PROject Management Oversight Training and Education (PROMOTE) Cancer Course

Course Directors

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Course Description

Developed by the Center for Global Health Equity at Dana-Farber Cancer Institute and the Zhu Family Center for Global Cancer Prevention at the Harvard. T.H. Chan School of Public Health, the Global Cancer Learning Lab **PROject Management Oversight Training and Education (PROMOTE)** course aims to maximize the rigor of cancer research by training researchers and project managers to develop, implement, and manage research projects, providing tools to find funding, prepare a proposal, and set up and manage their awards. The global training is appropriate for principal investigators and support staff who wish to build their career in cancer research. There is no cost to participate in the training.

The overarching goals of the PROMOTE course are to enable trainees to develop strategic and operational capacity and aims to:
1) develop trainees to use best practices that enable the highest quality cancer research
2) teach fundamental skills for leading research, and
3) foster career development to junior investigators and staff to lead and support cancer research.

The proposed training will provide training in competencies necessary to apply for, and manage, cancer research projects, and strengthen and develop cancer research leadership and support staff globally.

Intended audience

The course is designed for research investigators and project staff who wish to build their career in cancer research. It is expected that participants who have an assortment of different backgrounds or experiences will be interested in this topic.

Evaluation Plan and Benchmarks for Success

Evaluation will take place through quizzes and a certificate of completion will be available upon completion of the course. Students will be asked to assess the course curriculum and complete evaluations.

Learning Objectives

The objectives of this course are as follows:

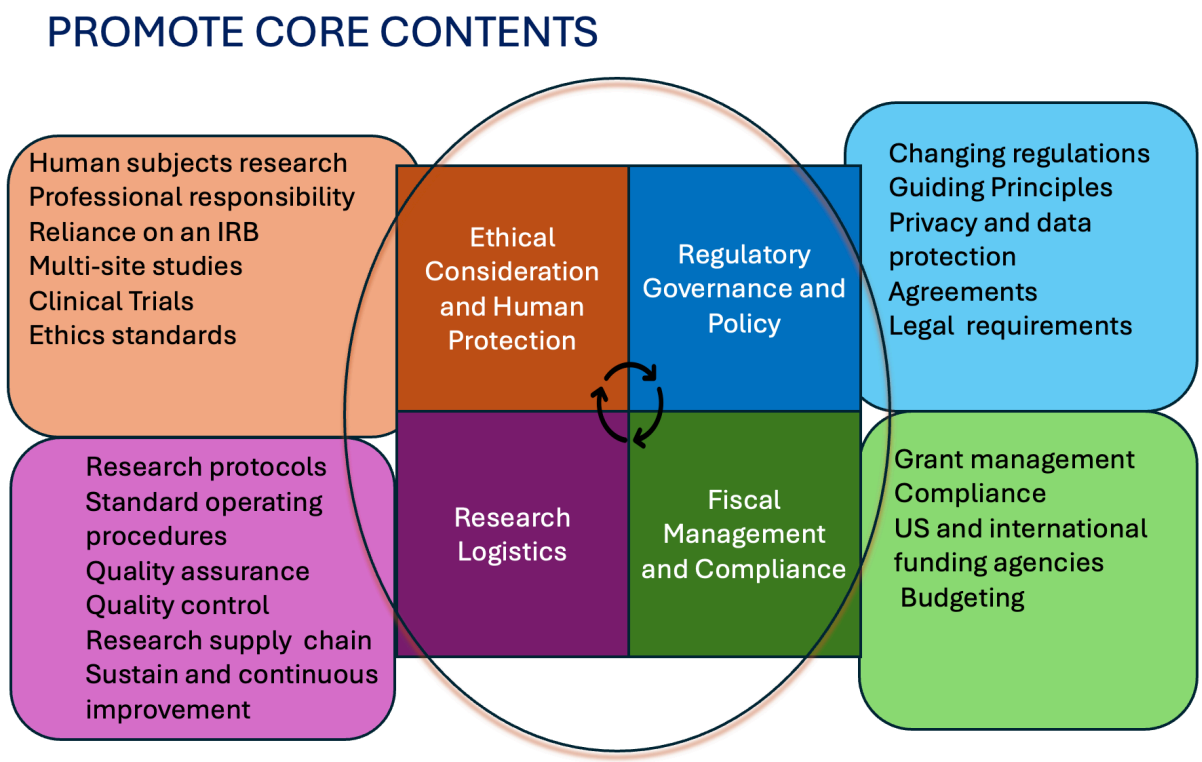
Obj 1: Equip participants with an understanding of regulations, policies, guidelines and agreements, and an understanding of ethics of human subject research to ensure responsible conduct of research.

