National Jewish Health® Science Transforming Life®	Institutional Policy	
	Policy Name	Reporting HIPAA and Compliance Issues
	Effective Date	01/29/2019
	Approved Date	01/29/2019
	Next Approval Date	01/29/2022
	Policy Owner	Shilay Mellyn
Approved by: Alicia Christensen		

POLICY STATEMENT

National Jewish Health ("NJH") requires its workforce members to report concerns or suspected violations of the Code of Conduct, laws or regulations, policies and/or unethical conduct. NJH will not tolerate retaliatory behavior against individuals who, in good faith, report these matters.

SCOPE

All NJH workforce members including officers, managers, faculty, affiliates, volunteers and others working at or on behalf of NJH, whether or not they are paid by NJH.

POLICY/PROCEDURE

1. Reporting is required. All workforce members are required to report any known or suspected violations of the Code of Conduct, laws or regulations, policies and/or unethical conduct. Below are some common compliance issues. You may also refer to any particular policy that addresses an issue in more depth or ask questions of any person listed below at Paragraph 2(b) as appropriate for receiving reports.

    a. *Privacy and Security Issues*, including
        i. Intentional inappropriate and/or unauthorized access, use and/or disclosures
            1. These include, but are not limited to, inappropriately accessing a patient's Protected Health Information (PHI), gossiping about a patient's PHI, stealing PHI, exposing family and friends to PHI or allowing students to observe care or records without an affiliation agreement or authorization.
        ii. Inadvertent inappropriate and/or unauthorized access, use and/or disclosures with a potential for patient harm.
            1. These include, but are not limited to, misdirected or overheard communications where sensitive PHI was disclosed to a workforce member without a need to know the information or to a person who is not a workforce member.
        iii. Access or use of PHI for research without Institutional Review Board or other required authorization.

    b. Conflict of Interest violations

    c. Code of Conduct Issues

d. Instances of fraud, waste or abuse

e. Physician and other referral source relationship issues under the Stark law or the Anti-Kickback Statute

f. *Regulatory Issues*
   i. Individuals providing services outside their scope of practice or without being appropriately licensed, registered or certified;
   ii. Unauthorized use of a Drug Enforcement Agency ("DEA") number or Colorado controlled substance registration number;
   iii. Hiring or contracting with ineligible, sanctioned or debarred persons or entities;
   iv. Coding or billing errors systemic in nature.

g. Research Issues
   i. Human subjects protection requirements including
      1. Institutional Review Board
      2. Federal Drug Administration
      3. Office of Human Research Protection
   ii. Research animal welfare requirements including
      1. Institutional Animal Care and Use Committee
      2. United States Department of Agriculture
      3. Animal Welfare Act and regulations
      4. Public Health Service Policy on Humane Care and Use of Laboratory Animals
      5. Office of Laboratory Animal Welfare, National Institutes of Health
   iii. Scientific and Research Misconduct including fabrication, falsification and plagiarism
   iv. Clinical research billing compliance
   v. Grants management
   vi. Institutional Biosafety Committee

h. Potential Diversion of any Pharmaceutical Items

i. Notice of audit/ investigation or arrival of auditors or enforcement officials from
   i. Office of Inspector General;
   ii. Centers for Medicare and Medicaid Services
   iii. Office for Civil Rights unless related to Human Resources/employment issues
   iv. Federal Drug Administration
   v. Drug Enforcement Administration
   vi. Colorado Department of Public Health and Environment
   vii. Other municipal, county, state or federal regulatory or investigatory departments

j. Any other issue or concern related to non-compliance or unethical behavior

2. <u>Expectations for Workforce Member Reports</u>

   a. *Report to be filed internally* - under most circumstances, a workforce member who has a concern or suspects a violation is expected to report such concern/problem internally prior to making any disclosures to external sources.

   b. *Internal Reports (written or oral) shall be made to one or more of the following:*

i. The workforce member's supervisor, manager or director
ii. The Privacy Officer, VP, Legal and Regulatory Affairs or Chief Compliance Officer (Executive Vice President, Chief Operating Officer)
iii. The Executive Vice President, Academic Affairs
iv. The Vice President, Human Resources
v. Other NJH senior leadership
vi. Compliance Hotline – 844-369-5635 or NJhealth.ethicspoint.com
    1. Reports can be made using either method 24 hours a day, 7 days a week.
    2. Reports using these methods are made to a neutral third party and the information is provided to the Compliance Office for appropriate response and investigation.
    3. Reports may be made anonymously. Only If the reporters request their information be retained will it be shared with the Compliance Office.
vii. Written Report to Compliance Office
    1. Please include as many details (dates, locations, names of other witnesses) as possible in order to provide a solid basis for an investigation.
    2. Written Reports may be marked confidential and sent to the attention of the Compliance Office, the VP, Legal and Regulatory Affairs and/or the Chief Compliance Officer at:

        Executive Office, M211c
        1400 Jackson Street
        Denver, CO 80206-2761

c. *Reporting outside NJH* – the expectations for internal reporting do not apply if the individual is participating in an accreditation survey, investigation or law enforcement activity that the individual did not initiate.

d. *Confidential information must be protected*– To the extent any report involves confidential or privileged information, the workforce member must ensure that such disclosure is limited to the appropriate internal authorities or to the appropriate governmental entity or regulatory agency.

