

Foreword 2018

The *Investigations Operations Manual* (IOM) is the primary operational guide for FDA employees who perform field investigational activities in support of the agency's public health mission. Accordingly, it directs the conduct of all fundamental field investigational activities. Adherence to this manual is paramount to assure quality, consistency, and efficiency in field operations.

Other FDA manuals and field guidance supplement, but do not supersede, the information in this manual. We recognize this manual will not address all situations encountered in the performance of field activities. In such cases, your division management must be informed and concur with any significant departures from the IOM.

In 2018, the IOM contains important changes which clarify or present new information and procedures. For example, this year we have included information relating to our new procedures for the use of eNSpect, updated procedures for the use of USB drives in ORA computer systems as well as additional safety information. We are continuing to update the IOM in response to our May 15, 2017 rollout of program alignment across ORA. These program alignment updates will continue as we incorporate new program-specific sections within the IOM. As with each new edition of the IOM, please take time to review sections of the manual for changes which may apply to your work. Additions to the IOM are highlighted in gray.

The "Blue Pages" are still located on FDA.gov along with the IOM to allow us to maintain a more accurate and useful listing.

The IOM has been posted on ORA's Internet Website, http://www.fda.gov/ora/inspect_ref/iom. The entire IOM is available there, with all graphics included. The online version of the IOM is now 'mobile-ready' meaning that it can be accessed and viewed from mobile devices in a form that is easy to read.

Future updates to the IOM will be performed periodically during the year to the on-line version. The hard copy is published annually. Remember, whether reviewing the "hard copy" or the "on-line" version of the IOM, the most recent version is the document of record.

We are committed to the continual improvement of the quality and usefulness of the IOM. Suggestions for the 2019 edition of the IOM or recommended changes, deletions, additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. If you are recommending a change or revision, please use the IOM Change Request Form (FDA-3651) available at <http://inside.fda.gov:9003/downloads/administrative/forms/fda/ucm035205.pdf>. Suggestions are accepted from the within the Agency, our state and local partners, industry and consumers.

Thank you for your continued hard work and dedication in protecting and promoting the health and well-being of the American people.



Melinda K. Plaisier

Associate Commissioner for Regulatory Affairs

U.S. Food and Drug Administration, Office of Regulatory Affairs

Vision

All food is safe; all medical products are safe and effective; and the public health is advanced and protected.

Mission

Protecting consumers and enhancing public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.

Quality Commitment

ORA is committed to quality and continual improvement. Our actions are dedicated to effectively meeting our customers' needs.

Values

- *Accountability* - We take personal responsibility for meeting individual, team, and organizational commitments.
- *Commitment to Public Health* - We demonstrate our commitment to safeguarding the public health in our actions.
- *Communication* - We provide information that is accurate and clear, and in our interactions with others, we actively listen to understand other points of view.
- *Diversity & Inclusion* - We embrace each individual's uniqueness and seek out their ideas and perspectives.
- *Integrity and Respect* - We adhere to the highest ethical standards by consistently being honest and trustworthy in our actions.
- *Quality* - We set high standards of excellence for our work and take the necessary actions to continuously improve.



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