January 7, 2021

FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Steering Committee Charter

Mission

The FDA Steering Committee (SC) for the Centers of Excellence in Regulatory Science and Innovation (CERSI) (CERSI-SC) provides advice and guidance to the Office of Regulatory Science and Innovation (ORSI) and to the CERSI academic institutions on the CERSI Program. It ensures that issues concerning the CERSI program and its activities are effectively communicated to FDA leadership and staff within their Center/Office (see Appendix 1).

Background

In support of FDA's Advancing Regulatory Science Initiative and the regulatory science priorities of the Agency's Centers and Offices, the CERSI Program was established by the ORSI in the Office of the Chief Scientist (OCS). The goal has been to provide FDA with capabilities for scientific collaborations with academic institutions under a cooperative agreement grant.

CERSI program participants conduct regulatory science research in collaboration with FDA that enables and supports the Agency's regulatory mission. The CERSI program also provides opportunities for participants to engage in scientific exchanges and regulatory science workshops, lectures, and training.

Research projects conducted under the CERSI program need to address a regulatory science priority area defined by FDA's Commissioner, Centers, or Offices (see current CERSI Regulatory Science Priorities). The CERSI-SC: 1) serves as the liaison between ORSI and the leadership and staff of FDA Centers/Offices, and 2) meets periodically with ORSI and CERSI academic institutions to provide advice on the CERSI program and specific CERSI projects.

Membership

The CERSI-SC is composed of senior scientists from Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Tobacco Products (CTP), National Center for Toxicological Research (NCTR), OCS/Office of Minority Health (OMH), OCS/Office of Health Informatics (OHI), and Office of Women's Health (OWH) that are appointed by their Centers and Offices. Each (participating) FDA Center and Office identifies a lead and secondary member for their Center or Office (see Appendix 2 for current CERSI-SC Members).

ORSI will chair and provide management support for the CERSI-SC. The Director of ORSI will chair the CERSI-SC. ORSI staff involved in managing CERSIs will attend CERSI-SC meetings as participants.

Responsibilities

CERSI-SC will:

1. Define and support the Mission, Goals, and Objectives of the CERSI program
2. Review the CERSI program annually, including its Mission, Goals, and Objectives as well as research priorities, and recommend any needed changes
3. Establish or endorse policies for the CERSI program, including but not limited to fellowships and training, and FDA visiting scientists program
4. Prioritize research projects supported by ORSI core funding and review topics for FDA-CERSI collaborative workshops and lectures
5. Review cross-Center/Office activities, including research and workshops
6. Define research priorities for the CERSI program that address unmet FDA regulatory science needs (see current CERSI Regulatory Science Priorities)
7. Define and implement metrics with which to evaluate CERSI research project performance, outcomes, and impact (see current CERSI Research Impact Metrics)
8. Ensure that pertinent CERSI matters are communicated effectively by Center representatives within their Center or Office; that their leadership and staff, including FDA subject matter experts (SMEs), are kept apprised of significant CERSI activities and solicit input, as needed
9. Facilitate identification of appropriate FDA SMEs as collaborators and, when needed, FDA Center/Office project managers for CERSI projects
10. Ensure review of CERSI collaborative research proposals for their Center/Office for:
    a. Appropriateness of the project for the CERSI cooperative agreement grant mechanism
    b. Technology transfer considerations (e.g., Material Transfer Agreement (MTA), Collaborative Research and Development Agreement (CRADA), commercial confidential information (CCI)/confidential information (CI))
    c. Compliance with FDA statute, regulations, and policies (e.g. Federal Advisory Committee Act (FACA); Paperwork Reduction Act (PRA); FDA's Good Guidance Practice (GGP) regulations; FDA's Research Involving Human Subjects Committee (RIHSC) requirements)

