NRG ONCOLOGY

Advancing Research. Improving Lives.™

NRG Oncology Research Misconduct Policy
Version 2: May 9, 2025

I. INTRODUCTION

NRG Oncology Foundation, Inc. (**NRG Oncology**) is committed to fostering a culture of integrity in medical research and to preventing situations and behaviors that could lead to allegations of research misconduct.

Practicing integrity in medical research and scholarship means planning, proposing, performing, reporting, and reviewing medical research in accordance with core values that help to ensure that the medical research enterprise advances scientific and scholarly knowledge that is reliable. These core values include objectivity, honesty, openness, fairness, accountability, and stewardship.

Since NRG Oncology is fully committed to ensuring it conducts its medical research activities with integrity and the highest ethical standards, it complies with U.S. Department of Health and Human Services (**DHHS**) regulations, including the Office of Human Research Protections (**OHRP**), Office of Research Integrity (**ORI**), and requirements as described in DHHS 42 CFR Parts 50 and 93.

II. DEFINITION OF RESEARCH MISCONDUCT

Participants in the NRG Oncology research enterprise stray from the norms and appropriate practices of science and other scholarly inquiry when they engage in research misconduct. *For the purposes of this policy*, "**research misconduct**" is defined as "*fabrication*," "f*alsification*," "*plagiarism*," or "*deliberate interference*" in "*research activities*" conducted by NRG Oncology Members (*as defined below*):

"**Fabrication**" is making up data or results and recording or reporting them;

"**Falsification**" is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research records;

"**Plagiarism**" is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit;

"**Deliberate interference**" is intentionally causing material harm to the research or scholarly work of others and may include damaging or destroying the property of others, such as research equipment or supplies; disrupting active experiments; or altering or deleting products of research, including data; and

"**Research activities**" includes proposing, conducting, reviewing, or reporting the results of research or other scholarly inquiry.

Research misconduct does **not** include:

Honest error;
Differences of opinion; or
Authorship disputes.

III. ADDITIONAL DEFINITIONS

Director refers to individuals appointed as the lead of an NRG Oncology department, Operations Center, or Statistics and Data Management Center (**SDMC**) office.

Fraud, for the purposes of this policy, is defined as the *intentional* fabrication, falsification, or plagiarism of *data*, or *intentional deception* in the conduct of research.

Group means the NRG Oncology Foundation, Inc.

Group Chairs collectively means the elected Chairs of the Group.

Non-Compliance, for the purpose of this policy, is defined as failure to follow federal regulations; state and local laws; and/or NRG Oncology policies or posted requirements. Non-compliance may be willful or unintentional.

NRG Oncology Member (Members) applies to all individuals involved in the development, conduct, and reporting of NRG Oncology research, including: personnel at NRG Oncology Operations Center, SDMC, or Biobank locations; protocol chairs and co-chairs; committee chairs and vice chairs; and investigators and research personnel responsible for enrolling patients and entering data into NRG Oncology protocols.

Principal Investigator (PI) refers to those individuals who serve as an NRG Oncology member institution PI or as the PI on a grant or subaward from NRG Oncology or the National Cancer Institute (**NCI**) to participate in NRG Oncology's National Clinical Trials Network (**NCTN**) research activities. PIs are responsible for a scope of work carried out at their organization associated with NRG Oncology.

Research Integrity Officer (RIO) is the individual appointed by NRG Oncology to assess complaints, conduct evaluations, and report on allegations of research misconduct, fraud, or non-compliance, and on other events/allegations with the potential for a serious negative impact on NRG Oncology's research or reputation.

IV. SCOPE

This policy applies to NRG Oncology Members. This policy compliments and is not intended to replace the requirements of the individual's local institution. This policy does not address protocol non-compliance which is required to be reported directly to the appropriate Institutional Review Board (**IRB**) or Ethics Committee (**EC**) or audit findings, which are reported according to the NRG Oncology's Audit Policy.

