



Male Contraceptive Initiative  
811 Ninth Street, Suite 120 #255  
Durham, NC 27705  
984.464.2951

**Funding Opportunity Title:** Male Contraceptive Initiative 2021 RFA

**Funding Categories:** *Development Awards (2021-100)*

*David Sokal Innovation Awards (2021-300)*

**Posted Date:** April 1st, 2021

**Letter of Intent (LOI) Due Date:** May 28th, 2021

**Application Due Date:** August 27th, 2021

**Earliest Award Notification Date:** Q4, 2021

## Section I: Funding Opportunity Description

**Purpose:** This funding opportunity will support research projects with applications in the development of reversible, non-hormonal male contraceptives.

**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 multiple awards that will allow investigators to take defined, measurable steps forward in male contraceptive research. **David Sokal Innovation Awards** (maximum of \$150,000 for a period of two years) support projects at early stages of contraceptive discovery.

**Development Awards** (maximum of \$300,000 for a period of two years) support research projects focused on active contraceptive development.

**A. The David Sokal Innovation Awards** (MCI Funding Category 2021-300) are named after the co-founder of Male Contraceptive Initiative, Dr. David Sokal, MD, who has consistently advocated for contraceptive innovation over a long career in contraception and health. Sokal Awards are intended to spur new avenues of thinking in contraceptive development as well as public understanding, and have a maximum award of **\$150,000 for a period of up to two years**. Applications may focus on the biology of validated contraceptive targets, early development of specific methods of achieving a contraceptive effect in men, discovery of compounds with potential contraceptive application, as well as tools and techniques that expand contraceptive research capabilities.

Sokal Awards are designed to enable projects that have Proof of Concept (see below) to either move into active contraceptive development or de-risk the project for further studies that facilitate a move to active development. Potential objectives for these applications include compound screening, the development of enzyme assays or other assays needed to assess inhibition of a specific target, and other efforts that identify specific compounds, devices or mechanisms that block male fertility.

Applications focusing on tools and techniques that expand contraceptive research capabilities must be aimed at developing methods, techniques, or assays that provide new or enhanced diagnostic or screening capabilities to monitor sperm functions required for fertilization. Examples include hyperactivated motility, the acrosome reaction, and sperm-egg fusion. Widely applicable methods that could be used by many investigators are preferred. Practical application and dissemination of information should be included in the scope of work.

**B. Development Awards** (MCI funding category 2021-100) are for projects in active contraceptive development with a maximum award of **\$300,000 for a period of up to two years**. This funding category supports research on male contraceptives in active pre-clinical stages of development, up to and through IND- or IDE-enabling studies. This funding category requires both Proof of Concept (see below) and measured progress towards a specific contraceptive compound or device. Measured progress may include lead compounds with suitable pharmaceutical properties for downstream development, *in vivo* or other pre-clinical data of relevant compounds or devices, or a clear, illustrated pathway towards IND / IDE submission.

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 such as pharmacokinetics / pharmacodynamics (PK/PD), absorption, distribution, metabolism, and excretion (ADME), toxicology studies, and other evaluations required to move towards clinical stages of development. Preference will be given to compounds or devices with demonstrated promise for development as a male contraceptive (such as evidence of specificity and effectiveness of a compound or device 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 that goal.

## Project Eligibility

Generally, projects in active contraceptive development that have identified a lead compound or series, are in pursuit of an IND / IDE, or are otherwise well-positioned for downstream development are eligible for Development Awards, whereas projects exploring the feasibility of a contraceptive target, identifying potential contraceptive compounds, or are otherwise early-stage are eligible for David Sokal Innovation Awards. Applicants seeking guidance on the potential

eligibility of their project for either a David Sokal Innovation Award or a Development Award are encouraged to contact the appropriate MCI officer at the end of this announcement.

For both David Sokal Innovation Awards and Development Awards, applications focusing on specific methods of achieving a contraceptive effect in men must provide Proof of Concept that the proposed mechanism of action will block male fertility. Proof of Concept in an animal model is preferred. Applications seeking to develop medical devices not acting through a pharmacological mechanism need not demonstrate Proof of Concept.

Examples of **Proof of Concept** may include, but are not limited to:

- Targeted deletion of a gene that results in male infertility in an animal model without other observed adverse phenotypes
- Administration of a contraceptive agent in an animal model, resulting in reversible male infertility
- Inhibited expression of the gene encoding the target through RNAi or another gene silencing method that results in infertility as demonstrated by a secondary method such as mating studies or *in vitro* fertilization
- Peer-reviewed citations and clinical evidence that a target is at minimum strongly correlated with infertility in men

For both David Sokal Innovation Awards and Development Awards, applicants focusing on the development of male contraceptives are encouraged to submit projects aligned with **MCI Priority Research Areas**, which include the following:

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

Applications not within MCI Priority Research Areas but fulfilling other eligibility criteria will be reviewed using the same process and criteria as applications aligned with MCI Priority Research Areas.

