

**THE HEKTOEN INSTITUTE FOR  
MEDICAL RESEARCH**

**COMPLIANCE PLAN**

# The Hektoen Institute for Medical Research

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## Letter from President

### **TO ALL EMPLOYEES, RESEARCHERS, CONTRACTORS, VENDORS AND AGENTS OF THE HEKTOEN INSTITUTE FOR MEDICAL RESEARCH AND ITS SUBSIDIARY COMPANIES:**

As a result of increased enforcement efforts by federal and state agencies in the health care industry, the Board of Trustees of The Hektoen Institute for Medical Research, an Illinois not for profit corporation, has established a Compliance Plan for the Institute, for its subsidiary company Hektoen Institute for Medical Research, L.L.C., an Illinois limited liability company, and for its other present and future subsidiary companies (collectively, "Hektoen").<sup>1</sup> The Compliance Plan will be overseen by the Compliance Officer. The purpose of this Plan is to educate trustees, officers, employees, researchers, contractors, vendors and agents of Hektoen, and others doing business or having dealings with Hektoen ("Covered Parties") concerning the risks of civil and criminal liability for Hektoen, to encourage Covered Parties to seek appropriate counsel on business activities, to require that they conduct their activities within the law and with the highest ethics, and to make certain that the organization continues to provide quality services in connection with our servicing of various research grants without inadvertently violating these laws.

The Hektoen Compliance Department under the leadership of the Compliance Officer will be responsible for the implementation and ongoing administration of the Plan. One of the most important aspects of this Plan will be to continually educate Covered Parties about the laws and regulations which affect Hektoen and its activities. Please review and become familiar with the basic concepts outlined in the attached material and the training programs that will be presented by Hektoen. These will be useful, informative and should help Covered Parties achieve their business objectives in full compliance with the laws. The Compliance Plan is an important component of our commitment to the highest organizational ethics. We encourage all Covered Parties to use our Compliance Hotline to report unethical, illegal or suspect behavior. The Hotline number is 312-948-2523 and will be published on the Hektoen web site [www.hektoen.org](http://www.hektoen.org) and will be posted throughout our facilities.

The Compliance Department will conduct audits and reviews of other departments as part of its regular duties to monitor the activities of Hektoen, as well as when specific complaints are made to the Compliance Officer or the Hotline. The Compliance Department will make every effort to conduct its audits with minimal disruption to other departments. I would appreciate your cooperation with these efforts to improve our business. Maintaining a compliant company is good business and can only benefit our company and our Covered Parties in the long term. If you have specific questions concerning the Compliance Plan or related issues, please call the Compliance Department at 312-948-2523. Thank you.

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President

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<sup>1</sup> As of April 18, 2006, the date of adoption of the Compliance Plan, subsidiary companies are Hektoen Institute for Medical Research, L.L.C., Hektoen Grant Services, L.L.C., and Hektoen Labs, L.L.C., each an Illinois limited liability company.

## **SECTION I: INTRODUCTION**

### **1.1 Plan Description**

The Compliance Plan (“Plan”) applies to all Board of Trustee members, officers, employees, researchers, contractors, vendors and agents of, and others doing business or having dealings with (“Covered Parties”) The Hektoen Institute for Medical Research, an Illinois not for profit corporation, its subsidiary company Hektoen Institute for Medical Research, L.L.C., an Illinois limited liability company, and its other present and future subsidiary companies (collectively, “Hektoen”)<sup>2</sup>, as applicable. The Plan addresses each of the seven elements of an effective compliance program listed in the Federal Sentencing Guidelines.

The Compliance Plan and supporting policies combine the use of checks and balances, ethics, common sense, trust and best practices to improve Hektoen’s activities. This Plan is a vital part of our commitment to the highest organizational ethical standards and assists our organization in achieving its goal of obtaining and servicing grants and furthering medical research while maintaining compliance with applicable laws and regulations. The Plan is a guide to ethical behavior and provides standards by which Covered Parties will conduct themselves in order to protect and promote organization-wide integrity and to enhance Hektoen’s ability to achieve its mission.

This Plan is a dynamic document, and will be modified or expanded as changes occur with regard to health care laws or as more information and knowledge is gathered about best practices and successful compliance programs. Through this Plan, Hektoen is providing guidance and structure to its Covered Parties to assist them in complying with civil, criminal and health care laws and regulations. Covered Parties should be aware that the development and implementation of effective compliance programs could raise many sensitive and complex legal issues.

It is expected that specific functional area and departmental compliance policies and procedures will be developed and implemented to carry out the mandates of the Plan. Such specific functional and/or departmental polices and procedures shall be Plan subcomponents and shall constitute a part of this comprehensive Plan. The Plan sets guidelines and serves as the compliance umbrella for all such subcomponents. Hektoen believes that the implementation of an effective compliance plan will achieve better quality control and reduce the risk of criminal and civil liabilities of Hektoen and its Covered Parties.

### **1.2 Plan Benefits**

There are a variety of benefits to be gained by implementing an effective compliance plan. Potential benefits are:

- Reduction of criminal wrongdoing,

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<sup>2</sup> As of April 18, 2006, the date of adoption of the Compliance Plan, subsidiary companies are Hektoen Institute for Medical Research, L.L.C., Hektoen Grant Services, L.L.C., and Hektoen Labs, L.L.C., each an Illinois limited liability company.

- Reduction of administrative or civil penalties,
- Identification of criminal and unethical conduct in business and clinical practice,
- Establishment of a culture which encourages Covered Parties to report concerns promptly and without fear of retribution or retaliation,
- Development of policies and procedures designed specifically to enhance compliance, and
- Achievement of good business practices.

### **1.3 Responsibilities of Management and Employees and Other Covered Parties**

Hektoen management personnel have the primary responsibility to set the benchmark for compliance. Managers and supervisors at all levels in the organization serve as the primary example for, and the primary source of information to employees and other Covered Parties. This requires educating employees and other Covered Parties regarding their responsibilities under this Plan and creating an environment in which individuals feel comfortable in raising issues concerning integrity and ethics. It also requires periodic assurance that each person understands and has complied with the Plan. All employees and other Covered Parties are responsible to ensure that their behavior and activity are consistent with the Plan. The effectiveness of the Plan depends on each person's willingness to bring compliance issues to the attention of his or her supervisor or the Compliance Officer. All persons involved in grants, research, sponsored programs and associated compliance areas of Hektoen will conduct their business in accordance with all applicable laws, regulations, policies and procedures, and the highest professional and ethical standards. Annually, directors, officers and staff members having administrative or managerial responsibilities shall review the plan and standards to assure they are complete and relevant. Other responsibilities include, at a minimum, the following:

- Knowing and Following Compliance Policies - All personnel have an affirmative duty to understand the Plan, follow its mandates, demonstrate compliance on a day-to-day basis and be accountable for compliance. Managers and supervisors of Hektoen must also be accountable for the compliance of the Hektoen employees and other Covered Parties they manage or supervise and the discipline of Hektoen employees and other Covered Parties violating this Plan, whether or not such managers or supervisors are Hektoen employees. Employees and other Covered Parties are required to comply with all applicable laws, regulations, and standards, whether or not specifically addressed in the Plan. If questions regarding the existence of, interpretation, or applicability of any law, regulation, or technical standard arises, they should be directed to the Compliance Officer.
- Training and Education - Managers and supervisors must communicate, formally and informally, the importance of compliance to employees and other Covered Parties and actively promote adherence to the Plan. Employees and other

Covered Parties must participate in training and ask whatever questions he or she may have about the Plan.

