

FDA Staff Manual Guides, Volume I – Organizations and Functions

Department of Health and Human Services

Food and Drug Administration

Office of the Chief Scientist

National Center for Toxicological Research

Office of Research

Division of Bioinformatics and Biostatistics

Effective Date: December 14, 2018

1. Division of Bioinformatics and Biostatistics (DCPFCE).

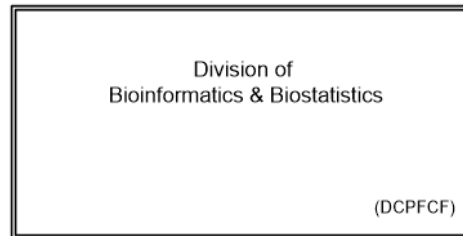
- A. Advises the Deputy Director for Research in the planning and implementation of strategies for achieving annual and long-range plans for research and research support in the area of biometry and risk assessment.
- B. Develops statistical testing methods and predictive systems for identifying potential health hazards associated with toxic substances.
- C. Develops biometrical methods for estimating risks associated with toxic substances to enable setting exposure levels that correctly reflect underlying uncertainties.
- D. Develops mathematical models for better representation of internal exposure levels of biological mechanisms in order to reduce uncertainty in estimates of risk.
- E. Provides expertise to the National Center for Toxicological Research (NCTR) scientists on design, conduct and analysis of research studies to evaluate the toxicity of regulated products.
- F. Assists other Food and Drug Administration (FDA) centers in conducting risk assessments for the regulation of specific products and in investigating generic risk assessment issues.

- G. Participates in interagency risk assessment activities to maintain knowledge of the state of the art, and to promote the improvement and unification of risk assessment practices across agencies.
- H. Conducts research in bioinformatics and chemoinformatics, and develops and coordinates informatics capabilities within NCTR, across FDA Centers, and in the larger toxicology community.
- I. Develops methods for the analysis and integration of omics (genomic, transcriptomic, proteomic, and metabolomic) databases with the objective of knowledge discovery and the elucidation of mechanisms of toxicity.
- J. Conducts of scientific computing which involves application of algorithms to extract knowledge, construct models, and make inferences from scientific data to support FDA regulatory need.

2. Authority and Effective Date.

The functional statements for the Division of Bioinformatics and Biostatistics were approved by the Secretary of Health and Human Services and effective on December 14, 2018.

**Department of Health and Human Services
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The following is the Department of Health and Human Services, Food and Drug Administration, Office of the Chief Scientist, National Center for Toxicological Research, Office of Research, Division of Bioinformatics and Biostatistics organization structure depicting all the organizational structures reporting to the Director:

Division of Bioinformatics and Biostatistics (DCPFCF)