SMG 9001

FDA Staff Manual Guides, Volume IV – Agency Program Directives

General or Multidiscipline

Gold Standard Science at FDA

Effective Date: 08/15/2025

1. Purpose

No concern is more central to the proper functioning of FDA than the need to ensure that the science underlying agency decisions is sound. The purpose of this Staff Manual Guide (SMG or Guide) is to provide an overview for all FDA staff on the core tenets of Gold Standard Science (GSS) contained in Executive Order 14303 (EO), "Restoring Gold Standard Science" (May 23, 2025) and further described by the Office of Science and Technology Policy (OSTP Memo).[1] This SMG explains how FDA practices and implements the core tenets of GSS and provides detailed information on reporting concerns related to GSS at FDA, including concerns related to the requirements of the EO.

2. Definitions

Centers, Offices, and Programs (COPs) refers to the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Tobacco Products, Center for Veterinary Medicine, Human Foods Program, National Center for Toxicological Research, Office of the Commissioner, Office of Inspections and Investigations, and Oncology Center of Excellence.

FDA Staff or **Staff** refers to all FDA employees, political appointees, contractors, fellows, and any other individuals acting at the behest of the agency.

Gold Standard Science (GSS) refers to science, which includes all scientific and technological

[1] Memorandum for the Heads of Executive Departments and Agencies, "Agency Guidance for Implementing Gold Standard Science in the Conduct & Management of Scientific Activities," Michael J. Kratsios, June 23, 2025 (OSTP Memo).

information, generated and evaluated in a manner consistent with the nine core tenets set forth in the EO, as further described and refined in this policy and the OSTP Memo. As discussed further in this SMG, GSS is notably reproducible; transparent; communicative of error and uncertainty; collaborative and interdisciplinary; skeptical of its findings and assumptions; structured for falsifiability of hypotheses; subject to unbiased peer review; accepting of negative results as positive outcomes; and without conflicts of interest.

Office of Scientific Integrity (OSI) refers to the office charged with assisting the Senior Appointee to preserve and promote GSS in scientific decision-making, helping to resolve certain GSS-related disputes at the agency level, and ensuring consistency on GSS issues across the agency.

Scientific and Technological Information refers to factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, physical sciences, or probability and statistics. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms.

Senior Appointee refers to FDA's Principal Deputy Commissioner, a role occupied by an individual performing the functions and duties of an individual appointed by the President.

3. Policy (Core Tenets of GSS)

In conducting our mission to protect and promote public health, FDA must generate and evaluate science in a manner that ensures FDA will make sound, objective decisions. Preserving and promoting GSS is essential to ensuring that FDA's mission succeeds and our regulatory decisions advance public health. Commitment to GSS makes certain that the science used in agency decision-making will be transparent, rigorous, and impactful. In turn, FDA's decisions as a regulatory agency will be objective and grounded in the best available evidence.

Establishing and maintaining GSS is crucial to the agency's ability to arrive at sound decisions and to maintain public trust. While there may be differing views about what can be concluded from scientific data and while there are often multiple options that can be considered during policy development or regulatory decision-making, FDA strives to present scientific and technological information—including uncertainties—in an unbiased manner. FDA applies the core tenets of GSS to both the scientific research it conducts or funds and to the scientific information it relies on when making regulatory decisions.

The following further describes the core tenets of GSS and how FDA practices and implements them:

A. Reproducibility

Reproducibility in science is the ability of independent researchers to test a hypothesis through multiple methods and consistently achieve results that confirm or refute it,

ensuring findings are generalizable and robust across different approaches. Replicability is the ability to perform the same experiment or study using the same methods and conditions to achieve the same result. Both are essential pillars of the scientific method: replicability ensures the integrity and precision of specific experiments, while reproducibility validates broader scientific claims. These concepts are fundamental to the scientific method, ensuring that findings are sound and verifiable, and not due to chance, bias, or error.[2]

FDA emphasizes the need for reproducibility and replicable science by prioritizing disciplined methods and experimental design, including by requiring clear, standardized, and justifiable protocols; comprehensive documentation; robust statistical methods; adequate sample sizes; validated methodologies; and appropriate controls. Where appropriate and consistent with specific FDA policies FDA staff will deposit scientific data and code that contribute to research outcomes in publicly accessible repositories. When FDA encounters barriers—such as incomplete reporting or resource constraints—the agency will foster training, share infrastructure, and create incentives for open science practices where appropriate. When possible, FDA will establish incentives, such as grant programs, awards, or recognition, to encourage researchers and agency components to prioritize both reproducibility and replicability.

B. Transparency

Transparency in science entails the open, accessible, and comprehensive sharing of all components of the research process—methodologies, data, analytical tools, and findings—to enable stringent scrutiny, validation, and reuse by the scientific community and the public. Transparency builds trust, fosters accountability, and promotes collaboration while reducing errors and bias. It complements reproducibility by ensuring that the materials and processes needed to replicate studies are accessible and clearly reported. It requires detailed disclosure of experimental protocols, raw data, software tools, and potential conflicts of interest, facilitated through platforms such as open-access journals, public data repositories, and standardized reporting frameworks.[3]

FDA prioritizes transparency to ensure accountability and public trust, and FDA fosters transparency by prioritizing clear, detailed reporting of methodologies, making scientific data and analytical tools publicly available, when feasible and lawful, and disclosing funding sources or conflicts of interest, if applicable. For research conducted or funded by the agency, FDA requires data sharing plans to include timelines and platforms for public release. When possible, FDA encourages the use of standardized metadata formats and data-sharing platforms to ensure accessibility and interoperability. Transparency also extends to peer and merit review processes, for research conducted or funded by FDA, where FDA encourages disclosing review criteria publicly and sharing anonymized reviewer comments with researchers, where feasible and appropriate.

