

Novant Health

Non-Novant Health worker documents to read

Novant Health is committed to the highest level of ethics across all segments of its business operations, and to maintaining a culture promoting the prevention, detection, and resolution of potential violations of the law or Novant Health policies.

Novant Health recognizes this is the responsibility of all employees, governing board members, administrators, physicians, students, volunteers, as well as those with whom we do business.

The Non-Novant Health Worker education self-study course provides resources to help us meet these responsibilities. Additionally, following Novant Health policies is also important to this goal.

TABLE OF CONTENTS

- Novant Health Compliance Plan and Code of Ethics (NH-LD-CP-260)
- Non-Novant Employed Worker's and Visitation Guidelines Policy (NH-LD-AD-120)
- False Claims Act Policy (NH-LD-CP-220)
- Gifts and Business Courtesies Policy (NH-HR-7080)
- Reporting of Wrongdoing Anonymous Policy (NH-LD-AD-213)
- Purchases from Physician Owned Suppliers Policy (ND-LD-LG-140)
- Healthcare Worker Influenza Immunization Policy (NH-EOH-IMM-407)
- Implant/Explant Management Policy (NH-PC-PR-2008)
- Cellular Phone Usage Policy (NH-EC-SA-5015)



**COMPLIANCE PLAN &
CODE OF ETHICS**
NH-LD-CP-260

February 19, 2019



Carl S. Armato
President and Chief Executive Officer

2085 Frontis Plaza Boulevard
Winston-Salem, NC 27103

NovantHealth.org

Dear team member,

At Novant Health, we have a reputation for integrity and honesty when fulfilling our mission to our patients, our credo to each other, and when dealing with vendors, regulating agencies, and the public. We are proud of this reputation; it is our heritage and our future.

Just as our values help us fulfill our mission, so does our Code of Ethics. Following a code of ethics is important for all businesses—especially for businesses like ours, as we care for our patients and communities, often in some of the most difficult of times.

Following a code of ethics is about acting honorably. It's about following rules and guidelines. It's about accepting responsibility for our actions. At Novant Health, we are committed to doing the right thing across all parts of our business operations.

The Novant Health Code of Ethics establishes our commitment to the highest ethical standards by putting in writing the ethical principles we follow when conducting our business. It is a clear statement of policy to team members, medical staff members, our Board of Trustees, independent contractors, students, volunteers, and anyone representing Novant Health. It outlines the rules and guidelines we should all follow while working to fulfill our mission.

Please read our Code of Ethics carefully. If you ever have any questions about our Code or concerns about the Code not being followed, you can always ask your leader or any member of management. You can also contact the Compliance team directly, or anonymously via The Alert Line. Remember that Novant Health policy prohibits retaliation against someone for making a compliance report in good faith.

Doing the right thing supports our commitment to our patients, our communities, and our team.

Thank you for your commitment to doing the right thing.

Sincerely,

A handwritten signature in blue ink that reads 'Carl S. Armato'.

Carl S. Armato
President and Chief Executive Officer

Table of Contents

	Page
Adoption of a Corporate Compliance Plan	5
Novant Health's Mission, Vision, and Values	6
Novant Health's Commitment to Legal and Regulatory Compliance	7
Purpose of this Compliance Plan	8
Compliance Standards and Procedures	8
Oversight Responsibilities	8
Duties of Corporate Compliance Officer	9
Duties of Compliance Staff	9
Compliance Committees	9
Delegation of Authority	10
Employee Training and Education	10
Auditing and Monitoring of Systems and A Method of Anonymous Reporting	10
Reporting Wrongdoing	11
Protection of Employees	11
Response and Prevention	11
Enforcement and Discipline	12
Novant Health Code of Ethics	13
Patient Rights	13
Emergency Treatment	14
Research Investigations and Clinical Trials	14
Accreditation	14
Privacy and Security Requirements	14
Bribes and Improper Payments	15
Interactions with Physicians	15
Physician Owners and Structuring of Joint Ventures	16
Environmental Compliance	16
Charging, Coding, and Billing for Services	17
Collection of Medicare Deductible and Co-Insurance Amounts	18
Cost Reports	18
Financial Reporting	18
Quality Initiatives	18
Conflict of Interest	18
Gifts and Business Courtesies	19
Speaking Engagements	19
Vendors, Suppliers, and Contractors	19
Engagement of Independent Contractors and Consultants	20
Marketing Practices	20
Marketing and Advertising	20
Antitrust	20
Gathering Information About Competitors	21
Record Management	21
Company Assets	21

	Page
Copyrights	21
Commitment to Charitable Purpose	21
Charity Care	22
Government Relations and Political Activities	22
Workplace Fund Raising and Charitable Activities	23
Controlled Substances	23
License and Certification Renewals	23
Health and Safety	23
Diversity and Equal Employment Opportunity	24
Harassment and Workplace Violence	24
Substance Abuse and Mental Acuity	24
Hiring of Former/Current Government Agency or Contract Employees	25

Resolution of the Board of Directors of Novant Health, Inc.

Adoption of a Corporate Compliance Plan

WHEREAS, Novant Health, Inc. (“Novant Health”) is an integrated health care delivery system that includes, among other health services, hospitals, physician clinics, clinical laboratory services, and other healthcare services;

WHEREAS, Novant Health has authorized the creation of a comprehensive Corporate Compliance Plan and a stringent Code of Ethics that will apply to operations of the entire Novant Health integrated delivery system;

WHEREAS, the Board has reviewed the Compliance Plan with the cooperation of officers and directors of Novant Health and other Novant Health employees; and,

WHEREAS, the proposed Compliance Plan is intended to satisfy the requirements set forth in the Federal sentencing Guidelines for Organizations;

NOW, THEREFORE, BE IT RESOLVED, that the Board hereby approves the adoption of the Corporate Compliance Plan with the expectation that all Novant Health employees and other agents shall be instructed in their respective duties under the Plan and shall comply fully therewith.

Adopted: Effective as of May 12, 1998
Revised: Effective as of March 6, 2000
Revised: Effective as of July 18, 2006
Revised: Effective as of February 21, 2011
Revised: Effective as of February 20, 2012
Revised: Effective as of February 18, 2013
Revised: Effective as of February 18, 2014
Revised: Effective as of February 17, 2015
Revised: Effective as of February 16, 2016
Revised: Effective as of February 21, 2017
Revised: Effective as of February 20, 2018
Revised: Effective as of February 19, 2019

Novant Health's Mission, Vision and Values

Mission: Novant Health exists to improve the health of communities, one person at a time.

Vision: We, the Novant Health team, will deliver the most remarkable patient experience, in every dimension, every time.

Values: **Compassion:** We treat our customers and their families, staff and other healthcare providers as family members by showing them kindness, patience, empathy and respect.

Diversity and Inclusion: We recognize that every person is different, each shaped by unique life experiences. This enables us to better understand one another and our customers. By engaging the strengths and talents of each team member, we ensure a strong organization capable of providing remarkable healthcare to our patients, families and communities.

Personal Excellence: We strive to grow personally and professionally, and we approach each service opportunity with a positive, flexible attitude. Honesty and personal integrity guide all that we do.

Teamwork: The needs and expectations of any one customer are greater than that which one person's service efforts can satisfy. We support each other so that together as a team, we can be successful in the eye of the customer as a quality service provider.

Courage: We act boldly in making the changes necessary to achieve our mission, vision and promise of delivering remarkable healthcare.

Our people: We are an inclusive team of purpose-driven people inspired and united by our passion to care for each other, our patients and our communities.

Our promise to patients: We are making your healthcare experience remarkable. We will bring you world-class clinicians, care and technology – when and where you need them. We are reinventing the healthcare experience to be simpler, more convenient and more affordable, so that you can focus on getting better and staying healthy.

Novant Health's Commitment to Legal and Regulatory Compliance

Novant Health is committed to the highest levels of ethics across all segments of its business operations and to an effective Compliance Program that helps maintain a culture promoting the prevention, detection and resolution of potential violations of law or Novant Health policies. Novant Health's Compliance Program recognizes that compliance is the responsibility of all employees, governing board members, administrators, physicians, students, volunteers, as well as those with whom we do business.

Novant Health provides varied healthcare services pursuant to applicable federal, state, and local laws. Novant Health expects and demands compliance by all of its employees with the statutes and regulations that govern Novant Health's business.

The Corporate Compliance Plan is designed to establish general standards of conduct that promote compliance with applicable law. These standards of conduct are complemented by more detailed policies and procedures that promote conformance with the standards.

However, it is impractical to develop policies and procedures that encompass the full body of applicable law and regulation. All applicable laws and regulations, whether or not covered in organization policies and procedures, must be followed. There is a range of expertise within Novant Health, including counsel and numerous other experts who may be consulted for advice. It is anticipated that this Plan will be amended from time to time as necessary to articulate standards of conduct that are necessary to promote regulatory compliance.

Purpose of this Compliance Plan

An effective program to prevent and detect violations of law means a program that is reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting improper conduct. Failure to prevent or detect any offense, by itself, does not mean that the program is not effective. The hallmark of an effective program to prevent and detect violations of law is that the organization exercise due diligence in seeking to prevent and detect improper conduct by its employees and other agents. Due diligence requires at a minimum that the organization must be taking the following steps:

Compliance Standards and Procedures

Novant Health has a wide array of policies and procedures to assure compliance with laws and regulations. These policies and procedures are widely disseminated and are reviewed and revised to assure the most appropriate and relevant content. These policies and procedures are part of a system of internal controls maintained by management that provides reasonable assurance of reducing the likelihood of violations of law or regulation. The compliance program includes policies and procedures that fall into three broad categories:

1. Code of ethics
2. Policies relating to the operation of the compliance program
3. Policies addressing the organization's principal legal and compliance risks

Oversight Responsibilities

Novant Health's leadership is knowledgeable of the content and operation of the program. Novant Health assigns high-level staff the overall responsibility to oversee compliance. Their responsibility is to ensure implementation and effectiveness of the program. These individuals are given adequate resources and authority to carry out this responsibility and report to the Novant Health Board of Trustees. Novant Health's Board of Trustees has created an audit and compliance committee of independent trustees to provide oversight to the auditing and compliance functions. This committee is knowledgeable about the context and operation of the compliance program to prevent and detect violations of law and exercises reasonable oversight with respect to the implementation and effectiveness of the program. This committee charters both the audit and compliance functions.

The Novant Health Chief Executive Officer shall appoint a corporate officer to serve as the Corporate Compliance Officer (CCO). The Audit and Compliance Committee of the governing board shall concur in the appointment. The CCO shall report administratively to the Novant Health Chief Legal Officer and functionally to the Audit and Compliance Committee of the governing board. Regular compliance reporting from the Vice President/Corporate Compliance Officer has been established to assist the Board in meeting its governance and oversight responsibilities. The CCO shall have the authority to report on matters of concern directly to the Novant Health Chief Executive Officer or to the Chairperson of the Audit and Compliance Committee at any time the CCO determines this to be necessary.

Duties of Corporate Compliance Officer

The Audit and Compliance Committee authorizes the CCO to implement and oversee the operation of Novant Health's corporate compliance program in accordance with the charter for the corporate compliance function established by the committee.

Duties of Compliance Staff

Compliance staff shall operate under the supervision and direction of the Corporate Compliance Officer. The staff will investigate possible compliance issues and recommend necessary compliance initiatives. They may also serve as the delegate of the Corporate Compliance Officer.

Novant Health values the support and engagement of all organizational leaders in their roles to support compliance. The compliance staff works closely with human resources, legal counsel, information technology, risk management and many other areas.

Compliance Committees

Compliance Committees are established to advise the Corporate Compliance Officer and compliance staff and assist in the ongoing growth of Novant Health's compliance program. Novant Health Senior Management is actively involved in routine ongoing meetings with the Corporate Compliance Officer and/or the compliance staff. These meetings serve as an effective means to assure communication regarding the program and compliance issues while maintaining and enhancing management's commitment and support of the corporate compliance program. In addition, committees may be at the business unit, departmental, facility or regional level and may be serving in an advisory capacity, an operational capacity, or in a functional capacity as needed to respond to dynamic environments. The Committees may consist of individuals with varying responsibilities within the organization.

These committees' functions may include:

- Analyzing specific risk areas;
- Assessing existing and developing new policies and procedures that promote compliance;
- Recommending and monitoring the development of internal systems and controls to carry out the organization's standards, policies and procedures daily operations;
- Receiving and processing information about government rules and regulations and corporate compliance audits;
- Understanding systems implications and coordinating common resources;
- Managing regulatory changes, including education;
- Planning and reporting on the implementation of required changes;

- Implementing changes at the work area level within each facility/department;
- Participating in monitoring and quality assurance;
- Assisting Corporate Compliance with internal investigations.

Delegation of Authority

Novant Health will use reasonable efforts and due diligence to assure that those who are given authority have not been convicted of violations of law, criminal or non-criminal. Novant Health does not employ, contract with, or bill for services initiated and/or rendered by an individual or entity that is excluded or is ineligible, suspended or debarred from participation in Federal healthcare programs, Federal government contracts, or has been convicted of a criminal offense related to the provision of healthcare items or services and has not been reinstated in a Federal healthcare program. Novant Health searches the Department of Health and Human Services' Office of Inspector General List of Excluded Individuals and Entities, the General Services Administration's System for Award Management, and applicable Medicaid lists of such excluded and ineligible persons.

Employees, vendors, and privileged practitioners at Novant Health facilities are required to report to Novant Health if they have become excluded, debarred, or ineligible to participate in Federal healthcare programs, or have been convicted of a criminal offense related to the provision of healthcare items or services.

Employee Training and Education

Compliance training and education have been developed to assure that employees throughout Novant Health are aware of standards pertinent to them. Basic compliance training occurs at the time a worker joins Novant Health and is a part of an annual mandatory education. Upon completion of basic compliance education annually, the worker documents training completion, pledges to adhere to the Code of Ethics and Compliance Plan, and acknowledges that he/she understands that failure to comply may lead to disciplinary actions. Additional compliance training in specific areas may be required of certain individuals depending on their role and function. Leader orientation encompasses education on the Compliance Plan and the Code of Ethics as they pertain to the leadership role.

Auditing and Monitoring of Systems and a Method of Anonymous Reporting

Novant Health maintains auditing and monitoring of its systems to detect violations of the law and to evaluate the effectiveness of the compliance program. These types of reviews permit the Corporate Compliance Department to evaluate compliance with regulations, policies and procedures. Through these reviews, we are continuously assessing the effectiveness of the compliance program and finding ways to improve it. Employees are expected to assist in responding to routine internal and external audits as well as compliance office investigations.

- **Reporting Wrongdoing**

Novant Health employees are obligated to report any knowledge of suspected wrongdoing. All reports of wrongdoing are taken seriously. Suspected wrongdoing may be reported to:

- The immediate supervisor/manager/director/officer
- The corporate compliance office
- The hotline: The Alert Line 1-800-350-0094 or <https://novanthealth.alertline.com>
- Human Resources at any time and during exit interview

Novant Health employees may also report any knowledge of suspected wrongdoing to state or federal government with jurisdiction over the area of perceived wrongdoing. Reporting may be done in a manner consistent with the Novant Health policies and procedures addressing reporting options, as amended from time to time.

- **Protection of Employees**

Employees reporting suspected wrongdoing to Novant Health, or to a state or federal government agency, will receive protection from retaliatory workplace actions, consistent with protections more fully described in the Novant Health policies and procedures addressing reporting options, as amended time to time.

All reports of suspected wrongdoing are investigated promptly and confidentially to the extent possible. Employees are expected to cooperate with investigation efforts.

Response and Prevention

If a reported allegation is substantiated, or if a violation is discovered as a result of auditing, monitoring or other source:

- the corporate compliance officer will be notified;
- the organization will initiate appropriate action, including, if indicated, making prompt restitution of any overpayment amounts;
- the appropriate governmental agency will be notified, if necessary;
- disciplinary action will be implemented, if appropriate; and
- changes will be implemented to prevent or minimize the likelihood of a recurrence.

It shall be Novant Health's policy to cooperate fully in connection with all government audits and investigations and to respond in a timely manner to all requirements imposed by involvement in litigation. Novant Health has developed policy and procedure to guide staff in responding to various government audits, investigations, and requests for information.

