

## PA-19-065

### FUNDING OPPORTUNITY ANNOUNCEMENT INFORMATION FOR APPLICANTS AND REVIEWERS

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## Medical Simulators for Practicing Patient Care Providers Skill Acquisition, Outcomes Assessment and Technology Development (R01 Clinical Trial Not Allowed)

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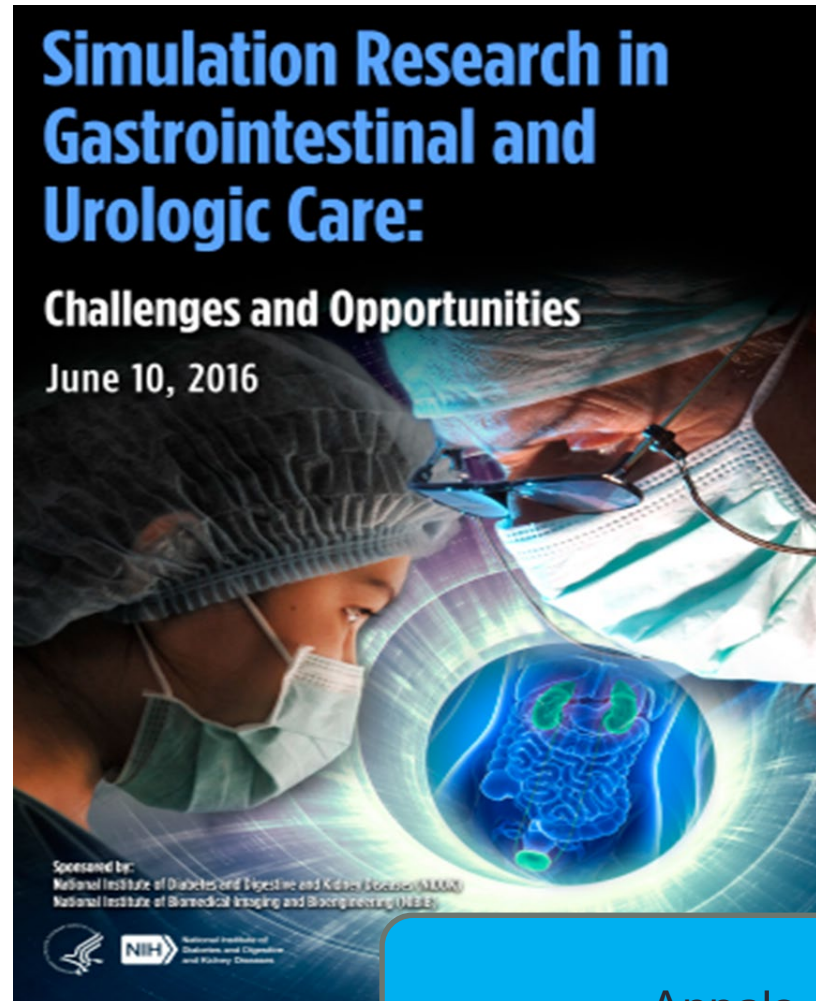
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# FOA inspired by NIDDK & NIBIB Workshop



ORIGINAL ARTICLE: CO-PUBLICATION

## Simulation Research in Gastrointestinal and Urologic Care—Challenges and Opportunities

*Summary of a National Institute of Diabetes and Digestive and Kidney Diseases and National Institute of Biomedical Imaging and Bioengineering Workshop*

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A workshop on “Simulation Research in Gastrointestinal and Urologic Care: Challenges and Opportunities” was held at the National Institutes of Health in June 2016. The purpose of the workshop was to examine the extent to which simulation approaches have been used by skilled proceduralists (not trainees) caring for patients with gastrointestinal and urologic diseases. The current status of research findings in the use and effectiveness of simulation applications was reviewed, and numerous knowledge gaps and research needs were identified by

**Keywords:** clinical skills retooling, expert performance, gastrointestinal diseases, simulation, urologic diseases

(*Ann Surg* 2018;267:26–34)

A workshop was held on June 10, 2016, at the Natcher Conference Center at the National Institutes of Health entitled “Simulation Research in Gastrointestinal and Urologic Care: Challenges and

### Workshop Report:

Annals of Surgery: January 2018 - Volume 267 - Issue 1 - p 26–34

doi: 10.1097/SLA.0000000000002228

# Focus Areas:

**1. Skill Acquisition** - Applications which assess the processes of skill acquisition, skill maintenance, and skill enhancement for practicing clinicians and healthcare providers.

