

**Funding Opportunity Title:** Male Contraceptive Initiative 2020 RFA

**Funding Categories:** *Discovery and Development Awards (2020-100); David Sokal Innovation Awards (2020-300; 2020-500)*

**Posted Date:** April 1st, 2020

**Open Date:** April 15th, 2020

**Letter of Intent (LOI) Due Date:** May 31st, 2020

**Application Due Date:** August 23rd, 2020

**Earliest Award Notification Date:** October 15th, 2020

## Section I: Funding Opportunity Description

**Purpose:** This funding opportunity will support research projects with applications in 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 or projects focusing on the social science of male contraceptives. **Discovery and 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 Categories 2020-300; 2020-500) 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. Applications may focus on the development of specific methods of achieving a contraceptive effect in men, tools and techniques that expand contraceptive research capabilities, or research that focuses on the social science of male contraceptives.

All 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.

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

Sokal Awards focused on specific contraceptive targets are designed to allow projects with Proof of Concept to move into active contraceptive 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 seeking to identify new male contraceptive targets are not responsive to this announcement.

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 should be included in the scope of work.

Applications focusing on the social science of male contraceptives may be aimed at improving the understanding of male contraceptive acceptability among men or their female partners. Other social science explorations are of interest to MCI, and investigators are encouraged to contact MCI for questions regarding eligibility. Research focusing on sexually active men aged 18-24 who are either single or in committed monogamous relationships is of particular interest.

Examples of research projects include, but are not limited to:

- Research on the needs and expectations of men and women as they relate to male contraceptive products
- Research on expected or preferred characteristics of male contraceptive products such as dosing regimens, application procedures, side effects, costs, efficacy, and more
- Research that assesses the current understanding of existing male contraceptive products, and / or male contraceptive products in development.

**B. Discovery and Development Awards** (MCI funding category 2020-100) 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 pre-clinical stages of development through IND- or IDE-enabling studies and requires both Proof of Concept (see above) and progress towards a specific contraceptive compound or device. 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 approval.

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

## 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, 2020** 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 Discovery and Development Award should apply with the subject line: "MCI Discovery and 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 an application. All applicants will be notified by **June 28th, 2020** whether they are invited to submit an application.

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## Research Application:

Invited applications are to be submitted by **August 23, 2020** 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 Discovery and Development Award Application" for Discovery and Development applicants, and "MCI Sokal Application" for Sokal Award applicants.

Applications must include:

### Section 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

### Section 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; provide plans for how current, proposed and future research will lead to pre-clinical and subsequent Phase I clinical trials.

If focused on behavioral / social science research, clearly describe the objectives and their relevance to the theme of the application, as well as the theory of human behavior and behavior change being used to design the proposed research.

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: 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).

Timelines are to be presented in a written format that details specific activities performed during each quarterly period, as well as displayed visually in a Gantt Chart formatted similarly to the following example.

	2020		2021				2022		
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3
<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									

Section 4:

Requested Budget: (Itemized by the following categories, if 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 Discovery and 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.

#### Section 5:

Curriculum Vitae (up to five pages each for awardee and key collaborators, the NIH biosketch format is preferred (available at <https://awards.nih.gov/awards/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 2 pages)

Supporting data, figures, or unique methods and materials. If applicable, information about intellectual property (IP) position may be provided here, including the feasibility of modification of chemical entities, known patentability of processes, molecules, etc. Information in this section should be used to provide a bolstering argument of the feasibility of the proposed approach in developing, promoting, or understanding the applications of novel male contraceptives.

## 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: If focused on development, 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? If behavioral, does the approach address a potential critical barrier to uptake of male contraceptive methods? Is the studied population inclusive and appropriate to advance scientific knowledge on factors affecting male contraceptive acceptance and potential use?
- Research plan: If focused on development, 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? If behavioral, is a theory of human behavior and behavior change explicitly used to motivate the design of the research? Does the proposal apply theoretical approaches or methodologies appropriate for assessing products that are still in development and/or future consumer populations? Are themes and concepts that will guide the development of questionnaires or discussion guides appropriate for the study

population? Has the proposal adequately addressed the Protection of Human Subjects in compliance with 45 CFR Part 46, if required?

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: If focused on development, does the proposal provide a plan for extending current and future studies through preclinical studies and on to Phase I clinical trials? If behavioral, does the proposal stand to provide insights into potential product characteristics that will increase acceptability and uptake of male methods?
- 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 awards management officer and will be sent via email to the grantee.

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.

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](mailto:grants@malecontraceptive.org). Both Discovery and 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:

Accomplishments (five 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 objectives 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

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

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Director of Operations and Programs

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