

**SMG 1119A.5**

**FDA Staff Manual Guides, Volume I – Organizations and Functions**

**Department of Health and Human Services**

**Food and Drug Administration**

**Office of the Commissioner**

**Office of the Chief Scientist**

**Office of Scientific Integrity**

Effective Date: December 14, 2018

**1. Office of Scientific Integrity (DCPD).**

- A. Develops and implements policies to promote and protect scientific integrity throughout all of Food and Drug Administration's (FDA) activities and organizational components.
- B. Helps ensure consistent understanding, application and implementation of regulatory standards throughout FDA to ensure integrity and accountability of FDA functions and processes.
- C. Advises and assists senior FDA leadership in coordinating responses to allegations of patterns of deviations by FDA or its components from appropriate standards of conduct and performance. Also advises and assists senior FDA leadership in preventing such deviations.
- D. Investigates and facilitates resolution of informal complaints and disagreements, whether generated internally or externally, with respect to the administrative processing of various applications for products regulated by the FDA as well as regarding the fair and even-handed application of FDA policy and procedures in this process.
- E. Processes all formal appeals, or requests for review, that are submitted to the Office of the Commissioner, whether generated internally or externally, including requests for hearings, appeals from administrative actions, and requests to review decisions at a lower level of the FDA. Examples include, but are not limited to, requests to review decisions by the Centers, the Office of Regulatory Affairs, and elsewhere in the Office of the Commissioner under 21 CFR 10.75,

appeals of formal or informal hearings, and FDA-level scientific dispute resolution matters.

- F. Advises and assists the Chief Scientist and senior leadership in evaluating and resolving all formal appeals, requests for review, and requests for hearings submitted to the Office of the Commissioner and coordinates responses to such appeals and requests.
- G. Develops regulations and procedures to promote an efficient and effective process for addressing and resolving formal appeals, requests for review, and requests for hearings, as well as any other types of disputes suitable for formal resolution in the Office of the Commissioner.
- H. Determines whether an informal complaint should be construed and treated as a request for formal review by the Office of the Commissioner under established regulations or procedures.
- I. Oversees and directs the FDA's ombudsman and appeals to ensure coherence in decision making and the efficient operation of these functions internally and across FDA.
- J. Advises and assists the Chief Scientist in developing policies and procedures for ensuring compliance with all statutes and regulations applicable to human subject research conducted by the FDA.
- K. Administers the FDA's Institutional Review Board (IRB) by providing program management support for the IRB to fulfill its responsibilities under applicable laws and/or regulations.

## **2. Authority and Effective Date.**

The functional statements for the Office of Scientific Integrity were approved by the Secretary of Health and Human Services and effective on 14 December 2018.

**Department of Health and Human Services  
Food and Drug Administration  
Office of the Commissioner  
Office of the Chief Scientist  
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, Office of Scientific Integrity organization structure depicting all the organizational structures reporting to the Director.

Office of Scientific Integrity (DCPD)