- procedural error analysis
- error prevention
- time course of skill acquisition and maintenance by experienced clinicians

**2. Outcomes Assessment** - Applications which assess the skills of experienced clinicians and correlate the simulation-based assessment of skill levels with the quality of care experienced by patients treated by these care-givers

- safety (e.g., morbidity and mortality)
- outcomes (e.g., being free of disease/condition, recovery and rehabilitation from interventions)
- costs (e.g., length of hospital stay, cost of treatment)
- Comparative studies of clinical skill measurement by simulation methods with the outcomes of patients treated by those practitioners whose skills have been assessed



# Focus Areas:

## 3. Technology development – next generation simulator development

- “virtual coaches” incorporating intelligent methods into existing simulators to provide adaptive, cognitive assistance to coach experienced practitioners in retaining, retraining and improving performance levels in the context of the user environment
- Simulators that incorporate artificial intelligence with theory-driven, physics-based, physiologically realistic models
- Simulators replicating “real life” work flows, including planning, warm-up exercises, and rehearsal leading up to the actual procedure
- Simulators based on physiologically realistic models that operate in real-time, capable of seamless integration in a variety of provider environments → e.g. rural and low-resource settings.

**Note:** End users are part of the technology development team





# Section IV: Instructions to Applicants

## Research Strategy



For Focus Areas 1 and 2 – Outcomes Assessment and Skill Acquisition:

- **Methods and Resources:** Applicants are encouraged to specify the simulation methods, equipment and resources that will be utilized, the end users that will be recruited to participate in the proposed studies, and how the simulation method proposed is expected to impact patient safety outcomes.
- **Project Design:** Applicants are encouraged to provide a project design and methodology plan that covers development, evaluation and validation activities for the assessment of skill acquisition and maintenance of practicing health care providers.
- **Projected Implementation Timeline:** Applicants are encouraged to outline how the simulation will be implemented in the proposed healthcare setting and include appropriate milestones and timelines for assessing skill acquisition and maintenance. The milestones should describe quantitative metrics to be used to indicate acceptable performance.

# Research Strategy:

## For Focus Area 3 – Technology Development:



- **End users and evaluation:** Applicants are encouraged to incorporate end users as part of the technology development team. These end users should sufficiently represent the needs and challenges of the larger community to be served by the proposed new simulation technology. Applicants should describe how the technology will be evaluated by the end user community.
- **Context of use, scope and timeline:** Applicants should clearly describe the context of use and the scope of the technology being proposed. The scope should be described in technology milestones, in which each should include the criteria for success and a go-no-go assessment. Applicants should propose a timeline for the scope of the project and are encouraged to present a longer timeline describing the overall scope and timeline for the final technology outcome.
- **VV&UQ:** Applicants should describe how verification, validation and uncertainty quantification will be addressed

# Research Strategy:

For all Focus Areas:

- **Data Management:** Applicants are encouraged to use appropriate data management practices, using standard documentation and metadata formats in planning for re-use, re-distribution, archiving and preserving access.
- **Data Analysis:** Applicants are encouraged to provide a data analysis and evaluation plan that addresses the projected dissemination, adoption, and sustainability issues associated with the simulation approach proposed.
- **Resource Sharing Plan:** Data and Software Sharing (as applicable)



# Interest Statements

## NIDDK

- The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is interested in applications targeted to focus areas 1 and 2, concentrating on abdominal, gastroenterological, and urological diseases and conditions. Studies which quantify or otherwise assess skills of practicing clinicians by the use of a task simulator and compare those skill assessments to the measured outcomes (e.g., morbidity, mortality or cost) of those patients treated by the clinicians are of interest. These studies constitute an observational study (and not constitute a clinical trial) and would be of interest to NIDDK for this FOA.

