

FDA Staff Manual Guides, Volume I - Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Center for Drug Evaluation and Research

Office of Translational Sciences

Office of Study Integrity & Surveillance

Effective Date: September 25, 2019

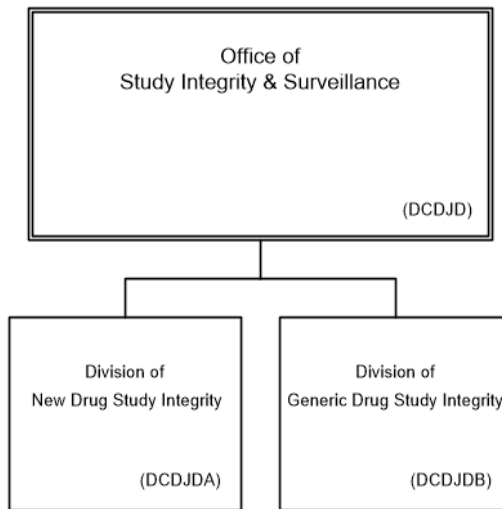
1. Office of Study Integrity & Surveillance (DCDJD).

- A. Develops and implements programs and policies for inspection, compliance, and enforcement of the following regulatory areas: nonclinical studies, bioequivalence studies, and human subject protections in clinical drug product studies.
- B. Develops and implements, with the Center for Drug Evaluation and Research (CDER), Office of Medical Policy, the CDER, Office of Compliance, and the Office of Regulatory Affairs, the Agency's Bioresearch Monitoring Program for Human Drugs under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Food and Drug Amendments Act, other Federal statutes, and applicable regulations.
- C. Develops and formalizes regulatory strategies and guidance including CDER's Manual of Policies and Procedures, Staff Guidance Manuals, and Compliance Program Guidance Manuals to promote compliance with Good Clinical Practice in research, human subject protections, Good Laboratory Practices, Bioequivalence, Adverse Drug Experience, Risk Evaluation and Mitigation Strategies, and Safety.

2. Authority and Effective Date.

The functional statements for the Office of Study Integrity & Surveillance were approved by the Secretary of Health and Human Services on September 25, 2019.

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Study Integrity & Surveillance**



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The following is the Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research, Office of Translational Science, Office of Study Integrity & Surveillance organizational structures depicting all the organizational structures reporting to the Director.

Office of Study Integrity & Surveillance (DCDJA).

These organizations report to the Office of Study Integrity & Surveillance:
Division of New Drug Study Integrity (DCDJDA)
Division of Generic Drug Study Integrity (DCDJDB)