Minutes of the Meeting of the Audit and Compliance Committee of the Board of Directors of the Cook County Health and Hospitals System (CCHHS) held Friday, August 20, 2021 at the hour of 8:30 A.M. This meeting was held by remote means only, due to the determination that a public health emergency exists.

I. Attendance/Call to Order

Chair Koetting called the meeting to order.

Present: Chair Mike Koetting and Directors Robert Currie (Substitute Member); Hon. Dr. Dennis Deer, LCPC, CCFC; Ada Mary Gugenheim and Robert G. Reiter, Jr. (4)

Board Chair Lyndon Taylor (ex-officio) and Directors Joseph M.

Absent: None (0)

Additional attendees and/or presenters were:

Cathy Bodnar – Chief Corporate Compliance and Privacy Officer
Andrea M. Gibson – Interim Chief Business Officer
Jennifer Kirchner – Interim Research Compliance Officer
Alisha Patel – Assistant General Counsel
Beena Peters, DNP, RN, FACHE – Chief Nursing Officer
Israel Rocha, Jr. – Chief Executive Officer
Deborah Santana – Secretary to the Board
Tom Schroeder – Director of Internal Audit

The next regular meeting of the Audit and Compliance Committee is scheduled for Friday, November 5, 2021 at 11:00 A.M.

II. Electronically Submitted Public Speaker Testimony

There was no public testimony submitted.

III. Report from Chief Corporate Compliance and Privacy Officer (Attachment #1)

Cathy Bodnar, Chief Corporate Compliance and Privacy Officer, provided an overview of the information contained in the Report. Jennifer Kirchner, Interim Research Compliance Officer, reviewed information in the report relating to the Research Compliance Program. The Committee reviewed and discussed the information.

During the discussion of the information regarding the Research Compliance Program, Director Gugenheim inquired regarding the membership of the Research Compliance Committee as referenced on slide 16. Ms. Bodnar responded that it includes the Chief Executive Officer and representatives from the General Counsel's office, Internal Audit, Medical Staff, Nursing, Privacy Officer and Corporate Compliance. In response to a question from Director Deer regarding whether it would be appropriate to have a member of the CCH Board sit on that internal committee, Ms. Bodnar made the following suggestion. She stated that the first meeting of the Research Compliance Committee is scheduled for mid-September. After that meeting, she and Ms. Kirchner will commit to connect with Chair Koetting and communicate with him the processes (what they reviewed in the meeting, how it is moving forward) and then allow Chair Koetting to make a decision on the question. It was determined that the plan Ms. Bodnar suggested was acceptable.

IV. Action Items

A. Accept Minutes of the Audit and Compliance Committee Meeting, June 21, 2021

Chair Koetting inquired whether any corrections were needed to be made to the Minutes.

Director Reiter, seconded by Director Gugenheim, moved to accept the June 21, 2021 Audit and Compliance Committee Meeting Minutes. On the motion, a roll call vote was taken, the votes of yeas and nays being as follows:

Yeas: Chair Koetting and Directors Deer, Gugenheim and Reiter (4)

Nays: None (0)

Absent: None (0)

THE MOTION CARRIED UNANIMOUSLY.

B. Any items listed under Sections IV and V

V. Closed Meeting Items

A. Report from Director of Internal Audit
B. Discussion of Personnel Matters

Director Deer, seconded by Director Reiter, moved to recess the open meeting and convene into a closed meeting, pursuant to the following exceptions to the Illinois Open Meetings Act: 5 ILCS 120/2(c)(**1**), regarding "the appointment, employment, compensation, discipline, performance, or dismissal of specific employees of the public body or legal counsel for the public body, including hearing testimony on a complaint lodged against an employee of the public body or against legal counsel for the public body to determine its validity," and 5 ILCS 120/2(c)(**29**), regarding "meetings between internal or external auditors and governmental audit committees, finance committees, and their equivalents, when the discussion involves internal control weaknesses, identification of potential fraud risk areas, known or suspected frauds, and fraud interviews conducted in accordance with generally accepted auditing standards of the United States of America."

On the motion to recess the open meeting and convene into a closed meeting, a roll call was taken, the votes of yeas and nays being as follows:

Yeas: Chair Koetting and Directors Deer, Gugenheim and Reiter (4)

Nays: None (0)

Absent: None (0)

THE MOTION CARRIED UNANIMOUSLY and the Committee convened into a closed meeting.