[2] *Id.* at 2.
[3] *Id.*

C. Communicative of Error and Uncertainty

Communicating error and uncertainty in science entails the clear, precise, and accurate disclosure of limitations, variability, and potential sources of error or limitations in measurements or research findings, enabling other scientists to critically assess, replicate, and extend the work... Effective communication of error and uncertainty requires researchers to quantify statistical uncertainties, document and report potential sources of error, clearly articulate assumptions and methodological limitations, and disclose potential biases. Communication of error and uncertainty can be accomplished by leveraging tools such as comprehensive documentation, statistical metrics, visualizations, and standardized reporting formats. [4]

FDA prioritizes the communication of error and uncertainty to drive robust generation of new science. Whenever possible, FDA staff should include quantitative measures of uncertainties—such as confidence intervals, error margins, or sensitivity analyses—alongside clear explanations of methodological constraints and assumptions and the intended scope of the research, including what the scientific findings do and do not establish. The agency encourages standardized formats for reporting uncertainty, such as graphical visualizations or concise, accessible summaries, to enhance clarity and utility for the scientific community. To prevent overstatement of results, FDA communications should be presented in cautious, evidence-based language in reports, publications, and public communications. Communications at FDA should avoid speculative claims or extrapolations that extend beyond the data's scope.

D. Collaborative and Interdisciplinary

Collaborative and interdisciplinary science refers to the strategic integration of a wide range of expertise, methodologies, and perspectives across disciplines and sectors to address complex scientific challenges and catalyze transformative discoveries. This approach is vital for generating new knowledge, as it fosters synergy, leverages complementary skills, and promotes the synthesis of ideas to raise new questions and tackle multifaceted problems that transcend traditional disciplinary boundaries. Effective collaboration and interdisciplinarity require open communication, shared resources, and inclusive frameworks, often supported by joint research initiatives, interoperable data-sharing platforms, cross-disciplinary training programs, and development of shared terminology. [5]

FDA encourages collaborative and interdisciplinary approaches in science. These approaches include recognizing limitations in an individual's or a division's expertise and engaging other individuals or divisions within FDA, or other agencies, for complementary expert support when appropriate and lawful to address cross-disciplinary problems. FDA will foster partnerships across agencies, disciplines, institutions, and sectors by supporting joint funding opportunities, interdisciplinary research, user facilities, and accessible data-sharing platforms. As a general principle and practice,

[4] *Id.* at 3.
[5] *Id.* at 3-4.

FDA embraces team science by encouraging clear protocols for collaboration, such as shared digital workspaces, interoperable software, and the use of tools for effective communication and data integration.

E. Skeptical of its Findings and Assumptions

Maintaining constructive skepticism of findings and assumptions in science refers to the critical and open-minded evaluation of research findings, methodologies, and underlying assumptions to ensure their validity, robustness, and reliability. This approach is essential for generating reliable new knowledge, as it encourages scientists to challenge conclusions, explore alternative hypotheses, and identify potential biases or errors, thereby strengthening the scientific process. Effective skepticism requires researchers to employ robust validation methods—such as peer and merit review, replication studies, sensitivity analyses, and uncertainty assessments—while cultivating an open mindset that embraces scrutiny, iterative refinement, and intellectual humility. A key component of constructive skepticism is actively avoiding confirmation bias—the tendency to favor evidence that supports pre-existing beliefs or hypotheses while dismissing contradictory data.[6]

FDA embraces a culture of constructive skepticism in science through policies and programs that emphasize critical evaluation, transparency, and objectivity. FDA supports innovative methods to promote constructive skepticism, such as collaborations where teams with differing hypotheses design studies to rigorously test results, minimizing confirmation bias. FDA encourages and supports replication studies and statistical validation methods, such as sensitivity or uncertainty analyses, to critically assess the reliability of research results. FDA expects and requires all staff to cultivate a working environment where research premises and results are thoroughly evaluated, potential overinterpretations are challenged, and alternative explanations explored.

F. Structured for Falsifiability of Hypotheses

Structuring science for falsifiability of hypotheses entails designing research studies and experiments to enable hypotheses to be carefully tested and potentially disproven through empirical evidence. This approach is essential for generating new knowledge, as it anchors scientific claims in testable, refutable predictions—promoting rigor and preventing the perpetuation of unverified assumptions. Effective falsifiability requires researchers to formulate precise, testable hypotheses, design experiments with measurable outcomes, and employ rigorous methodologies—such as controlled experiments, randomized trials, or advanced statistical tests—to systematically challenge predictions.[7]

FDA values science that is structured for falsifiability of hypotheses. Research should be designed to allow for the rejection of hypotheses based on empirical evidence, prioritizing studies that advance knowledge through thorough testing. FDA encourages

[6] *Id.* at 4.
[7] *Id.* at 4-5.

research proposals that articulate clear, testable hypotheses with explicitly defined, measurable criteria for falsification, supported by solid experimental designs and statistical methods. Whenever feasible, FDA favors research practices and designs that enhance falsifiability, such as pre-registration of study protocols, use of appropriate control groups, and transparent reporting of null or negative results in publications and data repositories.

G. Subject to Unbiased Peer Review

Subjecting science to unbiased peer review (sometimes referred to as merit review) refers to the impartial and independent evaluation, by qualified experts, of both research proposals and manuscripts that report results of federally-supported research, to ensure validity, quality, and credibility prior to funding, publication, or dissemination. This process is critical for generating trustworthy new knowledge that minimizes bias, ensures methodological rigor, and upholds scientific standards through objective scrutiny. Effective unbiased peer review relies on transparent, well-defined review criteria, competent and independent reviewers, and robust mechanisms to minimize conflicts of interest, often facilitated by double-blind or open peer review by qualified experts. [8]

FDA supports unbiased peer review to advance sound science in the review, selection, and awarding of grants and contracts, including competitive and discretionary awards originating from the agency. Research proposals for such grants and contracts should undergo independent, impartial peer review, guided by clear, transparent evaluation criteria and standardized, streamlined processes to ensure objectivity and consistency, whenever possible. Whenever feasible, FDA policies related to peer review in all contexts will endeavor to ensure appropriate reviewer selection; prioritize expertise, independence, and viewpoint diversity; and adopt double-blind review where appropriate, with clear disclosure of potential conflicts of interest.