V. ROLES AND RESPONSIBILITIES

1. NRG Oncology Members

Any NRG Oncology Member who has reason to believe that an individual has engaged in an act of research misconduct, fraud or non-compliance related to NRG Oncology sponsored or associated research or activities is required to report it immediately as detailed in Section VI.1 (Initial Reporting).

Members are to maintain confidentiality related to allegations of research misconduct, fraud, or non-compliance, and not discuss the allegation(s) with others who do not have a need to know. Members are to conduct themselves in keeping with the regulations and responsibilities of their position within NRG Oncology.

2. Group Chairs

The Group Chairs ensure that NRG Oncology conducts its activities according to the highest ethical standards for research and scholarship. They do this by instituting policies and procedures that require allegations of research misconduct, fraud, or non-compliance undergo an impartial and unbiased inquiry and require the Group to take the actions necessary to ensure the integrity of research, the rights and interests of research subjects and the public, and the observance of legal requirements and responsibilities.

To accomplish this responsibility the Group Chairs will:

a. Appoint the RIO and provide the resources required to implement this policy.
b. Remain at arms-length to any active inquiry, and while they may be briefed and review draft reports to assess the impact to the Group and the effectiveness of the inquiry, they will not play an active role in an inquiry or evaluation.
c. Review the recommendations resulting from initial inquiries and, if a subsequent investigation is performed, they will make the final decision on the implementation of the recommendations. The Group Chairs will review recommendations from external regulatory bodies and ensure, as appropriate, they are adhered to. They will recuse themselves when institutional or other relationships or interests may give rise to a perception of bias.
d. Ensure that confirmed allegations and/or findings are reported to the funding organization's programmatic officer (i.e., at the NCI) and as required in Section VI.4 (Reporting).

3. Executive Director

The Executive Director is responsible for maintaining and updating NRG Oncology policies and procedures related to research misconduct, fraud or non-compliance and ensuring that they are available and broadcast to all Members. The Executive Director will work closely with the RIO to evaluate allegations or reports of possible research misconduct, fraud or non-compliance and will conduct for-cause evaluations for compliance concerns and findings stemming from NRG Oncology business operations and administration as detailed in Section VI of this policy. The Executive Director will report findings and recommendations to the Group Chairs and implement process or policy changes as approved by the Group Chairs.

The Executive Director will:

a. Support any for-cause evaluation process conducted by the RIO, assisting in fact-finding, drafting reports, or other tasks as directed by the RIO.
b. Assist Member institution officials in their for-cause evaluation processes or initial assessments where reports or findings indicate potential concerns at a member institution related to NRG Oncology.
c. Recuse themself where institutional or other relationships or interests may give rise to a perception of bias.

4. Principal Investigators (PIs)

NRG Oncology PIs who identify or receive allegations or reports of possible research misconduct, fraud or non-compliance will conduct an initial assessment of the concern to identify if it relates to more than the office under their purview or has human-subject implications related to NRG Oncology research participants and/or their data. If the issue relates only to their area of oversight, does not have impact across NRG Oncology functional areas, and does not have human subject impact, the PI will handle the incident according to their local policies and procedures.

The PI is required to report to the RIO or Executive Director any allegation or finding that crosses NRG functional areas or offices, and/or has the potential to impact NRG Oncology human subject research or may be required to be reported to an external agency. PIs are also required to comply with their institution's local policies and procedures.

5. Research Integrity Officer (RIO)

The RIO is appointed by the Group Chairs and facilitates the evaluation process serving as the NRG Oncology point of contact regarding concerns of:

- Actual or alleged fraud, including allegations of plagiarism and/or falsification of data;
- Violations of criminal laws impacting NRG Oncology;
- External compliance violations requiring referral or reporting to a governmental agency (e.g., Federal, State, or local oversight agency) as well as matters triggering an external reporting obligation; and
- Matters with significant reputational risk, e.g., other ethical or compliance related matters that pose a high probability of garnering negative publicity or media attention.

