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December 28, 2007

Ivor Pritchard, PhD
Acting Director
Office for Human Research Protections
The Tower Building
1101 Wootton Parkway
Suite 200, Rockville, MD 20852

Dear Dr. Pritchard:

The Infectious Diseases Society of America (IDSAs) is strongly committed to facilitating clinical and epidemiological research. IDSAs represents more than 8,000 infectious diseases (ID) physicians and scientists devoted to patient care, education, research, and public health. Research is the primary activity of over one-third of our membership. Properly conducted research is a critical aspect of efforts to improve the prevention and treatment of infectious diseases.

Therefore, IDSAs is pleased to have the opportunity to comment on proposed changes from the Office for Human Research Protections (OHRP) to the "Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure," published in 1998.

IDSAs applauds the efforts of OHRP to clarify the criteria for expedited review. The expedited review mechanism is an important means for bringing efficiency to the review process for low-risk research while preserving a rigorous independent review. Confusion about the interpretation of the criteria for the use of expedited review appears to be leading IRBs to require full-board review for protocols that do not require that level of review. We recommend the following proposed changes:

- Include in the description of the "Categories of Research that may be reviewed by the IRB through an Expedited Review Procedure" contained in "Applicability Section D" of the Federal Register a definition or reference link for what qualifies as "classified" research.
- In Research Categories Section 3, Category G, change the wording from "amniotic fluid obtained at the time of rupture of the membrane prior to or during labor" to "amniotic fluid obtained at the time of spontaneous rupture or medically indicated rupture of the membrane prior to or during labor."
- In Research Category, Section 3, Category J, change "sputum collected after saline mist nebulization" to "sputum collected after saline mist nebulization or via spontaneous production."
- In Section 4, define "x-ray" or provide examples (for instance, radiographic procedures that expose the participant to ionizing radiation or other potentially harmful forms of radiation, including but not limited

to plain film radiography, computerized axial tomography, and nuclear imaging medical studies). In everyday usage, the term x-ray is often used imprecisely to describe a range of radiographic studies.

Comments on OHRP’s Proposed Amendment to Research Category 5

OHRP is proposing to amend expedited review category 5 to clarify that the category includes research involving materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research. We support the proposed revision.

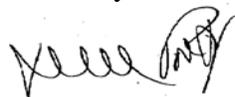
Comments on the recommended revision of the Secretary's Advisory Committee on Human Research Protections for Research Category 7

The Secretary’s Advisory Committee on Human Research Protections proposed to revise expedited review category 7 as follows: “Research (a) on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, affective states, interpersonal relationships, identity, language, communication, cultural beliefs or practices, and social behavior); or (b) employing methods commonly used in social, behavioral, epidemiologic, health services and educational research (including, but not limited to, survey, interview, oral history, participant observation, ethnographic, focus group, program evaluation, human factors evaluation, or quality assurance methods). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)”

We support the proposed revision and agree with the clarification. The stratification of research that would be considered possibly appropriate for expedited review procedure into A and B categories is appropriate, and we concur that a further elucidation of possible study data be included in Category B.

IDSA supports OHRP’s proposed changes in the criteria for expedited review. Greater clarity about the criteria for expedited review should help local IRBs appropriately use this important review mechanism. Should you have any other questions concerning this matter, please contact Beth Rada, MS, Program Officer for Science and Research, at brada@idsociety.org or 703-299-1216.

Sincerely,



Donald Poretz, MD, FIDSA
IDSA President