A. PURPOSE

This Manual Chapter describes the basis for appealing a decision of the Office of Technology Transfer (OTT) concerning the grant, denial, modification, or termination of a license for any invention administered by the National Institutes of Health (NIH), Department of Health and Human Services (DHHS) and establishes procedures for processing, reviewing, and responding to requests for reconsideration and appeals. All previous procedures are superseded.

B. BACKGROUND

The OTT has been delegated the authority to make any decision or determination concerning the grant, denial, modification, or termination of any license for any invention in the custody and control of the NIH. 37 CFR § 404.11 requires Federal agencies to establish procedures under which certain parties may appeal decisions or determinations relating to the licensing of government-owned inventions by that agency. The decision and determination of the OTT is final unless the procedures for reconsideration and appeal set forth below are initiated.

C. POLICY

The following person(s) may either request reconsideration by the Director, OTT or may subsequently appeal to the Director, NIH, any determination by the OTT granting, denying, terminating or modifying an NIH-administered license:

1. A person whose application for a license to 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 Director, OTT that such person may be damaged by the determination of the NIH.

D. PROCEDURES

1. Requests for Reconsideration
   a. A person/licensee may request reconsideration of a determination by the Director, OTT granting, denying, terminating, or modifying a license by filing with the Director, OTT a
written request for reconsideration within thirty (30) calendar days after the notice of
denial, termination or modification or a response to a Written Objection is sent by the
OTT to the person. The request for reconsideration shall concisely state the grounds for
reconsideration and include copies of all pertinent documents. The Director, OTT may
require submission of additional information or documentation.

b. When the Director, OTT receives a request for reconsideration, he or she shall appoint an
ad hoc review committee to review the case and make recommendations regarding action
to be taken. The committee may include OTT Licensing Specialists (but not the
Licensing Specialist who made the original decision that is at issue) as well as other NIH
employees (e.g. scientists, Technology Development Coordinators or attorneys from the
Office of the General Counsel).

c. The review committee shall provide a recommendation to the Director, OTT within
forty-five (45) days after the request for reconsideration is received by the OTT.

d. Within sixty (60) calendar days of receiving the request for reconsideration, the Director,
OTT shall send a final determination to the requesting party along with notice of the
party’s right to appeal the decision to the Director.

2. Appeals

a. A person/licensee who has received an adverse determination on a request for
reconsideration may appeal such determination to the Director, NIH. Appellants shall
not be entitled to an adversary hearing. The Appellant shall file a written appeal to the
Director, NIH, with two copies to the Director, OTT, no later than thirty (30) calendar
days from the receipt of an adverse decision by the Director, OTT concerning a request
for reconsideration. The appeal shall concisely state the grounds for appeal and include
copies of all pertinent documents. The appeal must include concise arguments as to why
the decision of the Director, OTT, should be rejected or modified. Upon review of the
appeal, the Director, NIH, or his or her designee, may require submission of additional
information or documentation.

b. If the Director, NIH, deems it appropriate, he or she may appoint an individual or a
committee which may include representatives from the OTT, OGC, and, if necessary,
scientists with expertise in the particular field of technology, to review the administrative
record including all documents submitted in support of the appeal.

c. The review committee shall submit a written recommendation to the Director, NIH, or
his or her designee, within forty-five (45) days after the written appeal is received by the
NIH. If no review committee is appointed, the individual acting on behalf of the
Director, NIH, shall review all documents and submit a written recommendation to the
Director, NIH, or his order designee, within forty-five (45) calendar days after the written
appeal is received by the NIH.

d. Within sixty (60) calendar days of receiving the written appeal, the Director, NIH, shall
send the final determination to the Appellant. The decision of the Director, NIH, or his
or her designee, shall constitute a final decision by the agency.

e. Judicial review is available as the law permits.

E. EFFECTIVE DATE

The policy and procedures set forth in this Manual Chapter are effective immediately upon issuance.

F. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057.