CASE WESTERN RESERVE UNIVERSITY
Clinical and Translational Science Collaborative

Cleveland Clinic

University Hospitals
Cleveland Medical Center

MetroHealth

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
VA Northeast Ohio Healthcare System

THE UNIVERSITY OF TOLEDO

Northeast Ohio
MEDICAL UNIVERSITY

2026 Annual Pilot Program Technical Webinar

Sept 15, 2025

Presenters

CASE WESTERN RESERVE UNIVERSITY
Clinical and Translational Science Collaborative

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Clinical and Translational Science Collaborative

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CTSC of Northern Ohio

Clinical and Translational Science **Awards**

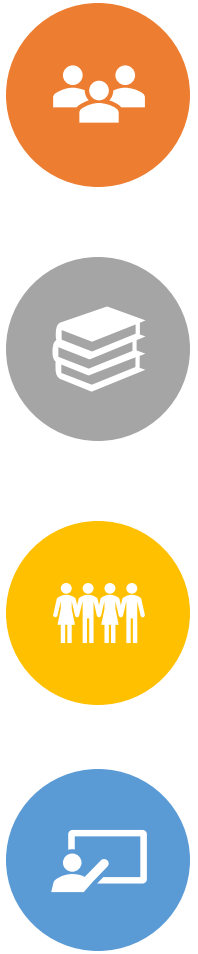
National Center for Advancing Translational Sciences

A network of over 60 medical research institutions working together to improve the process of translational research. The CTSA Program Goals are:

- Advance clinical and translational science.
- Promote partnerships and collaborations to facilitate and accelerate translational research projects locally, regionally and nationally.
- Create, provide, and disseminate innovative research programs and partnerships across institutions and communities
- Create and implement scientific and operational innovations that increase the quality, safety, efficiency, effectiveness and informativeness of clinical research.
- Provide a national resource for the rapid response to urgent public health needs.
- Create, provide and disseminate clinical and translational science training programs for clinical research professionals of all disciplines.
- Create, provide and disseminate clinical and translational science training and career support programs.
- Foster the development of the emerging field of translational science.

CTSC Mission and Aims

Our mission is to be a catalyst for high quality clinical and translational science and transformative research to positively impact the health of those in Northern Ohio and beyond



COMMUNITY ENGAGEMENT & COLLABORATION

DISSEMINATE & IMPLEMENT FINDINGS FROM NOVEL AND RESPONSIVE RESEARCH PROGRAMS

UNDERSTANDING HEALTH CHALLENGES AND OVERCOMING BARRIERS TO RECRUITMENT INTO CLINICAL RESEARCH

DEVELOP & TRAIN THE NEXT GENERATION OF RESEARCHERS AT ALL LEVELS

About the CTSC of Northern Ohio

Partners

- CWRU (Lead), Cleveland Clinic, University Hospitals, MetroHealth, Cleveland VA Medical Center, University of Toledo, and NEOMED

First CTSA Award Sept. 2007

- 2023 Cycle - $56.3M, 7 years

Companion Programs

- K12 (career development)
- T32 (predoc & postdoc)
- R25 (undergrad research)
- RC2 (innovation program; roadblocks in C/T Science)

University Hospitals Cleveland Medical Center

MetroHealth

Cleveland Clinic

VA U.S. Department of Veterans Affairs Veterans Health Administration VA Northeast Ohio Healthcare System

