

Scientific Integrity Report Card Food and Drug Administration

Scientific Integrity Grading Rubric	Total Possible: 100 Points	Total Awarded: 42 Points
Scientific Misconduct	Subsection Total: 40	Subsection Total: 13
A. Political Manipulation of Science	6	3
B. Breadth of Coverage	4	1
C. Whistleblower Protection	12	4
D. Investigations of Complaints	5	3
E. Investigation Independent from Chain of Command	6	2
F. Sanctions for Misconduct	6	0
Public Communications of Science	Subsection Total: 40	Subsection Total: 14
A. Process for scientist to publish or lecture regarding their official work with the general public, in external peer-reviewed journals or at scientific conferences	10	2
B. Absence of policy review or agency screening for the above	10	2
C. Ability of scientists to review press releases regarding their work prior to final publication	10	0
D. Explicit provision for agency scientists to be on governing and editorial boards of scientific societies	10	10
Transparency of Policy Decision-Making	Subsection Total: 20	Subsection Total: 15
A. Requirement that all agency policy decisions must be based on science subjected to external peer review	10	5
B. Original research documents are part of administrative record	10	10

I. Scientific Misconduct – (13/40 pts)

A. Political Manipulation of Science (3/6 pts)

1. *Prohibits alteration of technical/scientific documents for non-technical reasons (3/3 pts)*

“[U]nderlying research data and findings should be obtained and reported with integrity and should never be altered for any reason.”

2. *Prohibits intimidation or coercion to alter scientific data/analysis/conclusions for non-technical reasons (0/3 pts)*

The FDA’s Scientific Integrity Policy does not address this.

B. Breadth of Coverage (1/5 pts)

1. *Applies to political appointees and senior managers (1/3 pts)*

It is unclear exactly to whom the FDA’s scientific integrity policy applies.

2. *Applies to contractors, states, and other partners (0/2 pts)*

No. “This document addresses scientific decision-making and not, directly, scientific research conducted by, or in collaboration with, the agency.”

C. Whistleblower Protection (4/12 pts)

1. *Explicitly protects those filing misconduct complaints from retaliation (4/4 pts)*

“FDA’s SMG on scientific disputes states that, “[i]t is the responsibility of all those involved [in the dispute process] to ensure that all initiators of disputes are protected from any retaliation by their supervisors, peers, leadership and others, related to initiating or engaging in this process.”

2. *Protects scientists for retaliation based on content of work (0/4 pts)*

No.

3. *Provides that agency officials who engage in retaliation will be subject to discipline (0/4 pts)*

No.

D. Investigations of Complaints (3/5 pts)

1. *Defined process (1/1 pt)*

FDA's Scientific Integrity Policy contemplates that the scientific dispute resolution process, SMG 9010.1, *available at* <http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm215422.htm> created in 2009 will be used to address scientific integrity complaints.

2. *Timelines (1/1 pt)*

Yes.

3. *Ability of complainant to respond (0/1 pt)*

None specified.

4. *Transparency of findings and rationale (1/1 pt)*

“[A] written recommendation will be distributed to all internal parties involved in the dispute.”

5. *Relationship with the IG is clearly defined (0/1 pt)*

Neither the FDA's Scientific Integrity Policy nor SMG 9010.1 address this.

E. Investigation Independent from Chain of Command (2/6 pts)

Yes. “In every dispute, members of the Board from Center(s) where disputes arise will recuse themselves from the dispute review process.”

Each of the FDA's Centers is responsible for creating their own procedures to address a scientific dispute, including scientific integrity violations. This process is to be overseen by the Center Ombudsmen. The FDA recommends as a best practice, but does not require, the Centers to make avenues that avoid the chain of command available to report and address scientific integrity violations available. The FDA does have an agency-wide appeals process where any member of the reviewing panel in the chain of command of the alleged violator or complainant must recuse themselves; however, this appeals panel only reviews whether the Center's procedures were properly followed and whether all evidence was appropriately considered.

F. Sanctions for Misconduct (0/6 pts)

1. *States that misconduct is grounds for disciplinary action or dismissal (0/2 pts)*

No. Moreover, FDA's Scientific Dispute Resolution process, above, seems more focused on addressing differences of scientific opinion and ensuring that center processes were followed than on investigating the conduct of managers.

2. *Explicit procedure for discipline of sustained misconduct complaints (0/2 pts)*

No.

3. *Automatic review of court rulings based upon arbitrary and capricious application of scientific information or scientific findings (0/2 pts)*

The FDA's Scientific Integrity Policy does not address this.

II. Public Communications of Science – (14/40 pts)¹

- A. Process for scientist to publish or lecture regarding their official work with the general public, in external peer-reviewed journals or at scientific conferences (2/10 pts)

FDA is subject to the Department of Health & Human Service's media policies. Accordingly, those scores are applied here.

“HHS scientists may speak to the media and the public about scientific and technological matters based on their official work, with appropriate coordination with their immediate supervisor and the appropriate public affairs office.”

- B. Absence of policy review or agency screening for the above (2/10 pts)

In FDA's media policy currently under development, “[t]o reflect current practices, there will be an explicit provision prohibiting press officers from asking or directing federal scientists to alter scientific findings.”

- C. Ability of scientists to review press releases regarding their work prior to final publication (0/10 pts)

The Department of Health and Human Service's Scientific Integrity Policy, as applied to FDA, does not address this.

- D. Explicit provision for agency scientists to be on governing and editorial boards of scientific societies (10/10 pts)

“FDA further permits its scientists and engineers to become editorial board members, to participate in professional societies, and to receive honors and awards, consistent with applicable ethical rules.”

III. Transparency of Agency Decision-Making – (15/20 pts)

- A. Requirement that all agency policy decisions must be based on science subjected to external peer review (5/10 pts)

¹ “FDA is currently developing its own written media relations policy, consistent with HHS's guidelines and the agency's current practices”

FDA utilizes “peer review of data and research used in decision-making, where feasible, appropriate and consistent with the law.”

B. Original research documents are part of administrative record (10/10 pts)

Yes. “FDA’s regulations . . . [r]equire the agency to document any significant scientific decision – and the basis for that decision – in an administrative file that must include all ‘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.