Institutional Clinical and Translational Science Award
TR-12-006

Webinar NCATS Participants
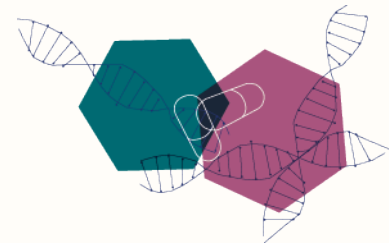
- Josie Briggs and Elaine Collier

- Irene Grissom – Office of Grants Management

- Sheryl Brining – Office of Review

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Outline for Today

- NCATS Mission

- CTSA Program

- TR-12-006 Purpose and Objectives

- Organization of Application

- Sharing Plans

- Review

- Terms and Conditions

- Questions

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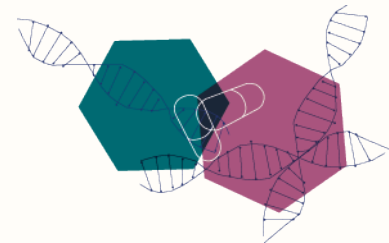
NCATS Mission

To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.
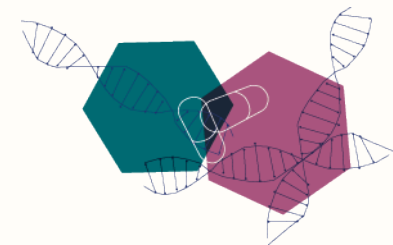
Clinical and Translational Science Award Program

- Ongoing since 2006

- Substantial input sought from stakeholders of the CTSA program as program transitioned into NCATS

- NIH CTSA Working Group

- Request for Information (RFI) on CTSA program

- NIH CTSA Transition Team with broad NIH institute participation

- CTSA Principal Investigators

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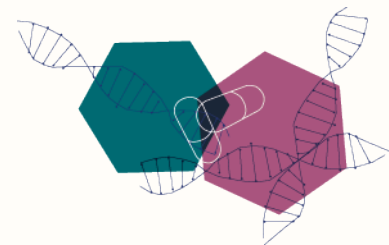TRANSLATIONAL SCIENCES
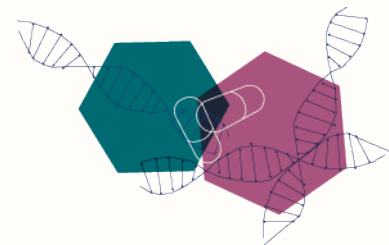
Institutional Clinical and Translational Science Awards

- Strengthen the entire spectrum of NIH supported translational research

- Build upon and support institutional strengths

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Institutional Clinical and Translational Science Awards

- Provide research resources and services that improve the quality, validity, generalizability, and efficiency of clinical and translational research

- Train the workforce for translational research

- Provide the foundation for translational research at academic institutions, particularly NIH supported research

- Promote innovation in the methods and processes to support high quality and efficient translational research at lower cost that are generalizable across disease and specialty domains
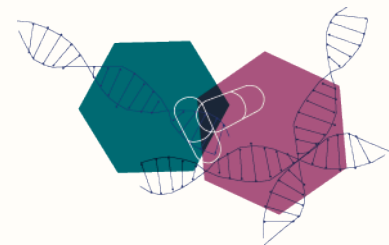
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NCATS: Institutional Clinical and Translational Science Awards

Specific Objectives:

Academic home forms an integrated research and training environment across an applicant institution and its partner institutions in order to:

- Promote an institutional environment that enhances quality, safety, efficiency, and cost effectiveness of clinical and translational research for all conditions

- Provide resources and services to support and speed the planning and implementation of clinical and translational research across the entire range of research and communities

- Facilitate the training and career development of a robust translational research workforce

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Structure of Application: Research Plan

- **Overall Strategy and Vision Introduction**
  (12 pages, 1 page Specific Aims)

- **Integrated Home Leadership Section**
  (30 pages, 1 page Specific Aims)

- **Clinical and Translational Resources and Services**
  (30 pages, 1 page Specific Aims)

- **Education, Training, and Career Development Section**
  (12 pages each for Education, K program, and optional T program;
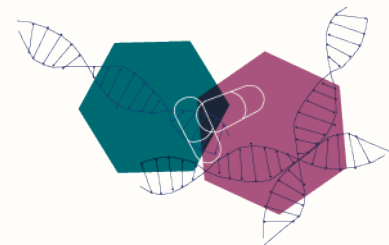 1 page Specific Aims)
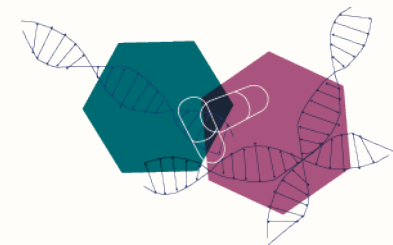
Structure of Application: Budget