H. Accepting of Negative Results as Positive Outcomes

Accepting negative results as positive outcomes in science refers to recognizing and valuing—as meaningful contributions to knowledge generation—null or unexpected findings that fail to support a hypothesis. This approach is essential for advancing pioneering science, as it counters publication bias, encourages comprehensive reporting, and provides valuable insights into ineffective approaches, thereby guiding future research directions and avoiding redundant efforts. Embracing negative results requires researchers to transparently document and share null findings using accepted methodologies, clear reporting formats, and accessible platforms, such as open-access journals or data repositories. [9]

FDA recognizes negative or null results as valuable contributions to scientific knowledge. This recognition includes expectations that research projects transparently report all outcomes, including null or negative results, in publications and publicly accessible data

[8] *Id.* at 5.
[9] *Id.* at 5-6.

repositories, accompanied by clear, detailed documentation of methods, analyses, and limitations, consistent with FDA policies on public access. In general, FDA encourages the submission and dissemination of negative findings internally and, where appropriate, externally, such as to dedicated journal sections or specialized repositories for null results.

I. Without Conflicts of Interest

Conducting science without conflicts of interest refers to ensuring that research is designed, executed, reviewed, and reported free from financial, personal, or institutional influences that could bias outcomes or undermine objectivity. This approach is important for generating trustworthy and credible new knowledge, as it upholds scientific integrity, fosters public confidence, and ensures that results reflect evidence rather than external agendas. Maintaining freedom from conflicts of interest requires researchers, reviewers, and managers to disclose all relevant affiliations, funding sources, and relationships relevant to the science conducted, adhering to stringent ethical standards supported by strong institutional oversight, transparent reporting systems, and independent expert review mechanisms.[10]

FDA commits to conducting and managing science free from conflicts of interest. Consistent with applicable federal law, FDA requires disclosure of all relevant conflicts of interest by researchers, reviewers, and agency officials involved in the funding or performance of research at FDA. FDA requires comprehensive, standardized disclosure of all financial, personal, or institutional interests in research proposals, publications, peer and merit reviews, and data repositories, with clear and standardized protocols to identify, mitigate, and manage potential biases. FDA requires the use of independent oversight approaches and enforces strict conflict-of-interest policies, consistent with federal legal and ethical obligations.

As they relate to regulatory decision-making, many of the core tenets of GSS are embedded in FDA's legal obligations under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and related laws. FDA also operationalizes these core tenets by practicing and implementing specific policies and procedures to preserve and promote GSS at both the agency and COP level. Many of these specific policies and procedures at the agency level are discussed in the next section of this SMG. FDA expects all staff to be familiar not only with these core tenets but with the specific policies and procedures that implement them, both at the agency level and within their COPs.

4. Practice and Implementation of GSS at FDA

Consistent with the core tenets discussed in the previous section, FDA uses a variety of policies and procedures to preserve and promote GSS at FDA:

[10] *Id.* at 6.

A. Fostering a Culture of GSS

As the core tenets make clear, a culture of GSS is one that ensures that scientific decisions are grounded in evidence and are the product of honest investigation, open discussion, and refined understanding. The Senior Appointee oversees GSS at FDA and works through a variety of institutions to preserve and promote GSS across the agency, particularly FDA's Office of Scientific Integrity (OSI). Created in 2009, OSI works with FDA's COPs to preserve and promote GSS in scientific decision-making, as well as consistency on GSS-related issues across the agency. In addition to addressing specific concerns related to GSS, OSI also oversees training for FDA staff on key GSS concepts and related procedures. FDA staff with questions about GSS issues are encouraged to contact OSI for assistance (web portal and email).

B. Promoting Transparency in Research and Regulatory Decisions

Open communication about science plays a valuable role in building public trust in the agency's work and enabling the public and other stakeholders to understand the basis for its scientific decisions. FDA collects a vast amount of scientific and technological information regarding the products it regulates and supplements such information with scientific research it conducts or funds. Facilitating the free flow of information underlying the agency's decision-making, to the extent permitted by law, allows the public, Congress, media, industry, and other stakeholders to better understand FDA's decisions.[11] This policy as a whole ensures the free flow of scientific information and activities, including ensuring that scientists' work and conclusions are accurately represented in agency communications. FDA's standard clearance processes ensure that our scientific staff be provided an opportunity for input on agency communications that rely directly on scientific research, identify them individually as an author or researcher, or represent their personal scientific opinion to help ensure the accuracy of those communications. If a member of FDA's scientific staff believes that a particular agency communication or proposed communication that relies on their research, identifies them individually as an author, or represents their personal scientific opinion is not scientifically accurate, that individual may contact OSI using the process for reporting a GSS-related concern described later in this document.

1. Transparency in Information Dissemination

In 2009, FDA launched an agency-wide Transparency Initiative to make its activities and decision-making more transparent to the public as well as to regulated industry. Since then, FDA has developed and published resources to facilitate transparency, such as:

- A collection of FDA's Transparency initiatives developed to help those in the private and public sectors use FDA public data to spur innovation, advance academic research, educate the public, and protect public health.

- FDA Meetings, Conferences, and Workshops – FDA sponsors or co-sponsors meetings,

[11] If an FDA staff member is uncertain regarding whether a particular disclosure is permitted, they should consult with relevant disclosure staff in their COP and/or the Office of the Chief Counsel.

conferences, and workshops about various topics to educate the public and seek the opinion of interested parties. Minutes, transcripts, summaries, and/or presentations for sponsored or co-sponsored meetings and workshops are made available as soon after the meeting as possible.

- Freedom of Information Act Requests – FDA makes many of its records containing scientific and technical information available to the public through its regulations in 21 CFR part 20, which implement the Freedom of Information Act. As stated in 21 CFR 20.20, FDA makes "the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption." Many COPs have also implemented their own specific policies on disclosure. Additionally, FDA has established electronic reading rooms that contain categories of frequently requested FDA documents.

