

# Advancing Research, Education and Awareness

# REQUEST FOR APPLICATIONS FOR RESEARCH ON MENTAL HEALTH PROBLEM COMORBIDITIES WITH GAMBLING DISORDER

Application Deadline: August 15, 2024

Funds Available: Up to \$187,500 total (see below for F&A maximum)

Study duration: up to 2 years

Number of awards: One

The International Center for Responsible Gaming (ICRG) invites investigators to apply for a two-year 'Large Grant' to study the impact of comorbidities on individuals diagnosed with gambling disorder.

Epidemiologic studies have found high rates of mental illness and disorders among persons with gambling disorder, and vice versa. Past studies have found associations with substance use, mood, anxiety, and personality disorders. Since the COVID Pandemic, people are also exhibiting loneliness, stress and other conditions that may or may not lead to a disorder. Studies have not been able to elucidate the temporal associations by sex, gender, response to treatment (if there is access to treatment), and types of substances used that lead to a disorder (tobacco, alcohol, benzodiazepines, cocaine, prescription pain pills, marijuana both recreational and prescribed and others). Just as the type of comorbid mental illness important, so is the type of gambling that leads to a disorder important. With new machines, sports wagering, and other gambling, the social determinants are especially critical now for prevention and intervention studies. Studies are lacking on the risks related to the gambling behavior as well as the risk factors related to the disorder. They may be similar or completely different.

Individuals with comorbid substance use disorder and gambling disorder have been found to exhibit worsened treatment outcomes compared with those with only one disorder. Thus, mental health disorders appear to be linked to a vulnerability to develop problem gambling, and vice versa. However, whether the behaviors are concurrent, simultaneous or sequential is not well understood.

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<sup>&</sup>lt;sup>1</sup> Wieczorek, L., & Dąbrowska, K. (2023). Unsatisfied treatment needs of people with comorbid alcohol/drug use and gambling disorder. *Journal of Substance Use, 28* (1), 87–93.

More research is needed to understand the role that comorbidity plays in the etiology of problem gambling symptoms, progression to gambling disorder, access to treatment, treatment utilization and types of recovery from the disorder (whether natural or treated).

The ICRG is open to proposals addressing these and other issues concerning the comorbidity of gambling disorder with other mental disorders.

## **Available Funding**

Applicants may request up to \$75,000 per year in direct costs plus up to 25% of direct costs in Facilities & Administration expenses. Total requests may not exceed \$187,500 for two years.

## The International Center for Responsible Gaming

The International Center for Responsible Gaming (ICRG) is a nonprofit 501(c)(3) organization that has served as the only national, private funder of scientific research on gambling disorder in the United States since 1996. The ICRG is a global leader in supporting peer-reviewed, scientific research on gambling disorder and responsible gambling.

The ICRG awards grants on a competitive basis under the leadership of the **Scientific Advisory Board**. Composed of leading independent scientists with expertise in addiction and related topics, the Scientific Advisory Board plays a vital role by ensuring the ICRG follows rigorous standards in awarding grants for only the highest quality research proposals. The current roster of members is listed on page 12.

## **Eligible Applicants**

Domestic or international, public or private, non-profit or for-profit organizations are eligible to apply for ICRG funding. The Principal Investigator (PI) must have a PhD, MD or other terminal degree.

#### **Review Process and Criteria**

The ICRG seeks proposals of high scientific merit from investigators who will disseminate their funded work at high-impact conferences and in peer-reviewed scientific journals.

An appropriate scientific review group convened in accordance with the standard ICRG peer review procedures, modeled on those of the National Institutes of Health (NIH), will evaluate applications for scientific and technical merit.

As part of the initial merit review, all applications:

- Will undergo a selection process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed and assigned a priority score.
- Will receive a written Summary Statement of the critiques of the reviewers.
- Will receive a second level of review by the Scientific Advisory Board, which makes the final funding decisions.

The peer review panel will evaluate proposals according to the following criteria, adapted from the NIH:

- 1. **Significance**. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services or preventative interventions that drive this field?
- 2. **Investigator(s**). Are the Principal Investigator (PI), collaborators and other researchers well suited to the project? If the project is collaborative, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- 3. **Innovation**. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation or interventions? Are the concepts, approaches or methodologies, instrumentation or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement or new application of theoretical concepts, approaches or methodologies, instrumentation or interventions proposed?
- 4. **Approach**. Are the overall strategy, methodology and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies and benchmarks for success presented? If the project involves clinical research, are the plans for protection of human subjects from research risks justified in terms of the scientific goals and research strategy proposed?
- 5. **Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations or collaborative arrangements?