The University of Toledo

Northeast Ohio Medical University

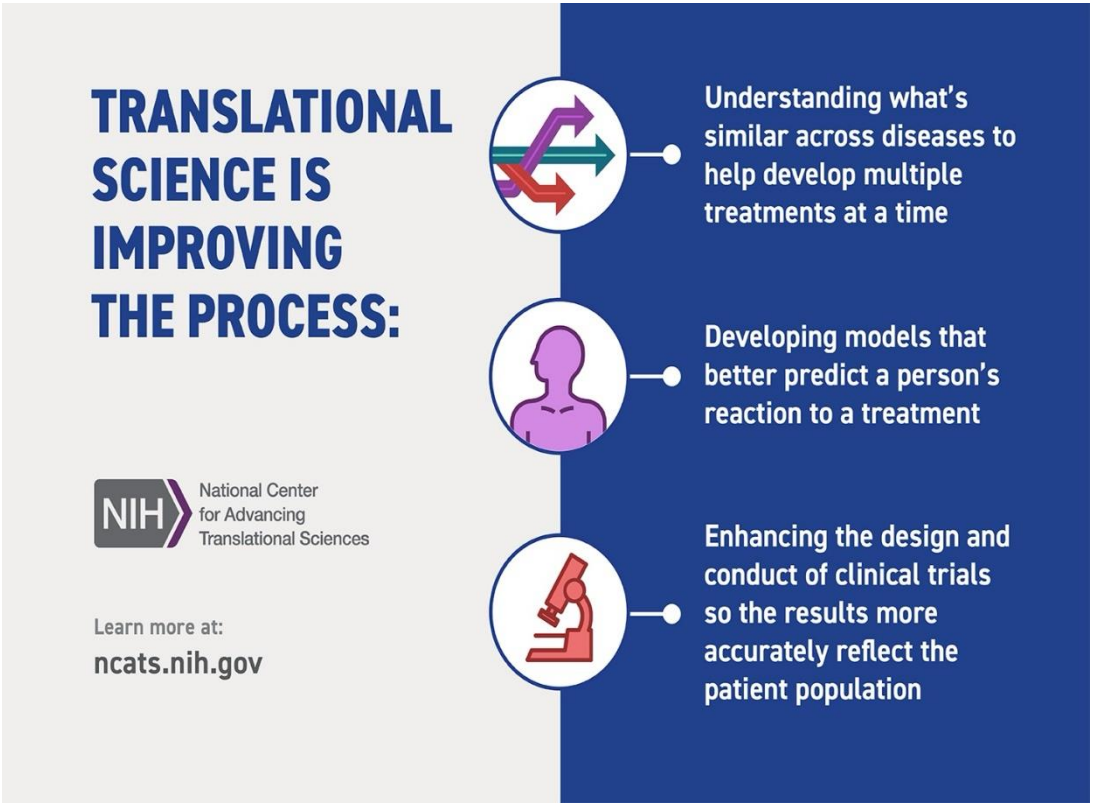
Translational Science & Translational Research

Stages of Translation

- **Translation** - the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public - from diagnostics and therapeutics to medical procedures and behavioral changes.

- **Translational Research** - The endeavor to traverse a particular step of the translational process for a particular target or disease.

- **Translational Science** - The field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.
  - **Disease agnostic**



Translational Science & Research In Action

COVID-19 Timeline 2020

WHO Declares COVID-19 a Pandemic

NIH Trial Shows Early Promise for Remdesivir

Saliva-Based Diagnostic Test Allowed for At-Home Use

FDA Panel Backs Moderna COVID-19 Vaccine

Translational **RESEARCH** happening (Diagnostic developments, COVID vaccine development; animal, then human clinical trials)

11 Mar. **29 Apr.** **9 May** **17 Dec.**

University of Minnesota Begins Testing Hydroxychloroquine

Remdesivir Wins Emergency Use Authorization (EUA)

FDA Advisory Panel Recommends Pfizer, BioNTech COVID-19 Vaccine

Slide courtesy of Darcy Freedman, PhD, MPH, Mary Ann Swetland Professor/Director, Environmental Health Sciences, Dept. of Population and Quantitative Health Sciences, CWRU School of Medicine