FDA also encourages staff to share scientific or technological information that may benefit the public health by giving speeches and publishing articles in professional journals or other publications, consistent with applicable laws and agency policies, as reflected in the following SMGs:

Two agency-level policies—"Public Access Requirements for Intramural Researchers and FDA Authors of Scholarly Publications Based on FDA-Funded Scientific Research" (SMG 2126.5) and "Public Access Requirements for Extramural Research" (SMG 2126.6)—further the agency's public health mission by increasing public access to peer-reviewed articles and data generated from FDA-funded research, whether conducted by FDA staff or outside organizations with funding from FDA. The broad availability of scientific information and underlying data allow for the critical review, replication, and verification of findings that are central to the scientific method. Making research findings and the data supporting those findings accessible and analyzable promotes robust and open communication with the scientific community, thereby bolstering the credibility of scientific findings and regulatory decision-making based upon those findings.

"Review of FDA-Related Articles and Speeches" (SMG 2126.3). This SMG is important for both FDA and public health in that it provides for a clear set of processes for staff to follow when they are contemplating an article or presentation that relates to their work, or the work of others, at FDA. Perhaps just as importantly, the policy makes it clear that FDA staff, including scientists, are free to publish or present their findings even when they are not in agreement with the agency on the findings, conclusions, or policy implications in the article or speech, provided they identify the findings, conclusions, or policy implications as their own and follow all statutes and regulations applicable to such activities. This policy and process thereby prevent agency officials from inappropriately stopping publication of scientific information and/or disrupting such publication through unreasonable delay, suppression, or alteration. Scientific staff are free to publish without supervisory or leadership approval, provided they do so according to the process

described in detail in this SMG.

2. Transparency in Scientific Decision-Making

FDA uses the following institutions and methods to augment transparency as it relates to scientific decision-making:

FDA Advisory Committees and Public Hearings. FDA seeks expert and public input on a broad scope of complex issues related to the products it regulates, consistent with the Federal Advisory Committee Act and the agency's implementing regulations (e.g. 21 CFR part 14). FDA has many advisory committees, some with multiple panels. The committees are established to provide functions that support the FDA's mission of protecting and promoting the public health, while meeting the requirements set forth in the Federal Advisory Committee Act.[12] FDA's advisory committees provide valuable independent expert advice on a range of complex scientific, technical, and policy issues. FDA considers the advice provided by advisory committees, but FDA is solely responsible for final agency decisions. FDA also conducts other types of public hearings to obtain valuable input on regulatory decisions, including hearings conducted according to the procedures described in 21 CFR part 12 (Formal Evidentiary Public Hearing), part 15 (Public Hearing Before the Commissioner), and part 16 (Regulatory Hearing Before the Food and Drug Administration).

Assessments of FDA Policies Made Public. FDA is subject to the requirements in the Information Quality Act (IQA),[13] and regularly offers staff trainings on these requirements. The IQA requires that information disseminated by the agency meet quality, utility, objectivity, and integrity standards, and that influential scientific information be peer reviewed by qualified specialists before it is disseminated.[14] The agency adheres to the Office of Management and Budget Final Information Quality Bulletin for Peer Review.[15] Peer reviews of influential scientific information can be found on FDA's public-facing website, Completed Reviews.

Agency Review Request. An agency regulation, 21 CFR 10.75, includes provisions that enable interested persons outside the agency to request internal agency review of a decision. See also "Requests for Review under 21 CFR 10.75 Submitted to the Office of the Commissioner by Interested Persons outside the Agency" (SMG 9010.5).

Agency Petitions and Comments. Agency regulations permit interested persons to petition the agency to revise our approach to particular scientific issues (21 CFR 10.30); petition the agency

[12] Pub. L. 92–463, §1, Oct. 6, 1972, 86 Stat. 770. Federal Advisory Committee Act.

[13] Pub. L. 106-554, Section 515, The Information Quality Act.

[14] Office of Management and Budget. "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies." *Federal Register*. 67 FR 8451, Doc. R2-59.

[15] Office of Management and Budget. "Final Information Quality Bulletin for Peer Review." *Federal Register*. 70 FR 2664, Doc. 05-769.

to stay or extend the effective date of any administrative action (21 CFR 10.35), petition the agency issue, amend, or revoke a regulation, or take or refrain from taking any administrative action (21 CFR 10.25), and comment on regulations and guidance documents, some of which bear directly on scientific issues before the agency (21 CFR 10.40, 10.115(f)-(g)).

3. Transparency in External Communication

FDA uses various modes of communication to reach and collaborate with stakeholders. Below are some of the avenues used to communicate regulatory information consistent with the core tenets of GSS:

The Office of External Affairs (OEA) in the Office of the Commissioner oversees agency-wide communications regarding the FDA's public health and regulatory activities. This includes the development and coordination of all FDA communications as well as outreach efforts to the news media, health professionals, patient advocates, industry, states, consumer groups, and the general public. External materials include FDA press announcements, FDA Voices blogs, and FDA Consumer Updates.

FDA's Office of Legislation (OL) ensures that Congress has the most accurate and up-to-date information about biomedical research, coordinates legislative activities with the Department of Health and Human Services, and manages FDA's response to requests from the various entities that serve Congress. As part of this role, OL helps to ensure that FDA's responses to Congressional inquiries, testimony, and other requests accurately represent scientific information.

a. Speaking on Behalf of FDA in an Official Capacity

The agency is committed to a culture of openness in its interactions with the public and follows HHS's news media policy, Guidelines on the Provision of Information to the News Media. FDA's COPs may have additional communications policies that govern COP-specific communications efforts with external parties (e.g., reports, scientific articles). FDA staff speaking on behalf of FDA should familiarize themselves with all applicable policies and limitations.

b. Sharing Personal Views as FDA Staff

FDA's Social Media Policy and HHS's News Media Guidelines encourage staff to use social media to share information that may benefit the public health, consistent with the guidelines set forth in these policies. It is important to remember that, when a staff member uses social media tools in a personal capacity, they are not speaking for the agency, and it shouldn't appear to others as though they are speaking for FDA. Before engaging in the use of social media related to FDA matters, FDA staff should be familiar with the guidelines and limitations discussed in FDA's Social Media Policy, including, but not limited to, legal limitations related to the Hatch Act (discussed later in this policy) and limitations related to the disclosure of confidential, commercial information or trade secret information. FDA's Social Media Policy thus recognizes the interest of staff in expressing their views via social media and does not require that staff

obtain permission or approval from supervisors or agency management before using social media in a personal capacity. In addition, HHS's News Media Guidelines describe how HHS staff are both permitted and encouraged to speak to the public about their work.