#### Additional Review Criteria

In addition to the above criteria, the following items will be considered in the determination of scientific merit and the priority score:

- Protection of Human Subjects from Research Risk: The involvement of human subjects and protections from research risk relating to their participation in the proposed research will be assessed.
- Inclusion of Women, Minorities and Children in Research: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research will be assessed. Plans for the recruitment and retention of subjects will also be evaluated.
- Care and Use of Vertebrate Animals in Research: If live vertebrate animals are to be used, the following five points should be addressed in the application:
- 1. Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex and number of animals to be used in the proposed work.
- 2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- 3. Provide information on the veterinary care of the animals involved.
- 4. Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. 5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the AVMA Guidelines for the Euthanasia of Animals. If not, include a scientific justification for not following the recommendations.
- **Biohazards**: If materials or procedures are proposed that are potentially hazardous to research personnel and/or the environment, determine if the proposed protection is adequate.
- **Budget:** The reasonableness of the proposed budget and the requested period of support in relation to the proposed research plan.

#### **Application Instructions**

Download the special application form, "2024 Large Grant for RFA on Comorbidities and Gambling" in one of the Resource Boxes at <a href="https://www.icrg.org/information/apply-for-icrg-funding">https://www.icrg.org/information/apply-for-icrg-funding</a>. (Contact Noelle Mancini (<a href="mancini@icrg.org">nmancini@icrg.org</a>) if you are having trouble downloading this document.) The first section of the application should be presented on this form. The application form provides the Face Page, Page Two and the Budget pages. You may use the NIH Biosketch form, or the one provided on the ICRG's website. The narrative section should be presented in your own document.

#### **Application Outline**

- Face Page (form provided)
- Page Two: Project Summary/Abstract, Senior/Key Personnel, Previous Support (form provided)
- Biographical Sketches (form provided or use NIH form)
- Budget Summary and Justification for Year 1 (form provided)
- Budget Summary and Justification for Year 2 (form provided)
- Research Plan (your own document)
- Human Subjects/Vertebrate Animals (your own document)
- Appendix: letters of support, citations, other materials. If human subjects are involved in the research project, download the Targeted/Planned Enrollment Form from the ICRG website and include in the Appendix.

# Face Page (1 page)

Insert text in the shaded areas on the Face Page form.

The **Principal Investigator (PI)** is the person responsible for the scientific and technical direction of the project and is the primary contact for the ICRG. Provide full name, degree(s), title, department, institution, mailing address, telephone number and e-mail address.

**Date of Proposed Period of Support.** Projects may begin on December 1, 2024, and conclude no later than November 30, 2026.

**Funds Requested**. Fill in the amounts requested for year 1 and year 2. Requests may not exceed \$75,000 per year in direct costs. A Facilities & Administration rate (also known as "indirect costs") higher than 25 percent is not allowable.

**Applicant Organization**. The Applicant Organization is legally and financially responsible for the conduct of activities supported by the award. Provide the name and contact information of the Applicant Organization's Administrative Contact.

**Regulatory Approvals**. Please check the appropriate box to indicate the use of animals (IACUC) or human subjects (IRB) in the proposed project. Note that the Principal Investigator must provide a copy of the IACUC and/or IRB letter to the ICRG before award funds will be released. Pending approvals at the time of application submission are acceptable.

**Certifications**. Provide the electronic signatures of the Principal Investigator and the Official Signing for the Organization by typing names in the shaded box and checking the box "Confirm Signature."

Page Two: Project Summary/Abstract; Senior/Key Personnel; Previous Support (1 page)

Insert text in the shaded areas on the form provided.

**Project Summary/Abstract**. Provide a succinct and accurate description of the proposed work suitable for dissemination to the public. State the application's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving the stated goals.