3. Investigation of Internal Reports

a. *Report* review. The Chief Compliance Officer or designee will promptly review all reports of known or suspected non-compliance. If the Chief Compliance Officer or designee concludes that a particular report does not merit investigation, he/she must record that conclusion and any analysis of supporting facts and circumstances.

b. *Investigation.* Unless the Chief Compliance Officer or designee concludes that a report is without merit, the report must be thoroughly investigated. Generally, this will be accomplished by the Privacy Officer, the VP, Legal and Regulatory Affairs and/or the Chief Compliance Officer. Additional individuals with particular expertise may be asked to assist with the investigations, such as Vice President, Human Resources, the Executive Vice President of Academic Affairs and legal counsel.

c. *Documenting Investigation.* The investigator will prepare a written report to document the investigation and provide it to the Chief Compliance Officer or designee.

d. *Maintenance of documentation.* All documentation involving a report and its investigation will be maintained within the Compliance Office.

e. *Develop and Implement Corrective Action* Plan. The Chief Compliance Officer or designee:
   i. will review the report of the investigation;
   ii. may solicit recommendations for corrective and/or disciplinary action or other sanctions;
   iii. will identify appropriate disciplinary or corrective actions to address substantiated allegations and other compliance concern; and
   iv. will assure that the corrective action plan is implemented in a timely manner.

f. *Limited sharing of Information with the initial reporter and others.* Due to confidentiality, legal and ethical reasons, details of the investigation, findings or outcomes may not be appropriate to share with individuals who report concerns or those who have reported anonymously. This information will be shared as appropriate and to the extent allowed by law.

g. *Maintenance of documentation.* All documentation involving a report and its investigation will be maintained within the Compliance Office.

4. <u>No Retaliation for Reporting in Good Faith, Whistleblower Protection</u>

a. *Retaliation prohibited*. Retaliatory behavior including harassment, unfavorable changes in working conditions without independent grounds or disciplinary action against any individual who, in good faith, reports concerns of suspected violations of law, policy, the Code of Conduct or unethical conduct is strictly prohibited.

b. *Protected Reporting Activities*. The following reporting actions are specifically protected:
   i. Reporting internally any conduct or behavior in violation of law, regulation, policy and/or the Code of Conduct.
   ii. Assisting with an investigation or proceeding which involves non-compliance conduct or behavior. Note: If during such investigation or proceeding it is found that the reporting party was involved in any non-compliance behavior, appropriate corrective or disciplinary actions may be taken.
   iii. Disclosing information to a government or law enforcement agency, where the individual has reasonable cause to believe that the information reveals a violation or possible violation of federal or state law or regulation.
   iv. Assisting in an investigation or proceeding being conducted by a federal or state regulatory or investigatory agency which involves any conduct that the individual reasonably believes to be a violation of:
      1. federal criminal law relating to Medicare fraud or abuse
      2. Any rule or regulation of the Department of Health and Human Services
      3. Any provision of federal or state law or regulation
      4. Any other violation of federal or state law or regulation.

c. Reporting Suspected Retaliation
   i. If any workforce member believes he or she has been subjected to any action that constitutes retaliation prohibited by the provisions of this policy, he or she may file a complaint with his or her own supervisor/manager/director, the VP, Legal and

Regulatory Affairs, the Chief Compliance Officer or the Vice President of Human Resources.

ii. The Chief Compliance Officer or designee and the Vice President of Human Resources will direct the investigation and take any action(s) indicated to protect the reporting employee and preserve the status quo until the investigation is concluded and the report is received.

iii. Upon determination that a workforce member has been subjected to any improper employment or other retaliatory action in violation of this policy, appropriate action will be taken to correct the situation.

5. Monitoring and Reports

a. *Tracking Log.* The Compliance Office will track internal reports of compliance and ethics concerns including the nature of the allegation, whether or not an issue was substantiated and whether any workforce member was sanctioned, disciplined or terminated.

b. *External Audits and Investigations.* Upon notification, the Compliance Office will track a description of the particulars of any audit or investigation, including its involvement, if any, and the outcome.

c. *Board* Reporting. The Chief Compliance Officer or designee will prepare and present reports of investigations of internal reports, external audits and investigations, outcomes and follow-up actions for the appropriate committee of the Board of Directors to ensure competent oversight.

RESPONSIBILITIES

1. Employees, affiliates and volunteers
    a. Be knowledgeable about this policy
    b. Report violations or suspected violations.

2. Supervisors
    a. Make employees, affiliates and volunteers aware of this policy.
    b. Upon receiving any report under this policy, advise appropriate compliance personnel.
    c. Cooperate with any appropriate investigation as necessary.
    d. Keep all details of a report or investigation confidential unless otherwise authorized to disclose information
    e. Take extra care to be certain no retaliation or harassment occurs if the identity of an individual who has filed a report is known or suspected.

3. Human Resources
    a. Accept and investigate protected disclosures regarding employment matters.
    b. Participate in the investigation of complaints of retaliation for making protected disclosures with the Chief Compliance Officer or designee.
    c. Maintain findings of wrongful conduct or false allegations in the individual's personnel file.

ATTACHMENTS

- Dial toll-free, within the United States, Guam, Puerto Rico and Canada: 844-369-5635
- Or file a report online at Njhealth.ethicspoint.com

REFERENCES

NJH Published Policies and Standard Operating Procedures including those within the department folders for:

Administration
Compliance Office
HIPAA Privacy
Research
Research Regulatory Affairs

Contacts:

- Privacy and Compliance Analyst, Shilay Mellyn, 303-398-1466, mellyns@njhealth.org
- VP, Legal and Regulatory Affairs, Chief Compliance Officer, Alicia Christensen, 303-398-1855, christensena@njhealth.org

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REVIEWED BY:

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