C. Resolving Disputes

Consistent with the core tenets of GSS, FDA provides robust dispute resolution procedures for scientific disagreements:

"Scientific Dispute Resolution at FDA" (Staff Manual Guide ("SMG") 9010.1) requires the COPs to establish processes for resolving scientific disputes. These processes must include, among other things: key messages that FDA staff are encouraged to voice scientific disagreements within their COP and that they are protected from retaliation and repercussions for raising such disagreements; a process for resolving such disputes at the lowest possible level, documenting differences of opinion, and elevating through increasingly higher levels of management when necessary; a requirement that the head of the COP render a written decision if the dispute cannot be resolved at a lower level; and appropriate timeframes. The agency-wide SMG also provides a mechanism for staff to elevate scientific disputes to the Office of the Commissioner. An agency Dispute Process Review Board, chaired by the agency's Chief Scientist, is then responsible for conducting full and fair evaluations of disputes to determine whether the appropriate processes were followed, whether the decisions made were based on consideration of all relevant evidence and views bearing on the scientific question at issue, and whether the initiating staff member was provided an opportunity to express their concerns at all appropriate levels.

"Cross-Center Dispute Resolution at FDA" (SMG 9010.2) describes policies and procedures for addressing differences of opinion regarding scientific or regulatory issues among personnel in different COPs, including but not limited to teams engaged in coordinated or joint reviews of combination products or related co-development projects (e.g., companion diagnostic and related therapeutic drug or biologic, development of guidance, or development or adoption of standards). The policy establishes an expectation that FDA staff will follow an orderly progression in the process of addressing a difference of opinion. Reasonable, good-faith efforts should be made to consider and resolve scientific or regulatory disagreements between COPs informally at the lowest operational level possible during the review process.

"Authorship Dispute Resolution at FDA" (SMG 9010.3). FDA encourages discussion among collaborating researchers at the outset of any research project concerning how authorship credit will be apportioned. A strong commitment to the successful resolution of authorship disputes is necessary to protect the overall integrity of research conducted by the agency's scientific community. As this SMG explains in more detail, FDA has adopted the International Committee of Medical Journal Editors (ICMJE) definition of authorship, which defines an author as someone who meets four criteria: (a) substantial contributions to the conception or design of the work, or the acquisition, analysis, or interpretation of data for the work; (b) drafting the work or revising the work critically for important intellectual content; (c) final approval of the version to be published; and (d) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately

investigated and resolved. FDA's SMG further describes how authorship disputes should be managed throughout FDA, sets forth recommended elements to be included in authorship dispute resolution processes adopted by COP policies, and establishes an agency-wide process for authorship disputes.

"Policy for Responding to Allegations of Research Misconduct" (SMG 9003.1) requires all FDA staff to report observed, suspected, or apparent research misconduct to the Agency Intramural Research Integrity Officer (AIRIO). This policy applies to allegations of research misconduct, which is fabrication, falsification, or plagiarism in proposing, performing, recording, or reviewing research, or in reporting research results.[16] FDA staff may discuss suspected research misconduct informally, anonymously, and hypothetically with the AIRIO. This SMG prohibits research misconduct by FDA staff and describes how FDA reviews allegations of research misconduct consistent with the legal obligations of an institution under 42 CFR Part 93.

D. Keeping Proper Records

Proper records management is an integral part of GSS. Staff Manual Guide (SMG) 3291.9, Essential – Vital Records Management Policy, effective August 7, 2018, establishes the policy and procedures to implement an essential records management program at FDA. Proper record keeping and management is not only important to (and legally required for) FDA's regulatory decision making, but it is also a necessary foundation for GSS at FDA. Adequate records help to ensure that open scientific debate is possible, and most of the core tenets of GSS implicitly rely on the availability of properly kept records, without which GSS at the agency would be undermined. Therefore, among other obligations, it is the policy of this agency to:

- Ensure the accuracy of the scientific record and to correct identified inaccuracies in accord with legal requirements;

- Require that staff represent their contributions to scientific work fairly and accurately and neither accept nor assume unauthorized and/or unwarranted credit for another's accomplishments; and

- Require that staff exercise appropriate diligence in preserving and maintaining research resources, such as records of data and results that are entrusted to them.

The agency must document every significant decision – and the basis for that decision – in an administrative file that must include, among other things, "relevant evaluations, reviews, memoranda, letters, opinions of consultants, minutes of meetings, and other pertinent written documentation" and must reflect "significant controversies or differences of opinion and their resolution" (21 CFR 10.70).

E. Leveraging Technology

[16] Public Health Service Policies on Research Misconduct 42 CFR 93.

FDA leads the Executive Branch in its early and effective adoption of Artificial Intelligence (AI) and other cutting-edge technologies. FDA's use of AI to streamline the review process and improve productivity at the agency is significant and ongoing (see, e.g., "FDA Launches Agency-Wide AI Tool to Optimize Performance for the American People"). For the latest information on the AI-powered tools available to staff, consult InsideFDA.gov.