- Reporting Compliance Issues - Managers and employees and other Covered Parties must require that actual or potential compliance issues are reported to a supervisor or the Compliance Officer. All supervisors and managers of Hektoen are required to report compliance issues to the Compliance Officer.
- Code of Conduct and Ethics - Each employee and other Covered Party is responsible for reading the Hektoen Code of Conduct and Ethics and for complying with such standards.
- Accountability - Each employee will be evaluated on his or her compliance during the performance review process. Managers and supervisors are accountable not only for their own actions, but also for the actions of their employees. To be successful, managers and supervisors must create an atmosphere that encourages compliance and fosters reporting of noncompliance. The success of each manager's and supervisor's efforts in implementing the Plan will be evaluated and reflected in the manager's and supervisor's performance review.

#### **1.4 Compliance Plan Policy Statement**

- Hektoen has established and will maintain and revise, as necessary, compliance policies and procedures to be followed by its employees and other Covered Parties.
- The Compliance Officer, at the direction of the Board of Trustees, is assigned responsibility to oversee compliance with such standards and procedures.
- Hektoen shall use due care not to delegate substantial discretionary authority to individuals whom it knows, or should know, through the exercise of due diligence, have a propensity to engage in illegal activities.
- Hektoen shall take steps to communicate effectively its compliance policies and procedures to employees and other Covered Parties by requiring participation in training programs and by disseminating publications that explain in a practical manner what is required.
- Hektoen shall take steps to achieve compliance with its guidelines by utilizing monitoring systems and auditing systems reasonably designed to detect violations by its employees and other Covered Parties and by having in place and publicizing a reporting system whereby employees and other Covered Parties can report violations without fear of retaliation.
- Hektoen's policies shall be consistently enforced through appropriate disciplinary mechanisms including, as appropriate, the disciplining of individuals who are responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense shall be a necessary component of enforcement. The

form of discipline shall be appropriate to the specific facts and circumstances of the violation.

- After a violation has been detected, Hektoen shall take reasonable steps to respond appropriately to the violation and to prevent similar violations, including any necessary modification to its plan to prevent and detect violations of law.
- Hektoen shall foster an environment in which compliance is everyone's business and incorporate active participation of employees, other Covered Parties, the Board of Trustees and management.

## **1.5 General Information**

- A. Compliance policies and the Code of Conduct and Ethics shall be regularly updated and distributed in accordance with Hektoen's policy. Additional policies and manuals for specifically identified functions or departments at Hektoen shall be formulated and considered subcomponents of the Plan as described in Hektoen's policies and this Plan. The compliance policies and the Code of Ethics will bring together the standards, policies, procedures and guidelines applicable to grants, research and sponsored program activities conducted or administered by Hektoen.
- B. The Code of Conduct and Ethics is:
- Published in booklet form and establish standards of conduct to assist and other Covered Parties in making appropriate decisions relating to Hektoen values, mission and commitment to the highest business and organizational ethical standards.
  - Distributed to each employee, who shall familiarize himself or herself with and comply with its requirements. Each employee receiving the Code must sign an acknowledgment that he or she has received a copy of the Code, has read and understand its contents and will abide by the Code. The Compliance Officer and Human Resources Department will maintain these acknowledgement documents.
  - Available to other Covered Parties, as appropriate.
  - Written at basic reading level, avoiding complex language and legalese.
  - Approved by the Board of Trustees and the Compliance Committee.
  - Developed to be specific as to areas of potential fraud and Hektoen's commitment to compliance.
- C. The Compliance Policies are:

1. Developed under the supervision and direction of the Compliance Officer in accordance with Hektoen's policy to address functional areas, which may include but are not limited to:

- Sponsored program activities, regardless of funding source (federal, state, private, nonprofit, etc.) or type of legal agreement (grant, contract, cooperative agreement, teaming agreement, memorandum of understanding, subcontract, etc.), in support of Hektoen's mission of research and public service
- Protection of human subjects in research
- Welfare of any animals in research
- Integrity in research
- Publication of research findings
- Laboratory safety
- Data acquisition and management
- Allowability and consistency of cost accounting practices
- Management of cash and accounts receivable
- Safeguarding of Hektoen property
- Applicable government regulations and grant/contract provisions
- Management and development of intellectual property
- External and internal reporting
- Retention and availability of records

The Plan will be responsive to changes in laws, grant/contract provisions, and Hektoen policies.

2. Made available to individuals who are affected by the respective policies. These individuals will familiarize themselves and comply with Compliance Policies that relate to their performance.

3. Formulated in an organized format, such as a three-ring notebook, or booklet permitting the filing of new or revised compliance policies and providing individuals with easy access to the written policies.

4. Readily understandable by Covered Parties (e.g., translated into other languages, if necessary).



5. Designed to encompass and address overall compliance issues, as well as specific departmental and functional area compliance.
6. Developed to ensure that all grants, research and sponsored program activities are conducted in accordance with the highest professional and ethical standards.
7. Designed to ensure compliance with all applicable laws governing research and sponsored programs, such as research activities, research integrity, fiscal stewardship, public safety, equal opportunity, diversity, environmental safety and health, data management, research and sponsored program funds management, accounting, etc.

## **1.6 Compliance Officer**

### **Policy**

The Compliance Officer has been designated by the Board of Trustees and is charged with the responsibility of implementing and operating the Compliance Plan.

### **General Information**

The Compliance Officer has the following responsibilities and duties:

#### **A. Compliance Function**

- Oversees and monitors the implementation and operation of Plan activities.
- Leads the Compliance Department.
- Chairs Compliance Committee meetings.

#### **B. Reporting, Access and Independence**

- Reports to the Board of Trustees and the Chief Executive Officer.
- Is empowered by the Board of Trustees with the independence to foster objectivity in carrying out the responsibilities of making the Plan effective.
- Has open access to senior management and the governing body and the freedom to investigate and act including authority to review any and all documents and other information relevant to activities.
- Develops processes and mechanisms which encourage managers, employees and other Covered Parties to report suspected fraud and other improprieties without fear of retaliation.

C. Policies and Procedures

- Develops and distributes Plan policies and procedures.
- Reviews department and functional area manuals, policies and procedures.
- Distributes changes or additions to the Plan based on changes in regulatory guidelines.

D. Monitoring

- Researches laws, regulations and guidelines and provides periodic “alerts” identifying areas of high risk.
- Monitors the Hotline, and independently responds to problems, questions and suggestions received from employees and other Covered Parties.
- Independently investigates suspected or actual violations with advice and counsel from Hektoen’s legal counsel and assures that corrective action is taken, if appropriate.
- Assists specific departments and functional areas in coordinating internal reviews and self assessments.

