

# Repurposing Research for Chicago 2024: Track 1 – Repurposing Research to Address Diversity, Equity and Inclusion (DEI) in the Chicago Area



## OVERVIEW

**“Repurposing Research to Address Diversity, Equity and Inclusion (DEI) in the Chicago Area” is one of 4 tracks for Cures Within Reach’s 2024 funding opportunity for Chicago area institutions and PIs. Specific focus areas for the other tracks include Early Stage Investigators, Pediatrics and Veterans issues. When submitting a Letter of Intent, applicants should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list all the applicable track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. Visit <https://bit.ly/cwrrfps> to learn more about each track.**

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking clinical repurposing trials from any research institution in the greater Chicago area to address Diversity, Equity and Inclusion (DEI), including repurposing clinical trials that **EITHER 1) are led by an underrepresented researcher OR 2) address health disparities among underrepresented patients OR 3) both 1) and 2).** While the funded institutions must be in Chicagoland, patients and collaborators can be both within and outside the Chicago area. Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials. Clinical trials utilizing telehealth or other 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 cellular/gene therapies, as well as 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 \$100,000 for this funding opportunity, which includes the required institutional match** (see Important Funding Information below).

- **For Principal Investigators (PIs) who are submitting a clinical trial addressing health disparities:** Engagement with community-based organizations (CBOs) that serve the target underrepresented patient population is required for all health disparities clinical trials. The PI should include any ideas and/or plans for engagement / collaborations with CBOs in the LOI submission, although full details are not required for the LOI and LOIs will not be scored on community engagement plans. CWR will provide \$5,000 - \$15,000 in additional financial support for approved community engagement costs, and this funding should be added to the requested funding amount submitted to CWR. Funding for community engagement costs is exempt from the required institutional match. For example, a submitted budget of \$110,000 which includes \$10,000 in community engagement costs would only require \$20,000 in institutional matching funds (20% of \$100,000). Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral.
- **For PIs who are not submitting a clinical trial addressing health disparities:** CWR may provide an optional \$5,000 - \$15,000 in additional financial support for approved community engagement costs to include underrepresented patients ([as defined by the NIH](#)) in the proposed clinical trial. Interested PIs may include any ideas and/or plans for engagement / collaborations with community-based organizations to engage underrepresented communities in the clinical trial. However, community engagement is not required, and community engagement costs should not be included in the requested funding amount submitted to CWR in the LOI. If a clinical trial is selected for funding, CWR will contact the PI about potential community engagement.

## Track 1 – Repurposing Research to Address Diversity, Equity and Inclusion (DEI) in the Greater Chicago Area

All submissions for this RFP are via our online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Geographic Specific Repurposing Research** program. Click on the “Apply Now” button on the right to begin a submission. PIs should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list the applicable Chicago-focused track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate. For LOI submission instructions and more information about CWR’s funding opportunities generally, visit <https://bit.ly/cwrrfps>.

CWR has a 2-stage submission process, starting with the LOI. **Full scientific details are not required at the LOI stage.** 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. 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 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org) with any questions.

### **FULL DESCRIPTION**

#### **Background**

This RFP is seeking clinical repurposing trials from Chicago-area research institutions that fall within CWR’s US-focused DEI efforts. **CWR is interested in any repurposing clinical trials addressing unsolved diseases that are EITHER 1) led by an underrepresented researcher OR 2) address health disparities among underrepresented patients OR 3) both 1) and 2). See more information below.**

An unsolved disease is one in which one or more of the following are true:

- There is currently no effective treatment
- The current treatment is only effective for a portion of the patient population
- There is a treatment that is effective, but many patients develop resistance to the therapy
- There is a treatment that is effective for the entire patient population, but the treatment is very expensive, and therefore some patients cannot get access to the treatment
- There is a treatment that is effective for the entire patient population with significant side effects, and for some patients the negative side effects outweigh the benefits of the treatment

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

- improving the health and healthcare of underrepresented 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
- supporting the careers of and closing the NIH funding gap for underrepresented PIs

Repurposed therapies can include drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as combination therapies. 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