In addition to harnessing the power of AI, FDA is also leveraging other technologies to promote GSS by fostering additional pathways for hypothesis generation, data validation, and collaboration, to name only a few. For example, FDA's Advanced Manufacturing Program aims to boost the use of new or innovatively applied medical product manufacturing technologies in a variety of public health contexts. FDA is also making use of New Approach Methodologies to accelerate cures and meaningful treatments while reducing the use of animal testing. The GSS underlying these technologies often involves model-based lab testing and real-world human data in addition to cutting edge computational modeling.

F. Behaving Ethically

FDA staff have a responsibility to the United States Government and its residents to place loyalty to the Constitution, laws, and ethical principles above private gain. To ensure that everyone can have complete confidence in the integrity of the federal government, staff shall respect and adhere to the standards of ethical conduct for employees of the executive branch.[17] FDA's ethics program is structured to provide advice and assistance to current and former staff in order to help ensure that decisions they make, and actions they take, are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity of the federal government.

Federal Standards of Conduct. FDA requires all staff to comply with all applicable rules and regulations regarding financial conflicts of interest (see 5 CFR 2635, 5501, and 5502). Training modules on conflicts of interest are available on the agency intranet, and FDA requires all confidential and public filers to take annual training. FDA's Ethics and Integrity Staff provide advice and assistance to staff on a variety of ethics-related matters including, but not limited to, financial disclosure, prohibited financial interests, outside activities, and post-employment restrictions. For example, FDA employees are subject to rules that restrict financial holdings in organizations that sell products regulated by FDA, also known as Significantly Regulated Organizations: FDA's Prohibited Financial Interests for FDA Employees webpage.

FDA employees must also abide by the Hatch Act, a law that restricts federal employees' political activity: The Hatch Act: Political Activity and the Federal Employee.

[17] Standards of Ethical Conduct for Employees of the Executive Branch 5 CFR 2635; Employee Responsibilities and Conduct regulations at 5 CFR 735; Office of Government Ethics. Standards of Ethical Conduct for Employees of the Executive Branch. The Fourteen General Principles; 45 CFR 73 - HHS Residual Standards of Conduct.

5. Practice and Implementation of GSS by COPs

To fully operationalize the core tenets of GSS, FDA's COPs will:

- implement appropriate COP-level policies and procedures consistent with the core tenets of GSS, as described in this policy, the OSTP memo, and the EO and as appropriately tailored to their specific research environments and regulatory operations;

- except as prohibited by law, and consistent with relevant policies that protect national security or sensitive personal or confidential business information, make publicly available influential scientific information—i.e., the data, analyses, and conclusions associated with scientific and technological information produced or used by them that they reasonably conclude will have a clear and substantial effect on important public policies or important private sector decisions—along with the models and analyses used to generate such scientific and technological information, consistent with the obligations and limitations described in EO Section 4(b);

- review "actions taken between January 20, 2021, and January 20, 2025, including regulations, guidance documents, policies, and scientific evaluations and take all appropriate steps, consistent with law, to ensure alignment with the policies and requirements" of the EO;[18] and

- ensure their staff are adequately trained on the core tenets of GSS, this SMG, and all COP-level policies and procedures implementing GSS.

COPs will implement these directives consistent with federal law and in consultation with FDA's Office of the Chief Counsel, where appropriate.

6. Reporting GSS-Related Concerns

A. When to Report a GSS-Related Concern

Maintaining GSS at FDA is the responsibility of all FDA staff. Whenever possible, as a first step toward resolving potential GSS-related issues, FDA staff should work directly with their colleagues, supervisors, COP ombuds offices, and other relevant personnel to attempt to address GSS concerns using the existing FDA policies. Typically, a particular concern related to GSS has a specific implementing policy and process that provides a path to address that concern. For example, a concern related to the publication of research conducted at FDA may be addressed by FDA's "Review of FDA-related Articles and Speeches" (SMG 2126.3), whereas a disagreement concerning the appropriate scientific approach to measure a particular component of a drug product under review, would be best addressed by "Scientific Dispute Resolution at FDA" (SMG 9010.1). Many of the policies implemented to promote and maintain GSS are referenced and described earlier in this SMG, and FDA staff are encouraged to seek help from OSI and COP ombuds staff to identify the appropriate policies and procedures to address specific GSS-related

[18] EO at 5.

concerns. Once identified, the governing process should be used to resolve the matter (e.g., SMG 9010.1 describes the process of resolving scientific disputes at FDA, including informal and formal procedures, appeals, etc.).

COP-specific policies and procedures for resolving GSS-related issues take various forms. For example, the Center for Devices and Radiological Health's policy, "Resolution of Internal Differences of Opinion in Regulatory Decision-Making," and the Center for Biologics Evaluation and Research's policy, "Resolution of Differences in Scientific Judgement in the Review Process," are COP-specific standard operating procedures for the resolution of internal scientific disputes. FDA staff should be familiar with all the COP-specific policies and procedures that apply to them and that may be useful to address GSS-related concerns.

When such good-faith efforts and existing policies and procedures do not resolve an issue related to GSS, FDA staff may consult with their COP ombuds or equivalent or OSI staff for help determining next steps. When existing policies or procedures do not clearly describe processes for addressing concerns about GSS at the agency, including deviations from FDA's implementation of the core tenets of GSS described in this SMG, FDA encourages staff to report those concerns using the process described in the next subsection.[19]

B. How to Report a GSS-Related Concern

Because FDA has implemented a variety of specific policies and processes in different contexts to address GSS-related concerns, FDA staff are encouraged to discuss their particular concern with OSI prior to submitting a description of the concern using the internal web portal described below. Such discussions are confidential and typically help FDA staff to better understand which pathways for resolution of a particular issue are available to them, often under existing policies and procedures. Please note, however, that such a discussion is not a prerequisite for submitting information related to a concern using the process describe below.

This SMG is not intended to limit FDA staff's use of other means to report potential wrongdoing as provided elsewhere by law or policy. FDA encourages staff to report potential concerns related to GSS to the agency using the reporting mechanism described here, in addition to any other applicable remedies available. To report a GSS-related concern at FDA that is not adequately addressed by other existing policies, the agency encourages FDA staff to contact OSI using "Reporting GSS-Related Concerns" located on the OSI intranet site. This internal web portal provides a mechanism for direct and/or anonymous reporting.

