



NATIONAL HEALTH COUNCIL

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**Comments of the National Health Council  
on the Food and Drug Administration's Proposed Rule for  
Institutional Review Boards; Registration Requirements**

**Docket No. 2004N-0242**

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Food and Drug Administration  
Division of Documents Management  
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The National Health Council (NHC or the Council) is pleased to submit these comments in response to the Food and Drug Administration’s (FDA) Proposed Rule requiring institutional review boards (IRBs) to register with the Department of Health and Human Services (HHS).

The National Health Council, a private, nonprofit umbrella organization of more than 110 national health-related organizations, works to bring quality health care to all people. Its core membership includes more than 50 of the nation’s leading voluntary health agencies (patient-based organizations), including the American Cancer Society, American Diabetes Association, American Autoimmune Related Diseases Association, National Mental Health Association, Lupus Foundation of America, and the Epilepsy Foundation—which collectively represent approximately 100 million people with chronic diseases and/or disabilities. Other Council membership categories include professional and membership associations such as the American Academy of Family Physicians, nonprofit organizations with an interest in health such as AARP, and business and industry including Pfizer Inc and Novartis.

The National Health Council fully supports FDA’s proposed rule to require IRBs to register with the federal government. The Council supports the development of a comprehensive and centralized list of IRBs within HHS and feels that such a reporting requirement will provide the FDA and HHS with valuable information related to IRB activity. Such data collection will allow the federal government to better assess and evaluate the extent and value of IRB accreditation. As a recommendation proposed in a 1998 HHS Office of Inspector General (OIG) report on IRBs states, “all IRBs should register with the Federal Government on a regular basis as part of an effort to develop more streamlined, coordinated, and probing means of assessing IRB performance and enhance the Federal Government’s ability to identify and respond to emerging problems before they result in serious transgressions.”<sup>1</sup>

### **Protections for Human Research Participants**

Clinical research and protections for human research subjects are a top priority for NHC. In 2001, NHC joined six other national organizations deeply committed to the ethical conduct of human research and human participant safety in creating the Association for the Accreditation of Human Research Protection Programs. AAHRPP is a nonprofit entity that employs a voluntary, peer-driven, educationally based model of accreditation. AAHRPP was founded on the belief that ethical soundness and scientific merit in research are inextricably intertwined, and are critical to ensuring the safety of people who enroll in research.

NHC joined as a founder of AAHRPP because of its concerns for protecting the rights and welfare of people who participate as research subjects. To promote the protection of research volunteers, to address allegations of carelessness and corner-cutting by investigators and their institutions, and to avert the federal government’s suspension of clinical research (which occurred in some of the nation’s most prestigious academic medical centers), research organizations must demonstrate that they conform to the highest ethical, participant protection, and scientific standards and to all federal and state requirements. In this way, research organizations will be as accountable to the public for human research as they are currently for

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<sup>1</sup> OIG, HHS, “Institutional Review Boards: A Time for Reform,” June 1998.

animal research. We believe that only full participation by research organizations will preserve the public's confidence in research, which holds so much potential to improve health and quality of life.

The primary mission of IRBs is to safeguard the rights and welfare of human test subjects -- both before and during their involvement in a medical research study. These impartial review panels perform the job of risk/benefit assessment -- ensuring that the risks are both minimized and fairly disclosed to study participants when testing drugs, vaccines, or medical devices.

IRBs have the authority to approve, require modifications to, or disapprove the proposed study protocols and consent forms for research which will involve human subjects. In addition, IRBs must review and approve or disapprove the investigator for the research. Once approved, the IRB must monitor the progress of ongoing research. IRBs are a crucial piece of the clinical research enterprise and are vital to ensuring the safety of human subjects and the integrity of the institution. The best way to ensure that IRBs are performing their duties properly is to make sure they are accredited.

The Council strongly encourages IRBs to become accredited. In fact, the Council encourages its members that provide research grants to include three questions in all of their grant applications: 1) Is your organization's human research protection program accredited? 2) If yes, by which accrediting body? 3) If no, does your organization plan to seek accreditation? This simple step will help to raise awareness among investigators and their research institutions about accreditation and send a clear message that voluntary health agencies take seriously the protection of human participants in research.

### **Benefits of Accreditation**

According to the HHS Secretary's Advisory Committee on Human Research Protections, the figures on accreditation are too limited to allow for a valid review of the self-regulatory system's effectiveness. This conclusion makes it clear that more data is needed to properly evaluate the value of accreditation. The Council recognizes that in many instances, the IRB is part of a larger organization such as a university or academic health center that will be registering its IRBs. It is also true that it will be organizations and institutions that will be accredited. The Council supports HHS' efforts to establish a simple, central repository that would make it easier for FDA and HHS to review research organizations, convey important information to them, and most importantly, collect the data necessary to fully evaluate the effectiveness of accreditation.

Proponents of accreditation point to its many benefits, from improving human research protection programs and improving research quality to building public trust and support for human research. However, more data is needed to scientifically validate such conclusions. HHS' proposal to require IRBs to register is an important first step in the data collection and evaluation process, and NHC supports this proposal precisely to facilitate this process.

### **Electronic Registration**

The Council also supports FDA's proposal to create a simple, electronic registration system that all IRBs, regardless of whether they review clinical investigations regulated by FDA or research conducted or supported by HHS, can use. The Council recognizes that in many instances, the

IRB is part of a larger organization such as a university or academic health center that will be registering their IRBs, so electronic access should not be a burden. However, the Council is aware that not all institutions have electronic capabilities or access to the Internet, thus, NHC supports FDA's proposal to allow such institutions that lack electronic registration capabilities to send its registration information in written format directly to FDA. Additionally, FDA has asked for comments regarding whether it should discontinue written submission of registration after an unspecified time period has elapsed. NHC supports conversion to electronic submission as soon as possible, but feels that it is important to allow smaller organizations to acquire the needed technology.

### **Enforcement**

In order to make any regulatory requirement fully functional, enforcement mechanisms need to be in place. The Council proposes that FDA amend the Investigational New Drug (IND) regulations to authorize the agency to place a study on hold if a sponsor or investigator uses an unregistered IRB. The Council also urges FDA to consider additional enforcement options such as refusing to consider information from an application for a research permit for a clinical investigation that is reviewed or is to be reviewed by an unregistered IRB.

### **Conclusion**

The National Health Council is committed to ensuring that human research subjects are protected and the clinical research enterprise remains vibrant and well-supported by the public, federal and state governments, and the private sector. Requiring IRBs to register with HHS is a necessary first step to ensure that people continue to believe that their support for, and personal involvement in, clinical research is valued, respected, safe, kept confidential when it needs to be, and, ultimately, will lead to new treatments and cures for those with serious chronic and often, life threatening conditions. NHC looks forward to working with the FDA and HHS on this important issue.