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COGR Talking Points on Determinations of Exceptional Circumstances (DECs)

- The Bayh-Dole Act of 1980 (35 USC 200 *et. seq.*) that enables universities to retain title to their federally funded inventions has been phenomenally successful in transferring university technology to the private sector for public use and benefit. Exceptions to normal university rights under the Bayh-Dole Act are discouraged as a matter of law and policy.

- Deviations from the standard Bayh-Dole rights of universities (and other nonprofit organizations and small businesses) to claim title to and patent inventions resulting from federally funded research are permitted only in limited circumstances (35 USC 202(b)(1); 37 CRF 401.3 (b)).

- One such deviation is a Determination of Exceptional Circumstances (DEC) that requires funding agencies to make a formal determination justifying the use of other than normal Bayh-Dole rights. DECs were extremely rare in the early years of the implementation of the Bayh-Dole Act, but their use by federal research agencies, in particular the National Institutes of Health (NIH) has become more common since the mid-1990's.

- Current NIH funding initiatives emphasize collaborations with industry for translational research. NIH has justified DECs in terms of encouraging industry participation in programs and activities involving university-industry collaborations. Universities are concerned that to accommodate the perceived needs of industry, NIH too frequently has adopted an unnecessarily extreme position of denying invention ownership to universities, to their disadvantage. Providing preferential rights to industry also threatens the essential Bayh-Dole balancing of incentives and obligations and public and private interests in rights to federally supported inventions, and raises potential tax issues for universities.

- Universities routinely deal with industry in a wide range of contractual relationships that are designed to protect both parties' rights and interests without requiring universities to give up ownership of inventions that may arise in the course of the activities. Examples include the ability of universities to obtain proprietary materials from industry for research purposes through standard Materials Transfer Agreements (MTAs).

- Where industry participates in NIH programs, use of DEC alternatives such as MTAs between the industry partner and the NIH funding recipient better promotes public policy objectives while preserving proper incentives for universities. DECs should be used only in "truly exceptional" situations, and their scope should be narrowed to only cover what is essential to address the

exceptional circumstances. NIH policy and practice should be modified accordingly.