

US Based Repurposing Clinical Trials to Address Diversity, Equity and Inclusion (DEI) – 2023



OVERVIEW

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking clinical repurposing trials from **US-based research institutions to address Diversity, Equity and Inclusion (DEI), including repurposing clinical trials that EITHER are led by an underrepresented researcher OR address health disparities among underserved patients OR both.** Clinical trials utilizing telehealth or other decentralized / remote strategies are encouraged to apply.

Repurposed therapies must be approved and/or generally recognized as safe for human use by some regulatory agency, such as the US Food and Drug Administration, European Medicines Agency, Health Canada or Japan's Pharmaceuticals and Medical Devices Agency, and can include **drugs, devices, nutraceuticals, diagnostics or combination therapies**. These repurposed therapies must be tested in a new indication for which they are not already approved or used widely in the clinic as standard of care.

CWR is accepting budgets of up to \$75,000 for this funding opportunity, which includes the required institutional match (see Important Funding Information below). Any health disparities-focused submissions must include ideas and/or plans for engagement / collaborations with community-based organizations to engage underserved communities in the clinical trial. **CWR will provide up to \$10,000 in additional financial support for community engagement for health disparities projects**, with at least \$5,000 required for community engagement. CWR recommends a range of \$7,500 - \$10,000. Funding for community engagement costs is exempt from the required institutional match. For example, a submitted budget of \$83,000 which includes \$8,000 in community engagement costs would only require \$15,000 in institutional matching funds (20% of \$75,000). Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral.

CWR has a 2-stage submission process, starting with the LOI. Full scientific details are not required at the LOI stage. All submissions for this RFP are via our online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Non-Disease Specific Repurposing Research** program. Click on the "Apply Now" button on the right to begin a submission. For LOI submission instructions and more information about CWR's funding opportunities generally, visit <https://bit.ly/cwrrfps>.

LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee and/or our Science Advisory Board (SAB) members, and the top-rated LOI submissions will be invited to submit a full proposal as the second stage. Principal Investigators (PIs) will be contacted approximately 6-8 weeks following the LOI submission deadline with a decision.

The LOI submission deadline is 11:59pm U.S. Central Time on June 26, 2023. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions.

FULL DESCRIPTION

Background

This RFP is seeking clinical repurposing trials that fall within CWR's US-focused DEI efforts. **CWR is interested in any repurposing clinical trials that EITHER are led by an underrepresented researcher OR address health disparities among underserved patients OR both. See more information below.**

CWR's goals for our US-focused DEI research – in addition to creating positive patient impact via clinical data – include:

- improving the health and healthcare of underserved patients, and/or
- reducing the fear and mistrust of clinical trial participation, and/or

- engaging and educating prospective participants about clinical repurposing trials using already approved therapies

Repurposed therapies can include drugs, devices, nutraceuticals and/or diagnostics. Repurposed therapies must be approved and/or generally recognized as safe for human use by some regulatory agency, such as the US Food and Drug Administration, European Medicines Agency, Health Canada or Japan's Pharmaceuticals and Medical Devices Agency.

Eligible submissions must:

- Be interventional clinical trials testing repurposed therapies, either alone or in combination with standard of care or other repurposed therapies, in a new indication
- **EITHER** 1) be led by an underrepresented PI (as defined by the NIH; <https://diversity.nih.gov/about-us/population-underrepresented>) **OR** 2) address health disparities among underserved populations as defined by the NIH (see <https://www.nimhd.nih.gov/about/overview>), led by any PI; **OR** 3) both 1) and 2).
 - Clinical repurposing trials led by an underrepresented PI may, but are not required to, focus on health disparities
- Be conducted at any US-based accredited academic, nonprofit and governmental research institutions and/or health systems significantly involved with medical research, where good scientific research and clinical practices can be assured
 - Although start-ups, biotechs, pharmaceutical companies and medical device companies are not eligible for this RFP, their collaborators at eligible institutions can apply
- Be led either by a previously funded investigator or by an early-stage investigator who has received little or no extramural research funding to date
 - PIs who have not received extramural funding previously and/or who do not currently have their own lab should include a Letter of Support from a funded, senior researcher who will act as a mentor for the proposed research and the investigator
- Not yet have funding (see Important Funding Information below) or already have funding from another source, when funding from CWR will help improve the chances of success of the project and/or help speed patient impact

CWR is interested in promoting DEI in biomedical clinical research by 1) supporting the careers of and 2) closing the NIH funding gap through funding for clinical repurposing trials for underrepresented PIs.

Underrepresented PIs include:

- Specific racial/ethnic minorities underrepresented on a national basis (Blacks, Hispanics/Latinos, Native Americans/Alaskans/Hawaiians and other Pacific Islanders)
- Individuals with physical/mental disabilities
- Individuals from disadvantaged backgrounds
- Women, who are underrepresented in academic medical research institutions at senior faculty levels in most biomedical-relevant disciplines
- See <https://diversity.nih.gov/about-us/population-underrepresented> for details and eligibility

Populations with health disparities include:

- Racial and ethnic minority groups
- People with lower socioeconomic status
- Underserved rural communities
- Sexual and gender minority groups
- See <https://www.nimhd.nih.gov/about/overview/> for details and eligibility

Examples of health disparities clinical repurposing trials include:

- A trial in a disease that disproportionately impacts an underserved population in incidence, prevalence or patient outcomes, and focuses enrollment on these patients (examples: sickle cell disease, triple negative breast cancer, lupus)
- A trial that includes specific enrollment goals to allow for data analysis by underserved population groups

Any health disparities-focused LOI submissions must include ideas and/or plans for engagement / collaborations with community-based organizations to engage underserved populations in the clinical trial. CWR will provide up to \$10,000 in additional financial support for community engagement for health disparities projects, with at least \$5,000 required for community engagement. CWR recommends a range of \$7,500 - \$10,000. Funding for community engagement costs is exempt from the required institutional match (see Important Funding Information below).

