COOK COUNTY HEALTH

Cook County Research Compliance Program

Annual Report
Fiscal Year 2021
December 1, 2020 – November 30, 2021

January 21, 2022

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I. Executive Summary

The CCH Research Compliance Program was first introduced at a meeting with CCH executive leadership on February 18, 2021. Research is a heavily regulated environment and as such, having a Research Compliance Program in place is fundamental for ensuring compliance with the various laws and regulations from multiple agencies and enforcement bodies. The development of a Research Compliance Program can aid in identifying legal and regulatory problems, correct deficiencies, and assist in preventing future problems. The CCH Research Compliance Program will also guide CCH as it builds more formal research office functionalities, including a structure for appropriate oversight.

Since the initial introduction meeting, significant activity has occurred to thoughtfully implement the program, alongside other compliance related priorities for the CCH Compliance Program. The Fiscal Year (FY) 2021 Research Compliance Program Annual Report summarizes the primary compliance activities that the Cook County Health (CCH) Research Compliance Program accomplished in FY 2021 and identifies priorities for FY 2022.

In its first year of implementation, the Research Compliance Program accomplished various goals and spearheaded several new initiatives. These achievements include:

- Research Compliance Committee: Developed and implemented an executive level Research Compliance Committee to aid in identifying, assessing and prioritizing research compliance risks. The purpose of the Research Compliance Committee is to advise and assist the CCH Research Compliance Officer in the development, implementation and oversight of CCH's Research Compliance Program.

- Research Compliance Risk Assessment: Initiated a Research Compliance Risk Assessment which focused on identifying current internal controls in place related to key risk areas for research, as observed nationally and as identified internally at CCH.

- Identification of Research Conducted at CCH: Developed an understanding of the scope of research activities conducted at CCH, including a tabulation of all active research studies and grant activities currently underway at CCH during FY 2021.

- Clinical Trial Agreement Review Process discussions: Collaborated with CCH Compliance, the Office of the General Counsel and representatives from Research & Regulatory Affairs and the Center of Health Equity & Innovation to review and streamline the process for review and signature for clinical trial agreements and grants, including the review of agreements and/or contracts that impact CCH protected health information (PHI).

- Federal Research Requirements Review: Review of federal research requirements and development of policies to address Financial Conflict of Interest Disclosure and Federal Contracting (NIH Grants Management Policy and the Federal Acquisition Regulation).

In FY 2022, Research Compliance plans to continue building the recently launched program, with a focus on continued collaboration with the various departments conducting research at CCH to

assess potential risk areas, identify areas of potential non-compliance and work toward strengthening and improving research compliance at CCH.

Notable priorities for FY 2022 include:

- Financial Conflict of Interest audit: Completion of a comparison audit between CCH personnel conflict of interest survey data and financial data from drug and device manufacturers posted on CMS Open Payments website for improvement related to existing disclosures processes.
- Audit Collaboration: In collaboration with the CCH Research & Regulatory Affairs department, review the current schedule of audits conducted and determine where Research Compliance may be leveraged for support for internal and external audit activities.
- Focused Review of Clinical Trial Billing Processes: Review and identify areas of improvement related to uniform clinical trial billing processes at CCH, including how CCH patients may be flagged as participating in a research study within the electronic medical record and whether enhanced bill review processes are needed for charges related to research studies.
- Policy Development: Continued development of the Federal Contracting policy and Financial Conflicts of Interest policy, as well as other policies deemed necessary based on the finalization of the Risk Assessment and upon request from CCH operations.
- Compliance Education: Development of compliance training materials specific to research compliance (in addition to that provided by the Institutional Review Board (IRB)), including materials addressing Financial Conflicts of Interest and newly implemented processes.
- Formalization of the CCH Research Office: Continued collaboration with departments involved in research activities to formalize research office functionalities and responsibilities, including potential identification of a solution for managing and tracking clinical trial activities.
- Regulatory Changes: Ongoing monitoring of regulatory changes impacting Research Compliance.