In preparation for or during a survey, audit, or investigation, Novant Health employees must never conceal, destroy, or alter any documents or make misleading statements to a government representative.

Employees must never attempt to cause another employee to fail to provide accurate information or obstruct, mislead, or delay the communication of information or records relating to a possible violation of law.

Enforcement and Discipline

All violators of the Compliance Plan or the Code of Ethics will be subject to disciplinary action. The precise discipline utilized will depend on the nature, severity, and frequency of the violation and will follow corporate progressive discipline policy. This may result in any of the following disciplinary actions:

- Documented oral warning
- Written warning
- Termination

Code of Ethics

Novant Health maintains a reputation for integrity and honesty in dealing with patients, employees, vendors, and regulating agencies, and the public. We are proud of this reputation; it is our heritage and our future.

The Novant Health Code of Ethics establishes our commitment to the highest ethical standards. The Code of Ethics puts in writing the ethical principles we follow when conducting our business. It provides a clear statement of policy to Novant Health employees, medical staff members, our Board of Trustees, independent contractors, students, volunteers, and anyone representing Novant Health. Novant Health also maintains separate policies that provide additional guidance on various specific topics. The Code of Ethics and these separate policies are key parts of Novant Health's corporate compliance plan.

All representatives and employees are responsible for reading the Code of Ethics and abiding by its terms. The Code of Ethics is rigorously enforced. Anyone who willfully violates the Code of Ethics is subject to disciplinary action up to and including termination. Individuals should report any violations of the Code, or even situations that give the appearance of a violation. Reports can be made to your supervisor or the Corporate Compliance department. You may also report potential violations anonymously to The Alert Line at 1-800-350-0094 or <https://novanthealth.alertline.com>. Any person who makes a good faith report of suspected wrongdoing will not be penalized for reporting.

The Code of Ethics is organized into categories that explain related topics in greater detail:

- Patient Care;
- Compliance with Laws and Regulations;
- Proper Use of Funds;
- Avoiding Conflicts of Interest;
- Protecting Company Assets;
- Charitable Organization and Status; and
- Employment

Patient Care

a. Patient Rights

We are dedicated to providing quality patient care while respecting individual autonomy and dignity, as reflected in our Patient's Bill of Rights. We encourage patients and their families to participate in decisions regarding patient care, and to be familiar with advance directives in the event the patient is unable to make decisions.

We comply with all laws prohibiting discrimination on the basis of: race, color, religion, sex, age, national origin, disability, veteran status, genetic information, gender identity, or sexual orientation. Patients are admitted to facilities and programs regardless of race, creed, or ethnic origin.

We make decisions related to admission, on-going care, transfer, and discharges based on a patient's assessed needs and our ability to meet those needs. The integrity of the clinical decision-making process will be maintained at all times. Financial incentives will not impact decisions for needed services. Referrals are made based on patient need or diagnosis; any benefit to the facility for such a referral is disclosed to the patient. The appropriateness and safety of care, treatment, and services do not depend on the patient's ability to pay.

b. Emergency Treatment

We provide an emergency medical screening examination and necessary stabilization to all patients that present to our Emergency Departments regardless of that patient's ability to pay, in accordance with the Emergency Medical Treatment and Labor Act (EMTALA).

Patients with emergency medical conditions may be transferred to another facility at the patient's request, or if the patient's medical needs cannot be met at the Novant Health facility (e.g., we do not have the capacity or capability), and appropriate care is knowingly available at another facility. Likewise, we accept patients by transfer who are in need of our specialized services, based on our capacity and capability to treat, without regard to ability to pay or any other discriminatory basis.

c. Research, Investigations, and Clinical Trials

We protect patients and respect their rights during research, investigations, and clinical trials. We provide patients who choose to participate in these programs with a full explanation of expected benefits, potential discomforts and risks, and alternative services that might prove beneficial. We also fully inform these patients of procedures to be followed, especially those experimental in nature. A patient gives informed consent to participate in clinical research or investigations. A patient's choice not to participate in any research or investigation project will not compromise his or her access to services.

We comply with federal and state laws and regulations for all research, investigations, and clinical trials conducted within any of our facilities. Any facility or employee applying for or performing research of any type is responsible for following appropriate research guidelines. Any human subject research is done in conjunction with the Institutional Review Board and should be consistent our policies regarding human subject research and IRBs.

We submit only true, accurate, and complete costs related to research grants.

d. Accreditation

We deal with accreditation and government survey bodies in a direct, open, and honest manner, whether before, during, or after any survey. We will never mislead accreditors or survey teams, either directly or indirectly.

Compliance with Laws and Regulations

e. Privacy and Security Requirements

We maintain policies and procedures to comply with the Administration Simplification Act of 1996 (HIPAA) and other applicable laws to ensure the appropriate protection of patient privacy and the security and integrity of personal information.

Pursuant to HIPAA, we provide patients with a written notice of our information practices. We also have processes for controlling access to, use, and disclosure of protected health information (PHI). Specifically, we maintain an information security program designed to safeguard PHI. We provide employee education on handling and safeguarding PHI and provide guidance on how complaints about privacy practices may be filed.

f. Bribes and Improper Payments

We cannot enter into any agreement or arrangement that involves a commission, rebate, bribe, kickback, or any other item of value, if it is known or reasonably suspected that the intent or likely result of that item of value is to improperly reward, either directly or indirectly:

- Any employee, official, or representative of the federal or state government or any of their departments or agencies;
- Any Medicare Administrative Contractor under contract with the federal or state government, or any of their departments or agencies for the administration of any health care insurance program in which Novant Health or any of its operating subsidiaries participates;
- Any officer, director, employee, shareholder, or other representative of a customer, supplier, or other institution with which Novant Health or any of its operating subsidiaries has existing or prospective business relations; or
- Any physician, health care provider, or any other person or company that is in a position to refer or encourage the referral of patients to Novant Health for the delivery of health care services by a Novant Health operating subsidiary.

Improper rewards include the giving or receiving of anything of value, not just money. Additionally, employees are prohibited from giving improper rewards (or something of value) to any individuals as an incentive to make decisions or take actions favorable to Novant Health, or to make referrals to a Novant Health operating subsidiary. It is not permissible to take any such action just because it appears to be customary in a certain location or a particular area of business activity.

To the extent possible, Novant Health requires that all business arrangements between it and possible sources of patient referrals conform to the safe harbor regulations under the federal Anti-Kickback Statute. Novant Health also requires that all compensation arrangements with physicians who make referrals to Novant Health conform with applicable exceptions to the federal Physician Self-Referral law, related regulations, and any similar state laws.

g. Interactions with Physicians

Two key principles govern our interactions with physicians:

1. We accept patient referrals and admissions based solely on the patient's medical needs and our ability to meet those needs. We do not pay or offer to pay or accept anything of value from anyone – colleagues, physicians, or other people or entities – for patient referrals.
2. We do not accept payment for patient referrals we make. We are not permitted to solicit or receive anything of value, directly or indirectly, in exchange for patient referrals. Similarly, when making patient referrals to another health care provider, we do not take into account the volume or value of referrals that the provider has or may make to us.

Federal and state laws and regulations govern the relationships between hospitals and physicians who refer patients to those facilities. In addition, the Internal Revenue Service prohibits people, including physicians, from receiving a private benefit as a result of their relationships with a tax-exempt health care organization.

Novant Health representatives who interact with physicians should be aware of the legal, regulatory, and policy requirements that address relationships between physicians and hospitals or health care systems. This is especially so when making payments to physicians for services rendered, leasing space, recruiting physicians to the community, acquiring physician practices, and arranging for physicians to serve in leadership positions.

Any business arrangement with a physician must be developed to ensure compliance with legal requirements, regulatory guidance, and our policies and procedures. All arrangements must be in writing and approved by the Novant Health Legal Department before making any payment to a physician. All contract payments or benefits provided to physicians should be supported with appropriate documentation reflecting the business purpose of the payments or benefits. Additionally, relationships with physicians must be diligently administered as agreed so as to avoid legal violations.

h. Physician Owners and Structuring of Joint Ventures

Health care providers that have physician investors or participants are subject to requirements designed to prevent physicians from benefitting from referrals to companies in which they have a financial or economic interest. The providers and physicians involved must ensure that the overall structure of the relationship complies with the requirements related to ownership interests, investment structure, and reporting.

i. Environmental Compliance

We comply with all environmental laws and regulations as they relate to our organization's operations. This means we:

- Act to preserve our natural resources to the fullest extent reasonably possible;
- Recycle where possible;
- Comply with requirements for the proper handling of hazardous materials;

- Comply with environmental laws and operate our facilities with the necessary permits, approvals, and controls;
- Diligently use proper procedures to prevent pollution and provide a beneficial environment of care;
- Immediately alert supervisors to any situation regarding the discharge of a hazardous substance, improper disposal of hazardous medical waste, or any situation that may be damaging to the environment; and
- Work with authorities to remedy an environmental contamination for which we may be responsible.

Proper Use of Funds

j. Charging, Coding, and Billing for Services

We have policies, procedures, and systems in place to facilitate accurate billing to patients, government payers, and commercial payers, which conform to related federal and state laws and regulations.

We do not knowingly present or cause to be presented claims for payment or approval which are false, fictitious, or fraudulent. Employees who perform billing, coding, or charge entry shall take every reasonable precaution to ensure that their work is accurate, timely, and in compliance with our policies, and federal and state laws and regulations.

Individuals who add to a patient's medical record must provide accurate information and not destroy any information considered part of the official medical record. Accurate and timely documentation also depends on the diligence and attention of physicians who treat patients across our locations. We expect those physicians to provide us with complete and accurate information in a timely manner, including the documentation of medical necessity.

Any subcontractors engaged to perform billing or coding services are expected to have the necessary skills, quality control processes, and appropriate systems and procedures to ensure that all billings for patients, government programs, and commercial insurance programs are accurate and complete.

Additionally, we implement and maintain a system of controls to ensure an appropriate charge capture process, including the continual updating of fee schedules and charge lists.

Examples of unacceptable billing and coding practices include: presenting, or causing to be presented, a claim for services that were not provided; or submitting bills with improper billing and coding practices, such as "upcoding" and "unbundling." Upcoding is the process of using a code to increase the reimbursement for a particular medical procedure, even though available evidence suggests another code with a lower reimbursement value is more appropriate. Unbundling is the process of billing various parts of one medical procedure separately in an effort to increase reimbursement.

Our employees are obligated to notify their supervisor or a member of management of any requests to deviate from accepted billing practices, or with any questions they may have in this area.

k. Collection of Medicare Deductible and Coinsurance Amounts

Our policy is to bill patients promptly for the services provided and to take all necessary and appropriate action to collect patient accounts. We are also required to collect deductible and coinsurance amounts from most patients.

l. Cost Reports

We maintain a system of internal controls to ensure compliance with federal and state laws, regulations, and guidelines relating to cost reports, which define what costs are allowable and how to claim reimbursement for the cost of services provided to program beneficiaries.

m. Financial Reporting

We maintain a high standard of accuracy and completeness in documenting, maintaining, and reporting financial information. This information serves as a basis for managing our business and is important to meeting our obligations to patients, colleagues, stakeholders, suppliers, and others. It is also necessary for compliance with tax and financial reporting requirements.

All financial information must reflect actual transactions and conform to generally accepted accounting principles in the United States. We maintain a system of internal controls to provide reasonable assurances that all transactions are executed in accordance with management's authorization and are recorded in a proper manner to maintain accountability of the organization's assets.

n. Quality Initiatives

Novant Health participates in various quality initiatives that rewards providers based on the quality of care delivered to patients. The programs are offered or sometimes mandated by government or non-government payers. Novant Health is mindful and strives to fulfill the duties and responsibilities associated with these programs. We maintain accuracy in reporting and adhere to protocols that govern these programs.

Avoiding Conflicts of Interest

o. Conflicts of Interest

Actual or potential conflicts of interest could detract from our mission as an ethical, effective and efficient healthcare organization. A conflict of interest occurs when an employee, in the course

of his or her job duties, has a financial or personal interest that may compromise or have the appearance of compromising his or her judgment with regard to the best interests of Novant Health or its patients.

Any circumstance that might lead to the appearance of a conflict of interest should be disclosed and reviewed to determine whether an actual conflict of interest exists. All employees must annually disclose actual or potential conflicts of interest. Anytime a potential conflict of interest arises, the annual disclosure should be updated. Our Conflict of Interest policy explains conflicts of interest and the disclosure process in more detail.

p. Gifts and Business Courtesies

Any gifts, favors, or hospitality, whether given or received by any employee, should contribute to our mission, vision, and values with highest regard for patient care. We should neither accept nor keep anything of value that has the potential to materially affect the ability to make decisions in the interests of patients. Additionally, we do not solicit vendors and manufacturer representatives for gifts for any purpose, including door prizes, except as allowed under Novant Health Foundations, or for company approved or endorsed fundraising. Our Gifts and Business Courtesies policy provides additional guidance on relationships with referral sources, vendors, industry groups, professional organizations, trade organizations, vendor sponsored conferences, and patients. Good judgment and decisions appropriate to the situation and reflecting the intent of the policy should be used when specific guidance is not found in the policy.

q. Speaking Engagements

We encourage employees to participate as a faculty member or speaker at educational programs and functions. In some cases, employees who participate in speaking engagements may accept reimbursement from the sponsoring party for expenses related to travel and registration fees that are required as part of the speaking engagement. Any honorarium may be kept by the employee if the employee prepares for and participates in the speaking engagement on his or her own time. Otherwise, the honorarium should be directed to the appropriate Novant Health Foundation

All speaking engagements should be disclosed in accordance with the Novant Health Conflicts of Interest policy, and if under contract, in compliance with any terms or conditions regarding honoraria.

r. Vendors, Suppliers, and Contractors

Our relationships with contractors, vendors, and suppliers must be managed in a fair and reasonable manner, free from conflicts of interest, and consistent with applicable laws and good business practices.

We promote competitive purchasing to the fullest extent practicable. We use the highest ethical standards in business practices for source selection, negotiation, determination of contract awards, and the administration of all purchasing activities.

Our contractor, vendor, and supplier selections will be made on the basis of objective criteria, including: quality, technical excellence, prices, delivery, adherence to schedules, service, and maintenance of adequate supply sources. Our purchasing decisions will be made on the supplier's ability to meet our needs, not on personal relationships and friendships.

During the selection process, we may find it beneficial to visit other facilities that purchased the vendor's products, or to consult with various technical experts. We should pay for the cost of any such trips, not the vendor. Budgeting and purchasing negotiations should accommodate travel and other expenses required to obtain the best products or services.

We do not communicate to any third-party confidential information given to us by our suppliers unless directed to do so in writing by the supplier. We do not disclose contract pricing and information to any outside party. Appropriate commissions, rebates, discounts, or other allowances are permissible if they are compliant with applicable laws and our policies.

We provide all vendors with access to our Code of Ethics and other pertinent policies. Contractors, vendors, and suppliers are expected to comply with this Code and healthcare laws, rules, and regulations.

s. Engagement of Independent Contractors, Agents, and Consultants

At times, we need services offered by contractors or consultants who are not employees of the company. We may enter into independent contractor agreements to acquire services that are necessary for legitimate business purposes at a reasonable cost. All independent contractor arrangements will be covered by a written contract, approved by our legal department. These contracts shall provide us with access to the contractor's records in accordance with applicable laws.

t. Marketing Practices

▪ Marketing and Advertising

We may use marketing and advertising to provide information to our communities, educate the public, increase awareness of our services, and recruit employees. We present only truthful, fully informative, and non-deceptive information in these materials.

▪ Antitrust

Antitrust laws are designed to create a level playing field in the marketplace and to promote fair competition. These laws could be violated by discussing Novant Health business with a

competitor. Examples of this may include: discussing how our prices are set; disclosing terms of supplier relationships; communicating market allocation among competitors; or agreeing with a competitor to refuse to deal with a supplier.

Additional subjects that must not be discussed with competitors include: any aspect of our pricing; our services in any market; key costs, such as labor costs; and our marketing plans. If a competitor raises any of these prohibited subjects, employees must end the conversation immediately and contact the Legal Department.