When reporting a GSS-related concern, regardless of the method of communication, a reporter should include the following information:

[19] Nothing in this SMG is intended to discourage FDA staff from using any and all legal avenues available to report wrongdoing or to seek whistleblower protections provided to them by other laws and policies, including independently seeking advice and assistance from HHS's Office of Inspector General, the Office of Special Counsel, and other sources. The reporting system described in this section is not intended to supplant these mechanisms for redress. Resources and contact information for these sources are provided in the References section.

Concern. What specific aspect of GSS at FDA may have been compromised?

Detailed Description. How specifically was GSS compromised? Explain what occurred with relevant details, including a timeline and other relevant facts that may be used to establish whether and how GSS was compromised.

Supporting Information. What witnesses and records help to prove the compromise occurred? No witnesses or documents are required to report a GSS-related concern, but both should be identified and provided, if possible.

Contact information. If the reporter is willing to be contacted regarding this report, provide a preferred contact method and information.

The FDA reporting website referenced above allows for anonymous reporting, and FDA staff who wish to remain anonymous may report GSS-related concerns using this portal. Please be aware that follow-up by OSI with the reporter of a concern is frequently critical to establishing whether GSS was compromised and to making use of the appropriate process to address it. As a result, FDA encourages all staff to identify themselves when reporting a such a concern if they feel comfortable doing so.

C. Retaliation for Reporting GSS-Related Concerns

Reprisals of any kind for the reporting of GSS-related concerns are antithetical to an atmosphere of open scientific discourse and are contrary to core tenets of GSS at this agency. All FDA staff, regardless of their role, must refrain from any such reprisals and should respect the often difficult decision of their colleagues to report GSS-related concerns. Further, FDA staff must respect the importance of such reporting to FDA's overall scientific functioning and refrain from any conduct that would punish or discourage such reporting. If any staff member experiences retaliation of any kind for reporting a GSS-related concern, in addition to other remedies available to federal employees noted below, staff may contact OSI for assistance in addressing such conduct.

Federal employees have the right to be free from prohibited personnel practices, including retaliation for whistleblowing and voicing scientific dissent. FDA is committed to making sure that all staff are aware of their rights as well as the safeguards that are in place to protect them. To ensure that GSS-related concerns, among others, are adequately addressed, FDA staff must feel free to express their concerns to agency officials, or protected sources such as the two entities mentioned below, without fear of retribution:

HHS's Office of Inspector General (OIG) has jurisdiction to investigate whistleblower reprisal allegations brought by FDA staff. Information on how to report suspected reprisals to OIG is available here.

The U.S. Office of Special Counsel (OSC) plays an important role in helping whistleblowers. OSC is an independent agency that protects federal employees from prohibited personnel practices including whistleblower retaliation and unlawful hiring practices, such as nepotism.

OSC also describes their role as providing an independent, secure channel for disclosing and resolving wrongdoing in federal agencies. OSC provides a list of prohibited personnel practices on their website as well as additional information for federal employees related to reporting such practices to OSC.

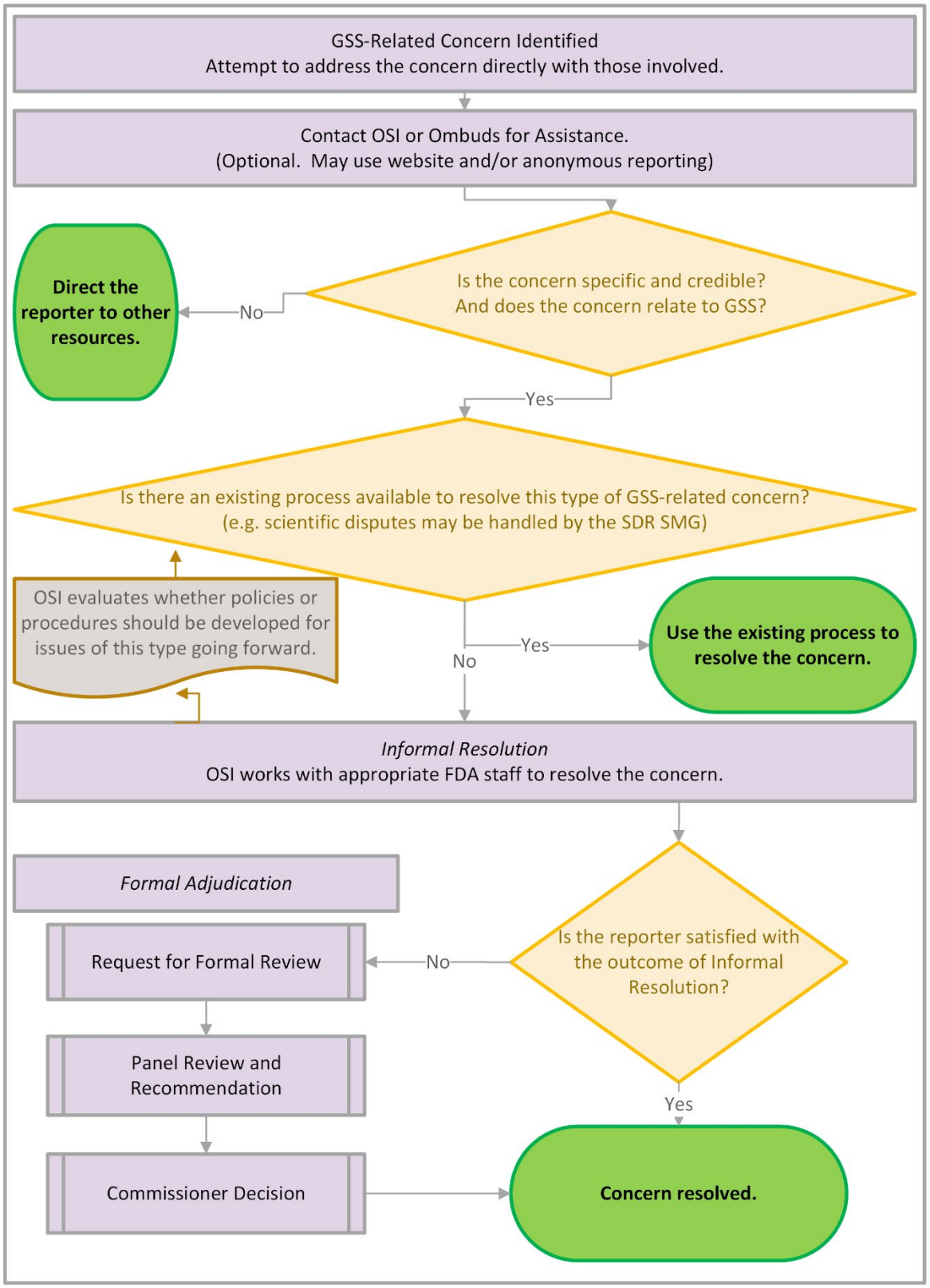
D. FDA's Process for Evaluating GSS-Related Concerns

