Society of Interventional Radiology Interventional Oncology Task Force: Interventional Oncology Research Vision Statement and Critical Assessment of the State of Research Affairs

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Abbreviations: ACRIN = American College of Radiology Imaging Network, CAIRR = Cooperative Alliance for Interventional Radiology Research, FDA = Food and Drug Administration, IGI = image-guided intervention, NCI = National Cancer Institute, NIH = National Institutes of Health, RCP = research consensus panel

THE Research Subcommittee of the Society of Interventional Radiology (SIR) Interventional Oncology Task Force has undertaken preparation of a vision statement and critical assessment of the state of affairs of research in interventional oncology as a first step in advancing the research agenda of interventional oncology under the aegis of SIR. This document was refined over multiple consensus meetings and adopted by the global SIR Interventional Oncology Task Force at its February 2005 meeting. Further input has been provided by the SIR Foundation during review before publication. In addition to this document, we further envision additional strategy and tactic documents on clinical trials and basic/translational research, which will include specific milestones to be achieved over the course of our 10-year vision.

GOAL

The goal of the research subcommittee of the Interventional Oncology Task Force of the SIR is to construct an overarching strategic vision of the research status within the field of image-guided oncologic intervention (hereafter called interventional oncology), and to thereafter suggest what portions of this vision can best be accomplished by which specific strategies and tactics. This will be accomplished by identifying strengths, weaknesses, and opportunities, followed by ideas and action items that will help achieve this mission statement.

VISION

Our overarching vision is that research in the discipline of image-guided interventional oncology will lead to significant discovery and clinical implementation of novel and effective diagnostic and therapeutic approaches to benefit patients with cancer.

In so doing, the discipline would be accepted by patients, referring physicians, and governing bodies as another defined arena similar and coequal to radiation oncology, surgical oncology, and medical oncology in the field of cancer clinical care and research. This will enable interventional oncology to have a pivotal role in the therapeutic management of cancer based on the basic and clinical

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research performed and the image-guided oncology practiced.

Feeding this mission, in the specific focus of research, this can only be accomplished if the discipline of interventional oncology is well-represented by a robust portfolio of basic, translational, and clinical research. Indeed, the task force envisions an overall 10-year goal of establishing a comprehensive, multipronged approach to image-guided interventional oncology with serious commitment to clinical, basic, and translational research. It is our belief that the SIR and the SIR Foundation should take a leadership position in organizing and facilitating a clinical and basic research agenda for interventional oncology to achieve these objectives.

The 2015 oncologic image-guided interventions (IGI) research vision that we support includes the following:

1. CLINICAL RESEARCH: BY 2015 THERE ARE:

- IGI committees in pertinent cooperative groups, including but not limited to the National Cancer Institute (NCI)–funded cooperative groups (eg, American College of Surgeons Oncology Group, Southwest Oncology Group, Eastern Cooperative Oncology Group, Cancer and Leukemia Group B), the American College of Radiology Imaging Network (ACRIN), and the Cooperative Alliance for Interventional Radiology Research (CAIRR);
- Consortia of IGI investigators at a subset of national cancer centers and/or Specialized Programs of Research Excellence;
- Consortia of IGI investigators performing multicenter international cooperative trials
- A number of phase A–D clinical trials within cooperative groups through the "quick trials" mechanism and/or as RO1 grants (as well as other funding mechanisms);
- Studies demonstrating differences or equivalence of various IGI techniques with and without adjuvant therapies.

This is facilitated and/or evidenced by:

- A well-developed portfolio of at least five or six completed and published IGI clinical trials of new devices and/or IGI therapies not currently clinically accepted or available;
- A well-developed portfolio of at least 10 completed and published IGI clinical trials of currently available devices and/or therapies;
- A well-accepted IGI clinical trials construct that is integrated into the NCI and US Food and Drug Administration (FDA) processes;
- Ten to 15% of the Cancer Therapy Evaluation Program trials budget supports IGI trials;
- Three to 5 trials completed under the aegis of ACRIN;
- Two to 3 trials supported by CAIRR;
- IGI clinical trials are used to support positive payment policy by Center for Medicare and Medicaid Services and Blue Cross/Blue Shield Technology Evaluation Center;
- IGI trials are used to achieve FDA indications;
- IGI included in all relevant guidelines for the therapeutic management of patients with cancer;
- NCI holds Investigational Device Exemptions and sponsors related trials.

2. TRANSLATIONAL RESEARCH: BY 2015 THERE ARE:

- A number (3–5) of established oncologic IGI cores within cancer centers and Specialized Programs of Research Excellence integrated within the institutional processes of translating basic science discoveries into IGI treatments;
- A number (2–4) of integrated imaging and interventional platforms and potentially a "plug-and-play" environment that includes multiple interventional "tools" and multiple image guidance modalities;
- A number (2–4) of functional and fused functional–anatomic image guidance systems to be used with oncologic IGI;
- A well-defined set of imaging endpoints that serve as the equivalent of the surgical "tumor-free margin" validated by animal models;
- A number of treatments developed and optimized through an improved understanding of tumor biology and the tumor microenvironment (tumor-specific and for cancers in general);
- Studies demonstrating differences or equivalence of various IGI techniques with and without adjuvant therapies.

This would be evidenced by:

- A well-developed portfolio of five to 10 funded investigators for projects that are translational with early-phase (A and B) clinical trials;
- Five to 10 new oncologic IGI treatments with approved FDA indications (or undergoing funded clinical trials designed to achieve FDA indications).

3. BASIC RESEARCH: BY 2015 THERE ARE:

- A number of IGI animal resource centers available to academia and industry for the development, optimization, and validation of oncologic IGI devices, imaging systems/agents, guidance and monitoring, and robotics, etc;
- A number of combined therapeutic and imaging devices/agents for oncologic IGI;
- A number of integrated imaging and interventional platforms and potentially a plug-and-play environment that includes multiple interventional "tools" and multiple image guidance modalities;
- A number of functional and fused functional–anatomic image guidance systems to be used with oncologic IGI;
- A well-defined set of imaging endpoints that serve as the equivalent of the surgical tumor-free margin validated by animal models;
- A number of treatment paradigms developed and optimized