

NIH Policy Manual

1170 - Relationships with the Office of the General Counsel

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Transmittal Notice

1. **Explanation of Material Transmitted:** This NIH Manual chapter contains current policies and procedures applicable to obtaining formal and informal legal advice and clearance services from the Office of the General Counsel (OGC) on NIH matters. The chapter is also being revised to comply with the requirement to update chapters over 5 years old.
2. **Filing Instructions:**

Remove: NIH Manual 1170 dated 06/05/03.

Insert: NIH Manual 1170 dated 09/30/09.

PLEASE NOTE: For information on:

- Contents of this chapter, contact the Office of Management Assessment on 301-496-2832.
- On-line information, enter this URL: <http://oma.od.nih.gov/manualchapters/>.
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A. Purpose

This chapter states the role of the Department of Health and Human Service (HHS) Office of the General Counsel (OGC) in providing legal advice to the NIH and establishes procedures applicable to obtaining formal and informal legal advice and clearance services from the Office of the General Counsel (OGC) on NIH matters.

B. Background and Policy

The Office of the General Counsel is responsible for providing all legal advice to agency officials within HHS. HHS, OS Statement of Organization, 38 Fed. Reg. 17032 (June 28, 1973), amended most recently at 59 Fed. Reg. 50234 (October 3, 1994) states: “The General

Counsel, as special advisor to the Secretary on legal matters, is responsible for providing all legal advice to the Secretary...and all organizations of the Department.” By serving as the sole, officially designated source of legal advice to the Department’s operating and staff divisions, the OGC ensures that all the operating and staff divisions receive uniform advice and that the OGC and Department of Justice are able to defend the agency’s position on such matters.

There are two exceptions to this policy. First, when litigation involving the Department or one of its components arises, the Department of Justice (DOJ) is statutorily authorized to represent the agency’s interest in court in close consultation with the OGC, 5 USC §3106; 28 USC §516. The second exception is that the Office of the Inspector General is authorized to have its own Office of the General Counsel to the Inspector General. 62 Fed.Reg. 30859-03 (June 5, 1997).

An Assistant Secretary for Health's memorandum to PHS Agency Heads, dated January 8, 1982, requests that each agency establish procedures for obtaining advice from its Legal Advisor. The General Counsel in a memorandum directed to the Heads of Operating and Staff Divisions on July 28, 2003, reminded HHS staff that the OGC provides all legal advice to agency staff.

HHS policy prohibits operating and staff divisions from having their own legal advisors. For purposes of this manual chapter, "legal advisor[s]" is defined as anyone, employee or contractor, who provides legal advice, whether or not he/she is a licensed attorney. Thus, operating and staff divisions may not spend appropriated or gift funds to obtain legal advice from any source other than the HHS OGC, absent a specific delegation from HHS OGC. Also, agency officials cannot solicit or accept legal advice as a gift from outside sources. Such an acceptance may be in violation of the Antideficiency Act and may implicate criminal penalties. 31 USC §1342. Seeking legal advice from outside sources could also jeopardize the NIH’s position in litigation or other important matters.

The NIH Branch of the Office of the General Counsel, Public Health Division, is located on the NIH campus. The Deputy Associate General Counsel for Public Health, NIH, is the head of this Branch and is known internally at NIH as the NIH Legal Advisor. The NIH Legal Advisor and staff are not NIH employees but they work closely with NIH employees in policy development and NIH business requiring legal insight and advice. The NIH Legal Advisor and staff traditionally work closely with NIH officials in formulating policy rather than simply acting as a sign-off point before the policy is implemented.

C. Definitions

For the purposes of this chapter, the following terms and definitions are useful in determining the appropriate procedures to be followed.

1. **Referring Official:** Includes the NIH Director, Deputy Directors, Associate Directors, NIH/OD Office and Division Directors, and Institute and Center, (IC) Directors, Deputy Directors, Executive Officers, and their delegates.

2. **Legal Advice:** Written or oral statements or opinions on (1) the interpretation and meaning of statutes, regulations and other legal instruments and requirements applicable to the operating and staff divisions; (2) the legal supportability and vulnerability of actions and policies; or (3) the judicial and legal defensibility of actions and policies.
3. **Formal Legal Advice:** Any written request, signed by a Referring Official and addressed to the OGC, asking for a formal opinion on which the requester intends to base significant official action.
4. **Informal Legal Advice:** Any request to the OGC used in formulating program level policies and procedures but not including matters requiring a formal legal opinion. This includes all oral requests for OGC assistance and may include written requests. It also includes discussions with OGC staff in drafting NIH work products.
5. **Legal Clearance Services:** Any written or procedurally established request for OGC review and/or approval (including OGC sign-off for Federal Register notices, delegations of authority, regulations, Legislative Implementation Action Plans, research contracts, NIH Manual Chapters).

D. Responsibilities

1. The OGC provides both formal and informal legal advice to NIH employees upon request following the procedures specified in this chapter. The OGC does not accept requests for formal or informal legal advice solely from non-employees, nor can OGC provide legal advice, services or representation to non-employees or to employees for private, non-work related matters. Should an NIH non-employee, e.g, a contractor or trainee, be referred to the OGC by an NIH employee to seek legal advice on an NIH-related matter, the NIH non-employee should specify the name of the referring NIH employee in the request.
2. A Referring Official must sign any request to the OGC for formal legal advice before the request is submitted to the OGC to ensure that the OGC receives only those requests for legal assistance that are in fact required and sought by the agency. Before referring a new request to OGC, the Referring Official determines if the request is applicable to: (1) any other NIH program; and/or (2) any other agency program within the Department. If the latter applies, the Referring Official calls the matter to the attention of the NIH Legal Advisor or staff.
3. Any NIH employee requesting written formal legal advice or opinions from the OGC must submit the request, through supervisory channels, to his/her Referring Official.
4. Operating and staff divisions are not to seek or obtain legal advice from sources other than the OGC. This prohibition includes seeking legal advice from temporary consultants or experts who have been hired to provide nonlegal services, as well as from agency program officials with legal educations and qualifications not in the OGC. The distinction to be made is between the uses of legal knowledge versus the practice of law. Specifically, an individual can apply legal knowledge and training to, for example, assist in drafting regulations and policy options, but only OGC can provide legal advice to NIH officials on, for example, enforceability or legal vulnerability of a proposed or prior agency action.

E. Procedures

1. **Formal Legal Advice:** Send each written request for legal advice or services directly to the OGC (Building 31, Room 2B50) after it has been signed by the Referring Official.
2. **Informal Legal Advice:** Contact the OGC directly (301-496-6043) when such advice is needed. Requests for such advice are confined to official business of the agency. The OGC is not available for counseling on employee's personal business, employee grievances, etc. The OGC is available for counseling on legal matters which may be the subject of Congressional testimony, judicial hearings, etc.
3. **Legal Clearance Services:** Contact the OGC directly according to previously established procedures (see C5).
4. **Special Procedures:** The OGC will establish procedures for dealing with those offices of NIH that have high volume of transactions or deal with especially sensitive matters.

F. Records Retention and Disposal

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of [NIH Manual 1743](#), "Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule,' Item 1100-M which covers Administrative Files. Refer to the NIH Chapter for specific disposition instructions.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

G. Internal Controls

The purpose of this chapter is to provide general information and guidance about requesting a legal opinion or information from OGC. Since the chapter is primarily informational, a management control review does not need to be performed.