BD² Breakthrough Discoveries for thriving with Bipolar Disorder

Frequently Asked Questions and Answers

Discovery Grants

Scientific Scope

Q Will clinical trials be funded?

A The Discovery Grants will not fund the development of new clinical trials or recruitment into current clinical trials. However, the Discovery Grants will fund the testing of potential mechanisms on existing clinical trial cohorts.

Q How connected or independent should the three aims be?

A It is up to the applicants on making their aims connected or independent, though all three aims should address a central hypothesis or question.

Q How do I know if the methodology that I employ in my lab (such as animal modeling, neuroimaging, longitudinal studies in humans, etc.) is relevant to the scientific scope?

A We recommend that you first focus on the hypothesis or scientific question you would like to address that would further implicate a new or existing hypothesis about the biological underpinnings of bipolar disorder. Then outline the variety of methodologies to address this hypothesis or question in different ways.

Lead and Co-PIs

Q Can I be on multiple applications as a co-PI?

A Yes, you can be on multiple applications as a co-PI. If you are a Lead PI for one grant, you can be a co-PI for another grant. However, keep in mind that you must dedicate at least 25% of your time to each application, if awarded, regardless of whether you are co-PI or Lead PI.

Q Can I be a Lead PI for more than one application?

A No, you can only be a Lead PI for one application.

Q Can the Lead PI be located outside of the US as well as the whole team?

A Yes

Q Can we all be from the same institution in one application?

A Yes. However, interdisciplinarity among team members is prioritized, especially collaborations between disparate and traditionally non-collaborative fields.

Collaborations

Q How do you prioritize existing versus new collaborations?

A While collaboration history is important, we will also honor new collaborations in this application. Regardless of collaboration history, the collaboration plan will be taken under consideration.

Q How do I find new collaborators?

A We highly encourage you use this opportunity to reach out to researchers to engage in new collaborations or connect with current and past collaborators that have yielded fruitful results. For those new to bipolar disorder research, Pubmed is a vital resource to understand the field and identify potential research teams that may be complementary of your work. Biobanks and other resources may also be found via Pubmed or Google search.

Q Can collaborations be from institutions outside of those of the Lead or Co-PIs?

A Yes, collaborations can be with other organizations. They must be disclosed in the Team Description.

Early Career Investigators

Q Are there separate grants for early career investigators?

A There is no funding mechanism separate for early career investigators and assistant professors. Assistant professors and other early career PIs are encouraged to be Lead and co-PIs and are eligible for funding from the Discovery Grants and other grants from BD^2.

Q Is parental leave or other career breaks taken into account in terms of the post-terminal degree time limit for the early career co-PI?

A If extenuating circumstances have played a major role in disrupting an individual's career timeline, please include it in the Team Description document for consideration. This may include parental leave and extenuating medical leave.

Q Can you please clarify the eligibility criteria regarding early career investigators?

A Early career scientists for PhDs are individuals who have earned their PhD or relevant degree in the last 10 years. This does not start at postdoctoral training.

A Early career scientists for MDs are within 10 years of the completion of their residency training. This does not start at the end of a fellowship.

Funding

Q How will my team receive funds?

A All funding will be provided to the Lead Institution, which will be responsible for sub-granting to the institutions of the co-PIs. The Lead Institution may not provide sub-grants to other entities outside of those mentioned in the grant without explicit written instructions by BD^2.

Q Will you fund all aims within a grant?

A BD^2 has the discretion to fund discreet aims of a proposal. If a co-PI is not listed on an aim that BD^2 intends to fund, that co-PI may not receive these funds.

Q Can Year 2 funding be used to offset higher-than-estimated startup costs of Year 1?

A Applicants are highly encouraged to keep annual budgets within the $1.5 million per year amount, inclusive of indirect costs of 15%. If the annual proposed budget is different from $1.5 million, please provide some justification as to why this is required on the budget template, and it will be considered.

Q Does the PM position need to be budgeted up front? How should it be budgeted in the budget sheet?

