Defense Health Agency (DHA) Clinical Communities Speaker Series

Resource List – September 2020

Military Health Care- Select Promising Practices

Ethical Implications of Human-Subject Research Oversight: A Generation of Vipers

Bioethics is the study of ethical, social, and legal issues that arise in biomedicine and biomedical research. Person-oriented research ethics: Integrating relational and everyday ethics in research, provides a toolkit to individual researchers, research groups, and research institutions in both biomedical and social science research. This article identifies five practical guideposts of person-oriented research ethics: respect for holistic personhood, acknowledgement of lived world, individualization, focus on researcher-participant relationships, and empowerment in decision-making. The relational and everyday aspects of human subject research is explored.

The National Institute of Environmental Health Sciences (NIEHS) has a Bioethics Program that provides educational, scholarly and administrative support for research integrity. This program provides annual training in responsible conduct of research and sponsors workshops, seminars, and focus groups on ethical issues in health research. Collaboration occurs with the NIEHS Ethics Office, Institutional Review Board, Office of Human Research Compliance and Office of the Scientific Director. The Bioethics program helps to develop institutional policies that promote research integrity and compliance with federal research policies and regulations.

The U.S. Food and Drug Administration (FDA) has a dedicated webpage for Clinical Trials and Human Subject Protection. The FDA's regulations for the conduct of clinical trials address both good clinical practice (GCP) and human subject protection. FDA regulations and guidance documents, and international GCP guidance documents on which the FDA has collaborated, and that have been adopted as official FDA guidance, are found here. The bioresearch monitoring (BIMO) program that conducts on-site inspections of both clinical and nonclinical studies is detailed.

The COVID-19 pandemic poses a threat to global public health and socioeconomic stability. Scientists around the world are feverishly studying the virus to determine treatment options and develop a vaccine. The World Health Organization published Key criteria for the ethical acceptability of COVID-19 human challenge studies. This document aims to provide guidance to scientists, research ethics committees, funders, policy-makers, and regulators in deliberations regarding SARS-CoV-2 challenge studies. Key criteria is outlined that would need to be satisfied in order for such studies to be ethically acceptable.

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References

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