
GENERAL PROCEDURES POLICIES

**FOOD AND DRUG ADMINISTRATION'S (FDA)
OFFICE OF THE INSPECTOR GENERAL (OIG)**

Process on OIG Studies:

- The FDA Division of Management and Policy (DMP) notifies the Center for Veterinary Medicine's (CVM) Liaison regarding the start of a new OIG study involving an audit or inspection into Agency programs and operations. The CVM liaison determines whether the subject study impacts CVM. If there is any question about whether a particular study involves CVM, the CVM liaison obtains clearance from the Center Management Team (CMT).
- The CVM liaison informs CMT (via e-mail) of the start of the new OIG study, providing any relevant information and recommendations for CVM study participant(s).
- The CVM liaison provides DMP with the name(s) of CVM study participant(s).
- The CVM liaison provides CVM study participant(s) with any relevant material transmitted regarding the study, including FDA ground-rules in interacting with OIG. For example, any information shared with OIG needs to be submitted through the CVM and FDA OIG liaisons.
- The CVM liaison, in coordination with the CVM study participant(s), prepares any needed material for the (internal) pre-entrance conference meeting and OIG entrance conference (including draft responses to advance questions from OIG).
- The CVM liaison accompanies the CVM study participant(s) to the Agency (internal) pre-entrance conference meeting and the OIG entrance conference.
- For the duration of the study, the CVM liaison interacts with DMP in providing information requested by OIG. The CVM liaison informs CMT of any relevant or controversial information that arise.
- OIG provides FDA with a working draft report for review and comment. The working draft may include tentative findings and recommendations. DMP transmits a copy of the working draft report to the CVM liaison with a request for comment.
- The CVM liaison reviews and provides a brief summary of the OIG draft report to study participant(s) involved in the study. If the findings of the OIG draft report have a

significant impact on CVM, the liaison briefs the CMT on the issue(s) prior to submitting CVM's response.

- In preparing a response to OIG's draft report, the CVM liaison drafts and coordinates responses with the CVM study participant(s).
- For most studies, FDA normally holds an internal meeting to discuss the Agency's comments to the draft report.
- The CVM liaison and the CVM study participant(s) attend the OIG exit conference. If any relevant information arises at the exit conference, the liaison informs the CMT (via e-mail or briefing).
- The CVM liaison adds the OIG study to the CVM tracksheet and provides status updates as necessary. A copy of the table is available on the CVM Intranet website.

For information on the processes for the U.S. Government Accountability Office (GAO) studies/audits, see P&P section 1240.2315