

## Application Instructions

**Solicitation Number: FRS-002**

**Proposal Title:** Fundamentals of Robotic Surgery: Curriculum and Technical Skills Validation Trial

**Abstract:** The technical skills curriculum entitled Fundamentals of Robotic Surgery (FRS) is a comprehensive curriculum developed for the training and assessment of the most basic robotic surgical skills. This curriculum is a course – and is limited to those technical skills (cognitive, psychomotor and team-training-communication) that occur from the time the patient enters the operating room, throughout any robotic operative procedure, and until the patient exits the operating room. It is presumed that the peri-operative assessment and care of the patient had been previously learned, in order for this course to focus upon the technical component of operative patient care. While the course and skills are designed to be agnostic as to the type of robotic system, the reality is that only the DaVinci Robotic Surgical System is FDA approved and therefore used in this course curriculum. The purpose of this validation trial is to demonstrate that 1.) the course has skills/tasks that can actually train a novice to proficiency - using the usual validity, reliability and practicality methods and measures, 2.) assessing whether training novices with course improves performance – using a novel task pre- and post training, 3.) to determine whether there is a difference in learning (learning curve) or performance (pre-test / post-test) using the 3 different modalities of a.) physical objects on the robot, b.) computer (virtual reality - VR) simulation if identical skills/tasks using the robotic surgical console with a VR simulation, and c.) free-standing VR simulator (Mimic) with identical software.

**Submission dates and times, format:** The solicitation will be released on the second Tuesday of April and concluded on the Saturday 6 weeks later

**Submission Release :** 15 APRIL, 2014

**Submission Due date:** 31 May, 2014

**Format:** Electronic return of attached FRS *Application Form* via email

### Application Review Criteria:

The proposals will be evaluated using the following criteria:

- 1) Qualification as an ACS-AEI site. [Pass/Fail]
- 2) Availability of two expert surgeons in each of three robotic surgical specialties. [Pass/Fail]
- 3) *Capabilities of the PI and Key Faculty and staff:* The experience (as manifest by past educational, administrative and clinical expertise) [Scored]
- 4) *Evidence of Scholarly Activity:* The publications and presentations of the PI and Key Faculty (in their CV) and the evidence of conducting courses in all three areas of the course – Didactic, psychomotor skills, and team-training and communications. [Scored]
- 5) *Resources of the institution:* The physical simulators, robotic systems, in addition to the technical and clerical personnel to be trained to administer the training/assessment of the learners and the informatics/database capability of administrative/clerical personnel to be able to download data to the FRS data repository. [Scored]

### Review and Selection Process:

The policy is to ensure impartial, equitable, and comprehensive proposal evaluations and to select proposals that meet the technical, policy, and programmatic goals.

The review process identifies proposals that meet the established criteria and are, therefore, a candidate for award. Each proposal is evaluated and scored on individual merit, not on a competitive basis. Prioritization of proposals will rank order the proposals as scored, and the 10 institutions with highest scores will be selected.

**Notification of Receipt and Selection of Proposals:** All notifications will be directed to the proposing institution's POINT OF CONTACT listed on page 1 [Cover Sheet, Administrative Information] of the Proposal Form. The following notifications will be made

1. Upon electronic receipt of the proposal
2. Upon selection for award (or non-selection)
3. If selected, notification from the FRS administrative staff for funding process

**Reporting Requirements:** If selected there will be quarterly teleconference with the PIs and a brief quarterly report (submitted electronically – form to be distributed).

**Human Subject Research (HSR) and Institutional Review Board IRB:** The FRS is negotiating with the Western Institutional Review Board (Connexus) (WIRB-C) <http://www.wirb.com/Pages/default.aspx> for approval of a comprehensive IRB which the PI may submit to their institution. Many institutions accept the WIRB-C for expedited review. There is no requirement to have the WIRB-C for selection.

**Intellectual Property:** There is no anticipated intellectual property. The curriculum (course) is open sourced and therefore not available as intellectual property, and freely available to all users. The curriculum (course) may not be resold by any of the participating institutions.

**Publication of Results:** The final analysis of the data and manuscript will be conducted by the PI and Co-PI. Upon completion of the draft manuscript, the draft will be sent to the PI of each institution for their review and comment. The PI, Co-PI and the Institutional PIs will be listed as co-authors in the publication. Acknowledgement of the participants of each institution will be placed at the end of the publication (as submitted by the institution's PI).

**Other Information:**

1. FRS Validation Trial – Criteria Summary
2. FRS Validation Trial - Proposal Form
3. FRS Validation Trial – Trial Protocol
4. FRS Validation Trial - Schedule and Milestones

**Points of Contact for FRS Project:**

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