- **Gathering Information about Competitors**

It is not unusual to obtain public information about other organizations, including our competitors, through various legal and ethical means. These may include public documents and presentations, journal and magazine articles, or other published or spoken information. However, employees should avoid seeking or receiving information about a competitor through any inappropriate means.

Protecting Assets

- u. **Record Management**

Effective corporate compliance requires a clear and complete documents system. Our record management policy establishes a system for the creation, distribution, retention, and destruction of corporate records.

- v. **Company Assets**

We strive to preserve and protect company assets by making sensible and effective use of resources, and by properly and accurately reporting the company's financial condition. The company's assets and our employees' services are intended to be used only for our business purposes.

Disclosing or using confidential, special, or inside information of or about Novant Health, for personal profit or advantage, or to provide an advantage to any vendor or supplier, is prohibited.

- w. **Copyrights**

Our employees may not copy for their own use documents, computer programs, or other materials in violation of copyright laws or licensing agreements.

Charitable Organization and Status

- x. **Commitment to Charitable Purpose**

Novant Health is a non-profit, tax-exempt organization committed to operating in a manner that furthers its charitable purposes, in compliance with all requirements related to tax-exempt healthcare organizations.

y. Charity Care

We provide patients and their families with information about charity care and various financial assistance programs. Our financial counselors work with patients and their families and sponsors to ensure that patients are appropriately qualified and referred to these programs. All discounts, relief from collection proceedings, and other financial arrangements are made only within the context of established programs.

z. Government Relations and Political Activities

We comply with all federal, state, and local laws governing participation in government relations and political activities. We are nonpartisan with respect to the nomination or election of candidates to public office, and do not support or take positions on political parties or the nomination or election of individual candidates to a political office.

However, we may from time to time take public positions on issues that are important to our welfare, that of our employees, the public, or other stakeholders. We may publically offer recommendations concerning proposed legislation or regulations when our experience might be helpful. We may also analyze and take public positions on issues that have a relationship to our operations when our experience contributes to the understanding of the issues. We will, however, refrain from taking a public position on an issue when doing so could be construed as an implied endorsement of a candidate for political office. However, we may employ and consider for employment elected officials and candidates for office.

We have many contacts and dealings with government bodies and officials, and may invite elected officials and candidates for office to address leadership groups for the purpose of education about government issues and challenges. Electioneering or fundraising activities are prohibited at such events.

Our contacts and transactions with government bodies and officials must be conducted in an honest and ethical manner. Any attempts to influence the decision-making process of a government official by an improper offer of any benefit are absolutely prohibited. Any requests or demands by a government representative for any improper benefit should be immediately reported to the Legal Department.

We may not use corporate funds, properties, or services, whether directly or indirectly, for the purpose of influencing the nomination or election of any candidate to public office. This includes financial and non-financial donations, such as using work time and telephones to solicit for a political cause or candidate, or loaning Novant Health property for use in a political campaign. This prohibition also includes indirect payments, loans, deposits or guarantees, the performance of services, and the furnishing of anything of value by an employee as part of his or her duties for Novant Health or its operating subsidiaries.

We encourage employees to participate in the democratic process of voting and may promote voter registration. We recognize that encouraging individual voter responsibility may include electioneering and personal finance contributions to election campaigns or political organizations on the part of our employees. However, these activities are at the employee's sole expense and we will not provide reimbursement in any form. Further, no electioneering or political activities by employees shall be conducted on the premises or time of Novant Health, or under any circumstance which may create the appearance that such activity is sponsored by Novant Health.

aa. Workplace Fund-raising and Charitable Activities

We support a variety of charitable activities, including: fundraising, community events, health and wellness promotions, and various social activities intended to support specific community charities.

When the company or a facility decides to support a charitable organization, no employee should be compelled to contribute to the charitable organization. Neither should there be any workplace consequences for non-participation.

Employment

bb. Controlled Substances

Many of our employees have routine access to prescription drugs, controlled substances, and other medical supplies. Many of these substances are governed and monitored by specific regulatory organizations and must be administered by physician order only. To minimize risks to patients and our employees, prescription and controlled medications and supplies must be handled properly and only by authorized individuals.

If anyone becomes aware of inadequate security of drugs or controlled substances, or the diversion of drugs from the company, the incident must be reported immediately.

cc. License and Certification Renewals

Employees, independent contractors, and privileged practitioners in positions requiring professional licenses, certifications, or other credentials, are responsible for maintaining the current status of their credentials. They shall comply at all times with federal and state requirements applicable to their respective disciplines. We do not allow any employee, independent contractor, or privileged physician to work without a valid, current license or credential.

dd. Health and Safety

Our facilities comply with government rules and regulations that promote workplace health and safety. Policies and procedures exist to protect our workers from potential workplace hazards.

Workers must become familiar with and understand how these policies apply to their specific job responsibilities and seek advice from their supervisor whenever they have a question or concern. It is important that any worker immediately notify his or her supervisor of any serious workplace injury or any situation presenting a danger.

ee. Diversity and Equal Employment Opportunity

The success of Novant Health depends in large measure on our ability to work together to fulfill our vision and goals. This means we treat employees, patients, and other persons fairly, and without regard to race, color, religion, sex, ethnic origin, age, disability, veteran status, genetic information, gender identity, sexual orientation, or any other classification prohibited by law.

No form of harassment or discrimination on the basis of race, color, religion, sex, ethnic origin, age, disability, veteran status, genetic information, gender identity, or sexual orientation, will be tolerated. Every allegation of harassment or discrimination will be promptly investigated in accordance with applicable human resource policies. For additional information, refer to our policies regarding sexual harassment, discrimination, and Equal Employment Opportunity.

ff. Harassment and Workplace Violence

Every employee has the right to work in an environment free of harassment and disruptive behavior. We do not tolerate harassment by anyone based on the diverse characteristics or cultural backgrounds of those who work with us. Degrading or humiliating jokes, slurs, intimidation, or other harassing conduct is not acceptable in our workplace.

Sexual harassment is also prohibited. This prohibition includes unwelcome sexual advances or requests for sexual favors in conjunction with employment decisions. Moreover, verbal or physical conduct of a sexual nature that interferes with an individual's work performance or creates an intimidating, hostile, or offensive work environment has no place at Novant Health.

Harassment also includes incidents of workplace violence. Workplace violence includes robbery and other commercial crimes, stalking, violence directed at an employer, terrorism, and hate crimes committed by current or former employees. Employees who observe or experience any type of harassment or violence should report the incident to their supervisor, a member of management, the Human Resources Department, or the Novant Health Alert Line.

gg. Substance Abuse and Mental Acuity

We are committed to an alcohol and drug-free workplace. All workers must be free of the influence of alcohol and illegal drugs when reporting for work. Using, possessing, or selling controlled substances or illegal drugs while on work time or on Novant Health property may result in disciplinary action, up to and including termination.

hh. Hiring of Former/Current Government Agency or Contractor Employees

We may hire former or current federal or state employees. However, their recruitment and employment, including independent contractor arrangements, may be impacted by conflict of interest regulations. Hiring employees directly from a government agency or contractor requires certain regulatory notifications. Corporate Human Resources and the Legal Department should be consulted by management prior to entering into any such employment negotiations.

TITLE	Non-Novant Health Workers and Visitation Guidelines		
NUMBER	NH-LD-AD-120	Last Revised/Reviewed Effective Date:	January 22, 2019
TJC FUNCTIONS	LD-AD		
APPLIES TO	<p>Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Caton Merchant House, Prince William Cancer Center, Corporate Departments and Entities, Foundations, Auxiliaries, Child Care Centers and Finance Focused</p> <p>NHUYA: HAMC, PWMC, NHMG, Caton Merchant House, Prince William Cancer Center, Prince William Auxiliary, Prince William Health Physician Services.</p>		

I. SCOPE / PURPOSE

This policy defines Non-Novant Health workers, establishes a process to engage Non-Novant Health organizations and workers and ensures that Non-Novant Health workers are compliant with Novant Health requirements and policies. This policy is applicable to all Novant Health locations.

II. POLICY

Non-Novant Health workers are any individuals who provide goods and/or services to Novant Health. They include, but are not limited to: leased employees; agency staff; outsourced services; independent contractors; students; volunteers; clergy; and vendors.

All Non-Novant Health workers are required to comply with Novant Health policies and requirements. Licensed medical & allied health Non-Novant Health workers are required to follow credentialing process as defined by the Central Verification Office (CVO) and the respective medical staffs.

Additionally, Non-Novant Health workers are required to comply with the requirements provided in the vendor management system. All Non-Novant Health workers are required to wear appropriate identification while at Novant Health facilities.

III. QUALIFIED PERSONNEL

Novant Health Team Members, Non-Novant Health workers

IV. EQUIPMENT

Vendor management system and computer hardware as required. Mobile Badge.

V. PROCEDURE

- A. Contracts
1. Organizations seeking to do business with Novant Health should follow the “Supply Chain Roadmap” instructions at www.novanthealth.org/employer-services/vendor-connections.
 2. It is expected that all goods and/or services provided to Novant Health will be conducted through an executed contract or service agreement in accordance with the [Contracts - NH-LD-LG-131](#)
 3. The contract may define additional vendor or service provider compliance requirements.
- B. Product Evaluation
1. For policy and procedures regarding product evaluation, refer to [New Product Introduction \(NPI\) and Product Evaluation Process - NH-LD-AD-1720](#).
- C. Gifts, Education, and Food
1. For policy and procedure regarding guidelines for accepting education, food, and other gifts, refer to [Gifts and Business Courtesies - NH-HR-7080](#).
- D. All Non-Novant Health workers fall into one of the following six categories (excluding patients, patient escorts and family members of patients).
1. **Pre-Sale/Contract Visitors** - Representatives invited on-site to any Novant Health location to present capabilities in pursuit of a contract or legal agreement with Novant Health, are not required to (a) be registered in the vendor management system and (b) be compliant with the Non-Novant Health Worker Program requirements, as set forth in Section V.G of this Policy. During the visit(s), the representatives must be (a) accompanied 100% of the time by a Novant Health team member and (b) the location of the visit is scheduled in an administrative area.
 2. **Post Sales/Contract Infrequent Visits** - After the contract or legal agreement is executed, representatives invited to come on-site to any Novant Health locations periodically (once a month – lasting only for 1 business day) are not required to (a) be registered in the vendor management system and (b) be compliant with the Non-Novant Health Worker Program requirements, as set forth in Section V.G of this Policy. During the visit(s), the representatives must be (a) accompanied 100% of the time by a Novant Health team member and (b) the location of the visit is scheduled in an administrative area.
 3. **Post Sales/Contract Frequent Visits** – After the contract or legal agreement is executed, representatives that come on-site to Novant Health locations more than once a month must be (a) registered in the vendor management system; (b) compliant with the Non-Novant Health Worker Program requirements, as set forth in Section V.G. of this Policy (c) have an

appointment and (d) sign in/sign out through the vendor management system.

4. **On-site Non-Novant Health Workers** – Non-Novant Health workers that are provided a Novant Health contractor badge by Novant Health must be (a) registered in the vendor business system and (b) compliant with the Non-Novant Health Worker Program requirements, as set forth in Section V.G. of this Policy.
5. **Off-Site/Remote Non-Novant Health Workers** – Non-Novant Health workers who support Novant Health business off-site/remote and have individual logical access to Novant Health systems must be (a) registered in the vendor management system and (b) compliant with the Non-Novant Health Worker Program requirements as outlined in the vendor management system for off-site/remote access.
6. **Off-Site/Remote Non-Novant Organizations** – Organizations that support Novant Health business off-site/remote and must have access to Novant Health systems but will have a vendor login must have an up to date contract or legal agreement that addresses logical access and protection of Novant Health systems.

E. Exclusions/Exemptions

1. Exemptions – there are entities with which Novant Health may conduct business that will be exempt from the Non-Novant Health Worker Program. Examples of exceptions are:
 - a. Delivery personnel dropping off goods in public areas (e.g., flower shop)
 - b. Catering personnel dropping off goods in public areas
 - c. City, County, State, and Federal agency personnel
 - d. Organ procurement organizations as mandated by Centers for Medicare & Medicaid Services (CMS)
 - e. Representatives of The Joint Commission and other similar regulatory or accreditation agencies
 - f. Members of the media
2. Exclusions – Non-Novant Health workers that are credentialed through Novant Health departments or through partnership agreements (listed below) are excluded from registering in the vendor management system.
 - a. Central Verification Office (CVO)/Medical Staff Office

- b. Student Programs
- c. Volunteers
- d. Central Staffing Scheduling Office (CSSO) Master Service Program
- e. Contracts through Master Service Program/Partnerships (EVS, Food & Nutrition, DPS Supplemental Staff)

F. Exemption Requests:

- 1. There may be times when in the course of doing business it may be necessary to exempt an organization from specific requirements in the vendor management system.
- 2. Requested exemptions will be considered on a case by case basis.
- 3. To request an exemption, the appropriate Novant Health leader must complete the Non-Novant Health Worker Company Policy & Standard Exemption Request Form and seek dual approval from both the VP/SVP of requesting department and either the SVP of Supply Chain or EVP/Chief Human Resource Officer.
- 4. A copy of the executed exemption form will be kept by the Novant Health Business Sponsor/Owner and attached to the Novant Health/Company contract.

G. Non-Novant Health Worker Program Requirements

- 1. All Non-Novant Health workers must:
 - a. Be registered, profile compliant and verified in the vendor management system (as stipulated in the executed contract, statement of work, Exemption/Exclusion list)
 - b. Keep the registration and profile information/documentation current and verified compliant at all times.
 - c. Coordinate all appointment requests through appropriate Novant Health team member. Appointments will be scheduled and entered into the vendor management system. **Note: (acute care facilities): Pharmaceutical representatives must coordinate all requests for appointments or in-service education through the Pharmacy Department (regardless of contract, request by Novant Health department or team member).**
 - d. Sign in prior to the appointment at the designated location and receive a Non-Novant Health worker access badge. (Acute care facilities have PC/kiosks with badge printers. NHMG clinics or designated locations require use of mobile badge).

- e. Wear the Non-Novant Health worker access badge and company identification badge prominently above the waist while at Novant Health acute care facilities. Wear company identification badge prominently above the waist and able to provide mobile badge upon request for NHMG clinics or designated locations.
- f. Return to designated check-in point at the end of the scheduled appointment, check out, and exit the Novant Health location immediately. (Use of the mobile app (application) for check-outs is also acceptable). Failure to comply is consider a violation of the policy as outlined is section H.
- g. Non-Novant Health workers who no longer provide goods/services to Novant Health should notify Novant Health and the vendor management system to remove or deactivate their account.

2. All Non-Novant Health workers must NOT:

- a. Visit a different department or Novant Health team member while on-site for the scheduled appointment. Non-Novant Health workers may not initiate requests for impromptu meetings with other Novant Health team members.
- b. Enter Patient Care or Restricted areas without appropriate escort or authorized access.
- c. 'Tailgate or 'Piggy Back' – be accompanied by other Non-Novant Health worker(s) that is not registered, compliant and without a scheduled appointment.
- d. Leave product samples with any Novant Health team member other than Supply Chain Operations Managers or NHMG Clinic Administrators. Product samples must only be left at designated drop off locations; Non-Novant Health workers must be escorted to the appropriate drop-off location for samples.
- e. Make presentations in any patient care areas unless properly authorized.
- f. For the protection of team members, patients and visitors, Novant Health prohibits solicitation of any kind by Non-Novant Health workers or organizations. [Solicitation and Distribution - NH-HR-6030](#)

F. Non-Novant Health Worker Responsibilities (Medical Procedures)

- 1. Non-Novant Health workers must not access any secure or restricted areas without escort or authorized access.
- 2. Non-Novant Health workers requesting to be present during any patient procedure must have the permission of the department director and/or leadership designee responsible for the area and in addition to being compliant in vendor management system, must also conform to all patient safety guidelines.
- 3. If a physician/surgeon requests that approved Non-Novant Health worker(s) assist with equipment or instrumentation, the Non-Novant Health worker(s)

must inform the department manager/designee 24 hours in advance (or as soon as possible) of the request indicating the specific need and the purpose of their assistance. Non-Novant Health worker(s) may be required to complete additional training prior to entering specified areas. Reference: Medical Staff Bylaws for additional requirements.