- Calculate maximum *annual* allowable total cost (direct and indirect costs) budget request based on FY 11 NIH funding base of applicant and participating institutions

- FY 11 NIH Funding Table = source for NIH funding base dollars used in calculation of budget request for applications

- Maximum *annual* allowable budget request is 3.0% of the FY 11 NIH funding base of all participating institutions

- Maximum *annual* allowable budget request cannot exceed $25.0 million total costs (direct and indirect costs)

- *Annual* allowable request is $4.0 million total costs (direct and indirect costs) if FY 11 base < $133 M

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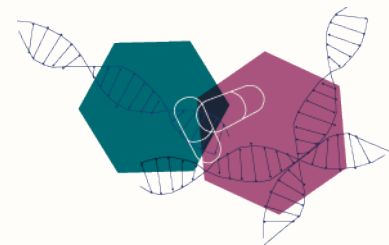
Structure of Application: Budget (continued)

- Applicants with a current CTSA award may request an initial budget based on prior approved award amount if this amount is greater than 3% of NIH funding base

- The budget requested in years two through five must be phased to meet the budgetary expectations based on FY 11 NIH funding base

- The phasing plan requires written prior approval from the NCATS program officer

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Structure of Application: Budget section

- Sheet listing applicant and all participating institutions, their FY 11 NIH funding from table, total of NIH funding base, and calculated allowable annual total cost (direct and indirect costs) budget request

- If a phased budget is requested, include documentation of written approval of plan from NCATS Program Officer

- Four sets of budget pages are required if optional T program is requested (three sets if no T program)
  - ✓ U program budget and justification
  - ✓ K Program budget and justification
  - ✓ T Program budget and justification (optional program)
  - ✓ Composite budget includes all above costs

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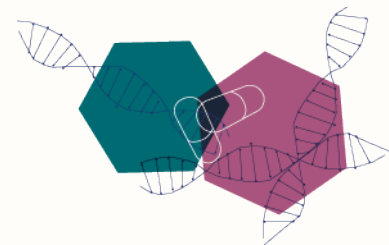TRANSLATIONAL SCIENCES
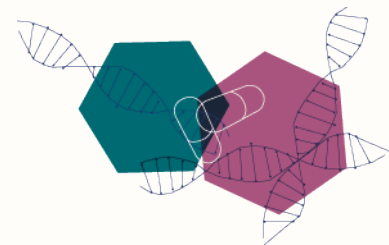
Sharing Plans

- Resource and Data Sharing plan

- Software Sharing Plan with specific goals

- Required letter from applicant and participating institutions indicating commitment, including their technology transfer offices, to the proposed sharing plans

- Reviewers will evaluate sharing plans and provide comments

- NCATS will consider the proposed sharing plans in making funding decisions

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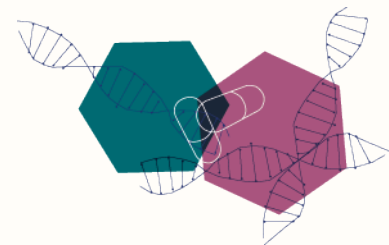**NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES**
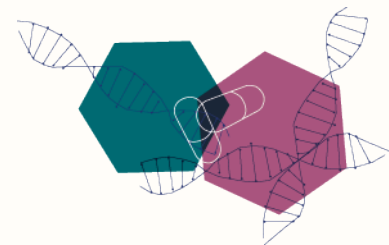
Terms and Conditions

- Terms and Conditions in FOA will apply to any awards issued in response to this FOA

- Plans proposed in the application (as modified after negotiation with NIH, if required) will be incorporated into the Terms and Conditions of award

- Reporting requirements for awards in response to this FOA will require transparency of the types and cost of resources and services provided to support research projects at participating institutions

- NCATS Clinical Trial Funding Restrictions require grantee tracking of clinical trials supported with NCATS grant funds; information must be available to NIH upon request

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General Information

- All applications, including those from institutions that currently have a CTSA award, will be considered new applications

- Only one application as applicant or participating institution

- Currently awarded CTSAs with project period end dates in 2014, 2015, 2016, *or beyond* are not eligible to apply

- Applications must be structured as outlined in the FOA

- Applications will be reviewed by the specific review criteria in this FOA

- Funding decision considerations: merit as determined by peer review, relevance to program priorities, proposed sharing policies, and availability of funds

