I. INTRODUCTION
NRG Oncology is committed to insuring our organization conducts its business with integrity and the highest ethical standards. As such, we comply with federal regulations for Department of Health and Human Services (DHHS) regulations, including the Office of Human Research Program (OHRP), Office of Research Integrity (ORI), and requirements as described in DHHS 42 CFR Parts 50 and 93.

II. DEFINITIONS

**Center Director** refers to those individuals who serve as Principal Investigators in receiving a grant or subaward as part of the NRG Oncology National Clinical Trials Network, such as the individual Operations Center offices. These individuals are generally directly responsible for their own organization as an independent entity, as well as for a scope of work carried out at that organization associated with NRG Oncology.

**Functional Director** refers to those individuals appointed as the lead of an NRG Oncology department.

**Integrity Officer (IO)** is the individual appointed within NRG Oncology to conduct evaluations and assess complaints and/or findings of research misconduct, allegations or findings of fraud, findings, or allegations of reportable non-compliance, or any complaints or allegations with the potential for serious negative impact on the reputation of the Group.

**Research Misconduct** refers to the fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. This does not include honest error or differences of opinion.

**Non-Compliance**: Failure to follow federal regulations; state and local laws; and/or organizational policies or requirements. Non-compliance may be willful or unintentional.

III. SCOPE
This policy does not address protocol non-compliance or audit findings, which are handled through IRB in accordance with the National Cancer Institute Clinical Trial Monitoring Branch. In regard to integrity and ethics, this policy applies to all individuals involved in NRG Oncology research, as well as the administration and operations supporting that research. This includes personnel at NRG Oncology Operations, the Statistics and Data Management Center, grant sub-awardee institutions, protocol chairs and co-chairs, and investigators and research personnel responsible for enrolling patients entering data onto NRG Oncology protocols. This policy
compliments and is not intended to replace the requirements of the local institution or entity involved.

IV. ROLES AND RESPONSIBILITIES

1. Individuals involved in NRG Oncology
   a. To report, in a timely manner, any concerns of fraud, misconduct or non-compliance to NRG Oncology Leadership through info@nrgoncology.org and/or to the local IRB or oversight body as appropriate.
   b. To maintain confidentiality related to the report being made, and not discuss the allegation with others who do not have a need to know.
   c. Conduct themselves in keeping with the regulations and responsibilities of ones position within NRG Oncology, including Good Clinical Practice Guidelines.

2. Group Chairs
   a. Promote the highest ethical standards for research and scholarship
   b. Ensure an impartial and unbiased inquiry and evaluation of findings or reported concerns.
   c. Take action 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.
   d. Ensure compliance with external reporting requirements and ethical conduct standards in review of any finding or alleged concern.
   e. Appoint the Integrity Officer and provide resources for the conduct of his/her official duties
   f. The Group Chairs serve as the final internal regulating body for any compliance or integrity concerns related to NRG Oncology under this policy. The Chairs will review and decide on any sanctions stemming from findings within the purview of the Group. The Group Chairs will review and accept sanctions and decide on recommendations from external regulatory bodies and ensure, as appropriate, they are adhered to.
   g. The Group Chairs will report to or consult with the grant programmatic officer at the National Cancer Institute at their discretion, except in the case of a finding that raises to the level of reporting to an external regulatory body or incidents garnering media attention in which case such reporting would be obligatory.
   h. The Group Chairs shall 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 effectiveness of the inquiry, will refrain from any active role in an inquiry or evaluation.
   i. Be available to the IO within a situationally reasonable timeframe once given notice of a need to be briefed on a potentially reportable incident or finding.
   j. Recuse ones-self where institutional or other relationships or interests may give rise to a perception of bias.
3. Executive Director
   a. Maintaining and updating Group policies and procedures related to compliance and integrity
   b. Ensuring staff have received position-appropriate training to conduct themselves in keeping with the highest ethical standards.
   c. Proactively review Group Operations to ensure a culture of compliance and integrity, ensure process standardization, appropriate controls, and compliance with guidelines and policies stemming from grant awards, regulatory bodies, accepted fiduciary standards, and other requirements as applicable.
   d. Evaluate findings or reports of possible non-compliance. Conduct for-cause evaluations for compliance concerns and findings stemming from NRG Oncology business operations and administration, reporting findings to the Group Chairs with recommendations, and implement process or policy changes as approved by the Group Chairs.
   e. Refer reports or findings of possible fraud, criminal violations, compliance violations requiring external reporting, or other risks to the Integrity Officer.
   f. Support the for-cause evaluation process conducted by the IO, assisting in fact-finding, drafting reports, or other tasks as directed by the IO.
   g. Liaison with Member Institution officials to assist in their own for-cause evaluation processes or initial assessments where reports or findings indicate potential concerns at Member Institution locations, where the issue of concern is related to NRG Oncology.
   h. Recuse oneself where institutional or other relationships or interests may give rise to a perception of bias.

4. Center Directors
   a. The NRG Oncology Center Directors who identify a finding or receive a complaint of such will conduct an initial assessment of the concern to identify if it relates only to a single office under their purview, and does not have human-subject implications related to NRG Oncology research participants and/or their data.
      i. In the event that the issue relates only to their area of oversight and does not impact across NRG Oncology functional areas, and does not have human – subject impact within NRG Oncology, the Center Director will handle the incident in accord with local policies and procedures for such.
   b. Any finding that crosses NRG functional areas or offices, and/or has potential NRG Oncology human subject impact, and/or may be required to be reported by NRG Oncology to an external agency must reported to either the IO or Executive Director for further handling, in addition to keeping with local policies and procedures.
c. A Center Director may serve to support a for-cause evaluation under the direction of the Executive Director or IO as appropriate to the circumstances, such as drafting reports, conducting fact-finding, or other tasks as directed.