4. Ensure a signed patient consent has been completed to be present during any procedure. This consent is provided in section 10 of the Novant Health Operation, Procedure or Treatment Consent form (NH-900003).
5. If approved by departmental leadership and the physician, Non-Novant Health workers who are deemed to be “healthcare industry representatives” with specialized expertise will function only in that capacity and must provide current documentation (upload into the vendor management system) that supports their competency/expertise.
6. Comply with all HIPAA regulations. Non-Novant Health workers in violation of HIPAA regulations will be held responsible for their actions and will forfeit their access to Novant Health.
7. Non-Novant Health workers are not allowed to attend facility conferences or meetings where patient-specific information is discussed or presented unless they have received patient consent, attended the patient procedure, are otherwise compliant with the Non-Novant Health worker guidelines, and have a scheduled appointment.

G. Novant Health Team Members Responsibilities

1. Novant Health physician(s) and clinical team members responsible for the patient’s care during any procedure are accountable to maintain the patient’s safety, privacy, dignity and confidentiality at all times.
2. Whenever possible, Novant Health team members and leaders should schedule meetings with Non-Novant Health workers in public areas. It may be necessary to meet with Non-Novant Health workers in offices (located in Restricted or Patient Care areas) provided that there are no breaches of patient privacy or PHI.
3. Purchase Orders:
 - a. Novant Health team members cannot imply or offer intent to purchase. All requests for price information, specifications, demonstrations, or trials of goods and services must be coordinated through Strategic Sourcing. All new product trials will follow [New Product Introduction \(NPI\) and Product Evaluation Process - NH-LD-AD-1720](#) .
 - b. Purchase orders for existing goods and services must be entered in Ariba and follow the normal approval process. Strategic Sourcing must approve and perform initial set-up for new items in Ariba. Purchase Orders will not be issued for any products that have already been shipped to a Novant Health location.

4. Challenging Unidentified Personnel:
 - a. Novant Health team members should tactfully approach unidentified individuals (not wearing a visitor or Non-Novant Health Worker Badge) the team member believes are Non-Novant Health workers and politely ask their purpose for being in the Novant Health location.
 - b. The Novant Health team member should inform the Non-Novant Health worker of the Non-Novant Health Worker Policy and Visitation Guidelines and if appropriate the Solicitation and Distribution Policy.
 - c. If the Non-Novant Health worker has an appointment, escort the Non-Novant Health worker to the designated location to print out an identification badge and then escort them to the department.
 - d. If the Non-Novant Health worker does not have an appointment, escort them to Public Safety, NHMG Clinic Administrator, or the nearest exit.

5. Reporting Noncompliance: Novant Health team members are responsible for reporting non-compliance with Novant Health policies to their immediate supervisor, Novant Health Corporate Compliance office, the Alert Line or Human Resources. See [Reporting of Wrongdoing - NH-LD-AD-213](#) for details.

6. Access to Vendor Management System: Novant Health team members having a business need will be given access to the vendor management system to make appointments and ensure Non-Novant Health workers are compliant with policies and program requirements.
 - a. Use of the vendor management system is subject to all Novant Health policies. Specific guidance can be found in [Acceptable Use of Information Resources - NH-IM-6004](#) and [Information Confidentiality - NH-IM-7060](#).

7. Departing Non-Novant Health Workers: When a Non-Novant Health worker or their organization is known to no longer be doing business with Novant Health (on-site or off-site access), Novant Health team members are responsible for:
 - a. Collecting any Novant Health issued identification badges,
 - b. Notifying DPS/IAM (Digital Product Service/Identity Access Management) to cancel any system access. Notification should take place as soon as possible.
 - c. Collecting any Novant Health issued equipment, proprietary documents etc. (An inventory list should be maintained by the Novant Health leader.)

8. Performance Management: Every January, Novant Health team members will be asked to complete the performance documentation (in the vendor management system) for each Non-Novant Health worker that has worked in their area(s) during the previous calendar year.

9. Violation: Novant Health team members who violate this policy will be

disciplined in accordance with Novant Health's [Progressive Discipline - NH-HR-6040](#)

H. Enforcement

1. There is no tolerance for Non-Novant Health workers who fail to adhere to Novant Health policies. Noncompliance may result in action up to and including disbarment from all Novant Health locations and contract termination. Novant Health may suspend a non-Novant Health worker from entering any Novant Health location during the investigation of the violation of Novant Health policy.
2. Policy violations will be addressed as follows:
 - a. First Violation – written notification to the Non-Novant Health worker and their supervisor.
 - b. Second Violation – access to all Novant Health locations suspended for up to 45 business days.
 - c. Third Violation – disbarment from all Novant Health locations indefinitely.
3. Novant Health may escalate its response to any violation at any time.
4. Access to Novant Health facilities may be terminated at any time at the discretion of Novant Health and if the Non-Novant Health worker:
 - a. Fails to demonstrate or maintain clinical competency;
 - b. Holds an expired, suspended or revoked professional license or certification;
 - c. Is excluded from any federal or state health care program;
 - d. Fails to abide by Novant Health's policies and procedures;
 - e. Engages in unprofessional or disruptive conduct.

VI. DOCUMENTATION

N/A

VII. DEFINITIONS

Non-Novant Health Workers – individuals who provide goods and/or services for Novant Health. Non-Novant Health workers may include but not be limited to:

1. **Leased employees:** lease employees are employed and paid by a leasing

company which leases the employees to Novant Health.

2. **Agency staff:** agency staff consists of employees of a staffing agency who perform services for Novant Health. Novant Health retains supervision and responsibility for the services but the workers are paid by the agency.
3. **Outsourced services:** outsourced services could include environmental services, food and nutrition and the like. Novant Health retains supervision and responsibility for the services but contracts with a third party for the services.
4. **Independent contractors:** independent contractors are self-employed individuals, including physicians and other service providers, who perform services for Novant Health under a contractual agreement and receive a 1099 from Novant Health.
5. **Vendors:** any company from which Novant Health purchases goods or services; vendors may consult, sell or maintain equipment and/or supplies, and may interact with Novant Health team members or patients.
6. **Students:** one who is enrolled or attends classes at a school, college or university; students are required to abide by Novant Health Student Program screening procedures and orientation/training guidelines specific to assignments.
7. **Volunteers:** persons who perform tasks and offer services voluntarily and without financial obligation; volunteers are required to abide by Novant Health Volunteer Services procedures and orientation and training guidelines specific to assignments.
8. **Clergy:** people ordained to perform pastoral or religion services and functions.
9. **Medical Staff & Allied Health Staff:** physicians, advanced practice professionals and other healthcare professionals that are required to be credentialed through the Novant Health Central Verification Office.

Vendor Management System – a web based tool used to track Non-Novant Health Workers and track their compliance, contract management and other Novant Health requirements as defined for program compliance.

Public Areas – areas within Novant Health locations in which access is available to the general public.

Patient Care Areas – areas within Novant Health location defined as patient rooms, clinical examination rooms, intensive care units, operating room suites, emergency rooms, ambulatory surgery centers and free standing imaging or rehabilitation centers.

Restricted Area – any area of a Novant Health facility that is not intended for public access or unauthorized access by Novant Health team members or Non-Novant Health Workers. Such areas may be identified with signs or placards and may

have access control measures to prevent unauthorized entry.

VIII. RELATED DOCUMENTS

- Novant Health [Background Screening - NH-HR-3006](#)
- Novant Health [Contracts - NH-LD-LG-131](#)
- Novant Health [News Media Relations - NH-IM-7049](#)
- Novant Health [Progressive Discipline - NH-HR-6040](#)
- Novant Health Informed Consent Policies
 - Novant Health [Informed Consent \(North Carolina\) - NH-RE-RI-120](#)
 - Novant Health [Informed Consent \(South Carolina\) - NH-RE-RI-121](#)
 - Novant Health [Informed Consent \(Virginia\) - NH-RE-RI-122](#)
- Novant Health Operation, Procedure or Treatment Consent Form
- Novant Health Privacy policies
- Novant Health [Acceptable Use of Information Resources - NH-IM-6004](#)
- Novant Health [Information Confidentiality - NH-IM-7060](#)
- AORN Standards for Health Care Industry Representatives in Operating Rooms
- Novant Health [New Product Introduction \(NPI\) and Product Evaluation Process - NH-LD-AD-1720](#)
- Novant Health [Gifts and Business Courtesies - NH-HR-7080](#)
- Novant Health [Solicitation and Distribution - NH-HR-6030](#)
- Novant Health [Reporting of Wrongdoing - NH-LD-AD-213](#)
- Medical Staff Bylaws
- Standard Terms and Conditions
- [Vendor and Visitor Management - NMG-LD-AD-131](#)

IX. REFERENCES

CMS Conditions of Participation, The Joint Commission

X. SUBMITTED BY

Marilyn Gilliam, VP Talent Acquisition and Retention
Michael Bianchin, VP Logistic Operations – Supply Chain

XI. KEY WORDS

Contract, Procurement, Supply Chain, Vendor, Visitation, Non-Novant Health Worker

XII. INITIAL EFFECTIVE DATE	09/01/01
DATES REVISIONS EFFECTIVE	10/2005, 02/2008, 02/2009, 09/2012, 04/2013, 01/22/2019
DATES REVIEWED (No changes)	10/2003, 01/2005, 09/2012, (Add HAMC 1-3-14), 12/2016
Date Due for Next Review	January 2022

SIGNATURE SHEET

TITLE	Non-Novant Health Workers
NUMBER	NH-LD-AD-120
TJC FUNCTIONS	LD-AD
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, HAMC, MMC, MPH, PMC (PMC main, COH & all other locations), PWMC, RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Caton Merchant House, Prince William Cancer Center, Corporate Departments and Entities, Foundations, Auxiliaries, Child Care Centers and Finance Focused
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
VP, Logistics Operations	Michael Bianchin		See electronic approval
SVP, Human Resources	Janet Smith-Hill		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date
N/A		

COMPANY POLICY & STANDARD EXEMPTION REQUEST FORM

A. Overview

A.1	Request Date	<i>Click here to enter a date.</i>	
A.2	Requestor's Name	<i>First:</i>	<i>Last:</i>
A.3	Requestor's Contact Information	<i>Phone</i>	<i>Email:</i>
A.4	Requestor's Department	<i>Dept Name:</i>	<i>Dept #:</i>
A.5	Requestor's Primary Facility		
A.6	Name of Responsible Director Sponsoring Your Request	<i>First:</i>	<i>Last:</i>
A.7	What is the specific exemption you are requesting?		
A.8	Number of Non-Novant Workers this exemption applies to?		
A.9	Are the Non-Novant workers in patient care areas?		
A.10	Exception duration		

B. Background

B.1	Background:	

C. Approvals (requires signature from both Department and either HR or Supply Chain depending upon the request)

C.1	(Department):	<i>VP/SVP</i> _____ <i>Date:</i> _____
C.2	HR:	<i>VP/EVP</i> _____ <i>Date:</i> _____
C.2	Supply Chain:	<i>VP/EVP</i> _____ <i>Date:</i> _____

TITLE	False Claims Act		
NUMBER	NH-LD-CP-220	Last Revised/Reviewed Effective Date:	Jul17
TJC FUNCTIONS	LD-CP		
APPLIES TO	<p>Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused</p> <p>NH UVA: HAMC, PWMC, Caton Merchant House, Prince William Cancer Center, Prince William Foundation, Prince William Health Physician Services</p>		

I. SCOPE / PURPOSE

It is the policy of Novant Health to provide health care services in a manner that complies with applicable federal and state laws and that meets the highest standards of business and professional ethics. To further this policy, and to comply with Section 6032 of the Deficit Reduction Act of 2005, Novant Health provides the following information about its policies and procedures, and the role of certain federal and state laws in preventing and detecting fraud, waste, and abuse in federal health care programs.

II. POLICY

Novant Health must ensure that all team members, including management and any contractors or agents, are educated on the federal and state false claims laws and the role of such laws in preventing and detecting fraud and abuse in federal health care programs.

False Claims Laws

Federal and state False Claims Acts allow the government to bring a civil action against individuals(s) or entity(s) that submit a false claim to a federal health care program, and collect damages and penalties against healthcare providers in violation. Additionally, many of these laws allow “qui tam” (or whistleblower) suits to be brought by individuals that have knowledge of the fraudulent activity.

The federal False Claims Act, 31 U.S.C. Sections 3729-3733, imposes liability on any person or entity who submits a claim to the federal government that s/he knows (or should know) is false. Specifically, the False Claims Act prohibits: knowingly filing a false or fraudulent claim for payments to a federal funded health care program; knowingly making or using a false record or statement material to a false or fraudulent claim to a federally funded health care program; knowingly making or using a false record or statement about an obligation to pay a federal funded health care program; knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to a federal funded health care program; or conspiring to commit a violation of one of the above.

“Knowingly” in this context means not only having actual knowledge that the information the claim is false, but includes acting in deliberate ignorance of whether the claim is true or false, or acting in reckless disregard of whether the claim is true or false. Specific intent to defraud is not required.

A person or entity found to have violated the False Claims Act is, generally, subject to civil or monetary penalties of between \$10,781 and \$21,562 per claim, plus three times the amount of damages that the government sustained. In health care cases, the amount of damages is the amount paid for each claim that is filed and determined to be false.

Additionally, a person may bring a *qui tam* (or “whistleblower”) action under the False Claims Act in the name of the United States. The government, after investigation, may elect to pursue the case in its own name or decide not to pursue the case. If the government decides not to pursue the case, the person who filed the action has the right to continue with the case on his or her own. If the suit is successful, the individual whistleblower may be awarded a percentage of the funds recovered, with the percentage being lower if the government joined the claim. If, however, the whistleblower is convicted of criminal conduct related to the claim, s/he will not be permitted to any recovery.

Another federal law, the Program Fraud Civil Remedies Act of 1986, provides administrative remedies for knowingly submitting false claims and statements. A false claim or statement includes submitting a claim (or written statement) for services that were not provided or one that asserts a material fact that is false or omits a material fact. A violation of this act results in a maximum of \$10,781 per claim plus up to double the amount of damages incurred by the government.

Many states, including North Carolina and Virginia, have adopted state false claims acts similar to the federal False Claims Act. Both state laws contain *qui tam* provisions similar to the federal law and prohibit retaliation by employers against employees who report the employer’s false claims. South Carolina, while not adopting a state False Claims Act with similar *qui tam* provisions, does have an anti-fraud statute that makes it unlawful to submit false and fraudulent claims to the South Carolina Medicaid program.

The Affordable Care Act also imposes False Claims Act liability on a person or entity who fails to report and return an overpayment from Medicare, Medicaid, or other federal funded health care program within 60 days the overpayment’s identification.

Hospital’s Policies and Procedures for Detecting and Preventing Fraud:

Novant Health provides varied healthcare services pursuant to appropriate federal, state and local laws. Novant Health expects and demands compliance by all of its team members and agencies with the statutes and regulations that govern Novant Health business. Accordingly, Novant Health has created a wide array of policies and procedures for detecting and preventing fraud, waste and abuse. For instance, Novant Health prohibits any team members or agent of Novant Health from knowingly presenting or causing to be presented claims for payment or approval, which are false, fictitious, or fraudulent. These policies include the Novant Health Compliance Plan, the Novant Health Code of Ethics, and Anonymous Reporting of Wrongdoing Policy.

Novant Health also has implemented policies, procedures and systems to facilitate accurate billing. These policies are available on the intranet and should be consulted.

Novant Health team members are obligated to report any knowledge of suspected wrongdoing. All reports of wrongdoing are taken seriously. Such reporting may be to the team members' immediate supervisor/manager, the corporate compliance office, the hotline (Alert Line 1-800-350-0094, or <https://novanthealth.alertline.com>) and/or Human Resources. Novant Health team members may also report any knowledge of suspected wrongdoing to state or federal government agencies with jurisdiction over the area of perceived wrongdoing.

Anti-Retaliation Protections

Individuals within the organization who observe activities or behaviors that may violate the laws in some manner and report their observations either to management or to governmental agencies are provided protections under certain laws.

