UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER PROCEDURE MANUAL

Chapter No. 607.1

NIH Procedures on Determinations of Exceptional Circumstances Under NIH Funding Agreements

A. PURPOSE

This Manual Chapter sets forth NIH procedures for making a Determination of Exceptional Circumstances ("DEC") with respect to a Funding Agreement[1] "[i]n exceptional circumstances when it is determined by the agency that restriction or elimination of the right to retain title to any subject invention will better promote the policy and objectives of [the Bayh-Dole Act]." 37 C.F.R. § 401.3(a)(2).

B. BACKGROUND

The Bayh-Dole Act, 35 U.S.C. §§ 200-212, permits Contractors[2] to elect title to Subject Inventions.[3] In exceptional circumstances, however, the Bayh-Dole Act authorizes the funding Agency to modify the terms of a Funding Agreement by restricting or eliminating the Contractor's right to title, or to retain title itself, to Subject Inventions, when doing so better promotes the policy and objectives of the Act.[4]

These objectives, as set forth in the language of 35 U.S.C. § 200, are:

> [T]o promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against non-use or unreasonable use of inventions; and to minimize the

[1] Under 35 U.S.C. § 201(b), a "Funding Agreement" means any contract, grant, or cooperative agreement (but not a Cooperative Research And Development Agreement as defined under 15 U.S.C. § 3710a).
[2] Under 35 U.S.C. § 201(c) and 37 C.F.R. § 401.2(b), as expanded by Executive Order 12591 (Apr. 22, 1987), a "Contractor" means any person, business firm, or nonprofit organization that is a party to a Funding Agreement.
[3] Under 35 U.S.C. § 201(e), a "Subject Invention" is any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.
[4] 35 U.S.C. § 202(a).

costs of administering policies in this area.

C. PROCEDURES

1. "Before utilizing [the exception of 37 C.F.R. § 401.3(a)(2)], the [NIH] shall prepare a written determination, including a statement of facts supporting the determination, that the conditions identified in the exception exist. A separate statement of facts shall be prepared for each exceptional circumstances determination, except that in appropriate cases a single determination may apply to both a funding agreement and any subcontracts issued under it or to any funding agreement to which such an exception is applicable." 37 C.F.R. § 401.3(e).

2. DEC Requirements

   (a) The proposed DEC should be prepared in consultation with the appropriate reviewing offices.

   (b) Notification of the purposes and application of the proposed DEC should be provided to potential Contractors.

   (c) The proposed DEC must address the corresponding statutory and regulatory requirements, as follows:

      (i) The restriction or elimination of the Contractor's right to elect or retain title to any Subject Invention will better promote the policy and objectives of Chapter 18 of Title 35 of the United States Code. *See* 37 C.F.R. § 401.3(a)(2).

      (ii) The DEC seeks "only such modifications as are necessary to address the exceptional circumstances or concerns which led to the use of the exception. For example, if the justification relates to a particular field of use or market, the [standard patent rights] clause might be modified along lines similar to those described in 37 C.F.R. § 401.14(b). In any event, the clause should provide the contractor with an opportunity to receive greater rights in accordance with the procedures at 37 C.F.R. § 401.15." 37 C.F.R. § 401.3(b)."In cases when 37 C.F.R. § 401.3(a)(2) is used, the determination shall also include an analysis justifying the determination. This analysis should address with specificity how the alternate provisions will better achieve the objectives set forth in 35 U.S.C. § 200." 37 C.F.R. § 401.3(e).

      (iii) A copy of "each determination, statement of facts, and, if applicable, analysis shall be promptly provided to the contractor or prospective contractor along with a notification to the contractor or prospective contractor of its rights to appeal the determination of the exception under 35 U.S.C. §202(b)(4) and [37 C.F.R. § 401.4]." 37 C.F.R. § 401.3(e).

3. In preparing the proposed DEC in view of the statutory and regulatory requirements, the following questions may be helpful for the NIH Institute/Center (IC) to consider.

   (a) What type of Funding Agreement is being considered -- a contract, grant, or cooperative agreement? Generally, DECs may be considered more appropriate for contracts, since contracts are for the direct benefit and use of the government, and involve a higher degree of agency control than grants or cooperative agreements.

   (b) Why is a change to the standard Bayh-Dole invention rights essential to achieve programmatic objectives? What alternative means of achieving programmatic objectives have been considered?

   (c) Has the IC communicated the proposed use of a DEC with potentially interested parties, and how have their responses, if any, been taken into consideration? This can be accomplished, for example, by publication in FedBizOpps (https://www.fbo.gov/) or the Federal Register.

   (d) Is the proposed deviation to the standard Bayh-Dole patent rights as narrowly tailored as possible to achieve the articulated programmatic objective?

   (e) Would Subject Inventions fall into classes? If so, what class(es) of Subject Inventions would fall under the DEC?

   (f) Does the proposed DEC provide for the funding recipient(s) to retain rights to Subject Inventions (in their entirety or by fields of use) that are unrelated to or outside the scope of the DEC?

   (g) Where appropriate, does the proposed DEC provide for the funding recipient(s) to retain or request rights to research uses of Subject Inventions (in their entirety or by fields of use) that are within the scope of the DEC?

   (h) How do the proposed changes to the Funding Agreement ensure that the obligations to take effective steps to achieve practical application of Subject Inventions and to report on their utilization (and efforts at obtaining utilization) will continue to be satisfied?

4. Routing of a DEC Package for a Determination

   The IC will submit the proposed DEC package to the following: NIH OTT, the NIH Office of General Counsel (OGC), NIH OER, NIH Office of Acquisition Management and Policy (OAMP) (if a contract) or the NIH Office of Policy for Extramural Research Administration (OPERA) (if a grant or cooperative agreement) and the NIH Head of Contracting (if contract), and NIH Office of Management Assessment (OMA). Final review and approval shall be made by the Director, NIH.

5. Routing of Deviated FAR Clause for Approval (if a Contract)

   Concurrent with routing of a DEC Package (if a contract), NIH OMA will send a copy of the proposed deviated FAR clause package to the NIH OTT, NIH OGC, NIH OER, OAMP, and the NIH Head of Contracting. The NIH Head of Contracting will forward the deviated FAR Clause Package to HHS on behalf of NIH, and will be responsible for arranging review and clearance by HHS of the deviated FAR clauses.

6. Post-Award Responsibilities

   The IC is responsible for satisfying all reporting obligations to the Department of Commerce and, if funding agreement is with a small business firm, the Small Business Administration. In addition to standard Bayh-Dole reporting obligations and procedures, the IC is responsible for ensuring that the funding recipient also reports its subject inventions to the IC's technology transfer office. Finally, if the altered Funding Agreement specifies that title to Subject Inventions vests with any party other than the Contractor, the IC is responsible for ensuring that the assignee of title is notified and agrees that then Bayh-Dole rights, responsibilities, and obligations apply to the assignee as if the assignee were the original Contractor.

D. EFFECTIVE DATE

The NIH procedures set forth in this Manual Chapter are effective March 14, 2013 and supersede in their entirety the NIH procedures in Manual Chapter 607, which was first approved on December 9, 1999. This Manual Chapter is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any other persons.

E. ADDITIONAL INFORMATION

For additional information on this Manual Chapter and related NIH procedures, contact the NIH Office of Technology Transfer, (301) 496-7057, or http://www.ott.nih.gov/contact-us , or the NIH Office of Extramural Research, Division of Extramural Inventions & Technology Resources, (301) 435-1986, Edison@nih.gov, or http://inventions.nih.gov.