E. Education and Training

- Oversees development of a multifaceted educational and training plan that focuses on the elements of the Plan and seeks to ensure that all employees, other Covered Parties and management are knowledgeable of and comply with federal and state standards.
- Coordinates with Human Resources Department and appropriate other personnel.

The Compliance Officer shall have direct access to the Chief Executive Officer and to the Board of Trustees.

## **1.7 Compliance Committee**

### **Policy**

The Compliance Committee is charged with the responsibility of assisting the Compliance Officer in the operation and monitoring of the Plan. The Compliance Committee will assign responsibility to specific individuals in and associated with the organization to provide feedback and assistance to the Compliance Officer in implementing and operating the Plan throughout Hektoen. Members of the Compliance Committee shall include representatives from key functional areas instrumental to the success of an effective Plan.

## **General Information**

The responsibilities and duties of the members of the Compliance Committee are as follows:

- Provide input regarding written compliance standards, policies and procedures.
- Analyze the organization's environment and the legal requirements with which Hektoen must comply in specific areas.
- Facilitate communication regarding the Plan to Hektoen departments and personnel.
- Recommend and monitor, in conjunction with functional areas and departments, compliance risk areas and the development of internal systems and controls to carry out Hektoen's policies and procedures.
- Meet according to a set schedule.
- Review compliance reports and make continuous improvement suggestions.
- Identify resources needed to implement compliance activities.

The Compliance Committee shall be accountable to the Board of Trustees in carrying out its responsibilities and duties. The Board of Trustees shall appoint the members of the Compliance Committee. Alternatively, the Board of Trustee may delegate such appointment responsibility to the Compliance Officer.

## **SECTION II: CODE OF CONDUCT AND ETHICS**

Hektoen provides its Covered Parties with practical guidelines for ethical business conduct. Those guidelines constitute the Hektoen Code of Conduct and Ethics. The Code's purpose is to address common business situations and ethical issues that Covered Parties may encounter with respect to Hektoen's operations. Upholding these ethical guidelines will preserve the integrity of Hektoen, the reputation of Hektoen, and the ability of Hektoen to administer its grants and programs and to conduct its operations. Copies of the Code may be obtained by contacting Human Resources or the Compliance Officer.

## **SECTION III: COMPLIANCE PLAN POLICIES**

### **3.1 Legal Compliance**

Hektoen, and those acting on its behalf, will strive to ensure that all activity by or on behalf of the organization is in compliance with all applicable laws. No illegal action by anyone, regardless of intent to benefit any researcher, research subject or Hektoen, will ever be permitted or sanctioned.

The Office of Inspector General of the Department of Health and Human Services and other Federal agencies charged with responsibility for enforcement of Federal law emphasize the importance of voluntarily developed and implemented compliance programs. The government will use its extensive statutory authorities to reduce fraud in Medicare and other federally funded healthcare programs, and with respect to research grant awards from the National Institutes of Health, and entities that apply for grants under the Public Health Service Act.

Prevention, identification, investigation and appropriate disposition are essential parts of any compliance plan. The Compliance Officer or designee shall investigate all potential misconduct, illegal or fraudulent activity identified by or reported to him or her and shall report the results of same to the Compliance Committee and the Board of Trustees.

### **3.2 Financial Reporting Compliance**

All employees will strive to preserve and protect Hektoen's assets by making prudent and effective use of Hektoen's resources and properly and accurately reporting its financial condition.

Hektoen has established control standards and procedures to ensure that assets are protected and properly used, and that financial records and reports are accurate and reliable. All employees of Hektoen share the responsibility for maintaining and complying with required internal controls.

All financial reports, accounting records, research reports, expense accounts, time sheets, and other documents must accurately and clearly represent the relevant facts or the true nature of a transaction. Improper or fraudulent accounting, documentation or financial reporting is contrary to the policy of Hektoen and may be in violation of applicable laws.

Travel and entertainment expenses should be consistent with the employee's job responsibility and the organization's needs and resources. It is Hektoen's policy that an employee should not suffer a financial loss nor a financial gain as a result of business travel and entertainment. Employees are expected to exercise reasonable judgment in the use of Hektoen's assets and to spend the organization's assets more carefully than they would spend their own. Employees must also comply with Hektoen policies relating to travel and entertainment expense, and any extraordinary expenditure must be pre-approved.

All employees are prohibited from converting assets of the organization to personal use. All property and business of the organization shall be used and conducted in the manner designed to further Hektoen's interest rather than the personal interest of an individual employee. Employees are prohibited from the unauthorized use of taking of Hektoen equipment, supplies, materials or services. Prior to engaging in any activity during employment time which will result in remuneration to the employee, or the use of Hektoen's equipment, supplies, materials, or services for personal or non-work related purposes, employees shall obtain the approval of the Compliance Officer.

### **3.3 Research Compliance**

#### **Ethical Conduct of Research and Other Sponsored Programs at Hektoen**

In order to attain and/or retain programmatic leadership of a project operating under the aegis of Hektoen, investigators/project directors must agree to comply with the general and specific regulations from all levels of government referred to below. In general, these principles conform to national, state, county, city and Hektoen-specific standards for the treatment, operation and management of sponsored programs. Some specific areas are referred to below, but whether referred to specifically below or not, all applicable laws, policies and regulations apply. For more comprehensive information concerning investigator responsibility, please see Lynda Brodsky, Office of Research Affairs and Bonnie Lubin, Director of Grants Administration, or their successors. Violations of these principles will be promptly investigated and the perpetrators will be removed from responsibility at the earliest opportunity.

Investigators will conform with all applicable laws, rules, regulations and policies regarding:

- Protection of Human Subjects
  - Belmont Report principles of
    - Autonomy
    - Beneficence
    - Justice
  - Compliance with Cook County Bureau of Health Services/Hektoen Institute IRB regulations concerning initial reviews and progress reports including all governing state and federal regulations, eg: 45CFR46
- Misconduct in science
- Falsifying data and findings
- Repressing unanticipated/contradictory findings

- Conflict of interest with funding agencies or because of other financial interest in the work being undertaken
- Plagiarism
- Intellectual property laws, regulations and grant agreements
- Compliance with HIPAA privacy regulations
- HIV Confidentiality Act
- Compliance with animal welfare regulations
- Compliance with laboratory safety regulations
- Compliance with funding agency rules, regulations and stipulations
- Reporting sponsored program findings according to proscribed rules and timeframes
- Fiscal management and reporting
- Compliance with personnel management, supervision and reporting requirements of host organization and any regulations embedded within specific granting agreements such as drug free workplace and compliance with equal opportunity employment regulations
- Compliance with clinical procedures and policies in host clinical organization
- Compliance with international regulations governing research and with cultural norms, policies and procedures of host countries
- Other grant agreements among cooperating institutions governing project specific research procedures and protocols

## **Policy**

The Grant Coordinator is charged with the responsibility of oversight over and compliance with all grants administered by and research conducted by, or supervised by, Hektoen. It is the policy of Hektoen to abide by the provisions of the Declaration of Helsinki regarding the protection of human subjects.