For example, the False Claims Act includes protections for people who file qui tam lawsuits as described above. The False Claims Act states that any employee who is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of lawful actions taken in furtherance of a qui tam is entitled to recover damages. He or she is entitled to all relief necessary to make the employee whole, including reinstatement with the same seniority status, twice the amount of back pay (plus interest), and compensation for any other damages the employee suffered as a result of the discrimination. The employee also can be awarded litigation costs and reasonable attorneys' fees. State False Claims Acts also include similar anti-retaliation protections.

Team members reporting suspected wrongdoing to Novant Health, or to a state or federal government agency, will receive protection from retaliatory workplace actions, consistent with the protections more fully described in the Novant Health policies and procedures addressing reporting options, including the Novant Health Compliance Plan, the Code of Ethics, and Anonymous Reporting of Wrongdoing Policy. All reports of suspected wrongdoing are investigated promptly and confidentially to the extent possible. Employees are expected to cooperate with investigation efforts.

III. QUALIFIED PERSONNEL

N/A

IV. EQUIPMENT

N/A

V. PROCEDURE

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

N/A

VI. DOCUMENTATION

N/A

VII. DEFINITIONS

N/A

VIII. RELATED DOCUMENTS

- [Compliance Plan and Code of Ethics - NH-LD-CP-260](#)
- Anonymous Reporting of Wrongdoing Policy (NH-LD-AD-213)

IX. REFERENCES

Federal False Claims Act and those included throughout policy

X. SUBMITTED BY

Legal Affairs; Corporate Compliance Office

XI. KEY WORDS

False Claims Act; whistleblower, fraud, waste and abuse, retaliation

XII. INITIAL EFFECTIVE DATE	September 2007
DATES REVISIONS EFFECTIVE	January 2011, April 2013, 07/2017
DATES REVIEWED (No changes)	(Add HAMC 1/3/14)
Date Due for Next Review	July 2020

SIGNATURE SHEET

TITLE	False Claims Act
NUMBER	NH-LD-CP-220
TJC FUNCTIONS	LD-CP
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, MMC, MPH, PMC (PMC main, COH & all other locations), RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, Caton Merchant House, Prince William Cancer Center, Prince William Foundation, Prince William Health Physician Services
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
VP Internal Audit & Compliance	Matthew Molbert		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date

TITLE	Gifts and Business Courtesies		
NUMBER	NH-HR-7080	Last Revised/Reviewed Effective Date:	Jul17
TJC FUNCTIONS	HR		
APPLIES TO	<p>Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused</p> <p>NH UVA: HAMC, PWMC, Caton Merchant House, Prince William Cancer Center, Prince William Foundation, Prince William Health Physician Services</p>		

I. SCOPE / PURPOSE

Overall, people give gifts to employees to extend a simple thank you or common courtesy for a job well done, or as a heartfelt acknowledgement during a holiday. However, some gifts may be meant to influence team member actions in a manner that is not in the best interest of patient care and our organization. Items and services received inappropriately could present legal and regulatory risks to you and Novant Health.

This policy provides guidance to Novant Health team members concerning giving and receiving of gifts and business courtesies, and relationships with referral sources, vendors and manufacturer representatives, industry groups, professional organizations, trade organizations, and patients.

Novant Health and its team members should not ask for, accept, offer, or give anything of value that has the potential to materially affect the ability to make decisions in the best interests of patients and other stakeholders.

Novant Health, through its foundations, solicits and receives gifts and contributions to the organization from the community, grateful patients, businesses, and many others. Nothing in this policy is intended to interfere or govern those activities when a Novant Health organization is the recipient of the gift. The foundations have explicit policies that govern these gifts.

This policy does not apply to the exchange of gifts or courtesies between Novant employees.

This policy does not apply to gifts based upon a family or personal relationship independent of any Novant business. This policy does not apply to gifts available to the general public on the same conditions.

II. POLICY

A. Definition of Gifts and Business Courtesies

A gift or business courtesy is any item or service received free or at reduced fares

or prices, which are not also available to the general public. Gifts made to a family member are considered gifts to you.

Some examples of gifts and business courtesies include:

- Cash and cash equivalents (including checks, gift cards, and gift certificates)
- Tangible items like merchandise, goods, food, or beverages
- Entertainment (such as tickets or entrance fees)
- Transportation (including air fare, car rental, etc.)
- Lodging or use of a residence (including hotel rooms or use of a vacation home)
- Conference attendance, or the educational value of practical, observational, or didactic training
- Payment for participation in vendor opinion research
- Recreational equipment or facility memberships
- Donations or payments on your behalf (such as to a charity, or for training or education)
- Securities, stocks, bonds, options, or loans (or loan interest rates)
- Stock offerings not available to other investors
- Time (including labor), materials, facilities or equipment, or other home improvement

Prohibited Gifts and Business Courtesies

Even if a gift or business courtesy is permissible under this policy, Novant Health team members may not offer or accept anything of value that influences or attempts to influence decision making while acting in your Novant Health role.

Novant Health team members may not offer, give, solicit, or accept any item or service that:

- takes into consideration the volume or value of health care referrals,
- is a direct or indirect bribe or kickback, or
- is any other unlawful payment or transfer of value.

Parameters for Giving and Receiving Various Gifts and Business Courtesies

All gifts, favors, or hospitalities, whether given or received, should contribute to our mission, vision, and values, with the highest regard for patient care.

This policy is not intended to represent every situation or circumstance. Good judgment and decisions appropriate to the facts and circumstances should be used when specific guidance is not found in this document.

B. Cash and Cash Equivalents

Novant Health team members may not give or receive cash or cash equivalents, including gift certificates and gift cards.

Novant Health team members may not give or receive: securities, stocks, bonds, options, discounts, or favorable terms, other than those generally available to the public, including loans at below normally available rates (conventional terms from banks or lending institutions), or participation in stock offerings not available to other investors.

Novant Health team members may receive a gift card or gift certificate under these circumstances:

- it is received as a result of a random drawing that was held at an event sponsored by a trade organization, health care industry group, or professional association;
- where drawing entry was available to all attendees; and
- the gift card/certificate is less than \$100.

A request to keep a gift card/certificate won under these circumstances but in an amount greater than \$100 should be made using a Gifts and Business Courtesies Exception Request Form. (Instructions for using this electronic form are located in [Exhibit A](#) of this policy.)

C. Gifts

- a. Perishable or consumable gifts of nominal value (less than \$100, such as flowers, fruit, or candy) given to a department or group are permitted. Team members may not accept any such items provided to them in their individual Novant Health job roles, but may donate them to their respective departments or groups.
- b. Departments or individuals may accept gifts of minimal value from vendors and manufacturer representatives (such as pens, pads, and similar items given as advertising or promotional items).
- c. Departments may not accept offers of “free” equipment (computers, fax machines, etc.). Equipment provided at no cost under a reagent or supply purchase commitment is not considered “free” equipment.
- d. Novant Health or its team members may not accept gifts or fees for participating in vendor opinion research.
- e. Novant Health or its team members may not accept gifts from vendors and manufacturer representatives designated for education to benefit particular individuals.
- f. Any gifts for education or opinion research must be made unrestricted, to a Novant Health Foundation, permitting Novant Health to determine its best use.
- g. Novant Health team members are prohibited from soliciting vendors for gifts for any purpose, including door prizes, except as allowed under Novant Health Foundations or for company approved or endorsed fundraising.

D. Meals

On any Novant Health campus:

Informational presentations by vendors and manufacturer representatives may provide valuable scientific and educational benefits. Occasional meals may be provided in connection with such presentations (as they are described in **Section F** below.

Educational Materials and Activities below) as long as the meals are:

- a. limited to employed staff who are appropriate to attend the meeting or training;
- b. reasonably limited to less than \$10.00* in value per attendee; and

- c. limited to less than \$100.00* in value per attendee per year from any single entity.

* These amounts align and will adjust with the Open Payments reporting threshold for Food and Beverage, adjusted annually by CMS.

Meals provided by vendors and manufacturer representatives are prohibited when no educational program is provided, and accepting “take-out” meals or “dropped off” meals for staff is not appropriate.

Off campus:

It is permissible to accept meals paid for by non-Novant Health entities that occur off-site of Novant Health locations if these meals are provided in conjunction with off-site activities as part of approved consulting activities, or when provided by a vendor at an organized business meeting.

In all cases, these meals should be:

- a. modest;
- b. infrequent from a single entity; and
- c. served during or in conjunction with a meeting where the predominate purpose is: medical education, healthcare information exchange or business, biomedical research discussions, or discussions of data relevant to clinical practice.

Meals may only be provided to those attending these meeting. Generally, inclusion of a healthcare professional’s spouse or other guests is not appropriate.

NOTE: Novant Health team members must pay for their own meals if attending an educational meeting organized by a vendor as an invitation-only event, held at a restaurant or resort.

E. Travel

Novant Health team members may not directly accept reimbursement or sponsorship for travel or expenses for site visits for training or to evaluate a product or service. Technical training associated with specific instruments or products should be provided for in relevant acquisition agreements.

Transportation associated with a business event, such as a shuttle bus service, typical cab ride, or transportation in a private vehicle, is not a gift.

**F. Educational Materials and Activities
Provided by Vendors or Manufacturer Representatives**

- a. In-house education provided by a vendor is acceptable if non-commercial and pertinent to professional practice. Any such education must be appropriate for the department or clinic, occur at a reasonable location and in a manner conducive to informational communication (this does not include entertainment or recreational events), and provide scientific or educational value.
- b. Vendors and manufacturer representatives may provide light meals or refreshments during such presentations to those attending. However, any

meals or refreshments must meet the requirements set out in **D. Meals** above.

- c. Novant Health and its team members may not accept gifts from vendors designated for education to benefit particular individuals.
- d. Technical training associated with specific instruments or products should be provided for in the acquisition agreements.

Provided by Trade Organizations, Professional Associations, or other Industry Groups

- a. Novant Health team members desiring to attend business associate sponsored conferences/seminars may do so only if the seminar related expenses are paid for by Novant Health at fair market value. Business associates may include trade organizations, industry groups, and professional associations.
- b. Conference/seminar attendees may not accept any direct funds from vendors or manufacturer representatives. Team members merely attending a conference may not accept funds for travel, conference fees, or lodging from vendors or manufacturer representatives. This includes educational content involving didactic and observational learning opportunities; however, team members may accept the educational value of the observational learning opportunity.

Provided by Novant Health or Novant Health Team Members

Educational events provided by Novant Health to the medical community and the general public may be underwritten by vendors and manufacturer representatives to reduce the overall cost for attendance. However, speakers must be selected by Novant Health, not by the vendors or manufacturer representatives. Also, commercial recognition for underwriters must be limited to oral or written acknowledgement.

The Code of Ethics offers guidance to Novant Health employees on speaking engagements.

G. Charitable Contributions and Donations

- a. Team members may participate in various recognized charitable activities supported or encouraged by Novant Health, such as fundraising for the arts, community welfare organizations, missions, and disease specific charities. Activities such as golf tournaments, dinners, fundraisers, and associated prizes or awards, are not considered gifts or business courtesies. Participation in these events is permitted and is not governed by this policy, as long as the activity involves a benefit to the recognized charity.
- b. Civic, charitable, educational, or religious organization awards for recognition of service or accomplishment may be accepted when the value is less than \$300 in a calendar year (e.g., local fast food restaurant volunteers to wash team members' vehicles as part of a local neighborhood goodwill campaign; team members may accept car wash).
- c. Vendors and manufacturer representatives may contribute to Novant Health's foundations and designate the funds to be used for team member, community, or medical staff education. Funds will be dispersed by the foundations according to authorized foundation policies.

H. Drug Samples

Providing drug samples not for patient use, not consistent with the Prescription Drug Market Act, is prohibited.

Providing drug samples for patient use in accordance with the Prescription Drug Market Act is not a gift and is acceptable, and is not subject to this policy.

I. Patients and Their Families

Giving Gifts to Patients and Their Families

It is Novant Health's policy that it will not provide goods, services, or other items of value to patients free of charge, or at a price below cost, in order to influence the flow of business to Novant Health or its operating subsidiaries.

We do permit team members to demonstrate compassion during unusual circumstances, such as helping a pediatric patient celebrate a birthday while hospitalized, or a hospice patient celebrate an anniversary. These special opportunities ease patients' stress while separated from their homes. These expenses are minimal in value.

Sometimes patients are provided an incentive of minimal value to comply with treatment and rehabilitation. Upon successful completion of the treatment or rehabilitation, items such as a pen or t-shirt may be given.

We will not pay patients or their families for referrals for any designated health service. Novant Health is permitted to provide, on a case by case basis, items of minimal value to patients when these are part of an established service recovery or customer care program.

Receiving Gifts From Patients and Their Families

Departments and individuals may accept flowers, homemade crafts, cookies and similar gifts of minimal value from patients or their families. In general, other gifts from patients and their families should be referred to one of the foundations. However, departments may accept gifts from grateful patients, families, or benefactors, which provide resources to further the department's goals. Items primarily for the benefit of patients may be accepted if they are not of substantial value (\$100 or less). Examples of these types of gifts include books and other learning resources, musical instruments, or other similar items.

Items should not be accepted on more than an occasional basis, even if each individual item is appropriate. Also, donations of items of substantial value (more than \$100) should be donated through the foundations.

In all cases, these gifts must be properly recognized and accounted for according to Novant Health policies on receiving contributions.

Solicitation For Gifts or Contributions From Patients and Families

In no circumstance may team members solicit or accept monies or gifts as payments for services provided to patients or their family members.

Solicitation for gifts or contributions from patients and their families must be accomplished through one of the Novant Health foundations and not by individual team members except through a campaign organized through the foundations.

J. Other Gift Considerations

- In the event that a gift or business courtesy is legally restricted or poses a regulatory risk, the gift may not be accepted even if the gift is deemed allowable under this policy.
- Unless specifically prohibited, the value of any gift or business courtesy given or received may not exceed \$100 per item or event. The total value of all gifts or business courtesies to or from a single source, within a single calendar year, may not exceed \$300.

K. Exceptions to This Policy:

In advance of the receipt of or giving of a gift or business courtesy that does not conform to this policy, a request for an exception should be submitted through the Conflict of Interest Committee using the Gifts and Business Courtesies Exception Request Form. Instructions for accessing this electronic form are located in [Exhibit A](#) of this policy.

It is the responsibility of the requestor to provide adequate information that supports the merits of accepting a gift. The submission of a Gift and Business Courtesies Exception request is an appeal to this policy; therefore, additional appeals are not available and the decision of the Conflict of Interest Committee will be final.

Submission of a Gift and Business Courtesies Exception Request requires that a current Conflict of Interest Disclosure form be on file. To be current, a Conflict of Interest Disclosure must have been submitted within the past 12 months, and you must update the form with any changes since your last submission. You should consult the Novant Health Conflict of Interest policy for additional information including instructions for submitting your Conflict of Interest Disclosure form. If you have questions or need verification that your most recent Conflict of Interest Disclosure submission is current, you should email the Conflict of Interest Program Coordinator at: compliance@novanthealth.org

The decision of the Conflict of Interest Committee will be delivered to the team member and his/her direct supervisor through an emailed memorandum.

III. QUALIFIED PERSONNEL

Does not apply

IV. EQUIPMENT

Does not apply

V. PROCEDURE

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

Does not apply

VI. DOCUMENTATION

Does not apply

VII. DEFINITIONS

Family Member: defined as spouse or domestic partner, parents (including adoptive, biological and step parents), mother-in-law, father-in-law, grandparents, brothers and sisters (whether by whole or half blood or step), children (adopted, biological and step), grandchildren (adopted, biological and step), and the spouses of children, grandchildren, and brothers or sisters.

Vendor: (1) Any company with whom Novant Health directly contracts for products or services, or has entered into any process to do business with Novant Health. (2) Any company who makes or receives patient or business referrals to or from Novant Health, or has entered into any process to make or receive patient or business referrals to or from Novant Health. Vendors also include manufacturers and manufacturer representatives.

Value: an exchange price that willing, unpressured, and well-informed buyers and sellers would reach through negotiations in an arm's length transaction.