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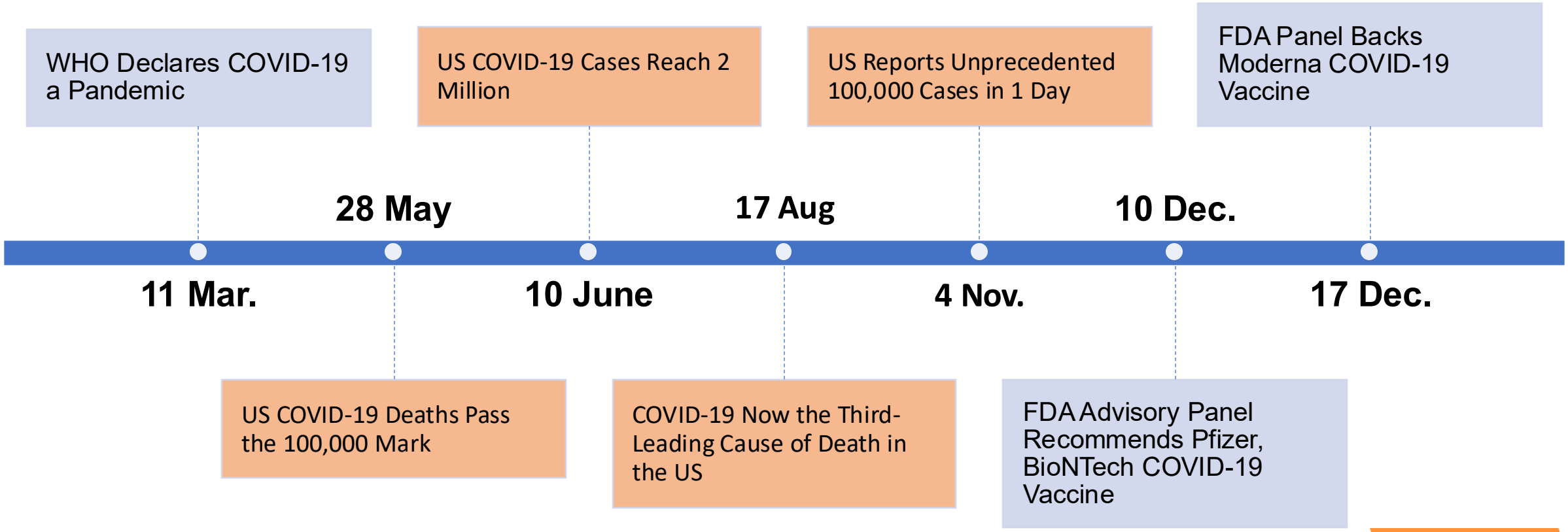
Source: A Timeline of COVID-19 Developments in 2020; AJMC (2021)

Translational Science In Action

COVID-19 Timeline 2020



Slide courtesy of Darcy Freedman, PhD, MPH, Mary Ann Swetland Professor/Director, Environmental Health Sciences, Dept. of Population and Quantitative Health Sciences, CWRU School of Medicine

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Source: A Timeline of COVID-19 Developments in 2020; AJMC (2021)

Translational Science & Research In Action

COVID-19 Timeline 2020

WHO Declares COVID-19 a Pandemic

States With COVID-19 Spikes Report Greatest Health Insurance Coverage Losses

FDA Advisory Panel Recommends Pfizer, BioNTech COVID-19 Vaccine

Translational **RESEARCH** happening (Diagnostic developments, COVID vaccine development; animal, then human clinical trials

11 Mar. **14 Jul.** **10 Dec.**

Young, Poor Avoid Care for COVID-19 Symptoms (cost main concern)

Rural Hotspots Face Lack of Intensive Care Unit Beds

FDA Panel Backs Moderna COVID-19 Vaccine

Slide courtesy of Darcy Freedman, PhD, MPH, Mary Ann Swetland Professor/Director, Environmental Health Sciences, Dept. of Population and Quantitative Health Sciences, CWRU School of Medicine

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Source: A Timeline of COVID-19 Developments in 2020; AJMC (2021)

Imagine Another Way

How could translational <u>research</u> have done more to…

- Understand the pathogenesis of coronavirus infection more quickly
- Develop more pathogen detection methods for SARS-CoV-2 RNA
- Screen for community asymptomatic and serological testing SARS-CoV-2 RNA for staff, students, and the wider population for public health benefit
- Support increased recruitment of patients into COVID-19 clinical trials of novel therapeutics and vaccines.

