**Funding Opportunity Title:** Male Contraceptive Initiative 2019 RFA  
**Funding Categories:** 2019-100; 2019-300  
**Posted Date:** April 15th, 2019  
**Open Date:** April 15th, 2019  
**Letter of Intent (LOI) Due Date:** May 31st, 2019  
**Application Due Date:** August 23rd, 2019  
**Earliest Start Date:** October 15th, 2019

Section I: Funding Opportunity Description

**Purpose:** This funding opportunity will support research projects with applications in reversible, non-hormonal male contraceptive discovery and development.

**Background:** Nearly half of all pregnancies worldwide are unintended. Furthermore, current contraceptive options do not adequately meet the needs of users who desire contraception. Male Contraceptive Initiative (MCI), a US-based 501(c)3 nonprofit, is a funding agency and advocate for male contraceptive solutions that are effective, safe, reversible, and non-hormonal.

**Research Scope**

MCI plans to fund up to five grants that will allow investigators to take defined steps towards contraceptive development. All applications must provide proof of concept, preferably in an animal model, that the proposed mechanism of action will block male fertility.

Exploratory projects at early stages of contraceptive discovery are eligible for a **Seed Grant** (MCI funding category 2019-300), with a maximum award of **$150,000 for a period of up to two years**. Potential objectives include assay development, compound screening and other efforts needed to identify specific compounds, devices or mechanisms that block male fertility.

Projects that have proceeded further in the contraceptive development pipeline are eligible for a **Discovery and Development Grant** (MCI funding category 2019-100), with a maximum award of **$300,000 for a period of up to two years**. This funding category supports research on pre-clinical stages of development from target validation through IND-enabling studies. Potential objectives include, but are not limited to, refinement of specific compounds to improve selectivity, potency and drug-like properties, refinement and testing of device modifications, and *or in vitro and in vivo* preclinical studies. Preference will be given to compounds or devices with demonstrated promise for development as a male contraceptive (such as target validation with a compound or device in mammalian species, evidence of specificity and effectiveness in animals, target druggability, evidence of reversibility). The ideal application should have a clear
pathway established towards IND / IDE submission, and precisely outline how a funded application will move towards approval.

Preference may be given to applications that focus on MCI Priority Research Areas, which include the following:

- Post-meiotic phase of spermatogenesis
- Sperm functions required for normal fertilization, such as sperm motility and the acrosome reaction
- Post-testicular processes required for fertility, including epididymal maturation and sperm transport in the excurrent ducts
- Other processes that lead to fast-acting, reversible male contraceptives
- The potential for Multipurpose Prevention Technology (MPT) products acting against sexually transmitted infections

Applications in the following areas are considered outside MCI interests and will not be reviewed:

- Steroidal mechanisms of action
- Male or female condom development
- Contraceptives with a proposed female delivery system
- Approaches that permanently inhibit fertility

**Section II: Award Information**

Support will be provided for up to two years for Discovery and Development / Seed Grant awards. Direct costs for Seed Grant awards shall not exceed $75,000 each year, or a total of $150,000. Direct costs for Discovery and Development awards shall not exceed $150,000 for each year, or a total of $300,000. Institutional overhead shall not exceed 15%, and is included in the total award amount.

**Section III: Eligibility Information**

This application is open to academic institutions, for-profit organizations, and other entities, foreign and domestic. Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as a Principal Investigator (PI) is invited to work with their organization to develop an application for support.

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.
MCI will not accept applications that are duplicate or highly overlapping grant awards from other funding agencies.

Section IV: Application and Submission Information

How to Apply

Letter of Intent:

Prospective applicants must submit a Letter of Intent (LOI) to apply by May 31st, 2018 to grants@malecontraceptive.org. The LOI should concisely outline the proposed research project to be considered. The LOI should not include confidential information.