## Track 1 – Repurposing Research to Address Diversity, Equity and Inclusion (DEI) in the Greater Chicago Area

- **EITHER** 1) be led by an underrepresented PI ([as defined by the NIH](#)) **OR** 2) address health disparities among underrepresented patient populations ([as defined by the NIH](#)), 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 Chicago area 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 PI or by an early stage PI 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 PI
- 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, Native Alaskans, Native 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://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html> for details and eligibility

### Populations with health disparities include:

- Racial and ethnic minority groups
- People with lower socioeconomic status
- Underrepresented 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 underrepresented 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 underrepresented population groups

**Any health disparities-focused LOI submissions must include ideas and/or plans for engagement / collaborations with community-based organizations (CBOs) to engage underrepresented populations in the clinical trial. CWR will provide \$5,000 - \$15,000 in additional financial support for approved community engagement costs, and this funding should be added to the requested funding amount**

**submitted to CWR.** 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. CBOs are already engaged with and trusted by underrepresented 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, patient-focused 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, pivotal, Phase I or Phase IIA clinical repurposing trials supported by strong preclinical evidence, real world 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, contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org).**

#### **Important Funding Information**

All funding requests are in US dollars. CWR is accepting budgets of up to \$100,000 for clinical repurposing trials, which includes the required 20% institutional match. For health disparities trials, CWR will provide \$5,000 - \$15,000 in additional financial support for approved community engagement costs, and this funding should be added to the requested funding amount submitted to CWR. 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 \$100,000, with \$0 for community engagement costs, CWR will provide \$80,000 (80% of \$100,000) and the research institution will provide \$20,000 (20% of \$100,000) as the required institutional match
- If the total funding amount submitted to CWR is \$110,000, including \$10,000 in community engagement costs, CWR will provide \$90,000 (80% of \$100,000 plus \$10,000) and the research institution will provide \$20,000 (20% of \$100,000) 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:

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- The project will cost \$100,000 to complete, and the maximum funding amount of the RFP is \$100,000. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$200,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$0 in existing funding / support. This project is not eligible for funding from CWR.

Any health disparities-focused LOI submissions must include ideas and/or plans for engagement / collaborations with community-based organizations (CBOs) to engage underrepresented populations in the clinical trial. CWR will provide \$5,000 - \$15,000 in additional financial support for approved community engagement costs, and this funding should be added to the requested funding amount submitted to CWR. Funding for community engagement costs is exempt from the required institutional match.

**If you have eligibility questions due to the budget or funding amount for your project, please contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto: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 **Geographic Specific Repurposing Research** program. PIs who are already ProposalCentral users should log into their existing accounts to submit. PIs who don't already have a ProposalCentral account should create a login at <https://proposalcentral.com/>. PIs should select "Chicago area" and "Other" for the "Type of Request for Proposals" question, and then list the applicable Chicago-focused track(s) for their research in the "Other" text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate.

**The LOI submission deadline is 11:59pm U.S. Central Time on June 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto: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.

# Repurposing Research for Chicago 2024: Track 2 – Clinical Repurposing Trials Led by a Chicago Area Early Stage Investigator



## OVERVIEW

**“Clinical Repurposing Trials Led by a Chicago Area Early Stage Investigator” is one of 4 tracks for Cures Within Reach’s 2024 funding opportunity for Chicago area institutions and PIs. Specific focus areas for the other tracks include Diversity, Equity and Inclusion (DEI), Pediatrics and Veterans issues. When submitting a Letter of Intent, applicants should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list all the applicable track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. Visit <https://bit.ly/cwrrfps> to learn more about each track.**

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking clinical repurposing trials from any research institution in the greater Chicago area led by an Early Stage Investigator, who is within 10 years of completing an advanced degree or medical residency, in any unsolved disease. While the funded institutions must be in Chicagoland, patients and collaborators can be both within and outside the Chicago area. Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials. Clinical trials utilizing telehealth or other 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 may include **drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as 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 \$100,000 for this funding opportunity, which includes the required institutional match (see Important Funding Information below).** Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral. For Principal Investigators (PIs) who are interested in including underrepresented patients ([as defined by the NIH](#)) in the proposed clinical trial, CWR may provide an optional \$5,000 - \$15,000 in additional financial support for approved community engagement costs. Interested PIs may include any ideas and/or plans for engagement / collaborations with community-based organizations to engage underrepresented communities in the clinical trial. However, community engagement is not required, and community engagement costs should not be included in the requested funding amount submitted to CWR in the LOI. If a clinical trial is selected for funding, CWR will contact the PI about potential community engagement.