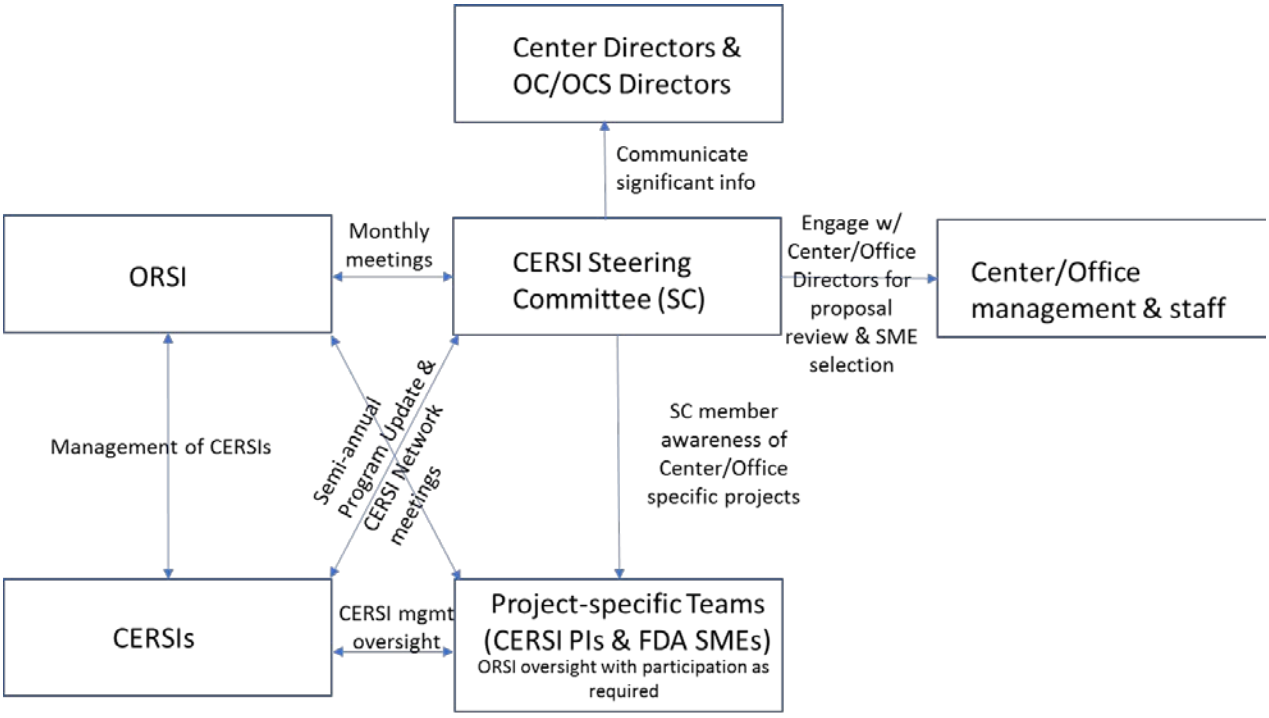
ORSI will:

1. Facilitate effective communication among ORSI, the CERSIs, and the CERSI-SC members
2. Manage the CERSI program and the individual CERSIs, including the following activities:
    a. Schedule CERSI-SC meetings with ORSI and CERSI Semi-Annual Program Update meetings with individual CERSIs; create (as needed) and provide relevant documents/handouts for meetings (e.g., Semi-Annual CERSI progress report)
    b. Maintain CERSI documents, including records of CERSI-SC activities
    c. Assist in establishing Project Specific Teams comprised of FDA SMEs and, when needed, FDA Center/Office project managers; facilitate, as appropriate, interactions with CERSI project scientists
    d. Provide advice and guidance to FDA Center/Office planning committee members for FDA-CERSI collaborative workshops
    e. Provide project management functions for each CERSI, to include (but not limited to) routine interactions with CERSI administration and management and monitoring of program and project status.

CERSI-SC Meetings

1. CERSI-SC will meet semi-annually with each CERSI academic institution to discuss its progress, any challenges, new opportunities, and plans/expectations for the next six months. Relevant FDA SMEs may be invited on an *ad hoc* basis.
2. CERSI-SC will meet monthly with ORSI to discuss issues pertinent to the CERSI program, including : 1) Prioritization of CERSI research projects for core grant funds, 2) Review of topics for FDA-CERSI collaborative workshops and lectures, 3) Development or review of CERSI program procedures and policies, including, but not limited to, research prioritization, fellowships, training and visiting scientists program, and 4) Review of the CERSI program's overall progress and achievements.
3. CERSI-SC will meet quarterly with the CERSI Network to discuss potential collaboration among the CERSIs, exchange experiences, and share best practices.

APPENDIX 1: FDA CERSI Program Management



APPENDIX 2: CERSI-SC Members

The Director of ORSI chairs the CERSI-SC. The following table lists the representatives of the CERSI-SC from each of the participating FDA Centers and Offices. ORSI staff involved in management of CERSIs will attend CERSI-SC meetings as participants.

FDA/Center/Office	Lead	Secondary Member
OCS/Office of Health Informatics	**Elaine Johanson**	**Roselie Bright**
OCS/Office of Minority Health and Health Equity	**Christine Lee**	**Richardae Araojo**
Office of Women's Health	**Bridget Nugent**	**Kaveeta Vasisht**
Oncology Center of Excellence	**Julie Schneider**	**TBD**
Center for Drug Evaluation and Research	**Ruth Barratt**	**Juan Ruiz**
Center for Biologics Evaluation and Research	**Emily Braunstein**	**Nisha Narayan**
Center for Devices and Radiological Health	**Edward Margerrison**	**Anindita Saha**
National Center for Toxicological Research	**Donna Mendrick**	**Tucker Patterson**
Center for Tobacco Products	**Jonathan Kwan**	**Keyur Patel**