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interest in order to minimize the reporting and recordkeeping burden.

Recommendation No. 9
Cognizance for regulations in the specific area of the protection of human subjects should be assigned to the Department of Health, Education, and Welfare, acting with the advice and consent of an appropriate interagency committee.

No agency other than HEW should be permitted to paraphrase, interpret or particularize these regulations. Enforcement responsibilities may, if desired, be assigned to other agencies, particularly if the organization involved has no grant or contract with HEW in which human subjects are used. However, in the regulations for a controversial subject of this nature there should be a mechanism for the Federal Government to speak with one voice.

Single Agency Cognizance

There has been a steady increase in the number of areas in which, as in the case of human subject protection, the Federal Government interacts with individuals and organizations of all types. Each individual and organization is likely to deal with a growing number f Federal agencies, each with its own regulations, constraints, and injunctions. In the absence of interagency coordination, these egulations may very well be inconsistent with one another and in some cases even be in direct conflict.

The cognizant agency concept has been used for many years as a means of coordinating Federal requirements in a given area. Such coordination is particularly needed when the area and the requirements are technical, complicated, or not readily comprehensible. Examples include the Internal Revenue Service, the Patent Office, the Copyright Office, and the Cost Accounting Standards Board. Another instance is the cognizance over Federal statistical activities which has been assigned to the Statistical Policy Division of OMB. These agencies have been assigned complete responsibility, within the limits imposed by statute, for the development of all regulations in their fields. In other words, they are the cognizant agencies in their areas.

A less effective arrangement is one in which a single agency acts as the lead agency, providing the major initiative. Under the lead agency concept, in contrast to that of the cognizant agency, separate regulations may be issued by agencies other than the lead agency, with a strong possibility of inconsistency, incompatibility, or conflict.

In some cases, cognizance may be assigned to two or more agencies, each being given a mutually exclusive area. In one instance, the equal employment opportunity requirements for Government contractors have been divided by sectors: cognizance for contract compliance in the education and other nonprofit sectors has been assigned to HEW, as pointed out in a ater section. In another instance, the financial audit and negotia-

tion cognizance for each college and university was assigned to a single agency. This was accomplished through the Office of Management and Budget Circular A-88, first issued May 15, 1968. This Circular, subsequently but temporarily renamed FMC 73-6, assigned most of these institutions to HEW, although others are under the cognizance of the Departments of Defense or Interior or of the Energy Research and Development Administration. These assignments have meant that each institution needs to deal with only one agency, a development that has proven more efficient for the agencies as well as for the institutions.

Use of the cognizant agency principle was suggested in this section for the protection of human subjects, and it is recommended in a later section for equal opportunity reporting. A further example, the disposition of patent rights under federally-sponsored programs, is given below. In addition, one section of the Commission's health report deals with the cognizant agency concept as a long-term approach for the elimination of unnecessary paperwork. The principle, as a long range approach, has potential value in the resolution of future problems and, indeed, in the prevention of problems.

Patent Rights. The disposition of rights to patents made under Government-sponsored contracts and grants was the subject of a Memorandum and Statement of Government Patent Policy issued by the President October 10, 1963. Some revisions, based on the results of studies and of experience gained under the 1963 Statement, were incorporated into a revised Presidential Statement issued August 23, 1971.

The Federal Council for Science and Technology, recognizing that a substantial amount of research is funded by the Government at universities and nonprofit organizations, established a University Patent Policy Subcommittee to determine whether special patent procedures for that sector may be required in order to facilitate utilization of inventions. The Subcommittee, headed by Norman J. Latker, Chief of the Patent Branch in the office of the HEW General Counsel, concluded that there are valid reasons for special procedures and suggested specific measures.

The Subcommittee report[7] described four different approaches now being used by different agencies for the allocation of patent rights under research grants and contracts with universities and nonprofit institutions. One of these involves the use of an Institutional Patent Agreement (IPA) for those institutions that are found to have an established technology transfer program that is consistent with the stated objectives of the Presidential policy. This procedure, already successfully used by HEW and the National Science Foundation, is recommended by the Subcommittee for use by all agencies, within the constraints, of course, of their statutory authority.

[7]Federal Council for Science and Technology, *Report of the University Ad Hoc Subcommittee of the Executive Subcommittee of the Committee on Government Patent Policy*, Washington, D.C., 1975. (Unpublished.)

A second procedure, now used by the Department of Defense, is based upon a "special situation" interpretation under the Presidential Statement, which also permits determination of patent rights when the contract or grant is awarded. The other two procedures, used by all other major agencies, involve a case-by-case decision on each invention, which requires the preparation, review, and response of detailed data on each separate invention and entails a substantial amount of administrative work on the part of both the institutions and the Government.

A proposed revision to the Federal Procurement Regulations (FPR), implementing the Subcommittee's proposals, has been circulated for comment both within and outside the Government. If the revision is adopted, the Department of Defense has indicated a disposition to amend similarly the Armed Services Procurement Regulation (ASPR). Although both FPR and ASPR apply only to contracts, the proposed regulations have been written for application to grants as well, and the major agencies are understood to be prepared to include grants under the IPA procedure.

Adoption of this procedure on a Government-wide basis would, as the Subcommittee report states, eliminate to the extent possible the wide difference in treatment of a particular institution doing similar work for different agencies (page 18) and reduce the administrative burden on all the parties concerned (page 19). In this instance, the Subcommittee has acted as a cognizant agency in designing a consistent procedure for all agencies. The success of this procedure will require the maintenance of a list of the institutions and organizations that have demonstrated their technology transfer capability and thus their eligibility for an Institutional Patent Agreement. A single cognizant agency could readily maintain this list.

Findings. The cognizant agency principle has proven effective in coordinating Federal requirements in a given area, particularly when the requirements are intricate and difficult to understand. Cognizance may be assigned to a single agency or be divided into mutually exclusive spheres with different agencies having cognizance for each. When several agencies issue separate regulations with respect to the same subject, inconsistencies, conflicts, and burdensome duplications can arise Even when a lead agency has published a carefully devised code, these incompatibilities may occur, some inadvertently and others by design.

Sole authority to promulgate regulations in the particular field must be assigned to the agency to which cognizance is given, although enforcement of these regulations may in some cases be assigned elsewhere. Even if an agency encounters an unforeseen problem that requires revision of the regulations, such revision must be made by the cognizant agency.

Attention has been given recently to the cognizant agency principle. For example, the Interagency Task Force on Higher Education Burden Reduction, to which the Commission staff contributed, proposed that the principle be applied where appro-

priate. This appears as Recommendation No. 16 of the Task Force Report. (See Appendix B.)

Although the cognizant agency principle should be considered for subject areas that are recognized today, its potential use for those that will arise in the future should not be overlooked.

Recommendation No. 10

The Commission on Federal Paperwork endorses the cognizant agency concept as a useful tool, particularly in cases that involve regulations that are technically intricate and require specialized experience for full comprehension and conformance. The Commission recommends to OMB that the assignment of a cognizant agency be considered in all cases of this nature where two or more agencies have overlapping jurisdictions that might result in duplicative or inconsistent regulations.