OSI will evaluate all reports of potential compromise of GSS at FDA reported under subsection B, including concerns related to alleged violations of the EO as described in Section 7. If an existing policy or process with an adjudicative component would adequately address the concern raised in a report, OSI staff will work with the reporter and other appropriate parties to address the concern through the applicable existing pathway. For concerns without such an existing pathway, OSI will assess reports to determine whether the concern is credible, specific, and relates to a core tenet of GSS. If so, OSI will then work informally with appropriate COP leadership, ombuds staff, managers, and other appropriate FDA staff to resolve the concern in a manner consistent with the core tenets of GSS described earlier in this SMG.

After this informal resolution stage concludes, the reporter may elect to request formal adjudication. To initiate such an adjudication and challenge any informal resolution, the reporter should submit a written request for formal review to OSI (web portal and email). For all qualifying adjudication requests (i.e., those requests following informal efforts to seek resolution that are not subject to an existing GSS-related policy with an adjudication component), OSI will assemble a three-person panel from FDA staff to evaluate the concern and make a written recommendation to the Commissioner describing the concern and specifying appropriate remedial measures, if any, that the panel determines would address the concern, consistent with the core tenets of GSS described earlier in this guide. The panel should include three members who do not have, or appear to have, a personal or professional interest in the outcome of the dispute. When possible, panel members should be selected based on any relevant knowledge or experience useful in understanding and evaluating the science at issue.

After reviewing the panel recommendation, the Commissioner will render a final decision for the agency, directing such remedial action as the Commissioner deems appropriate, if any. OSI will facilitate the implementation of any remedial actions directed because of this process and will work with all involved parties to ensure that remedial measures consistent with the Commissioner's determination are taken.

The following flowchart provides a visual overview of the process described in this section.


GSS-Related Concern Identified
Attempt to address the concern directly with those involved.
Contact OSI or Ombuds for Assistance.
(Optional. May use website and/or anonymous reporting)
Is the concern specific and credible?
And does the concern relate to GSS?
No
Direct the reporter to other resources.
Yes
Is there an existing process available to resolve this type of GSS-related concern?
(e.g. scientific disputes may be handled by the SDR SMG)
Yes
Use the existing process to resolve the concern.
No
OSI evaluates whether policies or procedures should be developed for issues of this type going forward.
Informal Resolution
OSI works with appropriate FDA staff to resolve the concern.
Is the reporter satisfied with the outcome of Informal Resolution?
No
Request for Formal Review
Formal Adjudication
Panel Review and Recommendation
Commissioner Decision
Yes
Concern resolved.

7. References

A. Internal FDA Resources

- Office of Scientific Integrity
  - Reporting and contact information: For reporting of concerns related to GSS, please visit this page for updated contact information**.**

- Office of Ethics and Integrity
  - Reporting and contact information: Ethics Advice Hotline at (240) 402-1111 or email FDAEthics_Advice@fda.hhs.gov.

- Office of External Affairs
  - Office of External Affairs
  - FDA Newsroom

- FDA Anti-Harassment Program
  - Reporting and contact information: AHP-CREW@fda.hhs.gov or ERIC Help Desk at 301-827-3742, (Option 3,3,3)
  - To report and allegation please go to: Anti-Harassment Program

- Conflict Prevention and Resolution Branch
  - Reporting and contact information: For addressing general workplace conflicts, email FDA's Alternative Dispute Resolution (ADR) program at adr@fda.hhs.gov or call 301-796-9420

- FDA Records Management Program

B. External resources

Below are helpful links to resources for FDA staff on whistleblower protections and the reporting of whistleblower reprisal.

HHS - Office of Inspector General Resources
OIG Hotline or 1-800-HHS-TIPS
Whistleblower Protection Coordinator Website or email
Whistleblower.Coordinator@oig.hhs.gov
Whistleblower Protection FAQs
Whistleblower Protection Information Brochure

Office of Special Counsel Resources *(for federal civilian employees)*
If you are a civilian federal employee and wish to make a whistleblower disclosure or report reprisal for doing so outside HHS, you may contact the U.S. Office of Special Counsel.

Whistleblower Disclosure Hotline: For Inquiries on How to Report Fraud, Waste, Abuse or

Dangers to Health and Safety, call 1-800-872-9855 or 1-202-804-7000, or email info@osc.gov
Prohibited Personnel Practices Information
OSC Fact Sheet: Your Role in an OSC Investigation

8. Effective date

The effective date of this guide is August 15, 2025.

9. Document History – SMG 9001, Gold Standard Science at FDA

Status (I, R, C)	Date Approved	Location of Change History	Contact	Approving Official
Initial	08/15/2025	N/A	OC/OSI	Steve Kozlowski, Acting Chief Scientist