How could translational <u>science</u> have made these processes better…

- 100% adoption of the COVID-19 vaccine
- Access to treatment for those in need
- Trust in healthcare
- Understanding of how policy helped reduce social drivers of risk
- Guidance for implementation of better approaches in healthcare, government, community settings, universities, drug companies, etc. as we plan for the next crisis

Edgeworth JD, Batra R, Nebbia G, Bisnauthsing K, MacMahon E, Sudhanva M, et al. (2020) Translational Research in the Time of COVID-19—Dissolving Boundaries. PLoS Pathog 16(9): e1008898. https://doi.org/10.1371/journal.ppat.1008898

Adapted slide courtesy of Darcy Freedman, PhD, MPH, Mary Ann Swetland Professor/Director, Environmental Health Sciences, Dept. of Population and Quantitative Health Sciences, CWRU School of Medicine

Translational Spectrum & RFA Scope

Translational Spectrum examples for Annual Program Pilot applications

Examples of T2 research include:
- Phase 2 and 3 clinical trials
- Development of clinical guidelines
- Comparative effectiveness trials

Examples of T3 research include:
- Community-based participatory research (CBPR)
- Phase 4 clinical trials
- Dissemination and implementation research

Examples of T4 research include:
- Population-level outcomes research
- Monitoring of morbidity, mortality, benefits, and risks
- Cost-benefit analysis
- Policy analysis
- Surveillance studies
- Program evaluation

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Annual Pilot Specifics

Annual Pilot Program Pilot goals

Innovative and unique combination of established research methods into powerful studies that focus on the significant burden of conditions disproportionately affecting rural and other populations

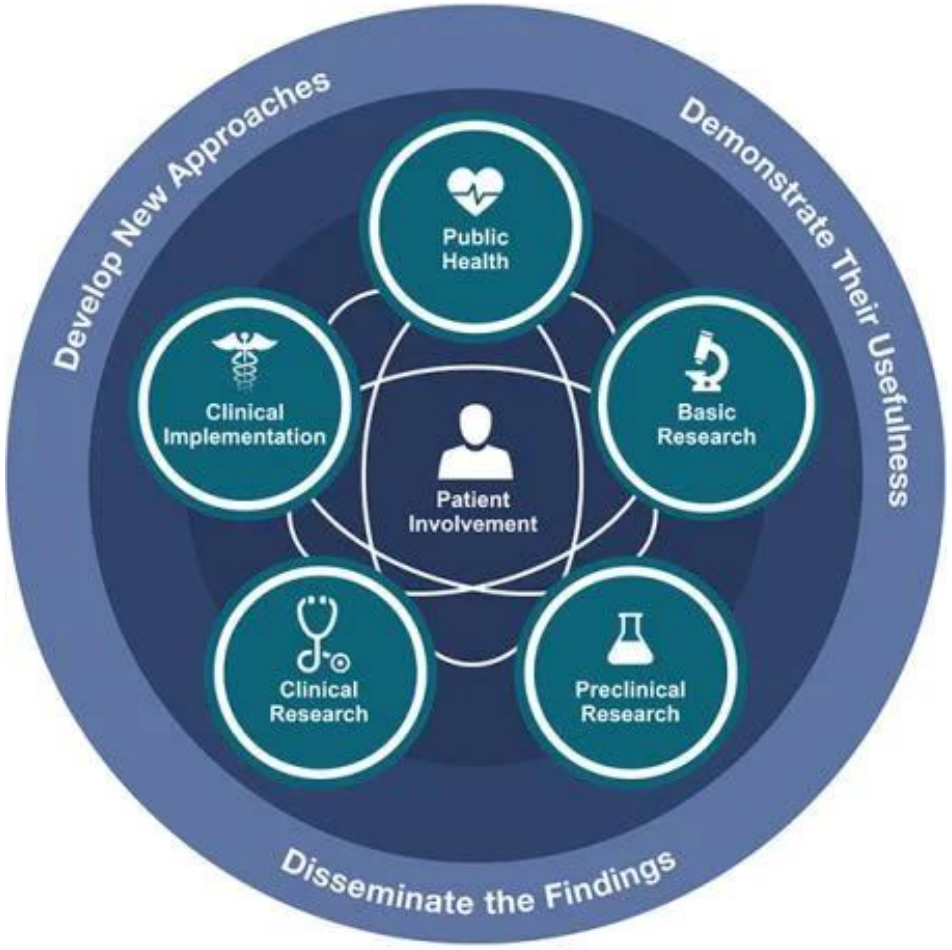
Multi-methodological research projects that make high-impact and meaningful differences in addressing and combating healthcare challenges