Obj 2: Provide participants with a framework to understand intramural and extramural grants lifecycles to manage a grant compliantly, from submission, to post award monitoring and controlling.
Obj 3: Provide tools and resources to enable participants to understand research supply chain, standard operating procedures, and protocol logistics and requirements.

Obj 4: Teach participants the importance of quality assurance and quality control, identifying relevant metrics for tracking and interpretation of data to measure success, and continuously evaluate and identify success metrics and areas for improvement.

Course structure
PROMOTE is a distance (web-based) 4 modules, 12-session, asynchronous, virtual training in research oversight skills, principles and compliance standards. Participants have access to a suite of twenty-four lectures, accessible via the Harvard T.H. Chan School of Public Health's Canvas Training Services Portal (TSP), recorded by international leaders in health policy, regulation and research standards. Lectures are complimented by required and recommended reading to build on concepts and methodologies and enhance general understanding of the course material. Participants are encouraged to post questions using a Canvas discussion board, accessible to training participants, lecturers and training staff. Short quizzes will be administered before and after each module. Upon completion of all lectures and assessments, students will receive a certificate of completion. No academic credit is earned through course participation.

Course Overview
The figure below provides a breakdown of the PROMOTE Course consisting of four modules: Ethics, Regulatory, Fiscal, and Logistics.



Module Overview and Learning Objectives
MODULE 1-ETHICS

Session	Lecture and Discussion Topic	Detailed Learning Objectives
1	**Human subject research** *Embry Howell, Health Policy Center, Urban Institute, Washington, DC, USA*	• Understand the rights of human subjects involved in research studies. • Understand key ethical guidelines and identify common ethical concerns governing human subject research. • Analyze historical cases of unethical human experimentation and their implications. • Define vulnerable populations and recognize their specific protections in research. • Understand inclusion and exclusion criteria of vulnerable populations in research.
	Professional Responsibility *Oluwafemi Popoola, University College Hospital, Ibadan, Nigeria*	• Describe the key components of professional health care obligation, including accountability and explain how these guide decision-making in clinical settings. • Identify and explain the legal and ethical responsibilities of health care providers to patients • Outline the roles and responsibilities of professional cancer healthcare providers, explaining how coordinated care improves patient outcomes.
	Confidentiality and HIPAA *Pedro Fernandez, Stellenbosch University, Stellenbosch, South Africa*	• Identify professional responsibilities and ethical principles in clinical practice • Navigate the complexities of ethical decision-making, analyzing cases using ethical frameworks. • Understand the importance of effective communication and collaboration in professional healthcare settings.
2	**Challenges of Multi-Site Studies** *Julie Chamberlin, Harvard School of Public Health, Boston, MA, USA*	• Explain key factors that contribute to the complexity of setting up multi-site operations. • Identify common challenges in managing multi-site studies. • Describe and apply strategies to effectively address multi-site management challenges.
	External Reliance on an IRB and sIRB *Julie Chamberlin, Harvard School of Public Health, Boston, MA, USA*	• Define an external IRB and explain it's role in reviewing research across multiple institutions • Identify when use of a single IRB is required and outline how is it developed. • Describe key institutional agreements that support the use of an external IRB.
3	**Cancer Clinical Trials** *Isaac (Olesegun) Alatishe, Obafemi Awolowu University, Ife, Nigeria*	• Identify key regulatory, ethical, and logistical requirements for conducting clinical trials. • Describe challenges of clinical trial implementation. • Explain strategies to address challenges to successful execution of oncology clinical trials.

Session	Lecture and Discussion Topic	Detailed Learning Objectives
4	**What is the IRB?** *Catherine Falade, University College Hospital, Ibadan*	• Define an Institutional Review Board (IRB) and explain its importance in protecting human research participants. • Describe how an IRB is established and identify it's key roles and responsibilities. • Outline the steps for submitting a research protocol and obtaining IRB approval. • Explain when an IRB amendment is required, and how to submit it for approval.
	Regulatory Compliance and Research Standards *Emmanuel Ezeome, University of Nigeria Teaching Hospital, Enugu, Nigeria*	• Describe the key elements of regulatory compliance. • Explain steps to establish and maintain regulatory compliance within an organization. • Identify methods to evaluate and ensure adherence to research standards.
	Global Ethics Standards and Compliance *Emmanuel Ezeome, University of Nigeria Teaching Hospital, Enugu, Nigeria*	• Define global ethics and compliance in international research and healthcare. • Identify common ethical issues encountered in global research. • Describe strategies to maintain ethics compliance within institutions.

