REGULATORY IMPACT ANALYSIS

1. Potential Benefits

The proposed rule implements 35 U.S.C 200-206. That Act authorized OFPP to issue implementing regulations and requires that OFPP issue a standard patent provision for all grants, contracts, and cooperative agreements (funding agreements) with small businesses and universities by July 1, 1981. The benefits that the Act and these regulations are intended to achieve are not readily quantifiable, but are discussed in Senate Report 96-480. They include:

(1) Increased commercialization and utilization of government support inventions by the private sector.

(2) The increased participation of small business firms in Government Research programs.

(3) The elimination of numerous, different, and often conflicting individual agency clauses and policies governing the patent rights of non-profit and small business contractors.

2. Potential Costs

This Circular should not increase any costs as compared to the current regulatory and administrative framework. It is intended to reduce substantially the administrative burdens on recipients, particularly those that deal with more than one Government agency. It should reduce the administrative costs in agencies by eliminating the need to process requests for waivers of individual inventions or requests for the issuance of Institutional Patent Agreements in agencies such as NSF, HHS, and DOC.

Depending on decisions made on the activities of the lead agency, this may involve a modest cost. However, a professional staff of between 1-3 FTE would only be required to perform the lead agency functions related to the implementation of the Act and the Circular. Moreover, these functions should eliminate the need for similar work to be performed in multiple agencies.

3. Potential Net Benefits

As the above discussion indicates, the benefits substantially outweigh any costs and, indeed, there should be net cost saving.

4. Alternative Approaches

Keeping in mind that the statute established the basic thrust of this or any other implementing regulations, the alternatives are somewhat limited.

One alternative would be to limit the Circular to the prescription of a standard clause while leaving all procedural details to the agencies. Such an approach, however, would frustrate the objective of achieving uniformity and minimizing

administrative burdens on recipients. Thus, it is deemed more effective to issue Government-wide standards in various areas.

For example, this Circular established uniform and fair standards for the exercise of march-in rights under grants and cooperative agreements. The Senate report recommended that this be included in the central regulation. The Circular also contemplates that a lead agency will work with the agencies to develop a standard format for the reporting by contractors of utilization efforts. The statute requires that the standard clause provide for the right of agencies to receive utilization reports. The Circular is designed to provide a mechanism for limiting the number and formats recipients will have to prepare.

Certain issues were raised by the public comments on interim Bulletin 81-22, which is superseded, by this Circular concerning particularly the requirements for reporting of inventions, electing title and filing a patent application by contractors. The Bulletin contained certain requirements not included in existing clauses that were objected to by university representatives as impractical and likely to frustrate the purposes of the Act. These provisions are revised in the Circular and it is believed that these requirements now represent an appropriate balance between the rights of the recipients and the need for agencies to protect their interests in inventions.

In addition, the Bulletin has been reformatted for easier reading and simplified reference to its provisions. For example, the standard clause has been moved from the body of the Circular to an attachment. Other less significant modifications based on the public comments on the Bulletin were made with the intent to ease the administrative burden of both contractors and the operating executive agencies.