A Yes, the PM position must be budgeted up front. Each team must dedicate at least 50% of one individual's time, who must be in the lead PI's lab and preferably with research experience. The PM position can be split between the three aims as needed. However, if an application is partially funded, the entirety of the budget requested for the PM will likely be supported. Regardless of how the PM's cost is split between the aims, that person will most likely be fully supported even if certain aims are funded.

Q How should sites break down funding across aims if a data source such as MRI is used across multiple aims? Will the cost be automatically recalculated across the funded aims?

A Research budgets will likely change throughout the three years of funding. The Program Staff will work with the PIs and Program Managers to handle any recalculations or changes needed in the budget.

Q How do collaboration grants work?

A Teams will have two opportunities to apply for up to $250,000 in collaboration grants. These grants are meant to incentivize additional collaboration beyond traditional partnerships to improve innovation.

A During the application phase: The only teams who are eligible for these collaborative grants during the application phase will be identified by the BD^2 team during the application review process. The review committee will contact teams who have the potential to collaborate and will allow these teams additional time to complete the short application process.

A During the funding phase: Teams who are funded by BD^2 will be given the opportunity to apply for collaborative grants on an annual basis. The first application window will open about 10 months into the application process, and again at 22 months. Applications must only include teams funded by BD^2. Applications can include as few as two individual research labs, who must be on separate teams.

Q Will there be future RFAs?

A We intend to host two additional cycles for the Discovery Grants.

Application

Q **Do you have a Letter of Intent phase?**

A No, we do not have an LOI phase. Reach out to discoverygrants@bipolardiscoveries.org for questions about whether a potential proposal idea falls under the scope of this application.

Q **Are there templates for the scientific rationale portion of the proposal?**

A There are no templates for the scientific rationale section, but please use 11-point font and 1-inch margins to improve legibility for the reviewers.

Review

Q **How involved will the Scientific Steering Committee (SSC) be in coordinating efforts between proposals?**

A The SSC will be hands-on in selecting and coordinating potentially new collaborations between proposals and funded teams. They will also potentially select certain aims from a full proposal to be funded and may link the teams with funded aims to collaborate. These teams will be eligible for $200,000 one-year collaboration grants to facilitate these partnerships.

Q **How will the review process be different from the NIH study section?**

A Projects funded by this program will be distinct from what NIH already funds, as to remove any redundancy of funding. The Discovery Grants have the capacity to fund higher risk proposals with high impact. All peer reviewers will be onboarded by the program staff to ensure that they understand the different lenses in which these proposals should be reviewed. Additionally, the SSC as well as the Program Board are fully committed to funding beyond what current funders are supporting.

Omics Program

Q **Is it a requirement that we use funding to expand existing brain tissue collections?**

A No, it is not a requirement.

Q **How much of the funding can we use to expand existing brain tissue collection?**

A It is recommended that you use no more than 50% of the funding to expand your brain tissue collection. Reviewers will want to see data using your existing brain tissue collection before the three-year funding period is up.

Q **What types of molecular assays should I prioritize?**

A We will leave this open for interpretation by the applicant, as certain organizations may have expertise in specific assays. The review committee will prioritize applications that can explain why the assays, brain areas, and general strategy would be vital for improving our understanding of the biology of bipolar disorder.

Q **Our brain bank does not have capacity to perform molecular assays but would like to apply to expand our existing collection. Should I apply?**

A We highly encourage you to partner with other institutions who may have expertise in molecular assays. We will not fund applications that will use the funding solely to expand brain tissue collections.

Q **What does diversity mean to you?**

A We will prioritize applications with brain tissue collections that are at least representative of a racial and gender diversity of people with bipolar disorder.

Q **We don't have all of the demographic and characteristic information of the brain tissue in our collection that is represented on your template.**

A While more information about each brain tissue sample is ideal, we understand that not all tissue samples will have such comprehensive data.

