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Project Title: ESPECIALLY DIFFICULT CHALLENGES IN EPIDEMIOLOGY AND PUBLIC HEALTH RESEARCH

Description:
The University of Miami project will produce three short courses on especially difficult challenges in epidemiology and public health research, and a workshop for journalists on how to cover issues in research ethics. While there is a sense in which many issues in epidemiology and human subjects research are "difficult," the goal here is to provide instruction and develop model curricula to address issues for which standard models of valid consent and scientific practice may be inadequate and for which too little attention has been devoted in scholarly research and literature. Thus, in addition to overviews and surveys, the following issues will be addressed:

- **Research in genetically isolated communities.** While challenges associated with banked tissue and sera are fairly well known, genetic research in isolated communities raise particularly acute problems related to overseas research in developing nations, consent and subgroup stigma. (Faculty: geneticist with projects in the Bahamas.)

- **Social goals of public health research.** The very idea of a health risk profile - which is required for guiding public health research and policy - embeds presumptions, often stereotypical, about communities and research cohorts. This raises the chance of bias at the core of some public health research projects. (Faculty: pediatrician-historian.)

- **Ethics and biostatistics.** The use of a broad variety of statistical tools raises ethical issues related to induction and error avoidance. Special attention will be paid to the use of meta-analysis in drawing scientific conclusions and need for IRBs to be familiar with meta-analytic research in evaluating risk. (Faculty: epidemiologist-biostatistician)

- **Ethical issues in occupational and environmental health.** The role of the "company doctor" raises a problem in terms of conflict of interest, workplace testing and screening, international harmonization and cultural relativism. (Faculty: physician-epidemiologist.)

- **Data sharing and proprietary interests in bioinformatics.** Controversies in basic science spill over into molecular epidemiology and genetic research when policies and practices impede the free flow of information - an issue that will increase in importance along with the expanding digitization of genetic information. (Faculty: cell biologist-informaticist)

- **Scientists as advocates for social policies.** From HIV-AIDS reduction strategies to homeless and poverty, health scientists often see or are convinced of the need to apply their research to social problems. However, scientists as advocates risk a conflict of interest as well as damage to their credibility. (Faculty: sociologist-ethicist.)

- **Role of the IRB in evaluating ethically challenging protocols.** The evolution of the IRB review process has been shaped by "standard" sorts of research, i.e., randomized, blinded, controlled experiments. However, many protocols are increasingly not of this sort at all, and IRBs need to become better able to evaluate them. To include a "mock IRB" session. (Faculty: physician-IRB chair.)
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