## **General Information**

The Grant Coordinator shall:

- Implement and interpret sponsor and Hektoen policies and procedures for compliance with applicable regulations.
- Train research personnel in preparation of grant/contract application and managing sponsored research.
- Propose policies and procedures to senior administration in compliance with grants and contracts management regulations.
- Coordinate with other Hektoen research and sponsored programs oversight committees, boards, and offices to ensure that specific proposals and projects have been reviewed and approved for compliance.
- Advise each research committee in which Hektoen participates (e.g., any Scientific Committee, Institutional Animal Care and Use Committee,

Institutional Biosafety Committee, and/or Faculty Research Committee), on compliance issues.

- Provide administrative support to any research committee in which Hektoen participates.
- Conduct pre-submission compliance review of proposals for external funding.
- Be responsible for oversight over grant accounting and auditing.
- Oversee internal audits of federal research grants.
- Monitor grant effort reporting.
- Coordinate with the Compliance Officer and the Compliance Committee with respect to investigating and reporting instances of alleged or apparent misconduct involving research or research training, applications in support of research, or research training or related research activities supported with government funding.

If applicable to Hektoen, this Plan will incorporate and adopt that certain Multiple Project Assurance of Compliance with DHHS Regulations for Protection of Human Research Subjects.

### **3.4 Employment And Contracting**

#### **Policy**

Hektoen shall not knowingly employ, contract with or associate with individuals who have engaged in illegal activities or have been sanctioned by any federal or state law enforcement, regulatory or licensing agency and shall take all reasonable steps to verify that the information provided in background checks and applications for employment or contractual representations are true and correct.

#### **General Information**

Standards for screening of employees and other Covered Parties shall consist of the following:

- A. Employees:
  1. Applicants for employment shall be asked in writing on their application if they have ever been convicted of any criminal violation of law or if they are under pending investigation or charges for violation of criminal law. A “yes” answer to this question shall require an explanation in writing by the applicant.
  2. All applicants for employment shall be asked in writing on their application if they have been the subject of any adverse action(s) by any

duly authorized sanctioning or disciplinary agency for either conduct based or performance based actions. A “yes” answer to this question shall require a written explanation from the applicant.

3. Employees who are the subject of a criminal investigation or proposed debarment or exclusion from federally or state funded health care programs shall be removed from direct responsibility for or involvement in Hektoen programs until resolution of such criminal charges or proposed debarment or exclusion.
4. Individuals convicted, debarred, excluded or otherwise ineligible for participation in federally funded healthcare programs shall be terminated in accordance with Hektoen policies.

B. Contractors, Vendors and Other Contracting Parties:

1. Due care shall be taken to avoid knowingly contracting with or retaining any person or entity which has been convicted of a criminal offense or listed by a federal agency as debarred, excluded or otherwise ineligible for federal plan participation.
2. Contractors, Vendors and other contracting parties shall be informed of the Plan and standards of conduct, as appropriate.
3. The contract with any individual or corporation convicted, debarred, excluded or otherwise ineligible for participation in federally funded healthcare programs shall be terminated in accordance with its terms.
4. Each contract shall state that the contracting party represents that it has never been excluded from any state or federal healthcare program, that vendor acknowledges the existence of Compliance Policies and Code of Conduct and Ethics and agrees to abide by their terms. A contracting party must also agree that if it ever becomes the target of any investigation for exclusion from state or federal healthcare programs or if it violates Compliance Policies or the Code of Conduct and Ethics, it must report same to Hektoen and that Hektoen may terminate the agreement immediately, without penalty, after reviewing the allegations, conviction or breach by the vendor.
5. To the extent feasible, Hektoen shall require each contracting party to abide by the Code of Conduct and Ethics.
6. Vendors and contractors who are the subject of a criminal investigation or proposed debarment or exclusion from federally or state funded health care programs shall be removed from direct responsibility for or involvement in Hektoen research programs until resolution of such criminal charges or proposed debarment or exclusion.



### **3.5 Communication**

#### **Policy**

The elements of the Compliance Plan shall be communicated to employees and other Covered Parties, as appropriate to their position.

#### **General Information**

Communication of the Plan's existence and content shall consist of at least the following:

- The Plan and Code of Conduct and Ethics shall be distributed to all new employees at orientation and to all employees upon revision.
- The Plan Hotline number shall be posted in common work areas.
- Specific information regarding the confidentiality and non-retaliation aspects of the Plan shall be communicated to employees to encourage communication and the reporting of incidents of potential fraud and noncompliance.
- Information concerning the Plan shall be distributed and made available to employees and other Covered Parties through various media to communicate the existence of the Plan and each individual's responsibility to adhere to Plan's guidelines. Such communication shall include publishing compliance related information and articles from time to time in Hektoen publications that are routinely circulated to employees and other Covered Parties.
- Hektoen shall insert standard compliance provisions in contracts with Covered Parties.
- Personnel shall acknowledge in writing that they have read and understand the Plan and Code of Conduct and Ethics and the Plan.
- Functional area personnel shall acknowledge in writing that they have read and understand the Code of Conduct and Ethics, the Plan and specific policies identified by the Compliance Officer as applicable to the respective areas.

### **3.6 Education And Training**

#### **Policy**

Formal compliance education and training programs shall be offered to employees and others associated with Hektoen. All compliance education activities shall be documented in the manner directed by the Compliance Officer. Education shall consist of orientation and introduction to the compliance program and specialized training in identified risk areas for individuals performing high-risk functions.

## **General Information**

Education and training offerings shall consist of at least the following:

- Initial training regarding the Plan shall be conducted in order that key personnel understand the program and its goals and objectives. Such training shall also be made available to independent contractors, as appropriate, and shall include discussion of responsibility to report misconduct and the consequences of failing to comply with the Plan.
- Publications and written educational materials regarding the program and compliance subjects shall be distributed from time to time as deemed appropriate.
- Employees shall receive the Code of Conduct and Ethics and information regarding the Plan as a part of new employee orientation training.
- Periodic reminders of the Plan's internal reporting policy shall be communicated to employees.
- Management personnel and employees shall acknowledge that they have read and understand the Code of Conduct and Ethics, the Plan and their responsibilities thereunder.
- Functional areas shall conduct compliance training using a variety of teaching methods and including all levels of personnel. Specific expectations regarding the minimum training hours required for specific employee categories shall be set forth in the specific functional area Compliance Policies and Procedures.
- Employee attendance and participation at mandatory educational sessions shall be a condition of continued employment.
- Management determines which specialty educational sessions shall be mandatory for employees and other Covered Parties. The Compliance Officer may require mandatory compliance training for employees and other Covered Parties at any time.
- Employees shall be encouraged to attend periodic professional education courses as may be required or advisable to maintain proficiency in the employees' areas of responsibility.
- Employees shall be encouraged to make their supervisors aware of training or education they feel is needed to assist carrying out their job responsibilities.

