

APPENDIX A1.1.8
DHHS LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Child Health
and Human Development
Bethesda, Maryland 20892

November 14, 2003

Karen Terry, Ph.D.
John Jay College of Criminal Justice
Department of Law, Police Science and Criminal Justice Administration
899 Tenth Avenue
New York, NY 10019

Dear Dr. Terry:

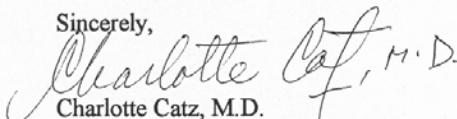
This letter responds to your request for a certificate of confidentiality under Section 301(d) of the Public Health Service Act, 42 U.S.C. 241(d), for a project entitled "The Nature and Scope of the Problem of Sexual Abuse of Children by Catholic Priests and Deacons within the United States." The project is funded through a contract from the National Review Board of the U.S. Conference of Catholic Bishops. Thank you for the extensive information you have provided in support of this application.

Your study offers the potential for new knowledge to be developed, and it is hoped that the causes of child sexual abuse may be better understood and that future harm to children may be prevented. NIH supports these goals and applauds your initiative in undertaking this important study. However, after careful deliberation concerning the relevant facts and circumstances, we have determined that a certificate is not necessary to achieve the research objectives.

Your study plan includes multiple and wide-ranging protections for subject identifiers such that the IRB reviewing your work determined the study design to be sufficiently subject-protective that it found no more than minimal risk to the subjects and waived the requirement for informed consent under 45 C.F.R. § 46.116. The authority to issue certificates of confidentiality is an extraordinary legal power vested with the Secretary, Department of Health and Human Services and his delegates to promote the participation of subjects in sensitive research by assuring them that investigators cannot be compelled to release information that could be used to identify them. NIH issues them sparingly and generally requires that subjects be informed about the certificate.

Given your study design and other factors identified in the written application and follow-up meetings, we do not believe a certificate is necessary to achieve your research goals. Again, thank you for providing us with the extensive information on which we based this decision. I wish you every success in completing your research.

Sincerely,


Charlotte Catz, M.D.
Special Assistant for Clinical Research