**Senior/Key Personnel.** In addition to the Principal Investigator, Senior/Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. In addition, stakeholders should be included under Key Personnel. Stakeholders are defined as individuals affected by the proposed research project. For example, a stakeholder might be a member of the population under study. List the Principal Investigator, last name first. Then list all other Senior/Key Personnel in alphabetical order, last name first. For each individual, provide name, institutional affiliation and role on the project.

Previous Support from the ICRG. Please list the title of any grant awards to the Principal Investigator from the International Center for Responsible Gaming, the National Center for Responsible Gaming, the Institute for Research on Pathological Gambling and Related Disorders and/or the Institute for Research on Gambling Disorders. Identify products resulting from the grant(s), such as publication in a peer-reviewed journal, a poster or presentation at a conference or subsequent support from other funding entities to continue the development of the research project.

## Biographical Sketches

Biographical Sketches of the Principal Investigator and Senior/Key personnel should be included (maximum of five pages each). Please use the NIH form or download the biosketch form from www.icrg.org.

#### **Budget (2 pages)**

Present the proposed budget for years 1 and 2 on the forms provided.

#### **Allowable Cost Items:**

- Personnel. Allowable personnel expenses include salary and applicable fringe benefits for the Principal Investigator, post-docs and graduate students (if they receive a salary) and other professional and technical staff.
- Consultant Costs. Identify consultants by name and estimate the number of days
  of service and rate of compensation.
- Study participants. Costs of recruitment (e.g., purchase of advertising), payments to subjects, patient care and other costs associated with the use of participants in the study.
- Equipment. Only equipment essential to the conduct of this project is allowed. In the Budget Justification section, explain how it directly relates to this project.
- Facilities & Administration costs. Up to 25 percent of the total direct costs.

 Travel. ICRG grantees are required to present a poster at the annual ICRG Conference on Gambling and Addiction. Budget for travel to the conference in Las Vegas, Nev. in the second year of the grant.

#### **Unallowable Cost Items:**

Funding will not be provided for the following:

- Administrative personnel
- Stipends
- Office furniture
- Tuition
- Dues and membership fees
- Maintenance/service contracts
- Construction, alteration, maintenance or rental of buildings or building space
- Relocation expenses
- Entertainment/social expenses
- Pre-award costs

## **Budget Justification**

In the space below the Budget Summary, explain and justify costs presented, providing calculations to demonstrate how amounts were determined. Enter text in the shaded area on the form provided.

#### Research Plan (Maximum 15 pages)

This section should be presented in your own document. Please observe the following formatting requirements:

- Arial 11-point font
- A smaller type size may be used in figures, graphs, diagrams, charts, tables, figure legends and footnotes. However, applicants should use their judgment and avoid the use of excessively small type that would be difficult to read.
- Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch.
- Margins of at least one half inch on all sides on all pages.
- Single-column format for text
- Standard paper size (8.5" X 11")
- Paginate all pages

Use any word processing software to create the text. Then, convert to a PDF using a PDF creation software such as Adobe® Acrobat® Professional. Scanning hard copies to produce a PDF typically results in excessively large files that can be difficult to e-mail or open and, therefore, will not be accepted for review.

Please follow the outline provided below.

**Specific Aims**. State the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved. List the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field or develop new technology).

**Research Strategy**. Organize the Research Strategy section according to the following outline:

## (a) Significance

- Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
- Explain how the proposed project will improve scientific knowledge, technical capability and/or clinical practice in one or more broad fields.
- Describe how the concepts, methods, technologies, treatments, services or preventative interventions that drive this field will be changed if the proposed aims are achieved.

# (b) Innovation

- Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
- Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation or intervention(s).
- Explain any refinements, improvements or new applications of theoretical concepts, approaches or methodologies, instrumentation or interventions.

#### (c) Approach

- Describe the overall strategy, methodology and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed and interpreted as well as any resource sharing plans, as appropriate. A data sharing Plan or an explanation of why data sharing is not feasible is expected to be included in all applications where the generation of data is anticipated. Reviewers will assess the reasonableness of the data sharing plan or the rationale for not sharing research data.
- Discuss potential problems, alternative strategies and benchmarks for success anticipated to achieve the aims.
- (d) The Relevance and Societal impact of the proposed research.