Ideas for possible community engagement must be included in the Research Description section of the LOI submission. Community-based organizations are already engaged with and trusted by underserved populations, and may include health-related organizations (i.e., community health centers), social services-related organizations (i.e., food banks) or other organizations (i.e., religious groups). Community engagement ideas do not need specific details at the LOI stage, and LOIs will not be scored on community engagement in the review process.

Our strongest preference is for proof of concept clinical repurposing trials supported by strong preclinical evidence or clinical observations. We may also consider later stage clinical trials that require additional funding. CWR is open to all clinical trial designs (open label, cross-over, dose determination, randomized, blinded, controlled, etc.) that have the opportunity to create a robust and well-defined outcome that will show reproducible clinical impact and/or generate data that can be leveraged into follow-on funding from other sources and additional clinical trials.

If you have a repurposing idea to impact DEI that isn't an exact fit for this RFP, or **if you have eligibility questions due to budget or other aspects, please contact Clare Thibodeaux, PhD at clare@cureswithinreach.org to discuss fit and/or submission options.**

Important Funding Information

All funding requests are in US dollars. **CWR is accepting budgets of up to \$75,000 for clinical repurposing trials, which includes the required 20% institutional match.** Any health disparities-focused LOI submissions must include ideas and/or plans for engagement / collaborations with community-based organizations to engage underserved communities in the clinical trial. **CWR will provide up to \$10,000 in additional financial support for community engagement for health disparities projects**, with at least \$5,000 required for community engagement. CWR recommends a range of \$7,500 - \$10,000. Funding for community engagement costs is exempt from the required institutional match. Below are some examples to help explain:

- If the total funding amount submitted to CWR is \$75,000, with \$0 for community engagement costs, CWR will provide \$60,000 (80% of \$75,000) and the research institution will provide \$15,000 (20% of \$75,000) as the required institutional match
- If the total funding amount submitted to CWR is \$83,000, with \$8,000 in community engagement costs, CWR will provide \$68,000 (80% of \$75,000 plus \$8,000) and the research institution will provide \$15,000 (20% of \$75,000) as the required institutional match

Specific budget definitions for different types of costs can be found in the LOI submission instructions on ProposalCentral.

Submitting an LOI does not commit the PI or the research institution to the 20% institutional match. If a submission is selected to move beyond the LOI stage, CWR will contact the PI and the research institution about this requirement.

The 20% institutional match must be real dollars committed to the project. The institutional match may come from the research institution itself (including salaries, patient costs, etc.); from government or other public funders; from individuals, foundations or other private funders; from industry (including the dollar value of donated drug); or from any combination of these sources. The CWR portion of the requested total funding amount cannot be used for indirect costs. However, **the 20% institutional match may be used for indirect costs.**

The total funding amount submitted to CWR must be sole, late or final funding required to accomplish the specific aims listed in the LOI. CWR funding cannot be the first funding raised for a project unless it is also the sole funding needed. The 20% institutional match is not counted as additional funds to be raised. Below are some general examples:

- The project will cost \$75,000 to complete, and the maximum funding amount of the RFP is \$75,000. This project is eligible for funding from CWR.
- The project will cost \$225,000 to complete, and the maximum funding amount of the RFP is \$75,000. The PI has already secured \$150,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost \$225,000 to complete, and the maximum funding amount of the RFP is \$75,000. The PI has already secured \$0 in existing funding / support. This project is not eligible for funding from CWR.

If you have eligibility questions due to the budget or funding amount for your project, please contact Clare Thibodeaux, PhD at clare@cureswithinreach.org.

CWR is open to working with other funders who share our desire to address DEI and are interested in these near-term repurposing opportunities. **We will accept projects that already have funding from another source, when this additional funding from CWR will help improve the chances of success of the project, and therefore increase the chance of patient impact.**

LOI Submission and Due Date

All submissions for this RFP are via ProposalCentral at <https://bit.ly/submittocwr> using the **Non-Disease Specific Repurposing Research** program. If you're already a ProposalCentral user, log into your existing account to submit. If you don't already have a ProposalCentral account, create a login at <https://proposalcentral.com/>.

The LOI submission deadline is 11:59pm U.S. Central Time on June 26, 2023. Contact Clare Thibodeaux, PhD at clare@cureswithinreach.org with any questions / issues about the LOI submission deadline. For more information about CWR's funding opportunities, visit <https://bit.ly/cwrrfps>.

Review Criteria and Review Process

Repurposing innovation, feasibility of the research plan, relevance to the patient population, potential clinical impact, "value" of the research for the funding and the research team are key ranking criteria for a successful LOI submission. LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee (representing research, industry, clinicians, nonprofits, government and the patient/community voice) and/or our Science Advisory Board (SAB) members, and the top-rated LOI submissions will be invited to submit a full proposal. PIs will be contacted approximately 6-8 weeks following the LOI submission deadline with a decision.