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 PI with their LOI submission.

All submissions for this RFP are via our online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Geographic Specific Repurposing Research** program. Click on the “Apply Now” button on the right to begin a submission. PIs should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list the applicable Chicago-focused track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate. For LOI submission instructions and information about CWR’s funding opportunities generally, visit <https://bit.ly/cwrrfps>.

CWR has a 2-stage submission process, starting with the LOI. **Full scientific details are not required at the LOI stage.** LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee and/or our Science Advisory Board members, and the top-rated LOI submissions will be invited to submit a full proposal as the second stage. 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. Eastern Time on June 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org) with any questions.

## **FULL DESCRIPTION**

### **Background**

This RFP is seeking clinical repurposing trials from Chicago-area research institutions led by a PI who is an early stage investigator, within 10 years of completing an advanced degree or medical residency, in any unsolved disease. An unsolved disease is one in which one or more of the following are true:

- There is currently no effective treatment
- The current treatment is only effective for a portion of the patient population
- There is a treatment that is effective, but many patients develop resistance to the therapy
- There is a treatment that is effective for the entire patient population, but the treatment is very expensive, and therefore some patients cannot get access to the treatment
- There is a treatment that is effective for the entire patient population with significant side effects, and for some patients the negative side effects outweigh the benefits of the treatment

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. Repurposed therapies may include drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as combination therapies.

### **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
- Be conducted at any Chicago area 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 by a Chicago area PI who is an early stage investigator, within 10 years of completing an advanced degree or medical residency
  - 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 PI
- 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

Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials supported by strong preclinical evidence, real world 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, decentralized, 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 that isn't an exact fit for this RFP, or **if you have eligibility questions due to budget or other aspects, contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org).**

### **Important Funding Information**

All funding requests are in US dollars. CWR is accepting budgets of up to \$100,000 for clinical repurposing trials, which includes the required 20% institutional match. **CWR will provide no more than 80% of the total funding amount submitted to CWR, and the PI's research institution will match at least 20% of the total funding amount submitted to CWR.**

For example, if the total funding amount submitted to CWR is \$100,000, CWR will provide 80% or \$80,000 and the research institution will provide 20% or \$20,000. 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 \$100,000 to complete, and the maximum funding amount of the RFP is \$100,000. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$200,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$0 in existing funding / support. This project is not eligible for funding from CWR.

All funding requests are in US dollars. Note: detailed project budgets are not required at the LOI stage.

**If you have eligibility questions due to the budget or funding amount for your project, please contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org).**

CWR is open to working with other funders who share our desire to support early stage PIs 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 **Geographic Specific Repurposing Research** program. PIs who are already ProposalCentral users should log into their existing accounts to submit. PIs who don't already have a ProposalCentral account should create a login at <https://proposalcentral.com/>. PIs should select "Chicago area" and "Other" for the "Type of Request for Proposals" questions, and then list the applicable Chicago-focused track(s) for their research in the "Other" text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate.

**The LOI submission deadline is 11:59pm U.S. Eastern Time on June 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto: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 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.



# Repurposing Research for Chicago 2024: Track 3 – Chicago Area Clinical Repurposing Trials to Impact Pediatrics



## OVERVIEW

**“Chicago Area Clinical Repurposing Trials to Impact Pediatrics” is one of 4 tracks for Cures Within Reach’s 2024 funding opportunity for Chicago area institutions and PIs. Specific focus areas for the other tracks include Diversity, Equity and Inclusion (DEI), Early Stage Investigators and Veterans issues. When submitting a Letter of Intent, applicants should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list all the applicable track(s) for their research in the “Other” text box: Early Stage Investigator, DEI, Pediatrics and/or Veterans. Visit <https://bit.ly/cwrrfps> to learn more about each track.**