Chair Koetting declared that the closed meeting was adjourned. The Committee reconvened into the open meeting.

VI. Adjourn

As the agenda was exhausted, Chair Koetting declared the meeting ADJOURNED.

Respectfully submitted,
Audit and Compliance Committee of the Board of Directors of the Cook County Health and Hospitals System

XXXXXXXXXXXXXXXXXXXXX
Mike Koetting, Chair

Attest:

XXXXXXXXXXXXXXXXXXXXX
Deborah Santana, Secretary

Requests/Follow-up:

Follow-up: Following the meeting of the Research Compliance Committee meeting in mid-September, Ms. Bodnar and Ms. Kirchner will review the meeting processes, etc, with Chair Koetting and he will determine whether a member of the CCH Board should be included in the membership of that internal committee. Page 1

Cook County Health and Hospitals System
Minutes of the Audit and Compliance Committee Meeting
August 20, 2021

ATTACHMENT #1

Corporate Compliance Report

Audit & Compliance Committee of the CCH Board of Directors

August 20, 2021

COOK COUNTY HEALTH

Meeting Objectives

Review

Implementation of a Research Compliance Program

- Establishing the Foundation
- Performing a Risk Assessment
- Identifying Goals
- Launching Next Steps

Research Compliance

An Overview

COOK COUNTY HEALTH

Research Compliance Program Overview

Why Implement a Research Compliance Program?

- Helps to facilitate compliance with the various laws and regulations from multiple agencies and enforcement bodies, including NIH, FDA, OHRP, OCR, ORI, PHS, OMB and more;
- Aids in identifying legal and regulatory problems, corrects deficiencies, and assists in preventing future problems;
- Provides support to ensure that proper scientific, ethical, and regulatory requirements are followed in research protocols and promotes research integrity throughout the organization.

Regulator Expectations

Encourage the use of internal controls to effectively monitor adherence to applicable statutes, regulations and program requirements

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may participate in the call in person with staff by reporting to the Aerospace Center Office Building, 901 D Street, SW., Office of Public Affairs Conference Room, 7th Floor West, Washington, DC, no later than 2:45 p.m., Daylight Savings Time. Please bear in mind that space is limited.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2) notice is hereby given that the President's Committee for People with Intellectual Disabilities will hold its third quarterly meeting by telephone conference call to discuss items related to people with intellectual disabilities. The conference call will be open to the public to listen, with call-ins limited to the number of telephone lines available. Individuals who plan to call in and need special assistance, such as TTY, assistive listening devices, or materials in alternative format, should inform Ericka Alston, Executive Assistant, President's Committee for People with Intellectual Disabilities, Telephone—202–619–0634, Fax—202–205–9519, E-mail: *ealston@acf.hhs.gov*, no later than November 30, 2005. Efforts will be made to meet special requests received after that date, but availability of special needs accommodations to respond to these requests cannot be guaranteed. This notice is being published less than 15 days prior to the conference call due to scheduling problems.

Agenda: The Committee plans to discuss the Social Security Administration's proposed amendments to the Ticket to Work and Self-Sufficiency Program, the Employer Work Incentive Act for Individuals with Severe Disabilities and an update on the Medicaid Commission. The Honorable Martin H. Gerry, Deputy Commissioner, Disability and Income Security

evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative proposals that impact the quality of life experienced by citizens with intellectual disabilities and their families.

Dated: November 15, 2005.

Lena Stone,

Program Analyst, President's Committee for People with Intellectual Disabilities.

[FR Doc. 05–23314 Filed 11–25–05; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice and comment period.

SUMMARY: This **Federal Register** notice seeks the comments of interested parties on draft compliance guidance developed by the Office of Inspector General (OIG) for recipients of extramural research awards from the National Institutes of Health (NIH) and other agencies of the U.S. Public Health Service (PHS). Through this notice, OIG is setting forth its general views on the value and fundamental principles of compliance programs for colleges and universities and other recipients of PHS awards for biomedical and behavioral research and the specific elements that these award recipients should consider when developing and implementing an effective compliance program.

SW., Washington, DC 20201 on Monday through Friday of each week from 8 a.m. to 4:30 p.m.

