

2024 Breakthrough Award Guidelines



Award Intent

The IOCDF is grateful for the opportunity to once again offer the Breakthrough Award to researchers pursuing impactful projects investigating OCD. The 2024 Breakthrough Award is intended to support innovative and potentially-groundbreaking projects — high-impact science that could make a profound impact on the field and accelerate progress toward new and more effective treatments for OCD. Please refer to the 2024 Request for Proposals (RFP) for more information.

Funding for the Breakthrough Award has been generously provided to the IOCDF by the Selig family.

Eligibility

Eligible principal investigators will have completed residency or their PhD before September 1, 2019, and must have at least five years of research experience. You may include study personnel, consultants, etc. in your application who do not meet these requirements, but they cannot occupy a PI or co-PI role. **Only projects that investigate topics in OCD will be considered for funding.**

2024 Topic of Interest: Increasing Access to Treatment for All

Although evidence-based treatments such as ERP and medications can help reduce OCD symptoms, they are currently not accessible to all people with OCD. Factors such as distance from providers, cost, misinformation, and stigma prevent many people from underserved and minority communities from receiving effective and potentially life-saving treatments.

Recognizing this disparity and in alignment with our mission of help, healing, and hope — for all — we are proud to announce our 2024 Topic of Interest: Increasing Access to Treatment for All. We are particularly interested in proposals related to improving access to treatment for underserved and underrepresented groups, such as rural communities and racial, ethnic, and sexual minority groups.

While this is our Topic of Interest for the 2024 Research Grant Program, other suitable proposals related to OCD will also be considered for the Breakthrough Awards.

Preparing Your Application

Your application must include the following documents uploaded via the application portal:

- Main proposal document (includes cover sheet, proposal, and references)
- Administrative section (attached to the end of the main proposal)
- Budget Worksheet (uploaded separately using Excel template)
- Individual biosketches for the PI, co-PI, co-investigators/collaborators, and all other significant contributors (OSCs) uploaded via the application form

Main Proposal

Formatting

Your proposal is limited to 10 pages, not including cover sheet, references, and narrative budget. Please use Arial font, size 11, single-spaced, with 0.7 inch margins.

Double-spacing is required between paragraphs. Each paragraph can be single-spaced, as long as there is a double-space between paragraphs. The cover sheet, references, and narrative budget justification are not counted toward the 10- page limit.

Please upload your proposal as one PDF that includes the following:

Cover Sheet

Include the name, address, phone, fax and email of the Principal Investigator, as well as the name and address of the sponsoring institution.

Proposal and References

Your proposal should address each of the following points (unless the point is not relevant to the work proposed):

- Background (prior work making this proposal reasonable and worthwhile). Limit to one paragraph
- Hypotheses that will be tested
- Methods
- Intended use of the results
- Describe how the results will improve our understanding of:
 - The etiology of OCD;
 - The epidemiology or clinical picture of OCD;
 - The pathophysiology of OCD;
 - The treatment of OCD; or
 - Increased access to OCD treatment
- Duration of the proposed study (5 years)
- Describe the funding that has already been obtained for this proposal, and the sources of that funding
- Describe the publication plan
- If the study involves pre-clinical/clinical research, describe how you intend to comply with the IOCDF inclusion policy (see below)
- If the study is submitted for the 2024 Topic of Interest, describe how you intend to comply with the IOCDF Topic of Interest policy (see below)
- If drafting of the proposal involves the use of generative artificial intelligence (AI), describe how you intend to comply with the IOCDF AI policy (see below)

- If the proposed study involves humans, include copies of the Informed Consent and the Institutional Review Board approvals as attachments at the very end of your proposal document. If approvals are pending, please note that fact in your proposal and be prepared to submit approvals for each study site prior to receiving payment.
- If the proposed study involves human gene therapy, you must submit a copy of the NIH Recombinant DNA Advisory
 Committee (RAC) review or waiver of review
- Bibliographic references (not counted toward page limit)

Pre-clinical and Clinical Research (Inclusion Policy)

It is the policy of the IOCDF that women and members of racial and ethnic minority groups shall be included in clinical research funded by the IOCDF, unless there is a clear and compelling reason on the basis of either the health of research participants or the purpose of the research, to exclude women and/or members of minority groups from a proposed study. The IOCDF will not fund clinical research that excludes women and/or members of minority groups without an appropriate justification (cost is not considered to be appropriate). Principal investigators are also expected to conduct analyses for the effects of sex/gender and race/ethnicity when appropriate.

If complying with this policy would risk the health and safety of research participants or conflict with the purpose of the study, please indicate this in your application and provide a detailed justification. All other applicants proposing clinical studies must include the following in their proposal:

- A description of the composition of the proposed study population that includes sex/gender and race/ethnic group data about the population;
- A description of proposed outreach plans for recruiting women and members of minority groups as participants; and
- A description of how effects of sex/gender and race/ethnicity will be addressed in the analytic plan. If there is prior literature either supporting the presence of such effects or suggesting their absence, this should be summarized and addressed. It is not expected that all studies will be adequately powered for analyses of sex/gender and race/ethnicity will be fully powered and it is thus understood that such analyses may be secondary/exploratory.