II. Introduction

The formal CCH Research Compliance Program was initiated and implemented during FY 2021, though CCH Compliance was engaged in review of research agreements in FY 2019 and FY 2020, prior to the establishment of a formal program.

Organizations that conduct Clinical Research are subject to a variety of laws and regulations from multiple agencies and enforcement bodies, as is common in the health care industry. With this in mind, CCH Compliance, in collaboration with CCH executive management and with oversight

from the CCH Audit & Compliance Committee, designed a CCH Research Compliance Program that would fundamentally work towards:

- Aiding in identifying legal and regulatory problems, correcting deficiencies, and assisting in preventing future problems;
- Facilitating compliance with the various laws and regulations from multiple agencies and enforcement bodies, including NIH, FDA, CMS, HFS, OHRP, OCR, ORI, PHS, OMB and more; and
- Providing support to ensure that proper scientific, ethical, and regulatory requirements are followed in research protocols and promoting research integrity throughout the organization.

The Research Compliance Program is focused on all research conducted at CCH, which includes the following:

- Clinical trials and research conducted based on IRB approval, including government funded studies (NIH, FDA, etc.), sponsor funded studies and home-grown research;
- Research grants, including government research grants (DOJ, SAMHSA, etc.) and research funded by private sector/organizations; and
- Grants that do not include "clinical research" per se (i.e., not reviewed by the CCH IRB), but where funds are still received by CCH.

Initial discussions regarding the implementation of the Research Compliance Program began at an internal meeting with CCH executive leadership on February 18, 2021. Subsequent meetings were held with individuals in operational roles within the CCH Research & Regulatory Affairs department, the Center for Health Equity & Innovation and the Finance department. Additional background and progress updates were provided to the Audit & Compliance Committee of the CCH Board on August 20, 2021. Finally, an executive level Research Compliance Committee, tasked with advising and assisting with the development, implementation and oversight of the Research Compliance Program, assembled on September 14, 2021, and November 16, 2021.

The implementation of the Research Compliance Program is essential for demonstrating CCH's ongoing commitment to promoting ethical and lawful conduct consistent with all applicable laws, and regulations, as well as CCH policies, procedures, and the Code of Ethics. All CCH workforce members are responsible for prevention, detection, and reporting of instances that may not comport with state, federal, or local law, or CCH policy, including those who are conducting research activities for or on behalf of CCH.

This annual report serves to summarize the implementation of the Research Compliance Program by looking at the infrastructure of the program, including a summary of eight Compliance Program Elements as recommended in the Department of Health and Human Services Office of Inspector General (OIG) in its Compliance Program Guidance publication addressing Clinical Research. The report also presents the activities throughout the county fiscal year 2021 (FY 2021) of the Research Compliance Program under the executive leadership of the CCH Chief Compliance & Privacy Officer, with support by the CCH Privacy Officer, Compliance Analysts and other

external compliance resources to assist with critical projects and temporarily fill staffing openings.