VIII. RELATED DOCUMENTS

- Novant Health Compliance Plan & Code of Ethics
- Novant Health Conflict of Interest Policy
- Novant Health Mission, Vision and Values

IX. REFERENCES

Does not apply

X. SUBMITTED BY

Directors, Compliance
Senior Vice President, Human Resources

XI. KEY WORDS

Gift, business courtesy, conflict of interest, vendor, sponsor, trade organizations, industry groups, gratuities, opinion survey

XII. INITIAL EFFECTIVE DATE	January 1, 2008
DATES REVISIONS EFFECTIVE	Dec 15 th , 2012, 07/2017

DATES REVIEWED (No changes) Add HAMC 11/25/13
Date Due for Next Review July 2020

SIGNATURE SHEET

TITLE	Gifts and Business Courtesies
NUMBER	NH-HR-7080
TJC FUNCTIONS	HR
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, MMC, MPH, PMC (PMC main, COH & all other locations), RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, Caton Merchant House, Prince William Cancer Center, Prince William Foundation, Prince William Health Physician Services
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
Senior Vice President of Human Resources	Janet Smith-Hill		See electronic approval
Director, Corporate Compliance (Ambulatory Services)	Kelly Patterson		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date

EXHIBIT A

Submitting Your Gift and Business Courtesies Exception Request

Novant Health uses a commercial disclosure management system, called COI-SMART, to facilitate employee Conflict of Interest disclosure and related needs such as requesting an exception to the Gift and Business Courtesy Policy. This web based product is accessible from most computers with internet access. Novant employees and physician partners may receive emails from COI-SMART.

COI-SMART is compatible with the following web browsers:

- Microsoft Internet Explorer version 6 or higher on Windows XP or higher
- Mozilla Firefox version 2 or higher on Windows XP or higher and on Apple OSX or higher
- Apple Safari version 3 or higher on Apple OSX or higher
- Various smart phones and tablets may be compatible but are not officially supported by the vendor.

Paper forms are not available.

All Novant Health new employees should have access to this disclosure system within two weeks of starting orientation. Please send an email to compliance@novanthealth.org or call 336.277.1046 if you have questions about submitting a Gifts and Business Courtesies Exception Request, or if you require technical assistance. Do not contact Novant Health IT for technical or password assistance.

Getting Started

1. To access the COI-SMART system, please click on this link or copy and paste the link into your Web browser: <https://novant.coi-smart.com/login.php>
2. This link takes you to Novant Health's COI-SMART homepage. You should see the image below on the homepage.



The image shows a login form with two input fields: 'Username : ' and 'Password : '. Below the fields is a red 'LOGIN' button and a blue link that says 'Forgot Password?'.

New Users and Returning Users Who Have Forgotten Their Password:

3. **Important:** You must have access to your Novant Health Outlook inbox to create or update your password.
4. Single left mouse click on "Forgot Password."
5. A new box will appear requesting your email address. Enter your **Novant Health email address**, and click "Submit". An email will be sent to this email address with instructions to create or reset your password.
6. Once you have access to COI-SMART, go to **step 10**.

Returning Users Who Know Their Password

7. Your six digit employee number is your user name. Type your employee number into the text box beside “Username”. Your employee number should be printed on the back of your ID badge.
8. Enter your password in the “Password” field. Click login.
9. If you incorrectly type your password five times within three minutes you will be locked out of the COI-SMART system. If you are locked out of the COI-SMART system you must either wait 30 minutes for the system to automatically unlock for you, or you may call 336.277.1046 or email compliance@novanthealth.org for assistance. If you are unsure of your password, please go back to step 3 and reset it.

All Users: Choosing the Correct Form

10. After logging into COI-SMART the user is directed to the Announcement page. Review the message, and click the button that says **CLICK HERE TO ACCESS YOUR QUESTIONNAIRE(S)**.
11. You will arrive at the default My Questionnaires page. At the top of this page you should see a box with the text “**VIEW SINGLE USE/NON-EDITABLE QUESTIONNAIRES.**” Single left mouse click on this box. Clicking on this box takes you to all one-time use questionnaires and forms. To submit your *exception request* to the Gifts and Business Courtesies Policy you will complete the form (questionnaire) called “**Elective: Gifts and Business Courtesies Exception Request Form (HR Policy #7080)**”. Find this form in the form list, and single left mouse click on the form name. Below this form name you will see a picture of a pencil and the text “Start A New Single Use/Non-editable Questionnaire” in blue font. Single left mouse click on this blue text to launch the electronic form. You must finish the form in one sitting. You may not save and return to the form at a later time to modify your answers.
 - a. If you do not have access to this form please email compliance@novanthealth.org and someone will research and reply as soon as possible. Please include your full name and a preferred phone number.
 - b. If you have questions about other forms which are available to you in this system email compliance@novanthealth.org
12. After all questions in the form have been answered you will arrive at a submission screen. You cannot submit an incomplete form. Follow the instructions to submit your form.
13. Once you have submitted your form you will be directed to a page confirming your submission. Also, an email will be sent to your Novant Health Outlook inbox confirming your form submission.
14. If you have another electronic form to complete (such as submitting your Conflict of Interest Disclosure form), open first “My Questionnaire” from the menu on the left of the screen, and then open “My Questionnaires” to locate additional forms. If you do not need to submit additional forms you may log out of the application by clicking “Log Out” at the top right of your screen.

Gifts and Business Courtesies FAQ

TEST YOURSELF . . .

1. Do I make sure that I do not solicit gifts?
2. Do I always follow vendor/purchasing policies?
3. Do I avoid accepting gifts or entertainment from patients, vendors, or suppliers?
4. Do I refrain from offering gifts or courtesies to patients, vendors, suppliers or customers with the understanding or intent to give or receive business in return?
5. Do I always reject any offer of cash or cash equivalent (e.g. gift card, check) from a patient, vendor, or supplier?
6. Do I contact my manager or Corporate Compliance when I am not sure whether I can keep a particular gift that I have been offered?

TITLE	Reporting of Wrongdoing		
NUMBER	NH-LD-AD-213	Last Revised/Reviewed Effective Date:	January 15, 2019
TJC FUNCTIONS	LD, RI, MS, CC		
APPLIES TO	Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, Caton Merchant House, Cancer Center, NHMG, Prince William Foundation, Prince William Health Physician Services		

I. SCOPE / PURPOSE

Novant Health is committed to lawful and ethical behavior in all of its activities and requires Board members, officers, and team members to act in accordance with all applicable laws, regulations and policies and to observe high standards of business and personal ethics in the conduct of their duties and responsibilities.

The purpose of this policy is to provide methods for team members, contracted staff, Board members, volunteers, vendors, providers, and participants in clinical research studies to report wrongdoing in good faith. Wrongdoing may include but is not limited to suspected misconduct, violations of law or regulations, questionable accounting, or concerns about suspected violations of the Novant Health Compliance Plan and Code of Ethics or other policy.

II. POLICY

1. It is the responsibility of all team members, officers and Board members to report violations or suspected violations in accordance with this policy. Suspected wrongdoing may be reported to:
 - The immediate supervisor/manager/director/officer
 - The Compliance office
 - The hotline: The Alert Line 1-800-350-0094 or <https://novanthealth.alertline.com>
 - The Alert Line for the ACO at 1-844-337-3620 or <https://aco.alertline.com>.
 - Human resources at any time and/or during exit interview

Novant Health team members may also report any knowledge of suspected wrongdoing to state or federal government with jurisdiction over the area of perceived wrongdoing. Reporting may be done in a manner consistent with the Novant Health policies and procedures.

2. Novant Health will maintain a method to anonymously report, in good faith, suspected wrongdoing. This method will protect the reporting person's identity and

maintain confidentiality. The hotline service is known as “*The Alert Line*”. The Alert Line is intended to provide an additional method of communication and is not intended to substitute for normal reporting or communications methods.

- The Alert Line services will be provided by a contracted third party. No employee of Novant will answer calls directly or receive web-based communications directly in order to shield the person reporting from voice or electronic identification. No method of call tracing, call origin, or electronic tracing may be used by The Alert Line service.
- Persons contacting The Alert Line will be given a case number and Personal Identification Number and advised of the time they may re-contact The Alert Line to receive information about the disposition of the allegation.
- Novant Health will take steps to ensure the hotline is well publicized. Information about The Alert Line services may be displayed in work areas, in Novant Health team member, board and vendor materials, and by other methods as needed to encourage and promote the availability of The Alert Line service. Contact information also will be included in written materials available to participants of medical research, research investigators and Institutional Review Boards.

3. All reports suggesting wrongdoing are considered serious matters and shall be investigated and resolved within reasonable time frames. Compliance will make every effort to maintain confidentiality of the reporter to the degree possible by disclosing information on a need to know basis to investigate and resolve the matter. Persons having a sufficient level of expertise/knowledge concerning the issue presented will investigate allegations. Where an internal investigation substantiates a reported violation, it is the policy of the organization to initiate corrective action, including, as appropriate, making prompt restitution of overpayment amounts, notifying the appropriate governmental agency or plan sponsor, instituting whatever disciplinary action is necessary, and implementing systemic changes to prevent a similar violation from recurring in the future.
4. Novant Health has a strict policy for non-intimidation and anti-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials. A team member who retaliates against someone who has reported a suspected violation in good faith is subject to discipline up to and including termination of employment.
5. Any individual reporting a violation or suspected violation must be acting in good faith and have reasonable grounds for believing the information disclosed is accurate.

III. QUALIFIED PERSONNEL

N/A

IV. EQUIPMENT

N/A

V. PROCEDURE

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

N/A

VI. DOCUMENTATION

N/A

VII. DEFINITIONS

The Alert Line: Name used to describe the *hotline* service for Novant Health.

Hotline: A telephone line or web site location that can be used without charge and is available 24 hours a day, 7 days a week.

Team member: Employee

Wrongdoing: Includes but is not limited to suspected actions of misconduct, violations of law or regulations, questionable accounting, or concerns about suspected violations of the Novant Health Compliance Plan and Code of Ethics or other policy.

VIII. RELATED DOCUMENTS

- Novant Health Code of Ethics
- Novant Health Conflicts of Interest Policy
- Novant Health Corporate Compliance Plan
- Novant Employee Handbook
- NH Research Misconduct Policy
- Novant Health Anti-Retaliation Policy

IX. REFERENCES

N/A

X. SUBMITTED BY

Director Corporate Compliance

XI. KEY WORDS

Ethics, hotline, The Alert Line, anonymous, wrongdoing, fraud, report, reporting, security, theft, crime, code of ethics, whistleblower

XII.	INITIAL EFFECTIVE DATE	Lines effective 1998
	DATES REVISIONS EFFECTIVE	8/20/2012, 12/15/2016, January 15, 2019
	DATES REVIEWED (No changes)	6/2002; 9/2005; 5/2009, 8/20/2012, (Add HAMC 1-3-14), 08/2015
	Date Due for Next Review	January 2022

SIGNATURE SHEET

TITLE	Reporting of Wrongdoing - Anonymous
NUMBER	NH-LD-AD-213
TJC FUNCTIONS	LD, RI, MS, CC
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, MMC, MPH, MHMC, PMC (PMC main, COH & all other locations), RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, Caton Merchant House, Cancer Center, NHMG, Prince William Foundation, Prince William Health Physician Services
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
VP Compliance; Novant Compliance Officer	Lee Decker		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date
N/A		

TITLE	Purchases from Physician-Owned Suppliers		
NUMBER	NH-LD-LG-140	Last Revised/Reviewed Effective Date:	Sep19
TJC FUNCTIONS	LD-LG, CP		
APPLIES TO	<p>Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused</p> <p>NH UVA: HAMC, PWMC, Caton Merchant House, Cancer Center, NHMG, Prince William Foundation, Prince William Health Physician Services</p>		

I. SCOPE / PURPOSE

This policy applies to all team members of Novant Health, Inc. and its wholly owned subsidiaries, including but not limited to hospitals, ambulatory surgery centers, physician practices, outpatient imaging centers, and long term care facilities (collectively, “Novant Health”). The purpose of this policy is to create safeguards which assist Novant Health team members when they review proposed purchases with Physician-Owned Suppliers (“POS”).

This policy applies to all contracts required to be negotiated and executed on behalf of Novant Health, Inc. and its wholly owned subsidiaries including but not limited to contracts for medical devices, medical supplies, medical equipment, pharmaceuticals, software, hardware, or Construction and Design services.

II. POLICY

A. General Rule

The United States Department of Health and Human Services, through its Office of Inspector General (“OIG”), has expressed the viewpoint that purchasing relationships that generate or maintain referrals from physicians who have, directly or indirectly, a financial interest in the utilization of the item or service purchased should be closely scrutinized.

Accordingly, Novant Health will prohibit Novant Health entities from entering a contract to lease or purchase a product or service, including but not limited to pharmaceuticals, implants, instruments, supplies, and other medical devices, from a POS in which a Referring Physician or Potential Referring Physician or his/her Immediate Family Members have an Ownership or Investment Interest. For the purposes of this policy, Potential Referring Physicians means any Physicians licensed in a state where Novant Health operates.

B. Exceptions

Exceptions to this policy may be warranted in unusual circumstances. Any request for an exception under this policy must be made in writing by an individual holding a Vice President or higher position at the Novant Health entity wanting to purchase the services or products. Such written request will be submitted to the

Office of Supply Chain Management and include, at a minimum:

1. the parties involved;
2. details surrounding the arrangement to be considered (including but not limited to annual estimated spend) ;
3. reasons why the exception is necessary, (including but not limited to information about other available sources of the product or service); and
4. all information known about the Ownership or Investment Interest by the Referring Physician(s).

Prior written approval by the VP/Strategic Sourcing, VP/Compliance and VP/General Counsel of any exception is required before entering into any contract with a POS. Any contract with a POS granted an exception to the general prohibition on purchasing from a POS must still comply with the [Financial Transactions with Physicians & Physician Family Members Policy](#).

C. **Contracts not in Scope**

This policy does not apply to contracts entered with physician(s) or medical group(s) for the acquisition of medical services

III. **PROCEDURE**

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

A. **Ownership Determination**

At the initiation of any new vendor request within the scope of this policy a Supplier Certification Form must be completed by the vendor (attached as an addendum to this policy). Until the Supplier Certification Form is returned to Strategic Sourcing, no new contract will be entered into with a vendor. Upon receipt of a Supplier Certification Form, if it is determined a vendor is a Physician-Owned Supplier as defined in this policy, Novant Health will not purchase any products or services from the vendor unless an exception is made.

VI. **DOCUMENTATION**

Supplier Certification Form (attached as an addendum to this policy)

VII. **DEFINITIONS**

Immediate Family Member or Member of a Physician's Immediate Family: means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; spouse of a grandparent or grandchild.

Ownership or Investment Interest: has the meaning set forth in 42 C.F.R. § 411.354(b) or any successor regulation. Ownership may be direct or indirect, and may be by means of equity or debt. There is no minimum percentage ownership below which this policy would not apply. Investments in publicly-traded securities or mutual funds are

excluded from the definition so long as they meet the requirements of 42 C.F.R. § 411.356(a) or (b) or any successor regulation. This definition also includes Royalty Interests or other payment to a Physician by a third party where the Physician has sold rights to that third party (e.g., where a Physician has sold intellectual property rights to a manufacturer and that manufacturer in turn sells a product to Novant Health).

Physician: means a doctor of medicine or osteopathy, a doctor of podiatric medicine, a doctor of optometry, a doctor of dental medicine or oral surgery, or a chiropractor.

Physician-Owned Supplier (“POS”): means any entity that derives revenue from selling, or arranging for lease or sale of services of products, including but not limited to medical devices, medical supplies, medical equipment, pharmaceuticals, software, hardware, or Construction and Design services, where a Referring Physician, Potential Referring Physicians or an Immediate Family Member has an Ownership or Investment Interest in such entity.

Referral: means any patient referral as well as any order for tests or services. Accordingly, a **Referring Physician** includes any Physicians who refer patients to a given Novant Health facility or orders any test or service from that entity. A **Potential Referring Physician** is any individual who could refer patients to a Novant Health facility or order tests or services from an entity, even if the individual has never done so. For the purposes of this policy, Potential Referring Physicians means any Physicians licensed in a state where Novant Health operates.

Royalty Interest: means payments made to the creator/owner of an item or intellectual property for each unit/copy of the property sold.

