Foreword 2016

The *Investigations Operations Manual* (IOM) is the primary policy 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 district management must be informed and concur with any significant departures from the IOM.

In 2016, 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 policy on procedures required to use USB drives in ORA Computer Systems. In addition, the recall chapter now includes detailed instructions on completing audit checks, form 3177, and what are considered ineffective audit checks. 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 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 2017 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.

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

Office of Regulatory Affairs

U.S. Food and Drug Administration