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

- Development of male contraceptives involving the exogenous administration of steroid hormones
- Approaches that induce active immunity
- Male or female condom development
- Thermal methods of male contraception

- Contraceptives with a proposed female delivery system
- Approaches that permanently inhibit fertility

Applications seeking to identify new male contraceptive targets are not responsive to this announcement.

## Section II: Award Information

Support will be provided for up to two years for both Development Awards and Sokal Awards. Multiple awards are expected in relation to this announcement.

Total costs, including direct costs and overhead for Sokal Awards shall not exceed \$75,000 each year, or a two-year total of \$150,000.

Total costs, including direct costs and overhead for Development Awards shall not exceed \$150,000 for each year, or a two-year total of \$300,000.

Institutional overhead shall not exceed 15%, and is to be included in the total award amounts listed in this section.

## Section III: Applicant 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.

Current MCI grantees are eligible to apply for continued funding through this mechanism.

MCI will not accept applications that are duplicate or highly overlapping grant awards from other funding agencies. Applicants should ensure that submissions to MCI are not duplicate or highly overlapping submissions under consideration by 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 28th, 2021** to [grants@malecontraceptive.org](mailto: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 Development Award should apply with the subject line: “MCI Development Award LOI”

Applicants seeking a Sokal Award should apply with the subject line: “MCI Sokal Award LOI”

Submit letter as a one-page pdf document (single-spaced, 11 point Arial 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

Letters of Intent will be reviewed by a panel of subject experts based on the program requirements and goals described in this RFA. Prospective applicants will be invited to submit a Research Application. All applicants will be notified by **June 28th, 2021** whether they are invited to submit a Research Application.

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### Research Application:

Invited applications are to be submitted by **August 27th, 2021** to [grants@malecontraceptive.org](mailto:grants@malecontraceptive.org). The application must be in pdf format, 11 point Arial font, with at least 0.5 inch margins.

Subject line must be: “MCI Development Award Application” for Development applicants, and “MCI Sokal Application” for Sokal Award applicants.

Applications must include:

Part 1:

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
4. Project Title
5. Research Abstract

Part 2:

Research Proposal (not to exceed 6 pages, excluding references):

1. Specific Aims: Concise summary of rationale of aims, questions to be addressed, hypotheses, predicted outcomes, novelty of compound or target or population 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. If focused on contraceptive development, 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.
4. References

Part 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: Expected outcomes should be listed in detail, measured by specific milestones, and allow for evaluation at least once quarterly.

Milestones should be specific and clear in how progress will be demonstrated. It is expected that proposed milestones will follow the SMART framework (specific, measurable, achievable, relevant, and time-oriented).

To be measurable, milestones should define success criteria as a specific targeted value

or metric. These target values or metrics should be objective, as well as structured to be appropriate for the current stage of development to inform following go / no-go decisions.

*Illustrative examples: a projected number of hits in a screening effort, a targeted IC50 value as measured by a described assay, a maximum tolerated size of molecules generated by medicinal chemistry efforts, the targeted specific efficacy of an animal study, the slowest tolerated metabolic clearance rate of a specific compound, etc.*

Timelines are to present objectives and milestones in a written format that details specific activities performed during each quarterly period, as well as displayed visually in a Gantt Chart. The following example should inform the requested Gantt Chart, and may be adapted in any way to fit the individual project. Objectives may be divided into as many sub-objectives, and other categories as needed such that they provide detailed activities that can be related directly to the milestones to be achieved in the same time period.

	2022				2023			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Specific Aim 1</b>								
Objective 1.1								
Objective 1.2								
<b>Specific Aim 2</b>								
Objective 2.1								
Objective 2.2								
Objective 2.3								
<b>Specific Aim 3</b>								
Objective 3.1								
Objective 3.2								
Objective 3.3								

Part 4:

Requested Budget: (Itemized by the following categories, when applicable. Include costs per

year, and total. 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 Development Awards, and \$10,000 for Sokal Awards)
5. Overhead: maximum of 15% of total award amount. Overhead is to be included as an itemized budget line as part of total award amount, which is not to exceed the applicable total listed in Section II.

Part 5:

Curriculum Vitae (up to five pages each for awardee and key collaborators, the [NIH biosketch format](#) is preferred)

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

Part 6:

Appendix (up to 2 pages total for Parts 1 & 2 - Continued development and Intellectual property statements, up to 5 pages for Part 3 - Supporting information)

1. Continued development statement: Use this space to describe how the proposed activities fit into the larger picture of male contraceptive development, given the current environment, expertise, and landscape.
  - How do these activities accelerate contraceptive development, and what does continued development of a successful outcome look like, given the current environment, expertise, and landscape?
2. (Optional) Intellectual property statement: Information about intellectual property (IP) position of the compound(s), device(s) or process(es) described in previous sections may be provided here.

Potential topics to comprise an intellectual property statement include, but are not limited



to:

- University or company IP policy
  - Summary of any patents, copyrights, trademarks, licenses or other intellectual property owned
  - Documentation relating to the transfer of any technology to the Company or any employee, consultant or other party
  - Proprietary Information and Invention Agreements signed by past or present employees and consultants
3. (Optional) Supporting information: Information in this section may be used to provide a bolstering argument of the feasibility of the proposed approach in developing novel male contraceptives.