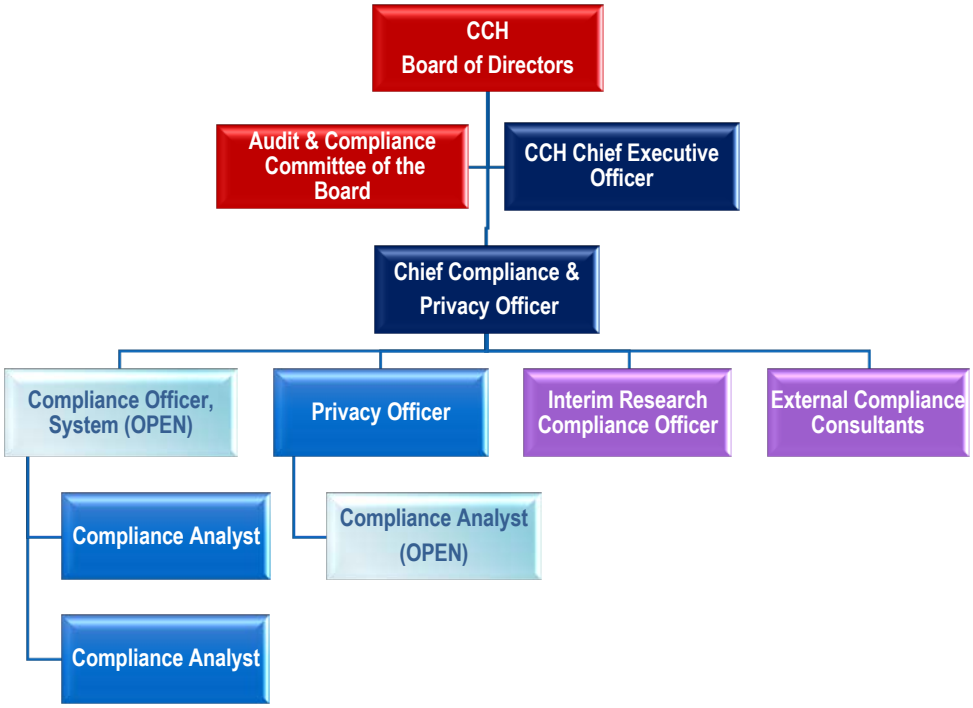
III. Building Blocks – Program Infrastructure and Scope

This Annual Report begins with a review of the efforts taken to design and foster an infrastructure that produces a comprehensive Research Compliance program.

The Research Compliance Program infrastructure relies upon the resources of the existing CCH Compliance department, which experienced continued staffing shortages in FY 2021. As such, the department engaged longtime department consultants, Strategic Management, LLC to assist with performing Interim Research Compliance Officer responsibilities, as well as other responsibilities to support the overall success of Research Compliance.

The existing Departmental Organization Chart follows:

Research Compliance Organizational Chart

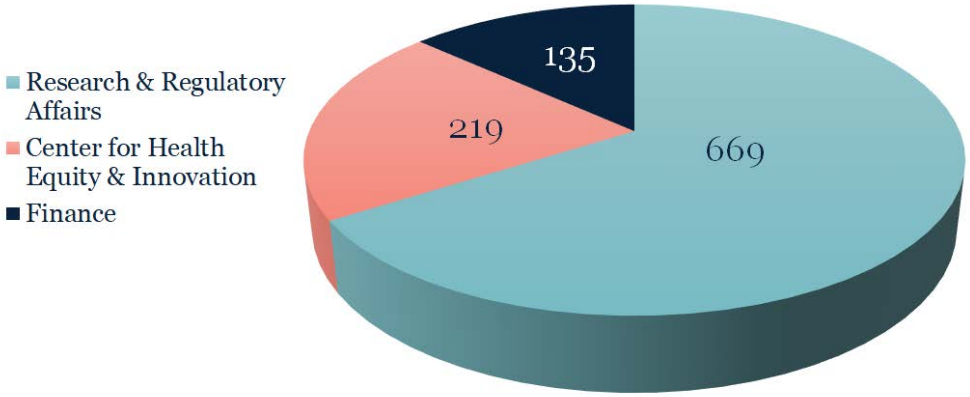


The Interim Research Compliance Officer reports up through the CCH Chief Compliance & Privacy Officer, with a close working relationship with CCH Office of General Counsel, the CCH Research & Regulatory Affairs department, the Center for Health Equity & Innovation and the Institutional Review Board.

Research Compliance Program Scope

As discussed above, the Research Compliance Program is focused on a variety of types of research activities conducted by CCH personnel. The term "research" includes activities that meet the more traditional definition of a clinical trial[1], which undergo review by the CCH IRB (and/or an external IRB) and are managed by the CCH Research & Regulatory Affairs department, as well as activities related to grants provided to CCH by external funding sources (e.g., government agencies, private sector organizations, non-profits, etc.), which are managed by the Center for Health Equity & Innovation and/ or the Finance department.