VIII. RELATED DOCUMENTS

- [Contracts Policy \(NH-LD-LG-131\)](#)
- [Financial Transactions with Physicians & Physician Family Members Policy \(NH-LD-LG-135\)](#)

IX. REFERENCES

- [Anti-Kickback Statute \(42 U.S.C. § 1320a-7b\)](#)
- [OIG Special Fraud Alert: Physician-Owned Entities \(March 26, 2013\)](#)

X. SUBMITTED BY

NH Strategic Sourcing Department with support from NH Compliance Department, NH Medical Affairs and NH Legal Department

XI. KEY WORDS

Physician Owned Supplier, Physician Owned Distributor, Anti-Kickback Statute

XII. INITIAL EFFECTIVE DATE	May 26, 2015
DATES REVISIONS EFFECTIVE	September 2019
DATES REVIEWED (No changes)	
Date Due for Next Review	September 2022

SIGNATURE SHEET

TITLE	Purchases from Physician-Owned Suppliers
NUMBER	NH-LD-LG-140
TJC FUNCTIONS	LD-LG, CP
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, MMC, MPH, MHMC, PMC (PMC main, COH & all other locations), RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, Caton Merchant House, Cancer Center, NHMG, Prince William Foundation, Prince William Health Physician Services
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
VP Strategic Sourcing	Martha Bergstedt		See electronic approval
SVP Medical Affairs	Sid Fletcher		
VP Chief Compliance Officer	Lee Decker		

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date
N/A		

VENDOR OWNERSHIP CERTIFICATION

Vendor: _____

Address: _____

Service or Product Type(s): _____

City/State/Zip _____

Organizational form: Corporation, profit
Proprietorship

Partnership Individual or Sole

Corporation, non profit LLC LLP Other _____

The person, company, business or other entity named above ("Vendor") hereby certifies that the selection made below is true and accurate:

SECTION I: Organization's Ownership Type. (Check only one box).

1	Vendor is publicly-traded, with less than \$75 million dollars in stockholder's equity as of the end of its most recent fiscal year *(please attach Balance Sheet); and no physician nor an immediate family ¹ member of a physician is known to own, directly or indirectly, an ownership interest.
2	Vendor is either: (a) not publicly traded, or (b) an individual or sole proprietorship, and in either case listed above at (a) or (b), no physician or an immediate family* member of a physician is known to own, directly or indirectly, an ownership interest.
3	Vendor is publicly traded with at least \$75 million dollars in stockholders' equity as of the end of its most recent fiscal year (Please attach Balance Sheet).
4	Vendor is not publicly traded, and is either: (a) an entity in which a physician or immediate family member of a physician owns, directly or indirectly, an ownership interest; or (b) an individual or sole proprietor which is or is owned by a physician or an immediate family member of a physician. Please list names of physicians on continuing page.
5	Vendor is publicly traded, with less than \$75 million dollars in stockholder's equity as of the end of its most recent fiscal year; and a physician or an immediate family member of a physician is known to own, directly or indirectly, an ownership interest. Please list names of physicians on continuing page.

If Option 4 or 5 is checked, does Vendor have a written, signed contract with any NOVANT HEALTH affiliated entity? Yes No

Contract Pending If "yes," please attach a copy to this certificate.

SECTION II (Box 7): Physician Compensation Arrangement.

Does the Vendor have a current compensation arrangement with a physician or immediate family member of a physician who refers patients, tests, or services to the Novant Health contracting party(ies)?

Yes No If "YES," please list names of the referring physicians on Continuing Page.

¹ An immediate family member means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

NOVANT HEALTH CONTACT INFORMATION (NOVANT HEALTH or Affiliate who is sending this request—
Please complete contact information below)

<p>Name of NOVANT HEALTH Affiliated Entity: _____.</p> <p>Contact Name: _____, Title _____, Phone Number _____</p> <p>Fax completed Certificate to: _____.</p>

Vendor agrees to promptly notify Novant Health Strategic Sourcing at [fill in address], of any changes in the above as soon as such changes are known.

For NOVANT HEALTH affiliate only: If you checked Box 4 or 5 in Section I of this certification, or if your answer in Section II, Box 7 is “Yes,” and a signed, written contract with any NOVANT HEALTH affiliated entity is produced, has it been approved by the Legal Department? YES NO

If the contract has not been approved by the Legal Department, obtain approval before proceeding with any arrangement with the vendor.

If you checked Box 4 or 5 in Section I of this certification, or if your answer in Section II, Box 7 is “Yes”, list the names of all physicians who have a direct or indirect ownership interest in the Vendor, or whose immediate family members have a direct or indirect ownership interest in the vendor.

Physician Name	Tax ID or National Practitioner Identifier

Physician Name	Tax ID or National Practitioner Identifier

“COMPANY”

Acknowledged by:

Signature: _____

Date: _____

Name: _____

Phone: _____

Title*: _____

*If not an officer of the vendor, please attach proof of authority to sign

TITLE	Team Member (Healthcare Worker) Influenza Immunization		
NUMBER	NH-EOH-IMM-407	Last Revised/Reviewed Effective Date:	November 4, 2019
TJC FUNCTIONS	EOH-IMM		
APPLIES TO	<p>Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused</p> <p>NH UVA: HAMC, PWMC, Caton Merchant House, Cancer Center, NHMG, Prince William Foundation, Prince William Health Physician Services</p>		

I. SCOPE / PURPOSE

The purpose of this policy is to outline the process for all team members to receive an annual flu vaccination when the vaccine becomes available. Team members include, but are not limited to all Novant Health System staff, physicians and allied health professionals (including NHMG providers), contracted personnel, volunteers, vendors and students. The influenza vaccination period will generally last for 4 weeks, starting in October. This period may be adjusted based on information received from the CDC or local Health Department.

Flu vaccine requirements for Independent Medical Staff are outlined in the Medical Staff policy [Seasonal Influenza Vaccination \(Medical Staff and APCs\) - NH-MS-300](#).

NHMG practitioners (physicians and allied health professionals) are also subject to the Medical Staff's flu vaccination policy. NHMG practitioners who receive the annual flu vaccination or a valid exemption per this Healthcare Workers Influenza Immunization policy automatically are deemed to have complied with the Medical Staff's Seasonal Influenza Vaccination policy.

II. POLICY

It is the policy of Novant Health that all persons with a student, volunteer, employment or contractual arrangement with any of our facilities, irrespective of contact with patients, take the necessary precautions to adhere to mandated guidelines that are established through this policy for each calendar year. The full letter and intent of this policy is to remain in effect until an end to the flu season is declared by the Novant Health Chief Medical Officer or designee.

A. Mandatory Guidelines

Novant Health requires that all Novant Health Team Members will receive the designated influenza vaccine during the influenza vaccination period or provide evidence of vaccine receipt within the stated time period. Mandatory guidelines have been established to assist with determining the course of action to be taken in order to reach compliance with the components of this policy.

1. Novant Health requires an annual influenza vaccination for all Novant Health

team members as a condition of employment unless a valid medical or religious exemption is granted. The timeline interval in which Novant Health will provide the influenza vaccine is defined by the Influenza Committee and Novant Health Chief Medical Officer. This is known as the Influenza Vaccination Period. Influenza vaccines given prior to the influenza vaccination period will be reviewed and considered as well.

2. If any Novant Health team member is vaccinated through services other than those provided by Novant Health (i.e., private physician office, public clinics, Novant Health contracted vendors), he/she must provide written proof of immunization to Employee Occupational Health (EOH) for the Novant Health flu program. All other Novant Health team members must provide documentation to their employer, school, or the appropriate Novant Health department, (e.g., for Volunteers, the Volunteer Office, for vendors, Materials Management). Examples of proof of immunization include a physician's note, a receipt containing the vaccine information or a signed and current vaccination consent form. Expenses for obtaining the vaccine from outside sources will not be reimbursed.
3. If after consulting with vaccine suppliers and public health officials, Novant Health concludes a vaccine shortage exists, Novant Health may temporarily delay, suspend, or extend the influenza vaccination period.
4. In the event of a vaccine shortage with some vaccine available, the situation will be evaluated and vaccine will be administered in a tiered fashion based on established guidelines.
5. An annual educational program will be available to all Novant Health team members which includes information about the vaccine, non-vaccine control and prevention measures, diagnosis, transmission and impact of influenza, the risk to patients, and patient exposure by hospital workers. This education may be provided through e-mail, I-connect, noflu.org or other forms or formats.
6. Documentation of receipt of flu vaccine must be received no later than 5PM on the last day of the influenza vaccination period. A Novant Health team member who has not provided documentation (or has failed to secure an approved exemption or immunization), by 5PM on the last day of the influenza vaccination period will be suspended without pay for no less than 2 business days and no more than 7 business days, after which suspension will be lifted when appropriate vaccination documentation is received by EOH. If vaccination documentation is not received in EOH within the 7 business days of suspension, the team member will be considered as having voluntarily resigned his/her employment effective immediately. Only documentation of influenza vaccine received prior to the end of the influenza vaccination period will be considered to be compliant with this policy.
7. Any Novant Health team member who obtains approval for a valid exemption will be required to wear a surgical mask for the duration of the flu season. The mask must be worn at all times when in direct contact, or likely to be in direct contact with or within 6 ft. of a patient. The duration of flu season will be defined by the Chief Medical Officer or designee and the Flu Committee
8. During the influenza vaccination period, new hires who have not provided documentation of compliance (or have failed to secure an approved exemption or immunization), will be listed as "pending" hire and not be allowed to start new hire orientation.

- a. New team member applicants will be given 7 business days from the date of the employment health screening to provide adequate documentation of exemption or vaccination. Based on the severity of the flu season, new hires employed after the influenza vaccination period may need to receive influenza vaccination or provide proof of vaccination even after the influenza vaccination period has ended. If documentation is not received in EOH showing compliance on or before 5PM of the 7th business day EOH will contact Talent Acquisition and advise the applicant is not cleared for hire.
 - b. New team member applicants employed after the influenza vaccination period has ended will be given the influenza attestation form. The applicant is to review and sign the form. The attestation form provides information for new hires to help them understand Novant Health requirements for influenza vaccination as a condition of employment for all healthcare workers.
9. Employed Team Members on leave who return to work after the influenza vaccination period are expected to be in compliance with this policy upon return to work. Employed team members returning from leave must provide documentation of policy compliance having secured an approved exemption or immunization prior to the scheduled return to work date. If no documentation is provided to the EOH office at the time of the return to work visit, immunization will be given to the employee during the return to work visit if vaccine is available. Team members will be required to wear a mask for 2 weeks after vaccine is given. If no vaccine is available, employees will be required to mask for the duration flu season.
 10. Employed Team Members who are out of work due to an infectious illness (such as, but not limited to influenza) are referred to the [Attendance Policy \(NH-HR-6065\)](#). During the Infectious Illness Exemption Period, unscheduled absences from work due to an infectious illness will not count as occurrences. Employed Team Members are eligible to submit a **one instance of unscheduled absences** to their timekeeper for approval. Employed Team Members must, follow their departmental guidelines when calling out of work and must identify the infectious illness. Employed Team Members are required to provide a doctor's note to Employee Occupational Health (EOH) for the infectious illness upon the employee's return to work.

B. Exemption requests for medical and/or religious purposes

Exemption to immunization may be available for medical contraindications or religious beliefs. The approval or denial of a requested exemption will be based upon documentation submitted by the individual in accordance with established guidelines. The process for NH employed team members, volunteers, allied health professionals and students is as follows:

1. Exemption request forms may be obtained in the EOH Office, Human Resources, Medical Staff Office and online on I- Connect . The exemption request form must be submitted to the "Flu Exemption" mailbox in Outlook no later than three (3) weeks prior to the start of the influenza vaccination period. Requests will be reviewed and the team member notified of exemption status generally within 5 business days of receipt.

2. Individuals requesting an exemption due to a medical contraindication must submit documentation in the form of a letter supporting the medical need for the exemption on his/her provider's office letterhead or on the Novant Health Medical Exemption Form no later than three (3) weeks prior to the start of the influenza vaccination period. Each request for medical exemption will be evaluated by Novant Health Medical Exemption Committee
3. Individuals requesting a religious accommodation must provide information to support the request and submit a religious exemption form no later than three weeks prior to the start of the influenza vaccination period. Each request for religious exemption will be evaluated by the Novant Health Religious Exemption Committee.
4. If an exemption is:
 - b. Granted, the individual and the Department Manager will be notified in writing. If an exemption is granted for a permanent condition, the individual does not need to resubmit a request each year. Otherwise, the individual will resubmit as needed.
 - c. Not Granted, the individual and the Department Manager will be notified in writing. The team member will be expected to adhere to the vaccination requirement or resubmit documentation requesting a different exemption.
 - d. Team members who were granted an exemption and make a decision to take the vaccine at a later date will be expected to take the vaccine the next flu season barring any change in medical or religious status.
 - e. NH contractors' and vendors' exemption applications will not be evaluated under this policy.

C. Methodology for calculating influenza rates

1. **Numerator** will include HCP and non-clinical staff and affiliated LIP's who have worked at the company for the period of October 1 to March 31 of the following year to include:
 - a. Employed Team Members vaccinated at the healthcare facility, reported by the team member in writing or documentation that influenza vaccination was received elsewhere; or
 - b. were determined to have a medical contraindication/severe allergic reaction to eggs or other components of the vaccine, history of Guillain-Barre Syndrome; or
 - c. declined influenza vaccination.
2. Numerators will be calculated separately for each of the above categories.
3. **Denominator** will include HCP and non-clinical who are working in the healthcare facilities during the period of time from October 1 to March 31 to include:
 - a. All clinical and Non-clinical employed team members who are on the facilities payroll
 - b. LIP and Physicians who are on the facility payroll
 - c. LIP and Physicians who are employed team members of Novant Health
 - d. LIP and Physicians who are affiliated with facility
 - e. Students/trainees and volunteers

III. QUALIFIED PERSONNEL

N/A

IV. EQUIPMENT

N/A

V. PROCEDURE

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

N/A

VI. DOCUMENTATION

- Influenza Consent Form
- Religious Exemption- Seasonal Influenza Vaccine
- Medical Exemption- Seasonal Influenza Vaccine
- Statement of Attestation- Seasonal Influenza Vaccine

VII. DEFINITIONS

Influenza vaccination period: Each year the flu committee and the Chief Medical Officer reviews information from the health departments and CDC to determine the optimal time for the influenza vaccine to be given. This influenza vaccination period lasts for approximately 4 weeks and is a corporate initiative when all eligible Novant Health and Non-Novant Health team members are vaccinated.