Note that all information submitted as part of the application remains under confidentiality. MCI may use this information to evaluate the potential of the program for further downstream investment in the form of either grants or other mechanisms.

Examples of useful supporting information include but are not limited to:

- Supporting data, figures, or unique methods and materials
- Letters of Support from key collaborators or institutions
- Target Product Profile (TPP) of the proposed product in development, with minimally acceptable and target criteria defined

## 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 anonymized and provided to the applicant as constructive feedback.

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 RFA description 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 the National Institutes of Health.

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 goals and priorities outlined in the RFA description
- 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 awards, MCI is required by the IRS to publish a list of its grantees. MCI also provides general descriptions of its awards on its web sites, in press releases, and in other marketing materials. Awardees may be asked to participate in promotional efforts by MCI, which may include interviews, outreach, and other publicity. These efforts will be voluntary, and will not impact the terms of the grant.

## Review Criteria

- Response to RFA: 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 through preclinical studies and on to Phase I clinical trials?
- 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 MCI awards management officer and will be sent via email to the grantee.

Projects are expected to target a start date in Q4 2021 or Q1 2022. Later start dates are possible. Contract negotiations between MCI and the parent institution may prolong proposed start dates.

MCI expects applicants selected for funding to work with MCI staff in establishing a specific milestone plan which will be used to evaluate progress of the award.

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 upon satisfactory progress and availability of funds. MCI may arrange for confidential meetings with consultants with relevant expertise to facilitate the development of products resulting from funded projects. MCI may also 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.

Grantees are responsible for adhering to the approved project proposal. Should it be necessary for project objectives or key personnel to change, grantees must contact their MCI awards officer at the earliest possible opportunity no later than 30 days to discuss how changes will be accommodated. These changes may require approval from MCI before release of funds.

Budget variances of more than 10% in any budget subcategory must be approved by MCI. MCI reserves the right to audit any of the relevant records of grantees.

Awardees are responsible for adhering to the Grant Progress Reporting Guide, which can be provided to prospective applicants on request and will be provided after award notification to successful applicants. The Grant Progress Reporting Guide outlines quarterly updates that are to be provided to MCI, either through informal email exchanges, written reports, or virtual meetings.

Ongoing funding is to be determined yearly by the MCI Research Committee. The decision of the Research Committee is reached using the quarterly updates detailed in the Grant Progress Reporting Guide and an annual written report, which details progress on proposal-specific milestones. The annual written report will be due 30 days before the end of the funding year to [grants@malecontraceptive.org](mailto:grants@malecontraceptive.org). Both Development and Sokal Award 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:

*Research Narrative (five pages maximum, include figures when appropriate):*

- List the major goals and objectives of the project for the current year and what was accomplished for these goals.
  - Include key outcomes or conclusions (both positive and negative), and a discussion of goals not met.
- Compare research progress against specific milestones and target dates against targets outlined in the project proposal and / or approved by MCI. List the specific milestones for the current year, if / when they were met, and the evidence of successful research progress.
- Explain any changes to original goals and objectives that require modification of research plans. Note that whenever possible, changes in goals, research scope, approaches, or methods should be communicated to the appropriate MCI contact at the earliest opportunity.
- Describe, in detail, any problems or delays that impacted the project, or potential problems for the upcoming reporting period.

*Budget (two pages maximum):*

- Provide a proposed budget for the coming year and justify amounts and purposes of planned expenditures. Include a reporting of expenditures to date, and compare against original estimates.

*Appendix (optional - no page limit)*

- The appendix may be used to provide any additional information that is relevant to the progress of the project. Examples include:

- Structures of chemical compounds mentioned in the Research Narrative, additional images or figures, relevant data tables, etc.
- Publications, presentations, media outreach, or other public representations
- Personal or professional accomplishments from the awardee or staff during the reporting period
- Inventions, patents, or licenses that have resulted from the award
- Opportunities for training and professional development
- Meetings with regulatory authorities, new partnerships, business developments, or leveraged / newly awarded funding

Informal updates and unscheduled communications from the awardee to MCI are welcome and greatly appreciated, especially in the event of unexpected challenges, recent accomplishments, or relevant information. Awardees are also encouraged to contact MCI with opportunities of any sort. Examples of new opportunities include leveraged funding, professional development, or other ways MCI can facilitate the progress of novel male contraceptives.

## Open Access

MCI is committed to dissemination of published research resulting from project funds to enable unrestricted access and reuse of all peer-reviewed publications (“Open Access”). Grantee shall publish all publications in a manner that will permit all users of the publication to have Open Access so that any reader may have access to an article without further permission or fees being required. Applicants are encouraged to consider Open Access fees in a prospective budget when applying for funding.

## 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

Questions regarding any aspect of the award or award process are encouraged. Please contact:

Logan Nickels  
Research Director

Male Contraceptive Initiative  
811 Ninth Street, Suite 120 #255  
Durham, NC 27705

[logan@malecontraceptive.org](mailto:logan@malecontraceptive.org)  
405-714-2083