



New Assurances in the IPF

Commons Working Group Meeting
5/22/2005



O. Smoke- Free Workplace

- The PHS strongly encourages all grant recipients to provide a smoke-free workplace and to promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

R. Prohibited Research

BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (Section 510)

- This section continues the current ban that prohibits NIH from using appropriated funds to support human embryo research. Grant, cooperative agreement, and contract funds may not be used for: "(a)...(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR Part 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). (b) For purposes of this section, the term 'human embryo or embryos' includes any organism not protected as a human subject under [45 CFR Part 46](#) as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."
- The NIH has published final guidelines on the allowability of Federal funds to be used for research on existing human embryonic stem cell lines. The URL is <http://stemcells.nih.gov/index.asp>.

R. Prohibited Research

LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES (Section 511)

"(a) None of the funds made available in this Act may be used for any activity that promotes the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C.812). (b) The limitation in subsection (a) shall not apply when there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage."

RESTRICTION ON DISTRIBUTION OF STERILE NEEDLES (Section 505)

"Notwithstanding any other provision of this Act, no funds appropriated under this Act shall be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug."

RESTRICTION ON ABORTIONS (Section 508)

"(a) None of the funds appropriated under this Act, and none of the funds in any trust fund to which funds are appropriated under this Act, shall be expended for any abortion."

S. Select Agents and Toxins

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) is designed to provide protection against misuse of select agents and toxins whether inadvertent or the result of terrorist acts against the United States homeland or other criminal acts. The Act was implemented, in part, through regulations published by CDC at 42 CFR 73 <<http://www.cdc.gov/od/sap/docs/42cfr73.pdf>>, Select Agents and Toxins.

- As a term of award, grantees who conduct research involving Select Agents (see 42 CFR 73 for the list; and 7 CFR 331 and 9 CFR 121 for the relevant animal and plant pathogens) are reminded that they must complete registration with CDC (or USDA, depending on the agent) before using NIH funds. No funds can be used for research involving Select Agents if the final registration certificate is denied.
- Research involving select agents and recombinant DNA molecules also is subject to the NIH Guidelines for Research Involving DNA Molecules (NIH Guidelines) (see Recombinant DNA and Human Gene Transfer Research in this subsection for applicability of these guidelines).

Other Information

- Reworded Assurances

- Human Subject Research
- Recombinant DNA Research, including Human Gene Transfer Research
- Complete assurances document at:
<http://grants1.nih.gov/grants/funding/phs398/phs398.html> (MS Word or PDF)



Commons Implementation

- Add these to IPF
- SO will need to check these off before any eSNAPs can be submitted
- What is best way to notify all SOs?
- Helpdesk will be in the loop