Develop new approaches and collaborations that can contribute to the generalizability and scalability of clinical and translational science and initiatives for all populations.

Accelerate the translation of established research methods into novel modalities that bring solutions to more patients within a population or a wider service geography

Application considerations

- Projects must be feasible within the proposed 12-month timeframe
- High methodological and scientific quality and answer important scientific questions
- Up to 8 grants will be awarded with budgets of up to **$50,000** each in direct costs.
- **All research activities must be completed by June 30, 2027.**



Credit: National Center for Advancing Translational Sciences

Additional considerations

- Both Translational Research and Translational Science projects are eligible (see RFA Appendices).
- Any CWRU school may apply
- For this RFA, applications MUST include 2 or more CTSC partner institutions of they will not be considered for funding
- NEOMED and University of Toledo faculty can be Co-Investigators (not PIs).
- Community organizations and additional institutions can be Co-Investigators and involved in projects as a 3rd partner.

Eligibility to apply

- ✓PIs must have a faculty appointment at Case
- ✓PIs from multiple partners
- ✓Be affiliated with a CTSC partner: CWRU, CC, MetroHealth, UH, VA
- ✓Eligible for a NIH grant
- ✓*Applications from new investigators and/or under-studied minorities are highly encouraged.*

- ✓Co-I may include University of Toledo faculty, NEOMED faculty, community health leaders, trainees, coordinators

https://grants.nih.gov/grants/policy/nihgps/html5/section_2/2.5.4_determining_eligibility_of_individuals.htm

Annual Pilot Priority Areas

- Disease-agnostic projects that focus on the process of turning research results into real-world applications
- Innovative, multi-center clinical studies that integrate community and clinical partners
- Dissemination & Implementation of research evidence & innovation to clinical practice
- Projects that leverage Cosmos or TriNetX informatics tools

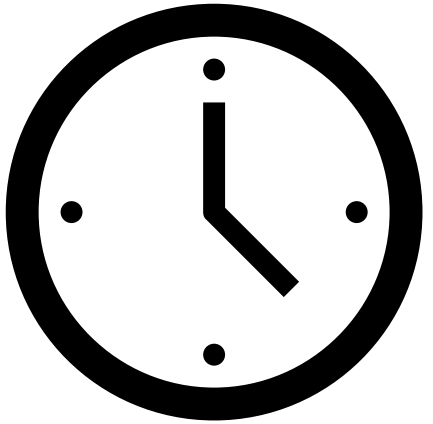
Priority areas continued

- Health issues related rural Ohio
- Innovative implementation methods promoting uptake of findings into routine healthcare in clinical or policy contexts
- Interventions at community and/or clinical practices to promote overall health
- Studies focusing on methods to improve research processes.

Letter of Intent

- The **required *one-page*** letter of intent (LOI) is due October 20, 2025 11:59 PM via InfoReady.

- Applicants selected to submit a full proposal will be notified on or about Dec 15th, 2025.