Q **Where are the templates?**

A All templates can be found through the Submittable grant portal. You can find that through our website, by clicking the "apply now" button on the appropriate grant platform page. You will need to create an account, which will link you to the budget template and sample description template.

Q **Do figures and references count towards the five-page limit?**

A Figures do, but references are separate (two pages, separate).

Q **Is there a sample number limitation?**

A We don't have a range because we recognize that a smaller number of sample from an underrepresented group could be more significant. Whatever sample number you are providing, you will want to make sure it's sufficient to answer the questions and get clarity on underlying biological mechanisms.

Genetics Program

Q **Can some funding be used for sequencing of controls or relatives?**

A Yes, we encourage the sequencing of appropriate controls and relatives, as well as psychiatric controls if available.

Q **Making data available is a major effort and expensive task – how much infrastructure should be included in the grant to make data available to the field?**

A Existing resources would be the most cost-effective, especially if the strategy you would like to employ is already being used by the field. It is up to you to apply the necessary budget to make data available.

Q **Is it a requirement that all data should belong to an US institution?**

A Data does not need to belong to a US institution, and you should comply with your local and regional data policies. We will work in partnership with the funded organization to ensure that data sharing requirements comply with existing laws.

Q **There are several ongoing sequencing studies already funded. What is the policy from BD^2 about co-funding?**

A Co-funding is appropriate as long as there is an unmet need that can be fulfilled by BD^2 funding that the existing efforts are not addressing. Any co-funding from other sources must be disclosed.

Integrated Network: Clinical Coordinating Center

Q **Are organizations located outside of the USA eligible to apply to become the CCC?**

A Yes. Proposals will be accepted from any qualified public or private sector organization, including nonprofit and for-profit organizations, universities, hospitals, laboratories, and healthcare systems.

Q **What is the proposed start date for the project?**

A The proposed start date is March 2023. Given our current timeline, we expect to announce the first six participating sites in early May 2023 giving the CCC a one-to-two-month lead to onboard, draft agreements, and complete other preparations.

Q **How do the funding period and data collection period overlap?**

A A total of $5.4 million USD is available to complete the scope of work. Contracts will be awarded through year 5 with funds to cover the subsequent data collection period (years 5-8).

Q **A key role of the CCC is to "Oversee and perform key diagnostic and clinical assessments across multiple clinical sites." Will the centralized raters be employed by, and located at, the CCC center and will they be responsible for conducting the SCID / YMRS / MADRS / BPRS / Childhood experiences?**

A Correct. Centralized raters will be employed by the CCC and will and conduct their assessments via a 'remote' (e.g., Zoom) assessment.

Integrated Network: Data Coordinating Center & Centralized Repository

Q **Does compliance with governmental regulatory requirements need to cover the US (FDA) only or should it include other international jurisdictions (e.g., GDPR)?**

A During year one, six sites will be recruited from the USA to launch the Integrated Network. During subsequent years, we will open recruitment to international sites. So, while we will launch in the USA, (covered under regulatory requirements such as the Revised Common Rule, HIPAA, and FDA) we will expand in the following years to include international sites which will likely include those in Europe which are covered under GDPR. Experience working with regulatory requirements of other countries outside Europe may be helpful but is not required.

Q **Will the data generated through the clinics be used as part of any FDA (or other body) regulatory submissions (e.g. any 21-CFR-PART 11 implications)?**

A Yes, they may be, so experience dealing with 21-CFR-PART 11 is helpful.

Q **Are you able to provide any additional detail regarding the analytics requirements?**

A Our goal will be to aggregate, analyze, and present data to:

i. clinicians and researchers,

ii. study participants, and

iii. biomedical researchers.

This will require the identification of common data elements, a task that will be completed with input from multiple stakeholders including the participating site providers.

The below case studies provide a brief overview of anticipated needs.

Use Case 1: A provider and Integrated Network site PI

Goal: Easily gain insights from EHR data and other sources to guide care improvement.

Requirements: Dashboard to visualize trends in patient care and outcomes. Compare select groups within the network to identify patterns and trends over time.