### **3.7 Internal Reporting And Hotline**

#### **Policy**

An open door, completely anonymous and non-retaliatory process shall be available to all employees and other Covered Parties affiliated with Hektoen to encourage communication and the reporting of suspected or alleged violations, misconduct and noncompliance.

#### **General Information**

Internal reporting guidelines are as follows:

- A toll-free “Hotline” telephone number shall be maintained which can be used by employees and other Covered Parties to anonymously report actual or alleged violations, or misconduct.
- A reporting form shall be completed for each call received.
- Employees and other Covered Parties have a responsibility to assist in reporting actual or alleged violations and shall be encouraged to report matters to the Compliance Officer.
- A log shall be maintained by the Compliance Officer recording incoming calls, the nature of the call, investigations and the results of such investigations.
- All employees shall have access, if necessary, to report directly to the Compliance Officer rather than through superiors.
- There shall be no retaliation for any report. Any threat of retaliation against the reporting employee shall result in discipline, including possible termination.
- Employees shall be encouraged not to guess, but to ask for clarification, if there is confusion or a question regarding a policy or procedure.
- Reports shall be promptly investigated and documented as to conclusions reached and appropriate corrective action taken, if any.
- Employees using the Hotline shall be informed that Hektoen shall strive to maintain employee confidentiality (when requested). However, there may be a point at which the employee’s identity may become known or may have to be revealed should the government or authoritative agent become involved.
- All personnel are expected to report any known or suspected noncompliant conduct related to grants, research or sponsored programs.
- Steps shall be taken to assure confidentiality in connection with all logs, reports and other documentation maintained by the Compliance Officer.

### **3.8 Problem Reporting And Nonretaliation**

#### **Policy**

All employees have an affirmative duty and responsibility for reporting perceived misconduct, including actual or potential violations of laws, regulations, policies, procedures or the Code of Conduct and Ethics. An open-door policy will be maintained at all levels of management to encourage employees to report problems and concerns. Employees are encouraged to utilize the Compliance Hotline and may remain anonymous or seek confidentiality of their identity to protect them from any possible retaliatory act. Employees may proceed up the chain of command or communicate with the Compliance Officer and/or Human Resources if their problem or concern is not resolved. No form of retaliation is permitted by any employee.

#### **General Information**

1. Knowledge of misconduct, including actual or potential violations of laws, regulations, policies, procedures, or standards of conduct must be immediately reported to management, the Compliance Officer or the Compliance Hotline at 312-948-2523.
2. Knowledge of a violation or potential violation of this non-retaliation policy must be reported directly to the Compliance Officer or to the Hotline.
3. Employees may also report problems or concerns to Human Resources.
4. If an employee's concern or problem cannot be satisfactorily resolved or special circumstances exist, the employee should report such concerns or problems to the Compliance Officer or the Hotline.
5. Management must take appropriate measures to ensure that all levels of management support this policy and encourage the reporting of problems and concerns. At a minimum, the following actions should be taken and become an ongoing aspect of the management process:
  - A. Meet with department staff and discuss the main points of this policy;
  - B. Provide all department staff with a copy of this policy; and
  - C. Post a copy of this policy on all employee bulletin boards.
6. The Compliance Officer will be responsible for the investigation and follow-up of any reported retaliation against an employee for reporting under this policy and will report the results of an investigation into suspected retaliation to the Board of Trustees and/or Compliance Committee.

### **3.9 Auditing And Monitoring**

#### **Policy**

Hektoen will conduct ongoing auditing and monitoring of identified risk areas related to compliance. Management will provide responses to audit findings and will resolve significant deficiencies discovered during audits to the Compliance Officer as described in this policy. Management will provide ongoing updates of monitored compliance issues as requested by the Compliance Officer and will resolve compliance issues discovered during routine monitoring as described in this policy. This policy is designed to promote adherence to applicable federal and state laws and to establish internal controls that promote compliance.

#### **General Information**

1. The Compliance Officer will recommend and facilitate auditing and monitoring of identified risk areas related to compliance with laws and regulations as well as organizational policies, procedures, and standards of conduct.
2. The Compliance Officer and Compliance Department will conduct an annual compliance risk assessment for the purposes of establishing annual monitoring and audit plans as discussed in this policy.
3. The Compliance Officer, Compliance Committee, and the Board of Trustees will create, review and approve an annual monitoring plan to be used by functional areas to monitor compliance risks identified through the Compliance Officer and compliance department. The Compliance Officer will provide guidance to functional areas in the performance of monitoring functions.
4. The Compliance Officer and Compliance Department will create an annual audit plan to review certain compliance risk areas. The Board of Trustees will approve the audit plan. Compliance analysts and/or external auditors, as necessary and reasonable under the circumstances of each case, will perform audits.
5. All significant audit findings and all deficiencies discovered by management during routine monitoring require a response, follow-up and resolution by functional areas.
6. The Compliance Officer and/or auditors will complete at least an annual audit of the Compliance Program, Plan, Policies and Procedures to evaluate the effectiveness of the Compliance Program.

#### **Procedures**

1. Risk Assessment
  - a. An annual risk assessment shall be conducted by the Compliance Committee at the direction of the Compliance Officer to identify the compliance risks facing Hektoen in the upcoming fiscal year.

- b. The risk assessment will consider internal risk identified by the Compliance Committee, management, previous measurement, external risks as posed by local, state and federal enforcement initiatives and all internal or external audit information.
  - c. The risk assessment shall serve as the basis of Hektoen's annual monitoring and auditing plans.
2. Annual Monitoring Plan
- a. The Compliance Officer will create an annual monitoring plan to review known or suspected compliance risks.
  - b. The monitoring plan shall consist of requests for reports from functional areas and divisions whose operations involve possible compliance issues.
  - c. The monitoring plan shall be distributed to, reviewed and approved by the Compliance Committee and the Board of Trustees on an annual basis.
  - d. Administrators for each department or functional area who are assigned a compliance monitor under the monitoring plan will be responsible for ensuring that the Compliance Officer receives written reports for all assigned monitors on a timely basis as outlined in the monitoring plan.
3. Annual Audit Plan
- a. The Compliance Officer will create an annual audit plan to review specific known or suspected compliance risks or to review past audit findings for resolution.
  - b. The annual audit plan may call for audits to be performed in certain functional areas by compliance analysts or auditors, as deemed necessary and prudent under specific circumstances as determined independently by the Compliance Officer.
  - c. All audit findings will be relayed orally and in writing to the Compliance Officer and to the Compliance Committee.
  - d. All audit findings will be reported to the Board of Trustees as soon as practicable.
4. Response, Follow-Up and Resolution of Audit and Monitoring Findings
- a. Functional areas/divisions audited during routine monitoring will establish and maintain tracking systems to assure the prompt and proper resolution and implementation of audit or review recommendations or the resolution of deficiencies. These systems shall provide a complete record of actions taken in response to audit and monitoring findings and recommendations and shall contain at least the following documentation:

- i. description of the action taken on each finding or an explanation on the basis for each non-concurrence with any finding or recommendation;
  - ii. identification of the target dates for implementation of corrective actions on deficiencies or weaknesses, and the procedures followed, and results of, follow-up reviews on the implementation of the corrective actions; and
  - iii. documents with sufficient detail to satisfy a reviewer that the findings were fully, effectively, and appropriately resolved.
- b. The Compliance Officer will receive copies of all reports, responses and information demonstrating resolution of significant findings and/or deficiencies and will be informed of scheduled meetings at which management is briefed on or discusses the results of audits and monitoring reviews. The Compliance Officer will maintain a tracking system of significant findings from audits or monitors that are reviewed until corrective action and follow-up verification are completed and provided in written form.
- c. The resolution process will include all actions required to fully correct all issues. Each resolution will include:
  - i. timely correction of management, system and program compliance issues/deficiencies;
  - ii. monitoring to ensure that the corrective actions on significant deficiencies were adequately implemented to resolve the problem and ensure that it does not recur; and
  - iii. verification that the corrective actions are operating effectively.
- d. Resolution occurs when corrective action is instituted and independently verified. Functional areas will resolve audit findings within 60 days of receiving the information either via formal written report or in oral briefing. If findings indicate the existence of legal or regulatory issues, functional areas must notify the Compliance Officer and resolve findings in no more than 30 days, and as soon prior to 30 days as possible. Administrators for the area(s) reviewed are responsible for the timely submission of resolution information to the Compliance Officer.
- e. Management is responsible for monitoring the organization's implementation of actions to correct deficiencies until the deficiencies are corrected. The manager or administrator of an area may conduct the follow-up review internally, or may request it be conducted by internal auditors, compliance analysts or external auditors.
- f. Verification of the effectiveness of corrective action should occur as soon as possible after the implementation date of the corrective actions.

- g. If follow-up review shows that Hektoen has not completed all actions needed to fully correct deficiencies, the functional area shall notify the Compliance Officer and report on the further actions needed and projected completion dates. Continued follow-up by the functional area is required until Hektoen has fully and effectively corrected deficiencies.
- h. Functional areas will submit at least monthly reports to the Compliance Officer for the area on the actions taken to resolve significant findings and the status of each open finding.
- i. The Compliance Officer may direct a follow-up review independently to verify that corrective actions were successful.
- j. The Compliance Officer will regularly report to the Board of Trustees on the status of all corrective actions.
- k. In a small number of cases, a satisfactory plan of corrective action cannot be instituted and verified within the prescribed period. In those cases, management must notify the Compliance Officer of the delay and provide an alternative resolution date.

#### 5. Annual Audit of Compliance Plan Effectiveness

- a. At least annually, a review of the Compliance Program, Plan, Policies, Procedures and Practices will be conducted by the Compliance Department to evaluate the effectiveness of the program as defined in the Federal Sentencing Guidelines and Compliance Program Guidance from the Office of Inspector General of the Department of Health and Human Services.
- b. At a minimum, the audit will review all areas of the Compliance Program including, but not limited to:
  - i. Hotline operations and responses;
  - ii. Sanction screening operations;
  - iii. Contract compliance;
  - iv. The existence, adequacy and compliance with Compliance Policies and Procedures;
  - v. The operation and effectiveness of the Compliance Committee;
  - vi. The imposition of discipline in compliance with policies regarding compliance requirements; and
  - vii. Auditing and monitoring techniques and effectiveness.



- c. Findings from all Compliance Program audits will be reported to the Board of Trustees and resolution of deficiencies shall be made by the Compliance Officer, as necessary, in accordance with the resolution and follow-up provisions of this policy.

### **3.10 Inquiries, Investigations And Issue/Complaint Resolution**

#### **Policy**

The Compliance Officer will inquire into all reports of wrongdoing or misconduct. All reports of perceived or actual wrongdoing shall be investigated to the point of satisfaction and recorded conclusion (including unfounded reports) as part of the Compliance Committee processes and for the Compliance Committee's use.

#### **Procedures**

1. The Compliance Officer will inquire immediately into an allegation or other evidence of possible misconduct. The Compliance Officer will complete such inquiry within 60 calendar days of its initiation, unless circumstances clearly warrant a longer period. The Compliance Officer will prepare a written report that states what evidence was reviewed, summarizes relevant interviews, and includes the conclusions of the inquiry. The individual(s) against whom the allegation was made shall be given a copy of the report of inquiry. If such individual(s) comment on that report, their comments may be made part of the record. If the inquiry takes longer than 60 days to complete, the record of the inquiry shall include documentation of the reasons for exceeding the 60-day period. The Compliance Officer will involve monitoring of management and other employees, as appropriate.
2. The privacy of those who, in good faith, report apparent misconduct will be protected to the maximum extent possible, and confidential treatment will be afforded to any affected individual(s), as well as a prompt and thorough investigation and opportunity to comment on allegations and findings of the inquiry and/or investigation. The Compliance Officer will conduct a fair, impartial review of all relevant facts and the review will be restricted to items necessary to resolve the issues.
3. The Compliance Officer should fully debrief the complainant, notify appropriate internal parties of the complaint, identify the cause of the problem, desired outcome, affected parties, applicable guidelines, possible regulatory impact and provide a complete list of findings and recommendations to the Compliance Committee and any other appropriate parties, to the extent possible with information provided by the complainant.
4. The Compliance Officer will report the inquiry and provide a copy of the written report to the Compliance Committee and notify any governmental agencies or officials as required by law.
5. The Compliance Committee will undertake an investigation within 30 days of the completion of an inquiry, if findings from that inquiry provide sufficient basis for conducting an investigation. An investigation will include an examination of all

documentation. The Compliance Officer, on behalf of the Compliance Committee, will conduct interviews, as possible, of all individuals involved and prepare summaries of such interviews. Such summaries will be provided to the interviewed party for comment or revision, and included as part of the investigatory file.

6. Investigations may be referred to and conducted under the direction of Hektoen's legal counsel, if necessary, as determined on a case-by-case basis, to preserve the attorney/client or work product privilege.
7. Investigations/follow-up shall be performed on all reported violations of the Plan and/or failure to comply with federal and/or state law. Such action shall be undertaken promptly to determine whether a material violation has in fact occurred, so that, if a violation has occurred, immediate corrective action can be taken.
8. The Compliance Committee shall take appropriate steps to secure or prevent the destruction, loss or mishandling of documents or other evidence relevant to the investigation.
9. The Compliance Officer will secure necessary and appropriate expertise to carry out a thorough and authoritative evaluation of the relevant evidence in any inquiry or investigation.
10. The Compliance Officer will take precautions, as necessary, against real or apparent conflicts of interest on the part of those involved in any inquiry or investigation.
11. The Compliance Officer will prepare and maintain documentation to substantiate any findings made by the Compliance Committee in an investigation. The Compliance Officer shall make such documentation available to any governmental official or agency as required by law, and keep any governmental official or agency informed as to any investigation, and any final outcome, as required by law.
12. The Compliance Committee will use diligent efforts, as appropriate, to restore the reputations of persons alleged to have engaged in misconduct when allegations are not confirmed, and to protect the positions and reputations of those persons who, in good faith, make allegations.
13. The Compliance Committee has authority to impose appropriate sanctions on individuals when the allegation of misconduct has been substantiated.