For pre-clinical studies, the applicant must address how sex as a biological variable will be considered in experimental design and analysis.

Guidelines for the 2024 Topic of Interest: Increasing Access to Treatment for All (Topic of Interest Policy)

Introduction

A "Topic of Interest" is an area considered by the IOCDF community, donors, and researchers to be in need of increased attention and consideration due to factors such as necessity for greater understanding and treatment of OCD and related disorders; promising potential for research, treatment, and practice; and consensus from the community. These do not serve as sole deciding factors in whether a proposal is accepted; suitable proposals in other areas are also considered and accepted based on the peer review process. Prior Topics of Interest included body dysmorphic disorder and the role of neuroinflammation in OCD.

Prior to the 2024 cycle, Topics of Interest were presented as categories for the Jenike Young Investigator Awards. This cycle, the Topic of Interest will apply to Breakthrough Awards as well. Applicants are reminded that Breakthrough Awards are specific to OCD research, and not inclusive of related disorder research.

The 2024 Topic of Interest is "Increasing Access to Treatment for All":

Although evidence-based treatments such as ERP and medications can help reduce OCD symptoms, they are currently not accessible to all people with OCD. Factors such as distance from providers, cost, misinformation, and stigma prevent many people from underserved and minority communities from receiving effective and potentially life-saving treatments.

Recognizing this disparity and in alignment with our mission of help, healing, and hope — for all — we are proud to announce our 2024 Topic of Interest: Increasing Access to Treatment for All. We are particularly interested in proposals related to improving access to treatment for underserved and underrepresented groups, such as rural communities, people with lower socioeconomic status, and racial, ethnic, and sexual minority groups.

While this is our Topic of Interest for the 2024 Research Grant Program, suitable proposals for other OCD and related disorders topics will also be considered.

Guidelines for Applicants

The following guidelines were created by IOCDF staff in collaboration with the IOCDF Board of Directors, the IOCDF Scientific & Clinical Advisory Board, the Chair and Vice Chair of the Research Grant Program, and the IOCDF Diversity, Equity, and Inclusion Action Council (DEIAC) to best represent needs related to diversity, equity, and inclusion in OCD and related disorders research.

All applicants who select that their proposal relates to the 2024 Topic of Interest must address the following points in their proposal (Note: Breakthrough Award proposals are for investigating OCD only, while Young Investigator Award proposals are for investigating OCD and related disorders.):

- 1. Does the study target an underrepresented or underserved population living with OCD or a related disorder?
- 2. Does the study sample(s) reflect the target population(s) who live with OCD or a related disorder? If not, are the differences potentially of importance or can otherwise be justified?
- 3. Does the study measure outcomes that are relevant to the target population with OCD or a related disorder?
- 4. Is the intervention designed and delivered in a way that is acceptable and feasible to a broad range of people of the target population(s) who live with OCD or a related disorder?
- 5. Does the study take into account active recommendations and/or involvement from persons with lived experience who are part of the underrepresented or underserved population?

Artificial Intelligence (AI) in Grant Proposal Generation ("AI Policy")

Although there have been exponential advances in generative AI technology in recent years, there are currently no regulations in the United States surrounding these tools and their use in research.

It is the policy of the IOCDF that generative AI tools should not be used in the conceptualization of a Research Grant Program proposal, though they may have a place in drafting one (e.g., using generative AI tools to translate text if English is not the principal investigator's first language). The principal investigator must indicate in the application whether any AI tools were used in its preparation, and if so, what this usage entailed.

This policy does not apply to the appropriate use of AI and machine learning (ML) in conducting a research study, which may be appropriate in certain cases. An Institutional Review Board (IRB) must approve the use of AI and ML, to ensure the confidentiality and proper handling of participant data.

For any questions, please contact Boris Litvin, IOCDF Research Communications Specialist, at blitvin@iocdf.org.

Administrative Section

At the end of your main proposal document (PDF upload), please include a separate administrative section with the following:

Narrative Budget Justification

This section will not count towards the application page limit.

Allowable Costs / Narrative Budget Justification Outline

The Breakthrough Award is a maximum \$500,000 grant. Winners will receive these grants in five equal, annual installments. Indirect costs are allowable but are capped at 15% of the total budget, and the total budget including indirect costs may not exceed the maximums listed above.

Please use the outline below for your narrative budget justification. Please state in your narrative budget whether or not you will be requesting indirect costs as a part of your project budget, and if so, at what rate.

Personnel

- Please list each member of the project team and their role, regardless of their percent effort or whether a salary will be paid.
 Please note the percentage of each team member's time that will be spent on the proposed project (percent effort).
- For members of the project team who will be paid, please list their salary. To calculate salary, multiply the individual's institutional base salary by their percent effort. This calculation provides the maximum salary that can be requested; a lesser amount may be requested in place of this amount. Fringe benefits may also be requested in accordance with your institution's rate.
- Please list consultants in this section, and justify the use of consultants by describing their role in the project, relationships to investigators, and expertise in the field. Please include an estimated total of hours that each consultant will spend working on the project.
- If your proposed project is supported by funding from other sources, please detail that support, including personnel whose salaries may be shared.