Note: Clinicians will be engaged in design workshops to form a consensus on the most relevant data sets and analyses.

Use Case 2: A data scientist

Goal: Support the application of AI and machine learning tools to generate new knowledge from practice and other data sources.

Requirements: Aggregated data sets (and data dictionaries) available for analysis.

Use Case 3: A study participant

Goal: Study participant has access to their own data.

Requirements: Will seek input from people with lived experience and their providers to determine what specific data types should be available.

Use Case 4: A biomedical researcher

Goal: Support data analysis and interpretation by basic researchers with expertise in bipolar disorder but not data science.

Requirements: Support data search, query, basic analyses, and visualizations. Exportable results including DOI.

Q From an ongoing operations and data management perspective – is there a preference for the respondent to take on full management in the near-term and long-term or only near-term?

A Preference for long-term management and operations.

Q Is there a requirement for the data to be hosted in the US or are other jurisdictions possible?

A Other jurisdictions can be considered so long as they meet with the regulatory requirements of the respective governing body (Revised Common Rule, HIPAA, GDPR, etc.).

Q Are there specific open source or commercial visualization tools of interest?

A We have not identified specific visualization tools at this stage but would prioritize tools that help clinicians to interpret data analytics faster, recognize trends and identify strategies to improve care. For example, we could envision enabling R shiny apps and potentially Jupyter notebooks.

General

Q What are your indirect cost rates?

A Our indirect cost rates are set at a maximum of 15%. This rate is set across all BD² programs and is inflexible.

Q Can pharma or biotech apply?

A Pharmaceutical or biotech companies, as well as other for-profit organizations, can be collaborators with the applications, but cannot be co-PIs or lead PIs of any proposal. All organizations must adhere to the Open Science and IP policies.

Q How much weight will funders have in final decisions?

A The program board, comprised of the philanthropic funders, will have the final approval for all funding decisions. They will take into considerable advisement the recommendations made by the Scientific Steering Committees.

Q How will you enforce your open science policies?

A Open science is a cornerstone of this initiative, and it is imperative that all applicants, as well as funded institutions, understand that BD² will enforce all open science policies listed in our document. Funding may be withheld or removed if teams actively refuse to participate in open science practices. Project Managers within the Discovery Grant teams will keep track of research outputs and datasets to be placed into appropriate repositories and ensure other open science practices as needed. Open science policies will be enforced similarly to efforts within Aligning Science Against Parkinson's (ASAP). You can find the Open Science Policy here.

Q Are there already preferred databases that would be used for data?

A There are no specific preferred databases as of yet. We will work with the funded teams to make any decisions on whether specific databases should be used for certain data types. All data repositories, however, must:

- Enable immediate open access to data upon preprint posting and manuscript submission,
- Allow reuse with licensing,
- Assign a unique and persistent identifier to the dataset, such as a digital object identifier or accession number that allows linking and citation,
- Ensure that data are deidentified health information are adequately protected,
- Provide long-term preservation and storage of data, which meet the ISO's trustworthy digital repository standards.

A See more in our Open Science Policy.

Q Are there any salary caps for PI salary similar to the NIH cap?

A Please use the NIH PI salary cap to budget PI salaries. The 25% effort would be based on this NIH cap. Each PI, including Lead and Co-PI, must give at least 25% effort.

Intellectual Property (IP)

Q Will there be additional language in the grant agreement regarding IP?

A The grant agreement will feature additional language to ensure all parties are aware of what they're agreeing to and their rights.

Q What is the intention of the IP clauses?

A Generally, the intention is to ensure that any commercially viable discovery will be translated to impact people with bipolar disorder as quickly as possible, but the IP does remain with the grantee and any potential revenue would be covered in a separate future agreement between BD² and the university.

Q What if my organization disagrees with an IP clause?

A Please send any specific inquiries to discoverygrants@bipolardiscoveries.org so we can better understand the potential points of conflict.