VIII. RELATED DOCUMENTS

- [Healthcare Worker Immunizations/Vaccinations Administration - NH-EOH-IMM-400](#)
- [Seasonal Influenza Vaccination \(Medical Staff and APCs\) - NH-MS-300](#)
- [Attendance – NH-HR-6065](#)

IX. REFERENCES

- CDC. **Prevention and Control of Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2011.** MMWR 2011 Aug 26; 60(33):1128-1132.
- The Joint Commission Standards for Accreditation: <https://e-dition.jcrinc.com/MainContent.aspx>
- **National Quality Forum**

X. SUBMITTED BY

Employee Occupational Health

XI. KEY WORDS

Flu shot, influenza, vaccination, vaccination period, influenza vaccination period, mandatory influenza

XII. INITIAL EFFECTIVE DATE 9/2012
DATES REVISIONS EFFECTIVE 9/15/2013, 6/2014, 11/15/2014, 6/15/2015, 07/15/2016, 09/12/2017, 8/06/18, 11/4/19
DATES REVIEWED (No changes) Add HAMC 11/25/13, 6/1/19
Date Due for Next Review 11/2022

SIGNATURE SHEET

TITLE	Team Member (Healthcare Worker) Influenza Immunization
NUMBER	NH-EOH-IMM-407
TJC FUNCTIONS	EOH-IMM
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, MMC, MPH, MHMC, PMC (PMC main, COH & all other locations), RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, Caton Merchant House, Cancer Center, NHMG, Prince William Foundation, Prince William Health Physician Services
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
Medical Director Employee Occupational Health	Charles Bregier, MD		See electronic approval
SVP Chief Safety, Quality, & Epidemiology Officer	David Priest, MD		See electronic approval
EVP/ Chief Medical Officer	Eric Eskioglu, MD		See electronic approval
EVP & Chief HR Officer	Janet Smith-Hill		See electronic approval
Sr. Director, Infection Prevention	Susan DeCamp- Freeze		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date

TITLE	Implant / Explant Management		
NUMBER	NH-PC-PR-2008	Last Revised/Reviewed Effective Date:	Oct 2018
TJC FUNCTIONS	PC-PR		
APPLIES TO	Novant Health: BMC (BMC main), FMC (FMC main, CMC, KMC, Offsite Surgical Centers, FMC's NHMG provider-based physician clinics), HMC (HMC main), MMC (MMC main), MPH (MPH main), MHMC (MHMC main), PMC (PMC main, COH, PMC's NHMG provider-based physician clinics), RMC (RMC main, Julian Road Outpatient Surgery Center), TMC (TMC main), Freestanding Surgical Centers, NHMG NH UVA: HAMC, PWMC (PWMC main), NHMG		

I. SCOPE / PURPOSE

The purpose of this procedure is to provide guidelines for team members who care, handle and document implant and explant medical devices. This procedure provides guidelines to assure the ability to track implantable devices through identification of the implant which the patient received in order to notify and recall the device. This policy applies to all procedural areas that implant and explant medical devices. Refer to Novant Health Tissue and Biological Implants Management for additional requirements when implanting or explanting biological tissue. [Tissue and Biological Implant Management - NH-PC-PR-120](#)

II. POLICY

- A.** Novant Health, in compliance with the U.S. Food and Drug Administration (FDA) regulations, will track all designated implantable devices. Designated implantable devices are subject to an FDA tracking order which fits within one of the three criteria of 21 C.F.R. § 821.1(a):
 - 1. The failure of the device would be reasonably likely to have serious adverse health consequences;
 - 2. The device is intended to be implanted in the human body for more than one year; and
 - 3. The device is a life-sustaining or life-supporting device used outside a device user facility.

- B.** Device Tracking
 - 1. A device user facility (refer to Definitions) will promptly submit tracking reports, per FDA guidelines (refer to References) and to the FDA as follows:
 - a) Submit reports of individual adverse events no later than ten work days after the day that Novant Health become aware of a reportable event
 - i. to the FDA and the manufacturer if the adverse event is a device-related death; or
 - ii. to the manufacturer if the adverse event is a device-related serious injury, or if the manufacturer is unknown, submit reports to the FDA.

- b) Annual reports, as described in 21 C.F.R. § 803.33, containing the following information:
 - Patient information;
 - Adverse event or device problem;
 - Device information;
 - Initial reporter information; and
 - User facility information.

See also, FDA Form 3500A.

2. A distributor, final distributor, or multiple distributor of any tracked device will, upon purchasing or otherwise acquiring any interest in such a device, promptly provide the manufacturer tracking the device with the following information:
 - a) The name and address of the distributor, final distributor or multiple distributor;
 - b) The lot, batch, model, or serial number of the device or other identifier necessary to track the device;
 - c) The date the device was provided to the patient;
 - d) The name, mailing address, and telephone number of the prescribing physician; the name, mailing address, and telephone number of a physician who regularly treats the patient;
 - e) If and when applicable, the date the device was explanted, the explanting physician, the date of the patient's death, or the date the device was returned to the distributor or manufacturer, permanently retired from use, or otherwise permanently disposed of.
3. FDA Regulations do not require that a patient give written consent to have a device tracked or to release their identity to the manufacturer.
4. FDA regulations provide for situations in which any person subject to the reporting requirements permanently ceases to do business: If a distributor goes out of business and other persons acquire the right to distribute the tracked devices, then these other persons become responsible for continuing the tracking responsibilities of the previous distributor. Therefore, newly acquired Novant Health facilities will implement a tracking system.
5. Life sustaining or life supporting devices used only in a user facility do not require tracking; however, if they are used outside the user facility, they may require tracking if they are subject of an FDA tracking order.

Refer to [FDA's Medical Device Tracking; Guidance for Industry and FDA Staff issued March 27, 2014](#) for devices that should and should not be tracked. For additional tracking requirements for biological tissue, refer to [Tissue and Biological Implant Management - NH-PC-PR-120](#).

- C. Implants and explants will be documented in the Electronic Medical Record (EMR).
- D. Only Novant Health team members and providers will open sterile implantable devices onto a sterile field.
- E. Facilities choosing not to allow explants to go home with the patient are excluded from Section B.1. & 2 in the Procedure Section of this policy/procedure.

III. QUALIFIED PERSONNEL

Registered Nurses, Providers, Surgical Tech's, licensed practical Nurses, Medical Assistants, and unlicensed assistive personnel.

IV. EQUIPMENT

N/A

V. PROCEDURE

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

A. Implantable Medical Devices

1. The provider performing the procedure will determine the type, model and size of the implant(s) to be used and communicate to appropriate team member within the facility.
2. If there are issues with availability of implants, the facility manager or designee will notify the provider and make alternate arrangements.
3. The healthcare team member including the provider will verify the implant information by showing the package to the provider and appropriate team member participating in the procedure and reads the type, model, size and expiration date, as well as any other unique identifiers, if applicable, from the package. The implant will not be dispensed to the sterile field until the provider has explicitly acknowledged the information and indicates that it is the correct implant for the patient.
4. The following information will be documented on the EMR record:
 - a) The location of implanted device
 - b) Type and size of implanted device
 - c) Expiration date, if applicable
 - d) Identifying information
 - 1) model number/catalog Number
 - 2) lot number/serial number, if applicable
 - 3) Manufacturer
 - e) Verification of the implant during the time out
5. Document the type, lot number and expiration date for the solutions/medications used with the implant.
6. Provide patient identification card if applicable.

B. Explanted Medical Devices (does not apply to products involved in a recall or explants that must be sequestered for review)

1. If a patient requests to take home an explanted medical device, team members will obtain informed consent in the pre-procedural area using the [NH Tissue, Prosthesis and/or Implant Release consent form](#). Provide a copy to the patient upon request.
2. Handling the explant:
 - a) Clean bioburden in the decontam room as necessary. If the explant is a pain pump, waste narcotics per policy.
 - b) Place the implant in a peel pack
 - c) Place the peel pack in a biohazard bag before returning to the patient.
3. When the provider requests to take the medical device follow the handling instructions above and obtain signature from the provider.
4. Medical Devices can also be returned to the vendor. Follow instructions for

- cleaning and packaging as requested.
5. If a conflict regarding disposition of the implant occurs, a discussion between the provider, patient and vendor will occur prior to the procedure.
 6. Documentation:
 - a) Document the removal of the explant in the EMR record including the lot and/or serial number and manufacturer if available, and disposition.

VI. DOCUMENTATION

- Electronic Medical Record
- Implant identification card (if applicable)

VII. DEFINITIONS

Allografts: The transfer of tissue between two genetically dissimilar individuals of the same species.

Device User Facility: A hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility.

Device: intended to be implanted in the human body for more than 1 year; a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device.

Items that are implants have unique identifiers that allow for tracking. The term does not include a device that is intended and used only for temporary purposes or that is intended for explanation in 1 year or less.

Distributor: A distributor is any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

Explant: A medical device previously implanted that is removed from the patient.

FDA Class II: devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance.

FDA Class III: devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

Final Distributor: any person who distributes a tracked device intended for use by a single patient over the useful life of the device. This term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities. A “final distributor” can be the person or institution who owns the device, e.g., a doctor or hospital can be a final distributor. See FDA’s Medical Device Tracking; Guidance for Industry and FDA Staff issued Nov. 17, 2006.

Implant: A device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore or replace the function of an organ system or structure of the human body throughout the useful life of the device either temporarily or permanently. Items that are implants have unique identifiers that allow for tracking.

Prosthesis: an artificial device to replace or augment a missing or impaired part of the body. a dental **prosthesis**.

Zenograft--a tissue graft or organ transplant from a donor of a different species from the recipient

VIII. RELATED DOCUMENTS

- [NH Tissue, Prosthesis or Implant Release Form](#)
- [Tissue and Biological Implant Management - NH-PC-PR-120](#)
- [Recall and Alert of Product or Clinical Equipment \(excludes pharmaceuticals\) - NH-LD-AD-250](#)
- [Medication Management - Storage, Security, Distribution, and Disposition - NH-MM-1003](#)

IX. REFERENCES

- AORN. (2018). *2018 Guidelines for perioperative practice*. Denver: AORN. Retrieved from <https://www.aorn.org/guidelines/clinical-resources/aorn-standards>
- Center for Devices and Radiological Health. (n.d.). *Medical Device Reporting (MDR)*. Retrieved July 23, 2018, from <https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>
- [21 C.F.R. § 803.10](#)
- [21 C.F.R. § 803.30](#)
- [21 C.F.R. § 803.3](#)
- [21 C.F.R. § 821.1](#)

X. SUBMITTED BY

Surgical Services Intra-Op BPET

XI. KEY WORDS

Implant, explant, medical device, vendor, procedure, distributor, FDA, device tracking

XII. INITIAL EFFECTIVE DATE	March 24, 2015
DATES REVISIONS EFFECTIVE	Oct 2018
DATES REVIEWED (No changes)	
Date Due for Next Review	October 2021

SIGNATURE SHEET

TITLE	Implant / Explant Management
NUMBER	NH-PC-PR-2008
TJC FUNCTIONS	PC-PR
APPLIES TO	Novant Health: BMC (BMC main), FMC (FMC main, CMC, KMC, Offsite Surgical Centers, FMC's NHMG provider-based physician clinics), HMC (HMC main), MMC (MMC main), MPH (MPH main), MHMC (MHMC main), PMC (PMC main, COH, PMC's NHMG provider-based physician clinics), RMC (RMC main, Julian Road Outpatient Surgery Center), TMC (TMC main), Freestanding Surgical Centers, NHMG NH UVA: HAMC, PWMC (PWMC main), NHMG
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
Vice President of Surgery and Anesthesia	Leslie Barrett, CRNA, MBA		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date
ELC	Julie Stratton, RN, BSN, MHA	06/15/2018
Surgical Services BPET	Stacey Davis, RN, BSN	12/21/2017
Surgical Systems Ops	John Mann, MD William Walker, MD	06/5/2018
NH Professional Nursing Council (NHPNC)	Susan Tharp, RN	06/25/2018
NHMG Clinic Standards/Patient Safety Committee	John Card, MD	06/28/2018
Cardiology BPET	Linda Harris, RN, MSN	07/20/2018

TITLE	Cellular Phone Usage		
NUMBER	NH-EC-SA-5015	Last Revised/Reviewed Effective Date:	March 15, 2018
TJC FUNCTIONS	EC-SA		
APPLIES TO	<p>Novant Health: Hospitals, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services LLC, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused</p> <p>NH UVA: HAMC, PWMC, NHMG, Caton Merchant House, Prince William Cancer Center, Prince William Foundation, Prince William Health Physician Services</p>		

I. SCOPE / PURPOSE

Novant Health recognizes its responsibility to provide a safe environment in patient care areas by avoiding interference problems between radio frequency transmission devices and patient care/medical equipment. This policy describes the control of cellular telephone and portable two-way radio use at all Novant Health facilities.

II. POLICY

It is the policy of Novant Health to take all practical steps to reduce or eliminate electronic interference with patient care equipment caused by cellular phones and radio transmitters. Due to reports in the literature about electronic interference with patient care equipment caused by cellular phones and radio transmitters, Novant Health prohibits the non-essential use of cellular phones and/or radio transmitters in critical patient care areas with monitoring equipment. Non-essential cellular phones should be turned completely off, not in the standby position, before they are brought into a Novant Health facility or department displaying appropriate warning signs.

Public Safety and nurse managers or their designees for critical patient care areas are responsible for communicating and enforcing this policy.

A. Non-Essential Cellular Usage

Anyone about to enter a Novant Health facility in possession of a cellular phone or a radio transmitting device is notified by appropriate warning signs that he/she must turn off the device before entering a critical patient care area. Radio transmitting devices include, but are not limited to, cellular phones and police, paramedic, maintenance, security or other similar two-way radios.

B. Essential Cellular Usage

Engineering, Clinical Engineering, Public Safety, physicians, and other Novant Health personnel whose duties are essential to patient care may use cellular phones or hand-held radio transmitters in all areas of Novant Health facilities. Personnel who must use a radio transmitter should maintain a distance of at least 10 feet (3 meters) from all patient care electronic monitoring equipment when

transmitting. In the event that emergency services personnel must use their cellular telephones or portable two-way radios in non-emergency situations, these devices must be at least 10 feet (3 meters) or as far away from any nearby medical equipment as possible. If possible, they should leave the immediate area to make a transmission.

C. Emergency Situation Usage

1. Individuals who require constant communication, such as police officers, firefighters, emergency service personnel, and others whose duties are essential for health and/or safety, may use cellular phones or portable radio transmitters in all areas of Novant Health facilities during an emergency situation.
2. All suspected cellular interference with patient care monitoring equipment should be reported to the Novant Health's Clinical Engineering Department.
3. Inservice education regarding the hazards of radio frequency interference with patient care equipment shall be provided to Novant Health personnel whose duties require regular use of portable radio transmitters.
4. Signs shall be posted near affected area entrances.
 - Signs shall include an illustration of a prohibited cellular telephone and the following text:
 “NON-ESSENTIAL USE OF CELLULAR PHONES PROHIBITED”
 “PLEASE TURN ALL CELLULAR PHONES OFF BEFORE ENTERING THIS AREA”
 “ESSENTIAL USE MUST BE AT LEAST 10 FEET FROM MONITORING EQUIPMENT”

III. QUALIFIED PERSONNEL

Applies to all persons within Novant Health facilities in possession of a cellular phone or radio transmitting device.

IV. EQUIPMENT

N/A

V. PROCEDURE

The procedure serves as a guideline to assist personnel in accomplishing the goals of the policy. While following these procedural guidelines personnel are expected to exercise judgment within their scope of practice and/or job responsibilities.

N/A

VI. DOCUMENTATION

N/A

VII. DEFINITIONS

Radio Transmitting Device: Equipment that generates radio waves for communication

purposes, such as cell phones and two-way radios.

VIII. RELATED DOCUMENTS

N/A

IX. REFERENCES

- “Medical Wireless Device Interaction” University of Oklahoma Program
- Cellular ONE. BellSouth Mobility
- FDA Facility Reporting Bulletin “FDA Concerned about Interference with Medical Devices.”
- The Advisory Board Company Fact Brief “Impact of Cellular Phones Upon Medical Equipment”
- Facility Care “Hazards of Cell Phones in Hospitals”

X. SUBMITTED BY

Biomed Taskforce

XI. KEY WORDS

Cellular phones, cell phones, radio transmitting devices, two-way radios, 2-way radios

XII. INITIAL EFFECTIVE DATE	1/1998 (TR), 5/2002 (SPR)
DATES REVISIONS EFFECTIVE	11/2000, 01/2003, 05/2005 (add TMC), 03/15/2018
DATES REVIEWED (No changes)	4/2005, 04/2008, July 2011 (add HAMC 11/25/13)
Date Due for Next Review	March 2021

SIGNATURE SHEET

TITLE	Cellular Phone Usage
NUMBER	NH-EC-SA-5015
TJC FUNCTIONS	EC-SA
APPLIES TO	Novant Health: BMC, FMC (FMC main, CMC, KMC & all other locations), HMC, MMC, MPH, PMC (PMC main, COH & all other locations), RMC, TMC, NHMG, Freestanding Imaging Centers, Freestanding Surgery Centers, Rehabilitation Centers, Pharmacy Services LLC, Corporate Departments and Entities, Foundations, Auxiliaries, and Finance Focused NH UVA: HAMC, PWMC, NHMG, Caton Merchant House, Prince William Cancer Center, Prince William Foundation, Prince William Health Physician Services
ACTION	Revised

APPROVED BY:

Title	Approved By	Signature	Date
Sr. Director, Corporate Clinical Engineering	David Wilson		See electronic approval

COMMITTEES APPROVED BY:

Committee	Chairperson/Designee	Date
Corporate Biomed Committee / Taskforce	David Wilson	08/05/2015
Corporate EC APET	Chip Phifer	05/29/2015