FOR FURTHER INFORMATION CONTACT: Richard B. Stern, Office of Counsel to the Inspector General, (202) 619–0335, or Joel Schaer, Office of External Affairs, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance (CPG) is a major OIG initiative that was developed to assist the health care community in preventing and reducing fraud and abuse in Federal programs. In the last several years, OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: clinical laboratories; hospitals; home health agencies; third-party medical billing companies; durable medical equipment, prosthetics, orthotics and supply companies; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; ambulance suppliers; and pharmaceutical manufacturers. Copies of these CPGs can be found on the OIG Web site at *http://oig.hhs.gov/fraud/complianceguidance.html.*

Under its governing statute, OIG's oversight responsibility extends to all programs and operations of the Department of Health and Human Services (HHS or Department) and, accordingly, OIG promotes compliance efforts by all recipients of Department funds.[1] One community of paramount importance to the Department's public health efforts is that of colleges, universities, and other recipients of public funds that conduct biomedical

- The "*Draft OIG Compliance Program Guidance for Recipients of PHS Research Awards*" provides a framework for developing and implementing effective compliance programs that prevent and reduce fraud, waste, and abuse, as well as promote adherence to Federal rules and regulations.
- The guidance encourages a risk-based approach and provides information on the benefits and suggested components of a comprehensive, well-managed compliance program.

COOK COUNTY HEALTH

Interim Research Compliance Officer

Jennifer Kirchner, Strategic Management Services

COOK COUNTY HEALTH

Foundation for a Research Compliance Program

Leverage existing Corporate Compliance Program structure

- Using the Elements of an Effective Compliance Program
  1. Implementing written policies, procedures and standards of conduct
  2. Designating a compliance officer and compliance committee
  3. Defining roles and responsibilities and assigning oversight responsibilities
  4. Conducting education and training programs
  5. Developing open lines of communication
  6. Performing auditing and monitoring
  7. Enforcing consistent discipline
  8. Responding promptly to problems and developing corrective actions

Compliance Program Research Risk Assessment

COOK COUNTY HEALTH

Developing the Research Risk Assessment

Understanding the Universe of Research Conducted by CCH

- Determining scope:
  - Federally funded studies
  - Industry studies
  - Home grown studies with no funding/data sharing only
- Identifying any/all entities that function as CCH fiscal agents
- Delineating Hektoen's responsibilities
- Defining CCH's responsibilities

Commencing Next Steps

These include:

1. Engaging management and staff to determine current state
2. Performing discovery reviews in partnership with Internal Audit and Legal
3. Compiling existing internal controls and address gaps identified
4. Recommending policy development or revision, training, and additional auditing and monitoring efforts

Clinical Trial Agreements

Examining the Review and Approval Process (Pre-Award)

Goal

- Ensure there is a formal and consistent review process by Compliance, Legal, Privacy and Security

Next Steps

- Develop a policy to outline the process
- Identify a database/tracking system for documenting the review and approval process

Coverage Analysis

Exploring Claims Review vs. Research Billing

Goal

- Delineate claims review processes

Next Steps

- Develop a coverage analysis:
  - Determine who is doing what (routine clinical care vs. research)
  - Triage studies for coverage analysis needs
  - Centralize the process
    - Ensure all studies are subject to the same process
    - Designate an individual(s) to perform the analyses

Financial Conflicts of Interest

Reporting and Developing Management Controls

Goal

- Identify and address potential conflicts

Next Steps

- Developing a policy to:
  - Specify reporting requirements,
  - Define financial conflicts and
  - Describe the process for analyzing and managing identified conflicts
- Drafting and Disseminating Disclosure Statement
- Forming a Committee to review and analyze potential conflicts

Grants Management

Developing Post-Award Controls

Goal

- Uphold terms and conditions for every award

Next Steps

- Establish processes and controls
  - Just-In-Time Submissions
  - Progress Reports
  - Time and Effort Reporting
  - Sub-award Management
  - Award Closeout

Moving Forward

COOK COUNTY HEALTH

Establishing the Research Compliance Program

Instituting the Compliance Structure

Next Steps

- Complete discovery review to understand scope and risk areas
- Build organizational support
- Designate permanent Research Compliance Officer and Research Compliance Committee

Next Steps

Establishing Written Guidance

- Complete Risk Assessment
- Develop Research Compliance Program Plan
- Create Standards of Conduct Related to Research
- Build Research Compliance Policies and Procedures

Designing Training and Education

- Incorporate newly defined scope and discovered risk areas into training for researchers and staff

Questions?

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