The RIO will work closely with the Executive Director to evaluate allegations or reports of possible fraud, non-compliance, potential harm to human subjects, research misconduct, criminal violations, or reputational risk and will conduct a for-cause evaluation of the allegation(s) as detailed in Section VI of this policy. The RIO will apprise the Group Chairs of the progress of inquiries and investigations and report findings to the Group Chairs with recommendations. On behalf of the Group Chairs, the RIO will report, or assure reporting, to external regulatory and/or oversight bodies as required, including, if appropriate, the relevant IRB(s). The RIO has the final authority to make decisions regarding whether a finding, or potential finding, requires external reporting.

6. NRG Publications Committee

The NRG Oncology Publications Committee will report to the RIO any confirmed or suspected instances of plagiarism, falsification, or fabrication of data in an NRG Oncology publication. If required, the Publications Committee will communicate with the appropriate journal concerning any required correction or retraction of NRG Oncology published or reported results.

VI. PROCEDURES

The process for responding to allegations of research misconduct, fraud, or non-compliance include the following procedures, which are outlined in further detail below:

- Reviewing the report of potential research misconduct, fraud, or non-compliance and conducting an inquiry;
- Conducting an initial investigation based on the inquiry;
- Conducting a full investigation, if warranted;
- Creating a final report; and
- Reporting to appropriate authorities.

1. **Initial Reporting.**
All individuals are encouraged to report allegations of potential research misconduct, fraud, or non-compliance related to NRG Oncology activities to the RIO, Executive Director, Group Chairs(s), or any member of the leadership team without fear of retribution or retaliation. Reports may be submitted directly to the NRG Oncology Membership Department in the Operations Office via email at info@nrgoncology.org or at 215-574-3173. Reporting is available 24 hours a day (leave a voice mail) and may be made anonymously. Individuals may also report concerns directly to OHRP through their online portal (https://oashsps.my.site.com/ohrpwebforms/s/incident-web-form) or request a reporting form via email IRPT.OS@hhs.gov.

   Reports that are submitted to the Group Chairs, other members of the leadership team or to the Membership Department via email or phone will be referred to the RIO and the Executive Director. The RIO and Executive Director will conduct an inquiry into the allegation(s).

2. **Conducting the Inquiry.**
Individuals who report an allegation of research misconduct, fraud, or non-compliance (the complainant) and the person(s) against whom the allegation is made (the respondent) shall be afforded confidential treatment to the maximum extent possible. The individual(s) shall also be afforded a prompt and thorough investigation and an opportunity to comment on allegations and findings of the inquiry and/or investigation.

   a. If there is evidence of fraud, serious non-compliance, potential harm to human subjects, research misconduct, criminal violations, or reputational risk, the incident will be referred to the RIO and a for-cause evaluation initiated. The RIO may make a determination to conduct a further inquiry to obtain a comprehensive understanding of the circumstances and will determine if reporting to the appropriate IRB or health authority is required.
   b. If there is evidence of operational or administrative fraud or non-compliance without human subject impact, the Executive Director will initiate a for-cause evaluation. If the evidence is insufficient, or facts remain unclear, the Executive Director will undertake a fact-finding phase until it is clear what non-compliance or other category of event has prompted the concern. If unable to make a determination, the Executive Director will consult with the RIO.
   c. Every allegation or reported finding will be assessed, and the assessment of that allegation or finding will be conducted within a reasonable timeframe and in keeping with the federal requirements. If further investigation is not deemed warranted, a written report summarizing the inquiry will be prepared and sent to the Group Chairs.