Supplies & Equipment

- Please itemize supplies as separate categories (e.g., lab ware, office supplies, or chemicals) and list the total for each amount. If the total budget for any category is over \$500, list examples of items to be purchased and their use. Any single item over \$300 should be itemized individually on the budget worksheet. Please list and describe any durable equipment purchases, the project need they would address, and how durable equipment will be utilized upon completion of your project.
- For particularly expensive items (e.g., certain medications), please describe the procurement process that will be used and how cost will be minimized.

Travel Expenses

Funds may be requested to cover travel costs for study subjects (e.g., parking or bus fare). The IOCDF does not generally fund travel expenses for personnel, with the exception of expenses related to attending the Annual OCD Conference or IOCDF Research Symposium. If you do request funding for travel expenses, please specify the reason for the travel.

Study Participant Recruitment and Advertising

• If requesting funds for study participant recruitment, please describe your recruitment plan and itemize costs by category (e.g., payments to participants, billboard advertising, or radio advertising).

Institutional Review Board

• In the event that you require IRB approval from an independent agency that charges for their services, you may include these costs in your budget. Please describe the reason for accessing an independent agency and provide an estimate of anticipated

charges.

In addition to the narrative budget justification, all applicants must complete the provided <u>budget worksheet</u> and upload it using the application portal.

Other Application Information:

Biosketches

Applicants must upload a biosketch for the PI/co-PI and all co-investigators, collaborators, and other significant contributors (OSCs). Please use the <u>provided template</u> and limit each biosketch to four pages maximum. Refer to <u>NIH guidance on team roles</u> if you are unsure of the definitions of these terms.

Budget Worksheet

In addition to the narrative budget, please complete and upload a budget worksheet using the provided template.

Review Criteria

Application reviewers will be asked to consider a range of criteria in evaluating your grant proposal. These include:

Significance and Impact: Does the project address an important problem? How will scientific knowledge, and/or clinical practice be improved with this project?

Approach: Are the strategy, methods, and analyses appropriate so that the aims of the project can be reached? Is the study feasible? Are the plans for the protection of human participants reasonable?

Environment: Where will the work be done? Will the institution support and contribute to the success of the investigators? Are the investigators well-suited to complete the project?

Reviewers will also be asked to consider how well the project conforms to these application guidelines, including the IOCDF's policy regarding women and minority group inclusion in pre-clinical/clinical research.

If the project is submitted for the 2024 Topic of Interest, reviewers will be asked to consider how well the project conforms to the Topic of Interest policy.

Award Conditions

The following conditions are attached to IOCDF Breakthrough Awards:

- Progress Reporting: Progress reports will be made twice per year during the term of the grant. Pls are expected to participate in a 10-15 minute progress report conference call with the Research Communications Specialist and/or other IOCDF staff every January in 2025-2029. Pls are also expected to submit one-page progress reports in June 2025-2029. A longer, final progress report must be submitted at the end of the term of the grant. Templates will be provided for all written progress reports.
- IOCDF Newsletter Article: Upon completion of their projects, PIs are expected to write and submit a 1,500 word article for a future issue of IOCDF's OCD Newsletter. The article should explain the PI's grant-funded research, their findings, and the significance of their work in language that is clear and accessible to a lay audience.
- IOCDF Research Symposium/Conference: Breakthrough Award winners are strongly encouraged, upon completion of their research, to participate in an IOCDF Research Symposium and/or Annual Conference. They are also encouraged to submit a poster for the Research Symposium and/or Annual Conference poster sessions.

- Acknowledgement: Award recipients are expected to include a credit line acknowledging the International OCD Foundation as a funding source on all published materials arising from IOCDF-funded research.
- Restrictions/Unused Funding: All funding from the IOCDF will be applied only to the project for which the Research Award
 was given. Any unused money available at the end of the one-year project must be returned to the IOCDF Research Fund.
- Grant Review Committee: PIs are expected to serve on the IOCDF Grant Review Committee for a term concurrent with the length of their award.

NO-COST EXTENSIONS

While the IOCDF strongly encourages that the Breakthrough project is completed within five years, it recognizes that there may be circumstances that may impede the progress and completion of the project in this time-frame. In the event that more time is needed to complete the study funded by the Award, the PI can email the IOCDF Research Communications Specialist requesting a one-year no-cost extension.

The request should explain the reasons for why the extension is required, including, but not limited to:

- Need for sufficient participant enrollment
- Need for sufficient data collection and time for analyses
- Scheduling issues for the PI and staff involved with the project
- Obstacles connected to uncontrollable events

The PI should send the no-cost extension request as a Word document or PDF, using the funded institution's letterhead. Once the request is received, it will be reviewed and a no-cost extension approval letter will be sent if the justifications are appropriate.

Questions & Additional Information

Please see our <u>FAQs</u> for additional information. If you still have questions, please email Boris Litvin, Research Communications Specialist, at <u>blitvin@iocdf.org</u>.



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