

Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online)

January – May 2025

Module 1: Introduction to the Ethical Conduct of Research

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| 1 | Framework for the Ethical Conduct of Research | Christine Grady, RN, PhD |
| 2 | History of Research Ethics | <i>Susan E. Lederer, PhD</i> |
| 3 | Institutional Review Boards | Holly Taylor, PhD, MPH |

Module 2: Informed Consent

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| 1 | Informed Consent | Christine Grady, RN, PhD |
| 2 | Research Involving Persons at Risk for Impaired Decision-Making | Scott Kim, MD, PhD |
| 3 | Capacity to Provide Informed Consent in Research | Carol Squires, MSSW, LCSW |
| 4 | Nuts and Bolts of Consent | Holly Taylor, PhD, MPH |

Module 3: Study Design, Value, & Children in Research

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| 1 | Introduction to Study Design | Holly Taylor, PhD, MPH |
| 2 | Risk-Benefit Assessment in Clinical Research | David Wendler, PhD |
| 3 | Ethical Inclusion of Children in Research | <i>Seema Shah, JD</i> |

Module 4: Equity, Subject Selection, & Recruitment

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| 1 | Equity in Clinical Research | Yukiko Asada, PhD |
| 2 | Participant Selection | Holly Taylor, PhD, MPH |
| 3 | Recruitment and Retention | <i>Aisha T. Langford, PhD, MPH, FSBM</i> |

Module 5: Genomic Findings

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| 1 | Ethics in Returning Genomic Research Results | Ben Berkman, JD, MPH |
| 2 | Outcomes Associated with Opportunistic Screening for Secondary Findings | Julie Sapp, ScM, CGC |
| 3 | Genetics and Inclusion of Indigenous Populations | <i>Katrina Claw, PhD</i> |

Module 6: Participant Experience

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| 1 | Healthy Participants in Clinical Trials | <i>Jill Fisher, PhD</i> |
| 2 | Enrollment of Uninsured Patients in Clinical Research: Case Discussion | Holly Taylor, PhD, MPH |
| 3 | Participant Panel | Various speakers |

Module 7: International Research Ethics

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| 1 | International Research Ethics: Introduction & Standards of Care | Robert Steel, PhD |
| 2 | Post-trial Obligations | <i>Joseph Millum, PhD, MSc</i> |
| 3 | Community Engagement in Health Research | <i>Dorcas Kamuya, PhD, MSc</i> |

Italicized names are for non-NIH guest lecturers.

Content for this asynchronous/online course was adapted from the live course, Ethical and Regulatory Aspects of Clinical Research, offered by the Department of Bioethics at the NIH Clinical Center, in fall 2024.