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HHS Proposes Revised Regulations on Misconduct in Research

On 16 April, the Department of Health and Human Services (HHS) proposed extensive changes to regulations related to institutional response to scientific misconduct¹. HHS proposed deleting 42 CFR, part 50, subpart A ("Responsibilities of Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science") and adding a new part 93 to "implement legislative and policy changes that have occurred since the regulation was issued, including the common Federal policies and procedures on research misconduct issued by the Office of Science and Technology Policy¹." These changes are expected to foster public confidence in scientific integrity and in the Public Health Service—(PHS)—supported research process.

The existing Final Rule (42 CFR 50.102) defines 'scientific misconduct' as "fabrication, falsification, plagiarism (FFP), or other practices for proposing, conducting, or reporting research." In line with the Office of Science and Technology Policy (OSTP), section 93.103 of the proposed regulation defines 'research misconduct' in relation to "proposing, performing, or reviewing research, or in reporting research results," and broadens the scope of the covered activities by including the review of research.

The following are additional definitions included in the proposed regulation:

Data or results: is defined in section 93.226 to include "all forms of scientific information about the research at issue without regard to the type of recording or storage media involved. The phrase would include, but not be limited to, raw numbers, field notes, interviews, notebooks and folders, laboratory observations, computers and other scientific equipment, CD-ROMs, hard drives, floppy disks, Zip disks, back-up tapes, machine counter tapes, research interpretations and analyses, tables, slides, photographs, charts, gels, individual facts,

Regulation Update

USDA Announces National Animal Identification System

On 27 April, US Department of Agriculture (USDA) Secretary Ann M. Veneman followed up on her December 2003 plan to implement a national animal identification system for all species. Veneman outlined the strategy for implementing a National Animal Identification System (NAIS) for identifying agricultural premises exposed to a foreign animal disease³. Hastened by the discovery of a BSE-positive cow in Washington State, the new system will improve USDA's response to animal disease outbreaks by speeding their detection, containment, and eradication.

Initially, USDA will transfer \$18.8 million from the Commodity Credit Corporation to fund the program in FY 2004, but additional private and public support will be required to make this program fully operational. The proposed FY 2005 budget includes another \$33 million for the effort. The implementation of a NAIS will be conducted in three main phases. In Phase I, USDA will evaluate current federally funded animal identification systems and determine which system(s) should be used for a NAIS. In Phase II, USDA will implement the selected animal identification system at regional levels for one or more selected animal species, continue communication and education efforts, address regulatory needs, and working with Congress on any needed legislation. Phase III will be marked by a scale-up of the identification selected system(s) to the national level.

The USDA will select an interim data repository to handle incoming national premises data, then enter into cooperative agreements with states, Indian tribes, and other government entities to help them adapt their existing systems to the new system.

statistics, tissue samples, reagents, and statements by individuals."

Statements by individuals: are "documented oral representations of research results made by scientists and, therefore, would also be considered to be 'data'."

Burden of Proof: would require that the FFP be a 'significant departure' from generally accepted practices.

Errors: "The proposed sections 93.106(a) and 93.516(c) require respondents to prove any affirmative defenses raised, including honest error and differences of opinion and any mitigating factors that the respondent wants the institution or HHS to consider in imposing administrative actions." The level of intent would be expanded beyond an intentional and knowing standard to include recklessness.

Plagiarism and the definition of research misconduct: "Section 93.102 of the proposed regulation would be applicable to PHS supported research 'including any research proposed, performed, reviewed, or reported regardless of whether the user or reviewer receives PHS support.' The misconduct regulation would cover respondent who have "copied or appropriated

ideas or data from another's PHS supported research, for example, where the respondent is a reviewer in the PHS grants review process or where the respondent is a reviewer for a scientific journal."

According to Jeffrey Brainard², of *The Chronicle of Higher Education*, the proposed changes to the regulations would:

- "Require institutions to protect "the positions and reputations" of whistle-blowers who file complaints in good faith, even if the allegations are subsequently proved wrong. However, institutions may also take actions against complainants who act "not in good faith," defined as making a complaint with knowledge or reckless disregard of information that the allegation is untrue.
- "Make institutions prove research misconduct by a "preponderance of the evidence," meaning that the allegation is more likely than not to be true. Some institutional officials have suggested using stricter standards of proof.
- "Impose a statute of limitations of sorts. The regulations would apply only to alleged misconduct that occurred no longer than six years before the research

institution or the Department of Health and Human Services received a complaint. Some exceptions would be provided.

- “Establish a more-detailed process for people found to have committed research misconduct to appeal that finding to the department. Research institutions must report their investigations of alleged misconduct to the department, which then decides whether to block the scientists from receiving federal research funds.
- “Give institutions the discretion to define research misconduct more broadly than has the department.”

References

1. HHS. Proposed rule. Public Health Service policies on research misconduct. *Federal Register* **69(74)**, 20777–20803 (16 April 2004).
2. Brainard, J. New rule proposed on research misdeeds. *Chronicle of Higher Education* (30 April 2004).
3. USDA. News Release. Veneman announces framework and funding for national animal identification system. (27 April 2004).