Foreword 2021

The *Investigations Operations Manual* (IOM) is the primary operational reference 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 instruction 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.

For 2021, the IOM contains important changes which clarify or present new information and procedures. 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 light gray.

The IOM is also posted on ORA's Internet Website https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual, with all graphics included.

The COVID-19 pandemic has proven to be a paradigm-shifting public health event and our response has shown ORA to be driven by our public health mission and compelled to achieve the best public health impact. While the pandemic has created challenges, 2021 will see optimization in the way ORA does business. The process for Remote Regulatory Assessment (RRA), a new tool, will continue to be developed across all programs along with other potential process improvements and will be captured in a future IOM. Additionally, 2021 will see the beginning of the IOM Refresh Project, which will provide a cover to cover, all-inclusive review of the IOM with a focus on what is relevant to FDA employees who perform field investigational activities.

The IOM is published hard copy annually. Until the IOM Refresh Project is completed, future updates to the IOM will continue to be performed periodically during the year to the online version. The online IOM version serves as ORA's official document of record.

ORA leadership is committed to continuously improving the quality and usefulness of the IOM. Suggestions for the 2022 edition of the IOM including recommended changes, deletions, and additions to the IOM may be sent via e-mail to IOM@FDA.HHS.GOV. Suggestions are accepted from within the Agency, our state and local partners, industry and consumers. All changes are reviewed by the IOM Committee, which is composed of a cross-functional group consisting of representatives from each commodity area in addition to imports, recalls, and policy.

Thank you for your continued exceptional work and commitment to protecting and promoting the health and well-being of the American people. It is an honor serving with you.

Judith A. McMeekin, Pharm.D.

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.

Judith A. McMeekin, Pharm.D.

Associate Commissioner for Regulatory Affairs

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