When informally tabulated in mid-November of 2021, the number of total active research studies identified at CCH was 1,023. The chart below contains a breakdown of the research activities identified per operational area at CCC:



With this scope in mind, CCH activities that fall into the Research Compliance purview include:

- Interpretation of federal, state, and local laws, rules, and regulations and contractual requirements implicating research activities at CCH;
- Creation, review and/or maintenance of policies and procedures addressing research Compliance subject areas;
- Investigation of allegations of compliance related issues impacting CCH research activities;
- Provision of communication and training to the CCH community on research compliance-related matters;
- Review of certain contracts/agreements, including clinical trial agreements and grants, data use agreements, and compliance provisions of master service agreements;
- Evaluation and guidance on potential conflicts of interest for individuals conducting research, in collaboration with the CCH IRB;

[1] Per the National Institutes of Health (NIH), a clinical trial is defined as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." See https://grants.nih.gov/policy/clinical-trials/definition.htm.

- Performance of monitoring and/or auditing efforts to address areas of risk for research;
- Collaboration on any government and/or regulator audits of CCH research activity; and
- Ensuring that the program is structured to prevent, detect, and equitably resolve research compliance issues.

IV. Research Compliance Program Structure: Performance of the Elements

The HHS OIG, in its Draft Compliance Program Guidance for Recipients of PHS Research Awards, emphasizes that institutions should consider implementing eight elements as part of an effective Research Compliance Program. Accordingly, the Research Compliance program was designed and is in the process of implementing each of the suggested elements, as outlined below. Several of the elements outlined below leverage existing structures, processes and/or resources already in place within the CCH Compliance Program.

Element 1

The development and distribution of written standards of conduct and policies and procedures that reflect the institution's commitment to compliance.

Code of Ethics

The CCH Code of Ethics applies to all CCH personnel, providers, agents and subcontractors who conduct research activities on behalf of CCH. The Code of Ethics supports the organization's commitment to comply with all federal and state standards, including but not limited to, applicable statutes, regulations and sub-regulatory guidance and contractual requirements and is reviewed on a regular basis.

Policies and Procedures

Policies and procedures are currently in place within CCH Compliance that address the structural and functional elements of a compliance program, as well as several areas of risk pertinent to research compliance, including conflict of interest and privacy/data sharing. These policies and procedures undergo triennial review.

Additionally, Research Compliance is in the process of developing and implementing several new policies and procedures with applicability to CCH research activities, including the following:

- Development of a Financial Conflict of Interest Disclosure policy (in collaboration with the IRB/Research & Regulatory Affairs department), to address NIH and FDA requirements for reporting financial conflict of interests for research studies; and

- Development of a Federal Contracting policy (in collaboration with Office of General Counsel and Internal Audit) to address requirements within the NIH Grants Management Policy and the Federal Acquisition Regulation (FAR).

Additional efforts are also currently underway to actively identify areas where research related policies and procedures may be needed.

Written Guidance

During FY 2021, the Research Compliance Program provided written guidance and/or insight regarding the following issue areas:

- Clinical Trial Agreement/Grant Review: Collaborated with CCH Compliance, the Office of the General Counsel and representatives from the Research & Regulatory Affairs and the Center of Health Equity & Innovation to review and streamline the process for review and signature for clinical trial agreements and grants.
- Data Sharing Agreements for Research: Collaborated with CCH Compliance, the Office of the General Counsel and Information Security to better understand review processes for data sharing, including the review of agreements and/or contracts that impact CCH PHI.
- Federal Contracting Requirement Review: Collaborated with CCH Compliance, the Office of the General Counsel and Internal Audit to review and outline the applicability of the NIH Grants Management Policy and the Federal Acquisition Regulation (FAR) to research conducted at CCH.
- Signature Authority for Certifications and Reliance documents: Researched and provided guidance on ability for research department lead to approve and execute sign off on Extramural Institutional Certifications and IRB Reliance Agreements.

Element 2

The designation of a compliance officer and a compliance committee that are responsible for developing, operating, and monitoring the compliance program, and with authority to report directly to the head of the organization.

CCH Compliance Program Oversight

The graphic here illustrates the communication and reporting structure for CCH Compliance, of which the Research Compliance Program is embedded within.