**Protection of Human Subjects/Vertebrate Animals (Maximum 2 pages)** 

Protection of Human Subjects

If applicable, summarize your plan to protect human subjects according to the following outline:

- 1) Risks to Human Subjects
- a) Human Subjects' Involvement and Characteristics
  - Describe the proposed involvement of human subjects in the work outlined in the Research Plan section.
  - Describe the characteristics of the subject population, including their anticipated number, age range and health status.
  - Identify the criteria for inclusion or exclusion of any subpopulation.
  - Explain the rationale for the involvement of special classes of subjects, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals or others who may be considered vulnerable populations. Note that "prisoners" includes all subjects involuntarily incarcerated (for example, in detention centers) as well as subjects who become incarcerated after the study begins.
  - List any collaborating sites where human subjects research will be performed and describe the role of those sites and collaborating investigators in performing the proposed research.

## b) Sources of Materials

- Describe the research material obtained from living individuals in the form of specimens, records or data.
- Describe any data that will be collected from human subjects for the project described in the application.
- Indicate who will have access to individually identifiable private information about human subjects.
- Provide information about how the specimens, records or data are collected and whether material or data will be collected specifically for the proposed research project.

# c) Potential Risks

- Describe the potential risks to subjects (physical, psychological, financial, legal or other), and assess their likelihood and seriousness to the subjects.
- Where appropriate, describe alternative treatments and procedures, including the risks and potential benefits of the alternative treatments and procedures, to participants in the proposed research.
- 2) Adequacy of Protection Against Risks
- a) Recruitment and Informed Consent
  - Describe plans for the recruitment of subjects (where appropriate) and the process for obtaining informed consent. If the proposed studies will include

- children, describe the process for meeting requirements for parental permission and child assent.
- Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

# b) Protections Against Risk

- Describe planned procedures for protecting against or minimizing potential risks, including risks to privacy of individuals or confidentiality of data, and assess their likely effectiveness.
- Research involving vulnerable populations, as described in the DHHS regulations, Subparts B-D, must include additional protections. Refer to DHHS regulations, and OHRP guidance (<a href="www.hhs.gov/ohrp">www.hhs.gov/ohrp</a>).
- Where appropriate, discuss plans for ensuring necessary medical or professional
  intervention in the event of adverse effects to the subjects. Studies that involve
  clinical trials (biomedical and behavioral intervention studies) must include a
  general description of the plan for data and safety monitoring of the research and
  adverse event reporting to the IRB and others, as appropriate, to ensure the
  safety of subjects.
- 3) Potential Benefits of the Proposed Research to Human Subjects and Others
  - Discuss the potential benefits of the research to human subjects and others.
  - Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to research participants and others.

#### 4) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

## 5) Data and Safety Monitoring Plan

- If the research includes a clinical trial, create a heading entitled "Data and Safety Monitoring Plan."
- Provide a general description of a monitoring plan that you plan to establish as the overall framework for data and safety monitoring.
- Describe the entity that will be responsible for monitoring and the process by which Adverse Events will be reported.

#### Vertebrate Animals

If vertebrate animals are involved in the project, address each of the five points below.

- 1) Provide a detailed description of the proposed use of the animals for the work outlined in the Research Plan Narrative. Identify the species, strains, ages, sex and numbers of animals to be used in the proposed work.
- 2) Justify the use of animals, the choice of species and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- 3) Provide information on the veterinary care of the animals involved.
- 4) Describe the procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs, and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain and injury.
- 5) Describe any method of euthanasia to be used and the reason(s) for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.

# **Appendix**

The Appendix should include items such as a list of references cited, letters of support (e.g., to demonstrate institutional support for the project), and other supporting materials. In addition, if the research plan involves human subjects, please include a targeted/planned enrollment form, available for download from www.icrg.org.

#### **Submission Process**

- Create a single PDF document named as follows: PI's Last
   Name\_Comorbidities\_2024. Use a PDF creation software such as Adobe®
   Acrobat® Professional to create the PDF rather than scanning hard copies to
   produce a PDF. Such files can be difficult to e-mail or open and, therefore, will
   not be accepted for review.
- Email the application to Travis Sztainert, Director of Research and Education (<u>tsztainert@icrg.org</u>) on August 15, 2024, by 5 p.m. Eastern.

Questions? Contact Christine Reilly, Senior Research Director (<a href="mailto:creilly@icrg.org">creilly@icrg.org</a>) until June 28, 2024. After that date, please contact Dr. Sztainert (contact information above).

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