Integrated Network

Wave 2 Site RFA | FAQs

September 2024

I. Personnel

1. What are the descriptions and desired profiles of the Clinical Lead, Research Lead, Data Lead, and Neuroimaging Lead?

- *The site's "Clinical Lead" (recommend at least 0.1 FTE) will assist the Lead PI* in all clinical care-related study activities. They are expected to be a practicing clinician with expertise in bipolar disorder. They should have a willingness to contribute to the interpretation of study data and champion the implementation of the BD² Learning Health Network at the site's clinical practice (i.e. someone committed to the process of care improvement). They – along with the Lead PI and Research Lead – are expected to attend regular (typically monthly) meetings with the BD² Leadership Team as well as participate in and contribute to Working Groups structured around their expertise.*

- *The site's "Research Lead" (recommend at least 0.1 FTE) will assist the Lead PI* in all research-related study activities. They are expected to be a faculty member with an active research program. They should have a willingness to contribute to the analysis of study data and the implementation of the Learning Health Network. They – along with the Lead PI and Clinical Lead – are expected to attend regular (typically monthly) meetings with the BD² Leadership Team as well as participate in and contribute to Working Groups structured around their expertise.*

  ** Some current sites have named either the Lead PI and the Clinical Lead or the Lead PI and the Research Lead as the same person.*

- *The site's "Data Lead" (recommend at least 0.1 FTE) will be a primary point of contact for all data-related study activities. They do not need to be an "expert" in the study-related data modalities but should be positioned to oversee all study-related data activities, including the data processing and curation activities required for transfer to the BD² Data Coordinating Center (DCC) and retention of study data at the institution. They should be the site's primary liaison with the DCC and are expected to attend regular (typically monthly) Working Group meetings with DCC personnel and Data Leads from all BD² sites. This position does not need to be filled by a faculty member.*

- *The site's "Neuroimaging Lead" will be a primary point of contact for all neuroimaging-related study activities. They will oversee BD² neuroimaging protocol implementation procedures as well as neuroimaging data collection & QC at the site. They are expected to contribute to ad-hoc Working Group meetings with Neuroimaging Leads from all BD² sites. This position does not need to be filled by a faculty member.*

II. IRB Review

2. What will the central IRB review process look like?

- *The Clinical Coordinating Center (CCC) manages the central IRB (BRANY) review process. If your institution does not allow central IRB review, please indicate so in your application, and the CCC will work with individual sites to manage IRB oversight and obtain local IRB ceding approval.*

III. Budget

3. Is there a salary cap sites should adhere to?

- *Yes, please use NIH salary caps.*

4. When budgeting, should sites assume 100% participant retention in the study?

- *For budgetary purposes, assume 100% retention.*

IV. Protocol

5. Which study assessments are administered by site staff, and is any specific training or degree level required for the site staff who will perform study assessments?

- *The following study assessments are administered by site staff; any required training or specialized degree level (i.e. clinician) is specified:*

Domain	Questionnaire or Assessments	Administrator Information
Biological	Biosample Collection (peripheral blood)	Site staff/Coordinator * processing/shipping trained by Centralized Biorepository
Biological	Metabolic Readout (height, weight, waist-hip ratio, body mass index)	Site staff/Coordinator
Biological	MRI (~45-min protocol)	Site staff * protocol provided by BD[2]
Biological	Vital signs (body temperature, pulse rate, respiration rate, blood pressure)	Site staff/Coordinator
Current Symptomatology	Clinical Global Impression scale for Bipolar Disorder (CGI-BP)	Site clinician * trained by BD[2]
Functioning	Functioning Assessment Short Test (FAST)	Coordinator * trained by BD[2]
General Medical	Health History Questionnaire	Coordinator * trained by BD[2]
Neurocognition	Brief Assessment of Cognition in Schizophrenia: Symbol-Coding (BACS)	Coordinator * trained by BD[2]
Neurocognition	Brief Visuospatial Memory Test-Revised (BVMT-R)	Coordinator * trained by BD[2]
Neurocognition	Category Fleuncy: Animals	Coordinator * trained by BD[2]
Neurocognition	Continuous Performance Test-Identical Pairs (CPT-I/P)	Coordinator * trained by BD[2]
Neurocognition	California Verbal Learning Test 3rd Edition (CVLT3)	Coordinator * trained by BD[2]
Neurocognition	Letter Number Span (LNS)	Coordinator * trained by BD[2]
Neurocognition	Stroop	Coordinator * trained by BD[2]
Neurocognition	Trails A	Coordinator * trained by BD[2]
Neurocognition	Trails B	Coordinator * trained by BD[2]

Neurocognition	Wechsler Abbreviated Scale Intelligence 2nd Edition: Vocab & Reasoning (WASI-II)	Coordinator * trained by BD^2
Neurocognition	Wechsler Memory Scale 3rd Edition: Spatial Span (WMS-III)	Coordinator * trained by BD^2
Neurocognition	Wide Range Achievement Test-Reading (WRAT)	Coordinator * trained by BD^2
Sleep / Activity	Fitbit (Inspire 3)	Coordinator * protocol provided by BD^2
Neurocognition	Balloon Analog Risk Task (BART)	Coordinator * trained by BD^2
Neurocognition	Penn Emotion Recognition (ER-40)	Coordinator * trained by BD^2
Treatment - Current	Breakthrough Discoveries for Thriving with Bipolar Disorder Bipolar Treatment Response and Switch Questionnaire (BDTR-SQ)	Site clinician * trained by BD^2
Treatment - History	Retrospective Assessment of the Lithium Response Phenotype Scale (ALDA)	Site clinician * trained by BD^2
Treatment / Symptomatology / Resilience	Qualitative Interview	Coordinator * trained by BD^2

V. Recruitment

6. **Can participants be recruited from a site's broader community, or can they only be recruited from the site's patient population? If participants are pulled from the site's broader community, will retrospective and/or prospective clinical data be collected?**
    - *The ideal is for 100% of participants admitted into the Integrated Network study to come from the site's own patient population, which will facilitate the capture of five years of retrospective data along with prospective clinical (EHR) data.*
    - *However, sites can advertise the study to the broader bipolar community with the goal of eventually accessing retrospective EHR data – in addition to prospective EHR data - from these "external" participants' respective healthcare providers.*

VI. Data

7. **Will sites be expected to transfer raw or processed data to the Data Coordinating Center (DCC)?**
    - *The DCC will provide sites with a pipeline to process raw data, which will then be transferred.*

8. **What data will site teams, clinicians, and participants receive from BD^2?**
    - *In the spirit of a Learning Health Network, BD^2 will develop dashboards for sites, clinicians, and patients to track their clinical data/progress and improve care. Patient data will be anonymized at the site level to ensure security.*