Letter of Intent components

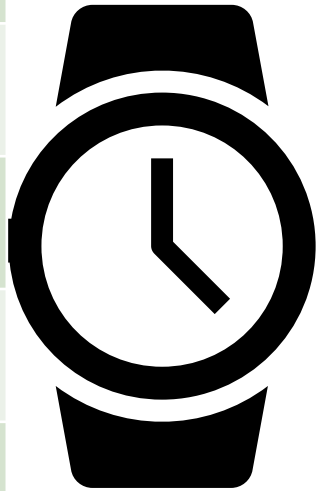
Project Title, Names and Affiliations of PI, Co-PIs, Co-Investigators and Collaborators and project sites

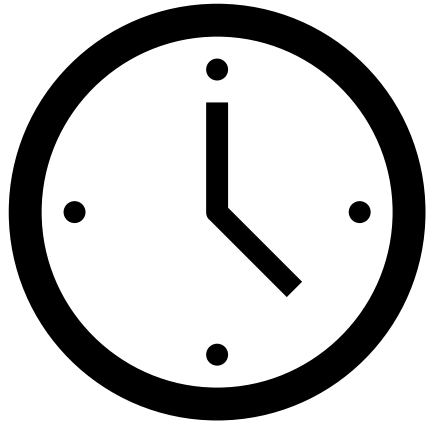
- Brief, focused project summary that includes:
  - Question/Hypothesis
  - Innovation/Translation section
  - Feasibility section
  - Project Milestones
  - Statement of Translation
  - Budget Summary
  - Human Subjects/IRB
  - Intellectual Property questions
  - Special Considerations

(see RFA for more detailed information)

Important Dates

Date	Event
October 20, 2025, 11:59 PM	LOI submission due via InfoReady
Mid Dec, 2025	LOI results announced
January 19, 2026	Full Application Deadline
April 3, 2026	Annual Pilot awards announced
May 31, 2026	Any applications with IRBs must have IRB approval IN PLACE
July 1, 2026	Annual pilot projects start date
June 30, 2027	Annual pilot projects end date





Notes on applying for CTSC funding

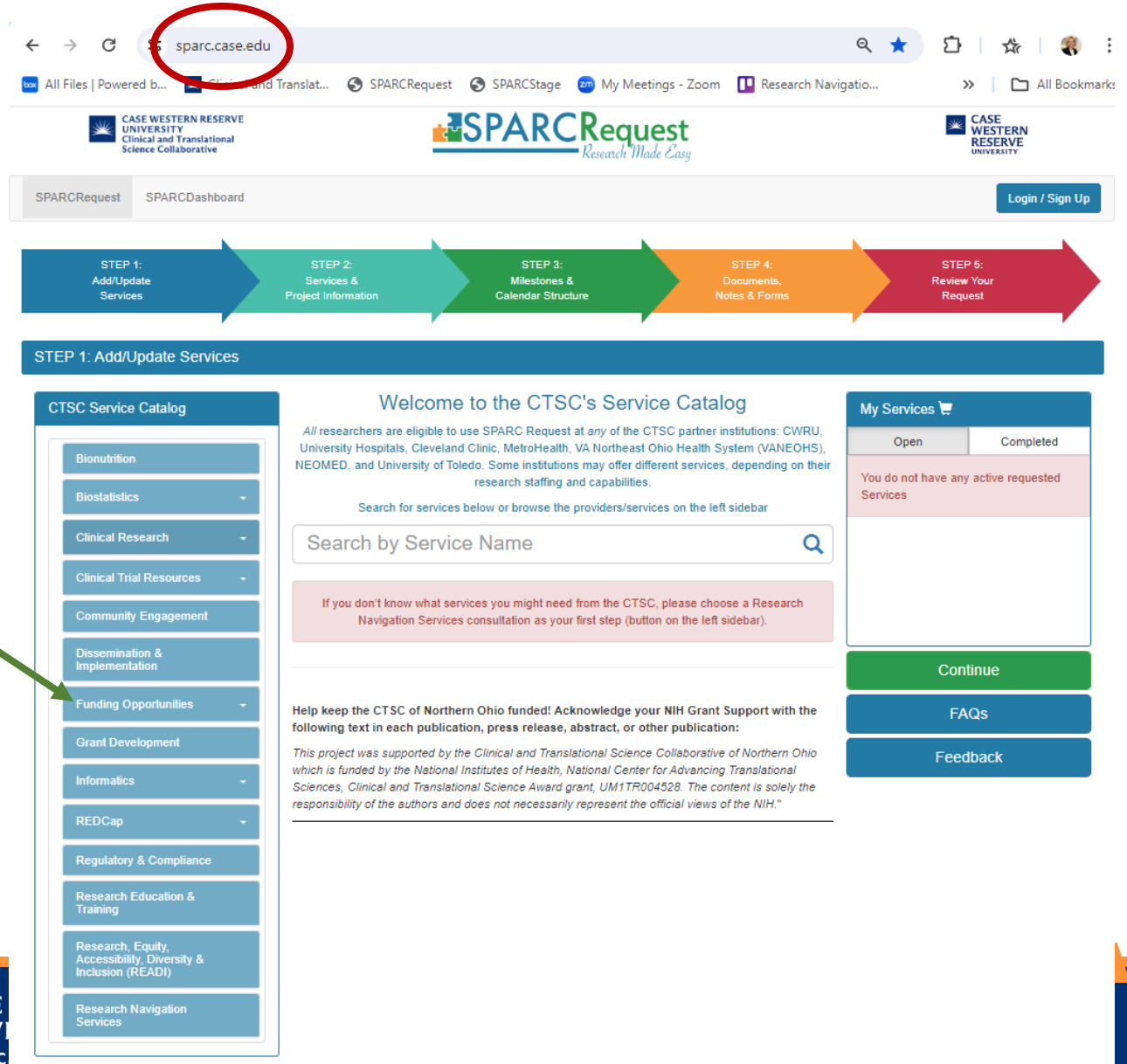
- **A TWO-STEP process: SPARC + InfoReady**
  (CTSC's request system + CWRU's centralized online grant proposal management system)