### NIDDK Clinical Trial Guidance

- Applications which propose clinical trials related to the diagnosis and treatment of diseases or conditions of interest to NIDDK (abdominal, gastrointestinal, and urologic diseases and conditions) and which are related to this announcement must be directed to PA-18-330 (Investigator-initiated Clinical Trials Targeting Diseases Within the Mission of NIDDK). A guideline for defining a clinical trial is available at <https://grants.nih.gov/policy/clinical-trials/case-studies.htm>. The study elements which qualify for designation as a clinical trial include the following:
  1. An intervention is employed in human subjects (which might include patients or healthcare providers)
  2. The subjects are prospectively assigned to the intervention(s)
  3. The study is designed to assess the effects of the intervention on the subjects
  4. The effects of the intervention are assessed as health-related outcomes.
- Therefore, applications which propose to develop, evaluate and validate simulation-based methods for the acquisition, improvement and maintenance of skills by practicing clinicians may be considered clinical trials if an intervention is employed, and the effects of that intervention on health-related outcomes are assessed.
- Applications which seek to improve the acquisition, or maintenance of clinically relevant skills of practicing clinicians through a comparison of methods (interventions) or before-and-after assessments of clinical outcomes after instituting a proficiency-based program of skill attainment on a task simulator would be designated as clinical trials, by the guidelines for clinical trials referred to above, and must be directed to PA-18-330 for applications of interest to NIDDK.
- Applications which are directed to PA-18-330 should reference this funding announcement in the rationale and significance portions of the application
- Applications which seek support for pilot studies for clinical trials according to the definition above should be directed to Pilot and Feasibility Clinical and Translational Research Studies in Digestive Diseases and Nutrition (R21 Clinical Trial Optional).



# Interest Statements

## **NIBIB**

- The National Institute of Biomedical Imaging and Bioengineering (NIBIB) is interested in supporting applications targeted to focus area 3, enhancing medical simulation technologies using multiple disease or conditions as testbeds for the technology development. Complicated or rare procedures, relevant to skilled practitioners in rural and low-resource settings are especially encouraged.
- The NIBIB is interested in promoting the development of medical simulation technologies that have broad diagnostic, therapeutic and interventional applications in diseases or health conditions. Areas of interest include medical simulation technologies to complement technology development in all other program areas of the NIBIB, <https://www.nibib.nih.gov/research-funding>.
- NIBIB will support applications that develop novel medical simulation technology solutions that can broadly apply to multiple disease and conditions. NIBIB will support an application focused on a single disease or condition if it is clear that the single disease or condition is an initial test bed for a medical simulation technology that could be applied to other diseases or conditions. NIBIB will not support any applications that are solely using and not developing enhanced medical simulation technologies. NIBIB will not support any applications targeted for focus areas 1 and 2.

## **NCCIH**

- The National Center for Complementary and Integrative Health (NCCIH) is interested in supporting research to develop and validate novel simulations technologies relevant to complementary and integrative health approaches, such as meditation, acupuncture, spinal manipulation and mobilization, massage, yoga, tai chi, music interventions, and art interventions, that are provided by patient care providers, including acupuncturists, chiropractors, massage therapists, physiotherapists, music therapists, and art therapists.

## **NICHD**

The Eunice Kennedy Shriver National Institute of Child Health and Human Development(NICHD) is interested in supporting simulation research that:

- Examines treatments and / or interventions used in caring for critically ill and injured children including therapies applied to adults that can be modified to address the needs of children
- Addresses gaps and disparities in outcomes among traumatized, injured, and critically ill children
- Studies interventions to reduce neonatal deaths occurring in and around the time of delivery
- Enhances the skills of attendants in complicated delivery situations and during gynecological, obstetrical, neonatal and pediatric emergencies
- Studies technologies relevant to gynecologic care including those used in the treatment of gynecologic conditions.

# Responsiveness:



Applicants should consider other FOAs for the following:

- Clinical Trials
- SBIR/STTR
- Exploratory Studies
- Team-based Simulation Studies
- Studies targeted to trainee practitioners



# Resources for Submission and Review:



- ❑ Learn about [NIH review](#) {search NIH CSR}
- ❑ Sign up to [become a reviewer](#) – encourage everyone to populate this pool! {search: NIH CSR, click on For Reviewers}
- ❑ Enter research project aims into [ART](#) during writing phase - a Natural Language Processing tool to determine most appropriate study section based on what was written in the aims – WORDS MATTER! {search NIH CSR ART}
- ❑ [Request study sections](#) during grant submission {search NIH ASSIST, search request a study section}