Applicants seeking a Discovery and Development award should apply with the subject line: “MCI Discovery and Development LOI”

Applicants seeking a Seed Grant award should apply with the subject line: “MCI Seed Grant LOI”

Submit letter as a one-page pdf document (single-spaced, 11 point Arial or Times Roman font, at least 0.5 inch margins). The letter should include:
A. Applicant’s name, title, institution (or private sector organization), and contact information
B. Project title
C. Research plan and strategy for how the proposal will achieve development of a male contraceptive

Prospective applicants whose Letter of Intent adheres to these guidelines and meets the goals indicated in the Program Summary will be invited to submit an application. All applicants will be notified by June 28th whether they are invited to submit an application.

Research Grant Application:

Invited applications are to be submitted by August 23, 2019 to grants@malecontraceptive.org. The application must be in pdf format, 11 point Arial or Times Roman font, with at least 0.5 inch margins.

Subject line must be: “MCI Discovery and Development Grant Application” for Discovery and Development applicants, and “MCI Seed Grant Application” for Seed Grant applicants.
Applications must include:

Section I:
Title Page (one page):
1. Applicant’s name, title, institution, and contact information
2. Collaborator’s (if any) name(s), title, institution, and contact information
3. Signature of institutional official verifying approval of MCI conditions for award
2. Project Title
3. Research Abstract

Section 2:
Research Proposal (not to exceed 4 pages, excluding references):
1. Specific Aims: Concise summary of rationale of aims, questions to be addressed, hypotheses, predicted outcomes, novelty of compound or target being studied.
2. Background: Key published and unpublished data underlying the proposed studies and the relevance of the methods and approaches to be used.
3. Research Plan: Describe design and sequence of studies to address Specific Aims; how proposed studies will validate and refine the usefulness of the potential male contraceptive under study; address evaluation of the safety, reliability and reversibility of its use; propose potential alternative approaches. Provide plans for how current, proposed and future research will lead to Phase I clinical trials.
4. References

Section 3:
Project Management (up to 2 pages)
1. Applicant’s role and responsibilities in performance of proposed research
2. Roles of key collaborators (if any)
3. Novel or essential facilities, equipment, and resources available for the proposed studies or how they will be accessed if not available
4. Project evaluation: Provide specific quarterly milestones for demonstrating successful research progress. It is expected that proposed milestones will follow the SMART framework (specific, measurable, achievable, relevant, and time-oriented).

Section 4:
Requested Budget: (Itemized by year, and total, including a maximum 15% overhead; two page maximum)
1. Personnel: names, prior experience, roles in project, percentage of salary and benefits to be covered for each
2. Reagents: cost for general categories, except for unique compounds and reagents
3. Animals: institutional cage costs, number and species to be used, IACUC-approved protocol numbers
4. Equipment: essential equipment not available and required for project, manufacturer, cost based on bid from supplier (up to a maximum of $20,000 for Discovery and Development
grants, and $10,000 for Seed Grants)
5. Overhead: maximum of 15% of total award amount for Personnel, Reagents, Animals, and Equipment

Section 5:
Curriculum Vitae (up to five pages each for awardee and key collaborators, the NIH biosketch format is preferred (available at https://grants.nih.gov/grants/forms/biosketch.htm)
1. Education, current and prior positions and appointments
2. Current and prior research experience, source and amount of current and prior research support
3. Publications relevant to application

Section 6:
Appendix (optional, up to 4 pages)
Supporting data, figures, or unique methods and materials

Review

Process and Confidentiality

Applications will be reviewed for scientific and technical merit by an appropriate review panel assembled by MCI. All applications reviewed by the panel will receive a written critique, which will be de-identified and provided to the applicant.

Reviewers will sign confidentiality agreements and be required to destroy, delete or return to MCI all copies of information acquired or created during the course of performing a review.

Applications that do not directly address research areas designated in the Program Summary will not be considered for review. The panel will be advisory to the MCI Board of Directors which has the final responsibility for funding decisions. Reviewers will certify adherence to the Conflict of Interest and Nondisclosure Rules adopted by NIH.

