
Government Reviews Protocol

It is the practice of the University of Vermont to cooperate fully, appropriately, and effectively with all lawful inquiries, inspections, audits, investigations, unannounced visits and other information-gathering activities conducted, directly or indirectly, by federal, state, or local Government regulators (Government Reviews). This protocol is intended to ensure that Government Reviews are handled in a manner that is deliberative and does not create confusion, duplication of effort or increased liability to the University.

In the event that a search warrant or subpoena is presented, the policy on Subpoenas, Complaints, Warrants and other Legal Documents must be followed.

Definitions

Compliance Matrix: the "working document" maintained by the Office of Compliance Services that identifies all of the laws and regulations that the University is subject to, as well as related University Policies.

Contact Person: means the person designated by the Responsible University Official to be the single University contact for a particular Government Review.

Government Review: includes inquiries, inspections, audits, investigations, unannounced visits and other information-gathering activities conducted, directly or indirectly, by federal, state, or local Government regulators, however they are made, including, without limitation, those made by email, letter, telephone, fax, personal visit, or by any other method, and whether made on campus, during regular business hours, or "off- hours" and "off-site."

Government reviews of affiliated entities that affect or pertain to University operations or personnel are also considered Government Reviews under this policy.

For purposes of this protocol, Government Reviews do not include: (i) external audits conducted by auditors or consultants hired by the University, (ii) accreditation visits or monitoring activities conducted by accrediting bodies, (iii) regularly scheduled clinical trial monitoring visits conducted by industry sponsors or other non-Governmental agencies, (iv) peer reviews and other programmatic site visits conducted in relation to competitive grant awards or renewals, or (v) routine facilities visits by the State Health Department or any local Fire Marshal.

Responsible University Official: the University official identified in the Compliance Matrix as having ultimate compliance responsibility for an area of law, regulation or policy.

Request for Production: a request by a Government regulator for documents, data or records that is made as part of a Government Review.

Operational Oversight Personnel: the individual(s) identified in the Compliance Matrix, as having day-to-day supervision or operational oversight responsibilities for an area of law, regulation or policy.

Procedures:

Any contact or communication by a federal, state or local Government regulator, however made, should be considered to be a Government Review and the protocols set forth below should be followed.

1. Advise Regulators of Protocol; Contact Supervisor/Compliance. The staff person, faculty member, receiving a communication from regulators announcing a Government Review should politely inform the regulators of this Protocol, transmitting a copy via email, FAX or, if the regulators are on campus, by hard copy. If the initial contact is made by phone, the regulators should be informed that they will be told promptly (within one (1) business day in the absence of extenuating circumstances) of the name of the Contact Person assigned to their Government Review. If the regulators have appeared without prior notice on campus, they should first be asked for identification and a written statement describing the nature of the Government Review, if available, and then should be asked to wait in a comfortable public or secure location. The staff person or faculty member should next immediately inform their supervisor of the communication or visit and provide the supervisor with any materials the regulators have furnished. If the immediate supervisor is unavailable, the staff person or faculty member should contact the next-level supervisor or, in his or her absence, the Office of Compliance Services. As soon as a supervisor is advised of the regulators' communication or presence on campus, the supervisor must report the matter to the Office of Compliance Services.

Affiliated organizations that are the subject of Government Reviews pertaining to University operations or personnel are required to notify the Office of Compliance Services upon their receipt of communication from regulators announcing a Government Review.

2. Designating the Contact Person. The Office of Compliance Services will inform the Office of General Counsel, the Office of Audit Services, the Chief Risk Officer and the Vice President for Executive Operations about the Government Review. Together with the Responsible Official, these individuals will collectively determine the appropriate Contact Person for the Government Review. In most cases, the contact person will be the person responsible for regulatory compliance at the operational level. The Office of Compliance Services will inform the individual designated as the Contact Person that they are the point of contact for the Government Review.
3. Monitoring the Government Review. If it is deemed advisable by the individuals described in paragraph 2, above, an *ad hoc* group shall be formed of representatives of some or all of those offices, or additional offices as appropriate, to monitor the Government Review. The Contact Person shall make reports to this group, advising them of any developments in the Government Review, including information related to document or interview requests.
4. Collection of Documents; Interviews
 - a. Collection of Documents. The Contact Person is principally responsible for managing the collection and organization of documents or data responsive to the requests of the Government regulators. The Office of Compliance Services and an attorney from the Office of the General Counsel shall review all regulator requests for information and one

or both offices may determine to review the proposed University response before such information is provided to the Government regulators.

- b. Interviews. Any substantive interviews must be postponed until any proposed interviewee has sought guidance from the Office of Compliance Services and the Office of General Counsel. The University may require that a representative(s) from the Office of the General Counsel and/or the Office of Compliance Services attend any of the visits, interviews, or meetings.
5. Entering Data. The Office of Compliance Services shall enter the information collected about the Government Review into a secure, shared data base to be viewable by Compliance Services, General Counsel, Audit Services, the Chief Risk Officer and the Vice President for Executive Operations.
6. Entrance Conference. The Contact Person shall attempt to schedule an “entrance conference” for the Government regulators. The purpose of the conference is for the University to ascertain the stated purpose of the inquiry, the scope of the inquiry, jurisdiction, timing and physical needs, if applicable, process, and to establish the role of the Contact Person. The entrance conference will customarily involve representatives from the offices identified in paragraph 2 above. At least one representative of the offices identified in paragraph 2 above must participate with the Contact Person in the Entrance Conference.
7. Walkthroughs and Physical Space. The Contact Person shall be responsible for accompanying the Government regulators in any walk-throughs through University buildings and spaces and shall also ensure that they have adequate, secure, physical space to work within the University.
8. Requests for Production. The Contact Person shall request of the Government regulators that any Request for Production be in writing. Once a written request is received by the Contact Person, it must be shared with the Office of Compliance Services and the Office of the General Counsel who will assist the Contact Person in determining whose assistance will be needed to respond to the request and, as necessary or desirable, to develop a response plan.

The Office of Compliance Services and the Office of the General Counsel must have the opportunity to review the proposed response(s) to any Requests, including data, documents and/or any narrative response, prior to the response being submitted.
9. Issues and Findings. The Contact Person shall immediately notify the assigned representative of the Office of Compliance Services and the Office of the General Counsel of any issues of concern that arise during the gathering of data or information. The Contact Person shall also immediately notify the Office of Compliance Services and the Office of the General Counsel of any preliminary substantive findings or comments of the Government Review of which he or she is notified.
10. Exit Conference. Upon notification of the completion of fieldwork or data collection from the Government regulators, the Contact Person should schedule an “exit conference” with Government regulators and appropriate University personnel. This meeting may be held by means of telephone conference if all parties agree.

11. **Final Report:** If a final report or written conclusion is issued by the Government regulators, the Contact Person must immediately convey a copy to Office of Compliance Services and the Office of the General Counsel

Contacts

Questions related to the daily operational interpretation of this policy should be directed to:

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Chief Compliance Officer
656.0847
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Related Documents/Policies

Policy on Subpoenas, Warrants, Complaints:

http://www.uvm.edu/policies/general_html/subpoenas.pdf