### **General Information**

1. The Compliance Committee may utilize certain persons to investigate various types of specific alleged violations.
  - Appropriate investigators shall be identified with advice of Hektoen's legal counsel, when appropriate, depending upon the nature of the alleged violation.

- Investigators shall not be involved or have any financial or other connection or relationship with the alleged violation.
  - If an investigation of an alleged violation is undertaken and it is determined that the integrity of the investigation may be at stake because of the presence of any employee under investigation, the employee allegedly involved in the misconduct may be removed from his or her current work activity or other arrangements may be implemented until the investigation is completed.
2. Documentation of the alleged violation, a description of the investigation process, copies of interview notes, key notes, and the documents reviewed shall be maintained. In addition, a report of the investigation results, the disciplinary action suggested, (if appropriate and necessary), the suggested corrective action plan (if corrective action is needed), and actual corrective action taken shall be prepared, and maintained.

### **3.11 Corrective Actions**

#### **Policy**

Prompt corrective action, as appropriate, shall be taken once an investigation reveals a violation did occur.

#### **General Information**

1. Corrective actions shall be promptly initiated as follows:
- If the investigation determines that the alleged matter is consistent with applicable laws and the deviation occurred for legitimate, explainable reasons corrective action shall be limited or no corrective action taken at all.
  - In cases in which an investigation confirms that a violation did occur, a corrective action plan shall be developed and immediate steps shall be taken to correct the problem.
  - Disciplinary action may be taken against employees and others who have violated internal compliance policies or applicable laws or who have engaged in wrongdoing as addressed in this Plan, and its attachments, as amended from time to time.
2. Reporting to Governmental Agencies:
- If an investigation is completed with a finding which affects a governmental agency, the Compliance Officer shall notify the applicable governmental authority of the outcome of the investigation, including a description of the impact of the alleged violation on the applicable government agency and/or plan, if deemed appropriate after consultation with Hektoen's legal counsel.

### **3.12 Disciplinary Action**

#### **Policy**

Hektoen shall take appropriate disciplinary action once an offense is determined.

#### **General Information**

1. Disciplinary actions shall be applied in accordance with the following:
  - Plan guidelines shall be consistently applied and enforced through documented disciplinary mechanisms for employees.
  - Immediate action shall be imposed for confirmed violations.
  - Disciplinary action may be appropriate when an employee or other person should have, but failed, to detect a violation.
  - Discipline up to, and including, termination of employment will be administered to any employee failing to report perceived or known legal, regulatory or policy violations or for retaliation against any employee making such a report in accordance with this Plan.
2. Disciplinary Actions:
  - Human Resources shall maintain written policy statements and procedures setting forth the degrees of disciplinary action used in carrying out disciplinary action against employees who have violated the Plan, Compliance Policies, applicable laws or who have engaged in wrong doing.
  - Agreements with contractors and vendors shall contain compliance requirements and provisions for appropriate sanctions should violations occur in accordance with this Plan.
3. Appropriate Sanctions:
  - Employees involved in a confirmed violation shall be subject to significant sanctions including, when appropriate, termination. Such disciplinary measures shall be consistent with Hektoen's policies and shall match the degree of severity of the improper conduct and may include oral reprimand, written reprimand, probation, suspension, immediate termination depending upon the nature of the violation.
  - Disciplinary sanctions for failure to adhere to the Plan, standards, laws and procedures shall apply equally to all levels, including senior managers and supervisors.
  - Repeated or patterns of violations shall result in termination.

- Vendors and contractors involved in a confirmed violation shall be subject to significant sanctions in accordance with contract terms and conditions including termination of the agreement when warranted.

4. Communication:

- Employees and others affiliated with Hektoen shall be advised that disciplinary action shall be taken on a fair and equitable basis.
- Employees and others affiliated with Hektoen (as appropriate) shall be informed of the disciplinary standards for violations and made aware that certain actions prohibited by these guidelines may also violate criminal laws, thus culminating in personal criminal prosecution and, upon conviction, fines and imprisonment

### **3.13 Records Retention And Records System**

#### **Policy**

Hektoen has implemented, or will implement, a records system which establishes policies and procedures regarding the creation, distribution, retention, storage, retrieval and destruction of documents.

#### **General Information**

The records system adheres, or will adhere, to the following:

1. The system includes, or will include, provisions for at least the following categories of documents:
  - A. Clinical, medical and research records and claims documentation required either by federal or state law as required in connection with federal or state funded grants; and
  - B. All records necessary to protect the integrity of Hektoen compliance process and confirm the effectiveness of the plan.
2. Such documents shall be retained for at least six years and longer if described specifically in Hektoen's record retention policies.
3. Issues of confidentiality and access are addressed in the records system policies.
4. Sufficiently detailed documentation will be maintained of all inquiries to permit a later assessment of the reasons for determining that an investigation was not warranted, if necessary. Such records will be maintained in a secure manner for at least three years after the initiation of the inquiry and, upon request, be provided to authorized governmental personnel.

### **3.14 Cooperation With Governmental Investigations**

#### **Policy**

Hektoen and all those working on its behalf will cooperate fully and promptly with investigations conducted by governmental and other regulatory agencies. Information provided to those agencies whether in writing or through personal interview, will always be truthful, complete and unambiguous. Alteration or destruction of documents in anticipation of a government or a regulatory agency request for them is prohibited. This policy requires that all requests for information beyond the normal duties of the employee, whether for written documentation or personal interview, be reviewed and approved by the Compliance Officer before any information is sent or an interview is granted.

#### **Definitions**

Subpoena: An order directing a person or company to appear and testify at a given time and place. A subpoena duces tecum requires the person to bring certain documents. A subpoena may be issued by a court or certain government regulatory agencies with such authority.

Search Warrant: A written court order entitling law enforcement officers to search a defined premises. A search warrant is usually granted to the government investigator with no notice to the party whose property is being searched. The formal requirements for a valid warrant are as follows:

1. must be signed by or on behalf of a judge or magistrate with jurisdiction over the premises to be searched,
2. must be directed to a named law enforcement officer and must command him or her to search the specified premises, and
3. must describe the material to be seized.

Civil Investigative Demand: A written request from the Attorney General demanding certain documents or testimony in connection with investigations.

#### **General Information**

The following guidelines and rules should be adhered to in connection with requests for information by federal and state agencies:

1. Hektoen may receive requests for information from time to time from a variety of investigators from federal and state agencies, such as the Department of Health and Human Services (including the Office of Inspector General), National Institutes of Health, and/or other regulatory agencies. It is the policy of Hektoen to fully cooperate with government investigations.