MODULE 2-REGULATORY

Session	Lecture and Discussion Topic	Detailed Learning Objectives
5	**Guiding Principles** *Akin Adebiyi, University College Hospital, Ibadan, Nigeria*	• Identify the key principles involved in establishing effective regulatory processes. • Define what a regulatory framework is and its purpose. • Outline the steps to design and implement a regulatory framework within an organization.
	Data Privacy *Decanda Faulk, USPASS (General Counsel), United States*	• Explain the fundamental principles of data privacy. • Identify best practices for safeguarding data. • Describe challenges in data management and protection. • Recognize ethical and legal considerations for data use
6	**Data and Material Agreements** *Emy Chen, Belfer Office for Dana-Farber Innovations, Dand-Farber Cancer Institute, Boston, MA, USA*	• Define data and material agreements and their purposes in research collaborations. • Understand the differences and similarities between data and material agreements. • Outline the steps to create effective data and material agreements
	International Transfer Agreements *Lindsay Petersen, Mediclinic Precise, Cape Town, South Africa*	• Understand the key requirements for international data and material agreements. • Identify country-specific regulations and describe how they affect international transfer agreements. • Describe the role of import and export permits and outline the process to obtain them.

MODULE 3-FISCAL

Session	Lecture and Discussion Topic	Detailed Learning Objectives
7	**Grant Funding: Cancer Research UK** *Talisia Quallo and Sarah Carden, Cancer Research UK, London, UK*	• Understand how the CRUK grant funding mechanism works. • Understand how to apply for and manage CRUK grant funding.
	Grant Funding: National Institutes of Health *Sudha Sivaram, National Institutes of Health, Bethesda, MD, USA*	• Understand how the NIH grant funding mechanism works. • Understand how to apply for and manage NIH grant funding.
8	**Challenges with Implementation of Award Requirements** *Angelina Fink, Moffitt Cancer Center, Tampa, FL, USA*	• Understand how the NIH grant funding mechanism works. • Understand how to apply for and manage NIH grant funding.
	Federal Requirements for Grant Funding *Leah Gibbons, Dana-Farber Cancer Institute, Boston, MA, USA*	• Understand the meaning of the institutional, regulatory, or funding requirements. • Explain the importance of these requirements in ensuring compliance and accountability
9	**The Basics of Budgeting, Invoicing, and Payments** *Osinkolu Babasanmi, University College Hospital, Ibadan, Nigeria*	• Describe the basics of budgeting, invoicing, and payment processes in grant and project management. • Understand reporting systems and grant application systems.

MODULE 4-LOGISTICS

Session	Lecture and Discussion Topic	Detailed Learning Objectives
10	**Standard Operating Procedures** *Jo McBride, Independent Consultant, Cape Town, South Africa*	• Understand Standard Operating Procedures (SOPs) and describe how they are developed, approved, and implemented in research settings. • Understand the components of a research protocol, and steps involved in its development.
	The Research Supply Chain *Diana Whellams, American Society for Clinical Pathology, University of British Columbia, Vancouver, BC, Canada*	• Describe the components and processes involved in the research supply chain. • Understand how to design, implement and manage an effective research chain.
11	**Quality Assurance** *Oluwafemi Popoola, University College Hospital, Ibadan, Nigeria*	• Explain the importance of quality assurance in maintaining standards and ensuring compliance in research. • Identify and describe the steps required to create and implement a quality assurance plan.
	Sustain and Continuous Improvement *Christine Cronin, Dana-Farber Cancer Institute, Boston, MA USA*	• Describe strategies for maintaining long-term project success and impact. • Identify steps to ensure continuous improvement on projects
12	**Success Metrics: Qualitative** *Anna Revette, Dana-Farber Cancer Institute, Boston, MA USA*	• Understand what qualitative success metrics are. • Describe how to design and apply qualitative success metrics. • Identify the limitations of qualitative success metrics.
	Success Metrics: Quantitative *Daniel Gundersen, Dana-Farber Cancer Institute, Boston, MA USA*	• Understand what quantitative success metrics are. • Describe how to design and apply quantitative success metrics. • Identify the limitations of quantitative success metrics.