3. **Conducting an Investigation**
   a. If it is determined that an investigation (i.e., an initial review of the evidence to determine if the criteria for conducting an investigation have been met) is warranted for research misconduct or fraud, the RIO shall complete the investigation, prepare the investigative report and allow the respondent a reasonable opportunity to comment on the report, within sixty (60) calendar days of its initiation. If the inquiry takes longer than sixty (60) days to complete, the RIO shall include documentation of the reasons for the delay in the investigation record. The report shall contain the following information:

      i. The name and position of the respondent(s);
      ii. A description of the allegations of research misconduct or fraud;
      iii. The federal support involved, including, for example, grant numbers, grant applications, contracts, or publications listing federal support;
      iv. The basis for recommending that the alleged actions warrant an investigation; and
      v. Any comments on the report by the respondent or the complainant.

   b. All assessments and evaluations of an allegation or finding will be conducted impartially, and the report will be provided to the Group Chairs even if the assessment or evaluation does not result in validating the allegation or finding.
   c. Any allegation or finding indicative of criminal activity will be reported immediately to the Group Chairs, and the appropriate authorities will be notified.

4. **Reporting.**
   a. NRG Oncology shall notify the appropriate governing body (i.e., ORI, health authority) and industry collaborators of the outcome of the investigation and submit a final report within one hundred twenty (120) calendar days of the initiation of the investigation. If NRG Oncology cannot provide a report within one hundred twenty (120) days to the appropriate governing body, NRG Oncology will submit a request for an extension for the ORI to complete the investigation for NIH-funded projects, and for non-NIH funded projects, will document the need for an extension. The extension request and documentation should include an explanation for the delay, an interim report on the progress to-date, an outline of what remains to be done, and an estimated completion date.
   b. The final report will include a description of the policies and procedures under which the investigation was conducted, how and from whom relevant information to the investigation was obtained, the findings, and the basis for the findings, text, or accurate summary of the views of any individual(s) found to have engaged in research misconduct or fraud, and a description of any sanctions taken by NRG Oncology.
   c. NRG Oncology will undertake reasonable and practical efforts, if requested and as appropriate, to protect or restore the reputations of persons alleged to have engaged in research misconduct or fraud but against whom no finding of research misconduct or fraud is made.
   d. NRG Oncology shall impose appropriate sanctions on individuals in the case of research misconduct or fraud when the allegation has been substantiated. Such

sanctions may include oral admonishment, written reprimand, and recommendation for demotion, suspension, or termination.

5. **Appeals.**
   a. An appeal of a finding or report to an external agency will be completed in accordance with that agency's policies and procedures.
   b. Any finding or sanction strictly under the purview of NRG Oncology may be appealed as follows:
      i. An appeal must be submitted, in writing addressed to the Group Chairs, within thirty (30) days of notification of the outcome of the finding or sanction. The appeal can be submitted via the RIO or Executive Director.
      ii. The Group Chairs will review the appeal and respond within twenty-one (21) days of receipt.
      iii. The result of the appeal is final.

6. **Record-Keeping**
   NRG Oncology shall maintain all records of the research misconduct proceeding, as defined in 42 CFR Section 93.317(a), for seven (7) years after completion of the proceeding, or any ORI or HHS proceeding under Subparts D and E of 42 CFR Part 93, whichever is later, unless NRG Oncology has transferred custody of the records and evidence to HHS, or ORI has advised NRG Oncology that it no longer needs to retain the records.

VII. REFERENCES

NCTN Program Guidelines (2012)
https://ctep.cancer.gov/initiativesPrograms/docs/NCTN_Program_Guidelines.pdf

OHRP Compliance Oversight Procedures for Evaluating Institutions (2009)
https://www.hhs.gov/ohrp/compliance-and-reporting/evaluating-institutions/index.html

DHHS 42 CFR Parts 50 and 93 Public Health Service Policies on Research Misconduct; Final Rule (2005) https://ori.hhs.gov/sites/default/files/42_cfr_parts_50_and_93_2005.pdf

Approved by NRG Oncology Group Chairs as of May 9,2025.

DocuSigned by:
Sharon Hartson Stine
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Sharon Hartson Stine
Executive Director

5/9/2025
Date

Version	Revision Description	Author	Version Date	Effective Date
1	New Policy	Kati Stoermer	May 2018	May 2018
2	Policy name and procedures updated to conform to NRG Oncology existing practices and HHS requirements.	Sharon Hartson Stine	09-May-2025	23-May-2025