

United States Public Health Service Technology Transfer Manual

Chapter No. 307

Appeals of Licensing Decisions

A. PURPOSE

This Manual Chapter describes the basis for appeals of a decision of an Institute/Center (IC) of the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or the Centers for Disease Control and Prevention (CDC) concerning the grant, denial, modification, or termination of a license for any invention administered by the NIH, FDA, or CDC. It also establishes procedures for processing, reviewing, and responding to appeals.

B. BACKGROUND

The CDC, FDA, and Institutes and Centers (ICs) of the NIH, collectively “Agencies,” have the delegated authority to make any decision concerning the grant, denial, modification, or termination of any license for any invention made in their respective laboratories. Under 37 CFR § 404.11, Federal agencies may establish procedures under which certain parties may appeal adverse decisions relating to the licensing of government-owned inventions by that Agency. Those appeals are decided by the Director of NIH, Commissioner of FDA, or Director of the CDC (each an “Agency Head”) or their designees.

C. POLICY

The following person(s) may appeal any determination by an IC, the FDA or the CDC that grants, denies, terminates or modifies an NIH-, FDA-, or CDC-administered license.

1. A person whose application for a license to a technology advertised as available has been denied;
2. A licensee whose license has been modified or terminated in whole or in part; or
3. A person who has timely filed a written objection in response to the notice published in the *Federal Register* as required by 37 C.F.R. § 404.7(a)(1)(I) or 37 C.F.R. § 404.7(b)(1)(I) and who can demonstrate to the satisfaction of the Agency Head that such person may be damaged by the Agency determination.

D. PROCEDURES

1. Appeals

- a. A person or licensee (an “Appellant”) who has received an adverse determination under 37 CFR § 404.11 may file a written appeal of such determination to the Agency Head where the determination was made or to the Agency Head’s designee, as appropriate, through the technology transfer office that provided an adverse decision, no later than thirty (30) calendar days from the receipt of such decision. The appeal must include concise arguments as to why the decision of the technology transfer office should be rejected or modified and must include all pertinent documents. Upon review of the appeal, the Agency Head or their designee may require submission of additional information or documentation. Appellants are not entitled to an adversary hearing.
- b. The Agency Head or their designee may appoint a person (the “Chair”) to form and chair an *ad hoc* committee to review the appeal and recommend a response. The committee may also include technology transfer staff from the Agencies, the NIH Office of Technology Transfer, NIH Office of Science Policy, and scientists having expertise in the relevant scientific field. Committee members may be employed at any of the Agencies; however, committee members must be independent of the IC or Center staff who participated in the license negotiation or decision to deny the license. The committee must not include staff from the Office of General Counsel (OGC), but the committee may consult the OGC on questions of law.
- c. The review committee has discretion to accept and consider evidence unilaterally offered by the Appellant after the appeal has commenced and may request additional documentation and information from the Appellant, which shall be provided within fourteen (14) days (or, at the discretion of the Chair, a reasonable additional time). The Appellant’s failure to provide requested materials may be deemed evidence that the materials are either unfavorable to the Appellant or do not exist. The committee also may independently investigate and consider evidence that was available to the Technology Development Coordinator (TDC) and/or the Appellant at the time of the decision, including information obtained from discussions with inventors and/or with staff who had drafted and negotiated the license.
- d. The review committee shall submit a written recommendation to the Agency Head or their designee within forty-five (45) days after they received the written appeal.

e. Within sixty (60) calendar days of receiving the written appeal, the Agency Head or their designee shall send the final determination to the Appellant. This decision constitutes a final decision by the Agency.

f. Judicial review is available as the law permits.

E. EFFECTIVE DATE

The policy and procedures set forth in this Manual Chapter are effective October 14, 2021 and supersede those set forth in PHS Technology Transfer Manual Chapters 307 and 307.1, which were approved on December 08, 2010.

F. ADDITIONAL INFORMATION

For additional information on this Manual Chapter, contact the Office of Technology Transfer, NIH, nihott@mail.nih.gov or the Division of Technology Transfer and Innovation Policy, Office of Science Policy National Institutes of Health, NIH, SciencePolicy@od.nih.gov. For the FDA contact FDAINVENTIONLICENSING@FDA.HHS.GOV and for the CDC contact tto@cdc.gov.