- To apply for a CTSC Funding Opportunity, you will first need a Project ID number from SPARC. This Project ID allows access to the RFAs and applications in InfoReady.

- Consult services for CTSC resources are available for investigators at CWRU and all CTSC partners.

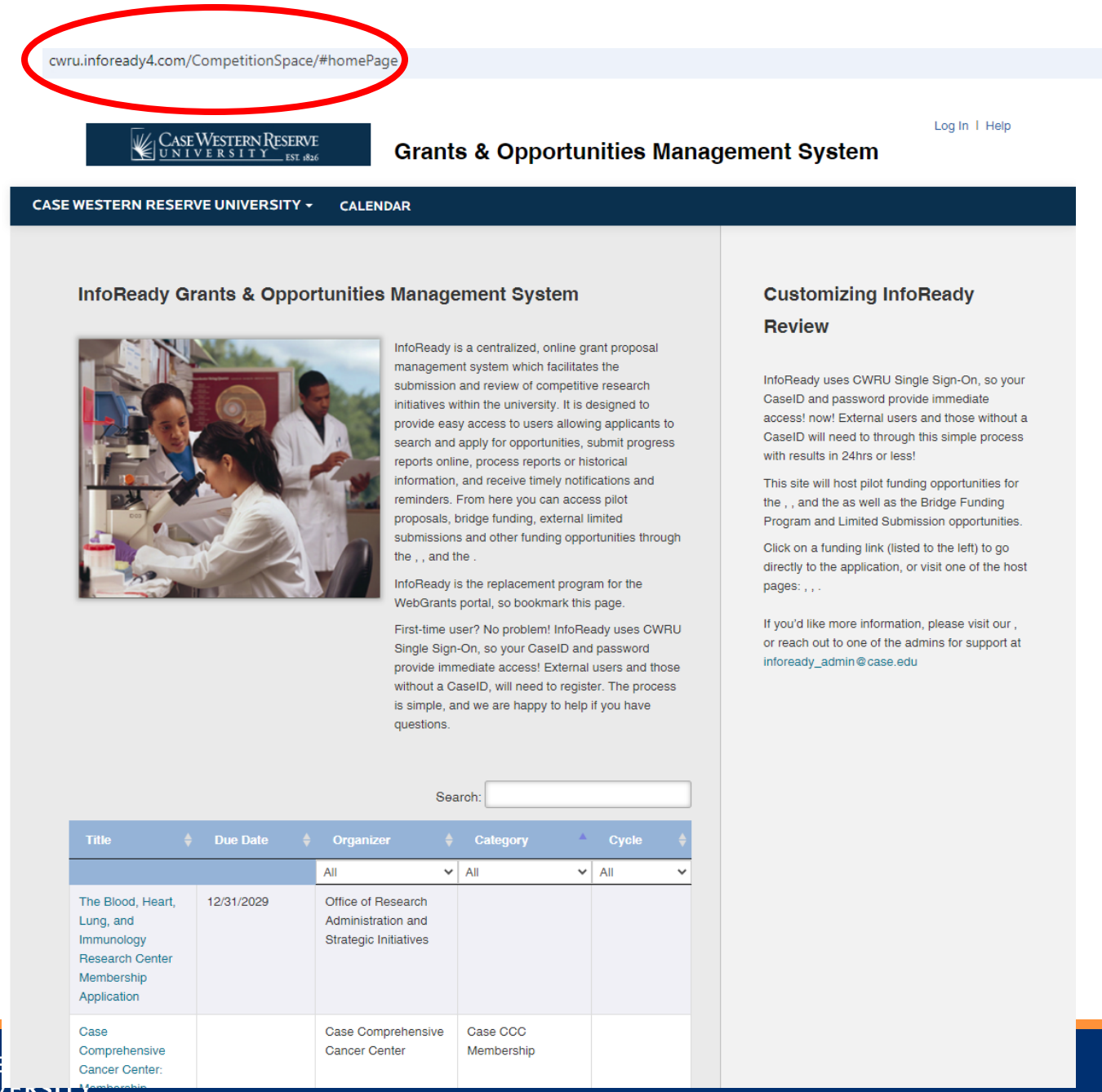
Step 1 for applying: SPARC

- Head to sparc.case.edu
- Sign up for an account if you don't already have one
- Under Funding Opportunities, select Annual Pilot Program and enter info about your project, this will give you a Project ID #
- Problems with SPARC? Email sparc-help@case.edu



Step 2: InfoReady

- Go to CWRU InfoReady website
- Sign up for an account if you don't already have one (CWRU users can use SSO, outside users need to register for an account.)
- Use the search bar or scroll down to find 2026 Annual Pilot Program Letter of Intent
- Enter detailed RFA information here *(this is where you'll need your SPARC project #)*
- Problems with InfoReady? Contact me at abt11@case.edu



- ✓ Submit a Letter of Intent (LOI) by October 20, 11:59 PM
- ✓ Schedule a consultation before submitting a LOI, request this service through SPARC.
- ✓ Be aware of critical dates:

Oct 20:	LOI submission due via InfoReady
Mid- Dec, 2025:	LOI results announced
Jan 19, 2026:	Full proposals due
April 3, 2026:	Annual Pilot awards announced
May 31, 2026:	Any applications with IRBs must have IRB approval *IN PLACE* by this date
July 1, 2026:	Annual Pilot project start date

Q & A

FAQs

Q. Does a community partner count as a 2nd partner?

A. No, for this RFA, applications must have 2 or more *CTSC partner institutions*. A community organization can be a co-investigator and would count as a 3rd partner

Q. How long should my LOI be?

A. Your letter of intent should be **one page maximum.** All LOI instructions are located in the Annual Pilot RFA.

Q. What if my project needs IRB approval?

A. Include a statement outlining plans to obtain IRB approval by March 31, 2026, dates of submission, and/or approval *(projects with already approved or nearly approved IRB will be more favorably reviewed).*

Q. Is a consultation required?

No, but it is recommended. Add IP, collaborators, etc.

Collaborate with the CTSC in multiple ways

Become a CTSC member and access CTSC resources, funding opportunities, and events by scanning the QR code below: