

## 4D Technology Development Pilot Projects Aim: To promote technology-based solutions for unmet needs across the healthcare system

(This pilot project program is supported by the ISMMS CTSA grant UL1TR001433 from the National Center for Advancing Translational Sciences, National Institutes of Health)

- Sinai researchers and clinicians are invited to submit the application for the current cycle of the 4D Technology Development Pilot Program (deadline APRIL 27th)
- This call is open to translational technologies addressing unmet needs in therapeutics, diagnostics, devices and digital health
- Multi-disciplinary teams are encouraged to apply
- Proposals will be evaluated and some will be invited to pitch their proposals to an internal review panel. They will receive guidance on preparing these presentations with the help of experts,
   MSIP and ConduITS
- At the pitch session, (date to be confirmed in late May), the review panel will evaluate and make funding recommendations. For proposals involving Human Subjects or Animal Research, protocols must be submitted to IRB/IACUC prior to the presentation
- Teams that have received awards will execute their project plans starting July/August 2018 and will have expended their budgets by March 31<sup>st</sup> 2019. For projects involving Human Subjects or Animal Research funding cannot be awarded until IRB/IACUC and NCATS prior approval has been awarded details are explained below:

## Instructions:

- The proposal template should be completed and be sent to <u>Louise.Lammers@mssm.edu</u> (April 27th 2018)
- Budget request guidelines
  - o Digital health submissions: \$10k-\$15k
  - o Other: max. \$40k
  - o The budget must be expended by March 31<sup>st</sup> 2019.
  - o In addition to this Conduits CTSA funding rules apply and there are restrictions as to what expenses will be allowable:

http://icahn.mssm.edu/static\_files/Test2/06081716/www.mssm.edu/finance/grant\_restricted\_funds/pdf/173.pdf . Please contact Sonia.kleiner-arje@mssm.edu, Director of ConduITS if you have questions regarding budget and expenses.

## Proposals involving Human Subjects or Animal Research

Proposals involving Human Subjects or Animal Research require extra steps which includes getting formal approval from NCATS.

Also, IRB/IACUC—IRB or IACUC approval is required for Human or Animal Research. *Protocols must be submitted to IRB/IACUC prior to the pitch session in June.* 

Special submission guidelines, instructions and checklists will be provided to you by the Office of Research Services for NCATS prior approval. You will submit your completed application documents through the ISMMS Grants & Contracts Office (GCO). The completed package must be submitted to NCATS 30 days prior to the beginning of your funding. Final award is contingent on NCATS & IRB approval.

- Special submission guidelines, instructions and checklists will be provided to you for NCATS prior approval.
- IRB: For assistance with determining whether or not your proposal involves human subjects and/or navigation of the ISMMS IRB submission process forplease contact the Program for the Protection of Human Subjects (PPHS) at 212-824-8200 or IRB@mssm.edu.or go to <a href="http://icahn.mssm.edu/research/pphs/researcher">http://icahn.mssm.edu/research/pphs/researcher</a>. There are many steps required for IRB submission and final award is contingent upon NCATS & IRB approval.
- IACUC: For assistance with ISMMS IACUC submission process please contact 212-241-0153 or <u>IACUC@mssm.edu</u> or go to: <a href="http://icahn.mssm.edu/research/iacuc/iacuc-applications">http://icahn.mssm.edu/research/iacuc/iacuc-applications</a>
- You will submit your completed application documents through the ISMMS Grants & Contracts Office (GCO). The completed package must be submitted to NCATS 30 days prior to your funding start date.

Please contact <u>Sonia.kleiner-arje@mssm.edu</u>, Director of ConduITS if you are having any issues obtaining help.

## 4D Pilot Project Proposal Template

(max. 5 pages)

Name of Technology	
Principal Investigator/Project Leader contact details	
Project team members & emails	Role
High Level Summary of technology	Main Conclusions only.
	Why are you so excited about this technology?
Data status	Present only the most significant validating data that is the
	center of the technology here. (max 1 page)
Addressable Market	Include specifics (if known) about patient #s, tests performed
Addressable Market	and/or \$\$s.
	and, or \$450
Competition	Focus on communicating the differentiating factor(s) of the
	technology compared to the current standard of care and
	other approaches.
	Note: <u>www.clinicaltrials.gov</u> may be helpful in providing upto-date information on competing studies.
	to date injoiniation on competing studies.
Regulatory	Do you already have internal IRB/IACUC approvals in place if
	relevant for the preject evention?

	How would you make a plan to achieve clearance to market?
Project end date	March 31 <sup>st</sup> , 2018 (Note: there is <i>NO</i> carry over for this cycle of 4D pilot funding)

Milestones	Budget
What are tangible main milestones could you achieve during the budget period, i.e. July 2017- March 31 <sup>st</sup> 2018. (even if the project would proceed longer)	Proposed budget for the budget period, link to milestones
	Total budget requested =
Briefly list longer term milestones and end	l goal.

What special experience/expertise do you and your team have in order to carry out the project? Are there any gaps in expertise?

Major anticipated risks & how you plan on managing them

Intellectual property: brief description of IP landscape and expected next steps.	