2. If an employee or Board member receives an investigative demand, subpoena, or search warrant involving Hektoen, the Compliance Officer and Hektoen's legal counsel shall be notified immediately and the following guidelines shall be followed:
  - A. Under no circumstance shall documents or records be altered, removed or destroyed. For this purpose, documents shall include all forms of media, including but not limited to, paper, audio tape, videotape, computer tape or disk.
  - B. Documents shall not be released or copied without advice and counsel from Hektoen's legal counsel.
  - C. If an investigator, agent or government auditor arrives unannounced for any non-routine audit, contact Hektoen's legal counsel and the Compliance Officer.
  - D. Ask the investigator or auditor to wait until Hektoen's legal counsel arrives before releasing any documents or participating in any interviews. If the investigator refuses this request, do not interfere with the investigation.
  - E. If an employee or Board member is approached by government investigators, auditors or agents off premises, the employee or Board member should remember that he or she has the right to request that all interviews take place only at Hektoen facilities, during business hours with Hektoen's legal counsel present.
  - F. Following consultation with Hektoen's legal counsel, Hektoen and its employees shall disclose information required by the government officials, supply payment information, provide information on subcontractors and grant authorized federal and state authorities immediate access to requested information. Failure to comply with these requirements could cause serious repercussions.
  - G. Employees must be aware of what information in their area is classified as privileged. These records shall be maintained in a manner that assures maximum protection for documents that the government is not entitled to take from the office, even with a search warrant. These documents include materials covered by legally recognized privileges such as attorney-client communications and certain categories of medical records. Contact the Compliance Officer if you are unsure which records may be privileged.
3. Contractors
  - Contractors who provide items or services to Hektoen shall comply with this policy and the guidelines established and shall immediately furnish the Compliance Officer with any information required as a part of any investigation.

### **3.15 Conflict Of Interests**

#### **Policy**

Trustees, officers, committee members and key employees owe a duty of undivided and unqualified loyalty to the organization. Persons holding such positions may not use their positions to profit personally or to assist others in profiting in any way at the expense of the organization.

#### **General Information**

All trustees, officers, committee members, and employees are expected to regulate their activities so as to avoid actual impropriety and/or the appearance of impropriety which might arise from the influence of those activities on business decisions of Hektoen, or from disclosure or private use of business affairs or plans of Hektoen.

While not all inclusive, the following will serve as a guide to the types of activities by trustees, officers, committee members, and employees, and household members of such persons, which might cause a conflict of interest:

1. Ownership in or employment by an outside concern which does business with Hektoen. This does not apply to stock or other investment interests held in a publicly held corporation, provided the value of the stock or other investments does not exceed 5% of the corporation's stock. Hektoen may, following a review of the relevant facts, permit ownership interests which exceed these amounts if management concludes such ownership interests will not adversely impact Hektoen's business interest or judgment of the covered person. Hektoen may also enter into business relationships with covered persons, or concerns in which covered persons, or concerns in which covered persons have an interest, when the existence of any such relationships are fully disclosed and any business transactions are consistent with applicable law.
2. Conduct of any business not on behalf of Hektoen, with any vendor, supplier, contractor, or agency, or any of their officers or employees.
3. Representation of Hektoen by a covered person in any transaction in which he or she or a household member has a substantial interest.
4. Disclosure or use of confidential, special or inside information of or about Hektoen, particularly for personal profit or advantage of the covered person or household member.
5. Competition with Hektoen by a covered person, directly or indirectly, in the purchase, sale, or ownership of property or property rights or interests, or business investment opportunities.
6. No directors, officers, committee members, or key covered person shall perform work or render services for any competitor of Hektoen or for any organization with which Hektoen does business or which seeks to do business with Hektoen outside of the normal course of his/her employment with Hektoen without the express approval of the Board



and the person's immediate supervisor. Nor shall any such employee be a director, officer, or consultant of such an organization, nor permit his/her name to be used in any fashion that would tend to indicate a business connection with such an organization.

7. Hektoen retains the right to prohibit membership on any Board of Directors/Trustees if such membership might conflict with the best interest of Hektoen.
8. A trustee, officer, committee member, or employee who is asked, seeks to serve on the board of any organization whose interest would not impact Hektoen (for example: civil, charitable, non-governmental, fraternal, etc) will not be required to obtain such approval.
9. All fees/compensation (other than reimbursement for expenses arising from board participation) that are received for board services provided during normal work time shall be paid directly to Hektoen.
10. Questions regarding whether or not board participation might present a conflict of interest should be discussed with a covered person's supervisor and the Compliance Officer.
11. Employees are, with the permission of their supervisors, encouraged to participate as faculty and speakers at educational programs and functions. However, any honoraria in excess of Five Hundred Dollars (\$500.00) shall be turned over to Hektoen *unless* the employee used his or her personal time (examples: after scheduled hours, weekend, vacation, sabbatical) to attend the program or that portion of the program for which the honoraria is paid.
12. It is Hektoen's desire at all times to preserve and protect its reputation and to avoid the appearance of impropriety.
13. Employees shall not accept gifts, favors, services, entertainment or other things of value to the extent that decision-making or actions affecting Hektoen might be influenced. Similarly, the offer or giving money, services or other things of value with the expectation of influencing the judgment or decision making process of any purchaser, supplier, customer, government official, or other person by Hektoen is absolutely prohibited. Any such conduct must be reported immediately to the Compliance Officer.
14. Employees may retain gifts from vendors, which have a nominal value. (Hektoen has made no attempt to define "nominal" as a specific dollar value. Rather, Hektoen expects its employees to exercise good judgment and discretion in accepting gifts.) If an employee has any concern whether a gift should be accepted, the employee should consult with his/her supervisor and the Compliance Officer. To the extent possible, these gifts should be shared with the employees' co-workers. Employees shall not accept excessive gifts, meals, expensive entertainment or other offers of goods or services which have more than a nominal value nor may the solicit gifts from vendors, suppliers, contractors or other persons.
15. At a vendor's invitation, an individual may accept meals or refreshments at the vendor's expense. Occasional attendance at a local theater or sporting event, or similar

entertainment at vendor expense may also be accepted. In most circumstances, a regular business representative of the vendor should be in attendance with the employee.

16. Attendance at local, vendor sponsored workshops, seminars and training sessions is permitted. Attendance, at vendor expense, at out of town seminars, workshops and training sessions is permitted only with the approval of an employee's supervisor.
17. All business relations with contractors must be conducted at arm's length both in fact and in appearance and in compliance with Hektoen policies and procedures. Employees must disclose personal relationships and business activities with contractor personnel which may be construed by an impartial observer as influencing the employee's performance or duties. Employees have a responsibility to obtain clarification from the Compliance Officer on questionable issues, which may arise and comply, if applicable, with Hektoen's conflict of interest policy.
18. Hektoen employees shall not seek to gain any advantage through the improper use of payments, business courtesies, or other inducements. Offering, giving, soliciting or receiving any form of bribe or other improper payment is prohibited.
19. Specific employees, board members, officers and certain contracted parties shall disclose potential dualities of interest and potential and actual conflicts of interest so that the Board of Trustees can make decisions in an objective manner without undue influence by persons with a private interest.

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