

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 Medical Officer

Office of Clinical Policy

Effective Date: May 13, 2024

1. Office of Clinical Policy (DCJA).

- A. Advises and assists the Commissioner, Principal Deputy Commissioner, Chief Medical Officer, and other key officials on clinical research and Good Clinical Practice issues that have an impact on policy, direction, and long-range goals.
- B. Serves as the Food and Drug Administration (FDA) focal point for special programs and initiatives that are cross-cutting and clinical, scientific, and/or regulatory in nature to support innovation in medical product development and review.

2. Authority and Effective Date.

The functional statements for the Office of Clinical Policy were approved by the Secretary of Health and Human Services on March 5, 2024 and effective on May 13, 2024.

**Department of Health and Human Services
Food and Drug Administration
Office of the Chief Medical Officer
Office of Clinical Policy**

Office of
Clinical Policy

Good Clinical Practice Staff
Human Subject Protection Staff

(DCJA)

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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Medical Officer, Office of Clinical Policy organization structure depicting all the organizational structures reporting to the Director:

Good Clinical Practice Staff
Human Subject Protection Staff