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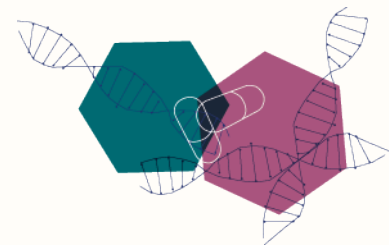TRANSLATIONAL SCIENCES**

General Information (continued)

- Funding Instrument is Cooperative Agreement with substantial involvement of grantee and NIH staff

- Awards will utilize the Linked Specialized Center mechanism

- PHS 398 Application is used for this FOA (paper)

- Page limits apply as outlined in the FOA

- No Appendices are allowed.

- Structure of specific sections as outlined in FOA

- Maximum allowable budget request is calculated per FOA

- Applications that do not comply with instructions in the FOA will be considered non-responsive and not reviewed
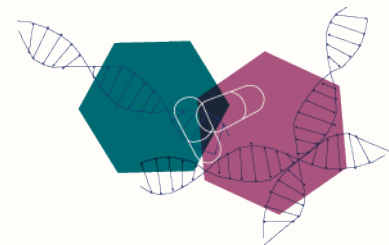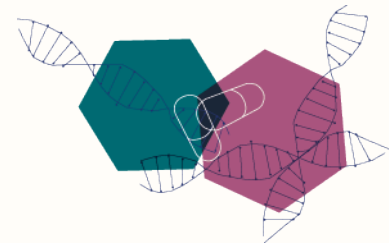
Review of applications

- All applications will be reviewed by specific review criteria in the FOA

- The three sections, e.g., *Integrated Home Leadership Section; Clinical and Translational Resources and Services Section; and Education, Training, and Career Development Section*, will be reviewed by the specific review criteria for each section

- The overall application will be evaluated by the Overall Review Criteria

- All applications are considered new applications; no renewal applications are allowed

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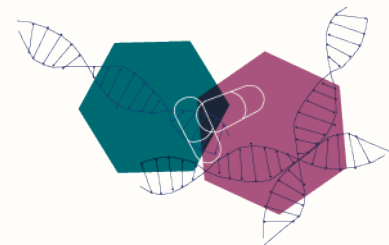**NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES**

Letter of Intent (LOI)

- Due to the NIH by December 10, 2012
- Assists NIH prepare for review of applications
- Not binding
- Include:
  - ✓ Name of Program Director/Principal Investigator
  - ✓ Names of other key personnel
  - ✓ List applicant institution and participating partner institutions
  - ✓ Indicate TR-12-006: Institutional Clinical and Translational Science Award (U54)
  - ✓ The LOI should be sent by email to: CTSAFOAQuestions@mail.nih.gov

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Frequently Asked Questions

Can you describe the eligibility criteria for the Principal Investigator?

The PD(s)/PI(s) is expected to:

- be an established clinician/scientist who reports directly to an official with broad trans-institutional authority
- have the authority and influence necessary to successfully create an institutional home for clinical and translational research
- have ultimate responsibility for the implementation and function of CTSA and daily involvement with its activities
- commit at least two months and preferably six months effort to the grant regardless of whether salary is requested

The application should address the qualifications of the proposed PI. The suitability of all proposed personnel will be considered as part of the review of the applications.

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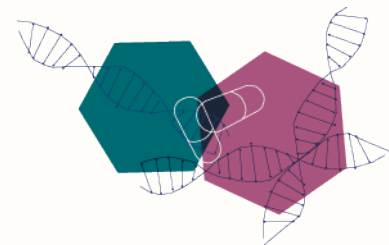
May I submit supplemental tables, graphs, figures, drawings and charts that do not count against sectional page limits? What about appendices?

In this FOA, no additional pages outside of the page limits for each section are allowed for tables, graphs, drawings and charts. If an applicant chooses to include such items, they must be within the page limit for a given section. No appendices are allowed in response to the FOA. Applicants are encouraged to be clear, concise and focused in describing their plans.
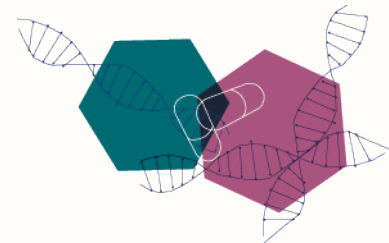
Thank you!

If you have questions after the webinar, please email them to:

CTSAFOAQuestions@mail.nih.gov

Also see the Frequently Asked Questions posted at:
http://ncats.nih.gov/ctsa-funding-faq.html