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking clinical repurposing trials from any research institution in the greater Chicago area using already approved treatments to address unmet and high-priority medical needs of pediatric patients, including adding a pediatric arm to an adult clinical repurposing trial. While the funded institutions must be in Chicagoland, patients and collaborators can be both within and outside the Chicago area. Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials. 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 may include **drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as 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 \$100,000 for this funding opportunity, which includes the required institutional match (see Important Funding Information below).** Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral. For Principal Investigators (PIs) who are interested in including underrepresented patients ([as defined by the NIH](#)) in the proposed clinical trial, CWR may provide an optional \$5,000 - \$15,000 in additional financial support for approved community engagement costs. Interested PIs may include any ideas and/or plans for engagement / collaborations with community-based organizations to engage underserved communities in the clinical trial. However, community engagement is not required, and community engagement costs should not be included in the requested funding amount submitted to CWR in the LOI. If a clinical trial is selected for funding, CWR will contact the PI about potential community engagement.

All submissions for this RFP are via our online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Geographic Specific Repurposing Research** program. Click on the “Apply Now” button on the right to begin a submission. PIs should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list the applicable Chicago-focused track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate. For LOI submission instructions and more information about CWR’s funding opportunities generally, visit <https://bit.ly/cwrrfps>.

CWR has a 2-stage submission process, starting with the LOI. **Full scientific details are not required at the LOI stage.** LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee and/or our Science Advisory Board members, and the top-rated LOI submissions will be invited to submit a full proposal as the second stage. 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. Eastern Time on June 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org) with any questions.

## **FULL DESCRIPTION**

### **Background**

This RFP is seeking Chicago-based clinical repurposing trials that address any unsolved disease facing pediatric patients in order to improve quality and length of life, including adding a pediatric arm to an adult clinical repurposing trial. An unsolved disease is one in which one or more of the following are true:

- There is currently no effective treatment
- The current treatment is only effective for a portion of the patient population
- There is a treatment that is effective, but many patients develop resistance to the therapy
- There is a treatment that is effective for the entire patient population, but the treatment is very expensive, and therefore some patients cannot get access to the treatment
- There is a treatment that is effective for the entire patient population with significant side effects, and for some patients the negative side effects outweigh the benefits of the treatment

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. Repurposed therapies may include drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as combination therapies.

### **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
- Be conducted at any Chicago area 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

Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials supported by strong preclinical evidence, real world 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, decentralized, 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 pediatrics that isn't an exact fit for this RFP, or **if you have eligibility questions due to budget or other aspects, contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org).**

### **Important Funding Information**

All funding requests are in US dollars. CWR is accepting budgets of up to \$100,000 for clinical repurposing trials, which includes the required 20% institutional match. **CWR will provide no more than 80% of the total funding amount submitted to CWR, and the PI's research institution will match at least 20% of the total funding amount submitted to CWR.**

For example, if the total funding amount submitted to CWR is \$100,000, CWR will provide 80% or \$80,000 and the research institution will provide 20% or \$20,000. 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 \$100,000 to complete, and the maximum funding amount of the RFP is \$100,000. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$200,000 in existing funding / support. This project is eligible for funding from CWR.
- The project will cost \$300,000 to complete, and the maximum funding amount of the RFP is \$100,000. The PI has already secured \$0 in existing funding / support. This project is not eligible for funding from CWR.

All funding requests are in US dollars. Note: detailed project budgets are not required at the LOI stage.

**If you have eligibility questions due to the budget or funding amount for your project, please contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org).**

CWR is open to working with other funders who share our desire to support pediatric patients 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 **Geographic Specific Repurposing Research** program. PIs who are already ProposalCentral users should log into their existing accounts to submit. PIs who don't already have a ProposalCentral account should create a login at <https://proposalcentral.com/>. PIs should select "Chicago area" and "Other" for the "Type of Request for Proposals" question, and then list the applicable Chicago-focused track(s) for their research in the "Other" text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate.

**The LOI submission deadline is 11:59pm U.S. Eastern Time on June 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto: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 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.

# Repurposing Research for Chicago 2024: Track 4 – Chicago Area Clinical Repurposing Trials to Impact Veterans/Military



## OVERVIEW

**“Clinical Repurposing Trials to Impact Veterans/Military” is one of 4 tracks for Cures Within Reach’s 2024 funding opportunity for Chicago area institutions and PIs. Specific focus areas for the other tracks include Diversity, Equity and Inclusion (DEI), Early Stage Investigators and Pediatrics. When submitting a Letter of Intent, applicants should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list all the applicable track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. Visit <https://bit.ly/cwrrfps> to learn more about each track.**

This Request for Proposals (RFP) from [Cures Within Reach](#) (CWR) is seeking clinical repurposing trials from any research institution in the greater Chicago area using already approved treatments to address unmet and high-priority medical needs of US veterans and/or active US military, including but not limited to mental health, post-traumatic stress disorder (PTSD) and brain injuries. While the funded institutions must be in Chicagoland, patients and collaborators can be both within and outside the Chicago area. Our strongest preference is for proof of concept, pivotal, Phase I or Phase IIA clinical repurposing trials. 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 may include **drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as 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 \$100,000 for this funding opportunity, which includes the required institutional match (see Important Funding Information below).** Specific budget definitions for different types of costs can be found in the Letter of Intent (LOI) submission instructions on ProposalCentral. For Principal Investigators (PIs) who are interested in including underrepresented patients ([as defined by the NIH](#)) in the proposed clinical trial, CWR may provide an optional \$5,000 - \$15,000 in additional financial support for approved community engagement costs. Interested PIs may include any ideas and/or plans for engagement / collaborations with community-based organizations to engage underserved communities in the clinical trial. However, community engagement is not required, and community engagement costs should not be included in the requested funding amount submitted to CWR in the LOI. If a clinical trial is selected for funding, CWR will contact the PI about potential community engagement.

All submissions for this RFP are via our online grant management platform on ProposalCentral at <https://bit.ly/submittocwr> using the **Geographic Specific Repurposing Research** program. Click on the “Apply Now” button on the right to begin a submission. PIs should select “Chicago area” and “Other” for the “Type of Request for Proposals” question, and then list the applicable Chicago-focused track(s) for their research in the “Other” text box: DEI, Early Stage Investigator, Pediatrics and/or Veterans. PIs can include as many tracks as appropriate. For LOI submission instructions and more information about CWR’s funding opportunities generally, visit <https://bit.ly/cwrrfps>.

CWR has a 2-stage submission process, starting with the LOI. Full scientific details are not required at the LOI stage. LOIs for this RFP will be reviewed, scored and ranked by CWR staff, our external Grant Review Committee and/or our Science Advisory Board members, and the top-rated LOI submissions will be invited to submit a full proposal as the second stage. 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. Eastern Time on June 7, 2024.** Contact Clare Thibodeaux, PhD at [clare@cureswithinreach.org](mailto:clare@cureswithinreach.org) with any questions.

**FULL DESCRIPTION****Background**

This RFP is seeking Chicago-based clinical repurposing trials that address unsolved diseases and conditions facing retired military veterans and active US military, including but not limited to mental health, PTSD and brain injuries, in order to improve quality and length of life. An unsolved disease or condition is one in which one or more of the following are true:

- There is currently no effective treatment
- The current treatment is only effective for a portion of the patient population
- There is a treatment that is effective, but many patients develop resistance to the therapy
- There is a treatment that is effective for the entire patient population, but the treatment is very expensive, and therefore some patients cannot get access to the treatment
- There is a treatment that is effective for the entire patient population with significant side effects, and for some patients, the negative side effects outweigh the benefits of the treatment

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. Repurposed therapies may include drugs, devices, nutraceuticals, diagnostics or cellular/gene therapies, as well as combination therapies.

**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
- Be conducted at any Chicago area accredited academic, veteran 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

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If you have a repurposing idea to impact veterans 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](mailto:clare@cureswithinreach.org).**

**Important Funding Information**

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**For VA hospitals and VA-related nonprofits ONLY:** the Institutional Match may include funding from either or both organizations (for example: salaries paid by both the VA hospital and the VA-related nonprofit). Also, up to 30% of the submitted budget may be used for indirect costs. In this case the 20% institutional match must be used for indirect costs, and CWR funds can be used to cover the remaining indirect costs.

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