5. Integrity Officer
   a. Serve to facilitate the for-cause evaluation process or serve as the point of contact in matters impacting the Group in regard to concerns of
   - Actual or alleged fraud, including allegations of plagiarism and/or falsification of data
   - Violation 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
   - 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
   b. Refer findings involving human subjects or human subject data to the appropriate IRB as necessary, work with IRB in conducting any review of such.
   c. Apprise Group Chairs in a timely manner of these matters, including reporting deadlines if needed, unless prohibited by law
   d. Present findings and/or recommendations related to findings stemming from for-cause evaluation
   e. Report, or assure reporting, to external regulatory and/or oversight bodies as required.
   f. IO will report to external bodies only after briefing Group Chairs of such. In event there is question as to whether or not a finding, or potential finding, rises to the level of external reporting, the IO has the final authority to make that decision.

6. NRG Publications Committee
   a. The NRG Oncology Publications Committee plays a key role in the identification and reporting of potential plagiarism, falsification, or fabrication of data in publishing as well as non-compliance with NRG publication guidelines and approvals. The Committee is expected to have procedures in place to assist in evaluating for this risk as publications are submitted for review, and is expected to report any concerns or findings to the IO as soon as concerns are identified.

7. NRG Oncology Institutional Review Board (IRB)
   a. The IRB may be required to review findings referred to them from the Executive Director, Group Chairs, and/or Integrity Officer from compliance or integrity finding to assess the seriousness and, as needed, oversee the
reporting of concerns in keeping with OHRP guidelines or review such actions from a Member Institution where the concern may have occurred.

V. PROCEDURES

Initial Reporting. Any individual is encouraged to report concerns of non-compliance or allegations of potential fraud or abuses related to NRG Oncology activities to the NRG Oncology Integrity Officer, Executive Director, or Group Chairs(s), or any member of the leadership team without fear of retribution or retaliation. Individuals also may report concerns directly to OHRP Division of Compliance Oversight via email ohrp@hhs.gov; fax (240) 453-6909. Reports may be submitted directly to NRG Oncology via email at info@nrgoncology.org

1. Response.
   a. A reported concern or finding will be initially assessed for seriousness and potential need for external reporting. This initial assessment should occur at the time of reporting.
      i. 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 IO and a for-cause evaluation initiated. The IO may make the determination to refer it to the IRB immediately, or conduct further inquiry to have the comprehensive understanding of the circumstances prior to referring it to the IRB.
      ii. If there is substantive evidence of operational or administrative non-compliance without human subject impact, the Executive Director will initiate a for-cause evaluation.
      iii. 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 IO.
   b. 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.
   c. All assessments and evaluations of a concern or finding will conducted impartially, and a report of such provided to the Group Chair even where the assessment or evaluation does not result in validating the finding or concern.
   d. Any finding indicative of criminal activity will be reported immediately to the Group Chairs, and authorities dually notified.
2. **Appeals.**
   a. An appeal of a finding or report to an external agency is handled in accord with that agency’s policies and procedures.
   b. Any finding or sanction strictly under the purview of the Group may be appealed under the following process
      i. An appeal must be submitted, in writing, within 30 days of notification of the outcome of the finding or sanction and submitted to the Group Chairs. This can be submitted via the IO or Executive Director.
      ii. The Group Chairs will review the appeal and respond within 21 days of receipt.
      iii. The result of the appeal is final.

3. **Record-Keeping**
   a. Records of relevant documents necessary to substantiate findings shall be kept as a confidential file in the Executive Offices of the NRG Oncology Foundation for a period of 3 years after completion of the case (including any appeals). Upon request, duly authorized DHHS personnel will be given access to the file. When feasible, NRG Oncology Foundation will request that authorized personnel provide notice of their request 3 business days prior to their need of the documents for review. Further, it will be requested that review take place during routine business hours.

4. **Prevention**
   a. The first and best defense in issues of non-compliance and misconduct is prevention. Through education, deployment of appropriate controls, and having sufficient procedures in place that are available to impacted individuals in the course of conducting their work are the best defenses. NRG Oncology posts its Group Bylaws and policies publically on its website, and develops and maintains standard operating procedures (SOP’s) for job functions that are readily available to those conducting those functions.
   b. The Executive Director, Senior Directors, and functional leaders within the Group evaluate the deployment and use of SOP’s across the functional areas within the Group, and ensure adherence.
   c. NRG Oncology processes and procedures as described in the grants are evaluated by an IRB for adequacy of protection of human subjects.
   d. Group Communications occasionally include information intended to educate or remain participating investigators and clinical research associates of the group policies.
   e. Non-compliance or other findings are reviewed with the intention of implementing policy and/or procedure changes to minimize the potential for a repeat of the finding.
VI. REVIEW. The policy shall be reviewed no less than every three years after its effective date, or May 2021.

VII. REFERENCES

NCTN Program Guidelines (2012)  

OHRP Compliance Oversight Procedures for Evaluating Institutions (2009)  

DHHS 42 CFR Parts 50 and 93 Public Health Service Policies on Research Misconduct; Final Rule (2005)  

Approved: see Group Chairs Meeting Minutes, 4/30/2018