The following considerations will be taken into account with funding decisions:

- Scientific and technical merit as evaluated by the review panel
- Availability of funds
- Relevance of the proposal to the program summary
- Relevance of the proposal to MCI Priority Research Areas
- Relevance of the proposal to a balanced MCI funding portfolio
- Readiness of the proposal and project to move into later stages of contraceptive
development

For questions regarding the grant and application requirements please see “Section VI: Contact”. If a question leads to a change or significant clarification of the grant application instructions, other applicants who have submitted a letter of intent will be notified of the change or clarification.

During the review, MCI may share non-confidential information provided either orally or in writing - such as in the letter of intent - with third parties, including key partners and potential co-funders.

For awarded grants, MCI is required by the IRS to publish a list of its grantees. MCI also provides general descriptions of its grants on its web sites, in press releases, and in other marketing materials.

Review Criteria

- **Response to Program Summary**: How well does the proposal address one or more of the research areas identified?
- **Demonstrated promise**: Is the proposal based on a target or compound likely to be developed as a male contraceptive? Is there evidence of specificity and effectiveness in animals? Is there a strong scientific premise for the project?
- **Research plan**: Does the proposal provide a well-designed plan for validating and refining the usefulness of a potential male contraceptive and address the evaluation of the safety, reliability and reversibility of its use? Are the studies well-focused and is the scope of work, overall strategy, methods and approaches appropriate to achieve the specific aims of the study within the budget and time available (first and subsequent years of support)? Are potential problems and alternative strategies considered?
- **Contraceptive development**: Does the proposal provide a plan for extending current and future studies to a Phase I clinical trial?
- **Investigator**: Does the applicant have the knowledge, training and experience needed to perform the research? Will the investigator be able to devote sufficient time and effort to the project for it to be successful?
- **Environment**: Are the facilities, equipment and institutional support available to the applicant sufficient for the proposed studies to be successful? Is the support plan to facilitate the proposed research well-conceived?

**Section V: Award Administration**

A formal notification will be provided to the applicant organization for successful applications. The notification will be signed by the grants management officer and will be sent via email to the grantee.
Any costs incurred before formal notification of award are at the risk of the awardee, and are not reimbursable.

Progress Reports & Monitoring

Continuation of funding beyond the first year is contingent on satisfactory progress and availability of funds. MCI may arrange for confidential meetings with consultants with relevant expertise to facilitate development of products resulting from funded projects.

Awardees will be required to participate in a quarterly digital meeting where their progress on proposal-specific milestones is presented. MCI may contract with a third-party monitor to evaluate progress and provide consultation on the project, including evaluation of quarterly benchmarks as indicated in Section III of the proposal. Awardees will be required to furnish financial information about funds on-hand and expenses during quarterly meetings.

Awardees are also responsible for submitting a Progress Report 30 days before the end of the funding year to grants@malecontraceptive.org. Both Discovery and Development and Seed Grant awardees will be provided with a grant code, and should use the subject line “[Grant code] Research Grant Progress.” The Progress Report will be a confidential document and should be submitted in pdf format. It is to include:

Accomplishments (two pages maximum):

- What were the major goals and objectives of the project for the current year and what was accomplished for these goals?
- What were the benchmarks for the current year, were they met, and what is the evidence of successful research progress?
- Were there problems or delays or changes to original goals and objective that require modification of research plans?

Budget (one page maximum):

- Provide a proposed budget for the coming year and justify amounts and purposes of planned expenditures.

Global Access

MCI requires that grantees establish a Global Access strategy for the products generated, if any, under the Project. Grantees will make a good faith effort to conduct and manage all Project research, product development, technologies and innovations in a manner, consistent with global access commitments, to disseminate knowledge gained during the conduct of the Project to the scientific community, subject to a limited delay to seek intellectual property protection.
where such protection would best facilitate the achievement of the Project’s charitable objectives, and to work collaboratively to ensure that any products developed from Project Funds are made accessible (with respect to cost, quantity and applicability) to the people most in need within the developing countries and public sector markets in developed countries of the world.

Section VI: Contact

Logan Nickels  
Director of Operations and Programs  
Male Contraceptive Initiative  
logan@malecontraceptive.org