medicine, Center for Cognitive Neuroscience, Memory Disorders Clinic, and Duke Institute for Brain Sciences.

7. Communication Plan:**CRU Communication Plan**

Communication across many levels is essential to the health of the Psychiatry CRU. We have established a number of regular meetings designed to ensure effective communication among the leaders of the CRU and throughout the community of Investigators and Coordinators.

3.1. Communication of Institutional direction

The Psychiatry web portal will be the communication nexus for the Psychiatry CRU. As such institutional direction will be disseminated through its intersection with the DOCR website. CRU initiatives and organization will be posted to the PsychWeb portal along with associated email feeds to disseminate updates and changes as well as training captured through Lectopia and Adobe Connect.

3.2 Mechanism to represent faculty /staff needs to advisory council

Open forums and one-on-one meetings with faculty members will be scheduled as necessary. The Director will provide a forum for CRU concerns at the monthly departmental meeting of faculty. The CRU Research Practice Manager will conduct periodic meetings with the Study Coordinators and the Financial Practice Manager with the financial group managers. The Faculty Advisory Board will meet on a quarterly basis.

3.3 Mode of Communication.

1. Meetings are scheduled within the CRU to address the various constituents as needed, as well as telephone contact.
2. Email communication will allow speedy transmission of updates and policy changes.
3. Institutional notices and regulatory compliance issues will be disseminated via email, PDF document and departmental blog notices.
4. The CRU Intranet and the month newsletter will be the communication nexus for the Psychiatry. Components of the web portal will include the overview and plan, financial practice sops, research news and announcements, Policies and procedures, Guides and templates, HRPP, Journal of Clinical Research Practice and ACRP Newsletters and FAQs and Contacts.

3.4 Frequency of Communication.

The aforementioned will provide channels of communication as needed.

3.5 Expectation of Leadership

One means of promoting effective communication is a recurrent weekly meeting of the Psychiatry Medical Director, Research Practice Manager, and Financial Practice Manager. Unit meetings will provide the intended effect of coordinating efforts across the department. Monthly meetings between the director and the Chairman of the Department will also occur. The Department administrator may attend these meetings as well.