Nicole Almiro, the Chief Compliance & Privacy Officer, reports to the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer. In turn, the CCH Audit & Compliance Committee of the Board and the CCH Chief Executive Officer each report to the CCH Board of Directors.

The **Audit & Compliance Committee of the Board** advises the CCH Board of Directors regarding the implementation of standards and processes to assure professional responsibility and honest behavior, compliance with regulatory requirements, and risk management.

The interim Research Compliance Officer reports to the Chief Compliance & Privacy Officer and is responsible for the development, oversight and monitoring of the Research Compliance Program, which is supported by the CCH Compliance program.

The primary duties of the **Interim Research Compliance Officer** include the following:

- Overseeing the Research Compliance Program interpreting and applying regulatory laws and guidance governing research, including financial and non-financial regulations.
- Coordinating and administratively leading the Research Compliance Committee meetings and serving on any Research related committees, including ad-hoc committees.
- Serving as CCH's subject matter expert for regulations and guidelines governing research, including, but not limited to, the Uniform Guidance, National Institutes of Health Grants Policy Statement, and regulations governing research conflicts of interest, human research protections, environmental health & safety, export controls, clinical research billing, and research misconduct.
- Keeping current on new federal regulations, rules, revisions and other industry standards that govern research and demonstrating an understanding of current events that influence research guidelines and regulatory processes.
- Acting as a resource for research compliance-related inquiries and policy clarification.
- Maintaining open lines of communication with other departments including the Office of Research & Regulatory Affairs, Center for Health Equity and Innovation, the CCH IRB and CCH Compliance.
- Implementing policies and procedures that govern the Research Compliance Program.
- Developing, implementing and overseeing institutional research-related compliance policies, procedures, guidelines and programs that enable the conduct of research while ensuring compliance with regulatory requirements.
- Collaborating with business units to define roles and responsibilities for research compliance-related activities, including activities of the research compliance program and operational responsibilities of business units.
- Overseeing internal investigations into research-related compliance issues and coordinates investigations.
- Collaborating with key CCH/Research Institute leadership, employees, and physicians to identify, research, investigate and resolve research-related compliance issues.
- Partnering with business units to ensure corrective action resulting from investigations is taken, including disciplinary action as applicable.
- Tracking and trending research compliance-related allegations, investigations, and outcomes.
- Collaborating with CCH Compliance and Office of General Counsel and escalates issues to CCH leadership as appropriate, when investigating issues that may violate criminal law and/or require reporting to government bodies.
- Providing communication and training to the CCH community on research compliance-related matters.

- Developing, coordinating, and participating in an educational training program that ensures compliance with pertinent policies and federal and state standards and augments training and communication for high-risk areas, including, but not limited to, research misconduct, conflicts of interest, foreign influence, etc.
- Overseeing response to and communicating new regulatory changes to affected departments/individuals by assembling work groups and developing/providing education and training.
- In collaboration with CCH Compliance, conducting a risk assessment to proactively identify areas of research-related risk for CCH.
- Developing and managing an annual Research Compliance Work Plan based off the risk assessment to reduce organizational risk.
- Ensuring that the program is structured to prevent, detect, and equitably resolve research compliance issues.
- Participating in projects related to processes or systems that further promote an effective Research Compliance Program.

In addition to the aforementioned relationships, the Research Compliance Officer receives support and guidance from the internal **Research Compliance Committee**, an assembly of executive leaders within CCH who meet on a quarterly basis, including but not limited to, the CEO, Chief Medical Officer, the Chair of the CCH IRB, the Chief Equity and Inclusion Officer, the Chief Financial Officer, the Office of General Counsel, the System Director of Internal Audit, Chief Information Officer, the Director of Research & Regulatory Affairs, the Assistant Grants Management Director and CCH Principal Investigators who are currently conducting research activities on behalf of CCH. The purpose of the Research Compliance Committee is to advise and assist the CCH Research Compliance Officer in the development, implementation and oversight of CCH's Research Compliance Program.

Element 3

The development and implementation of education and training programs for all affected employees that are provided regularly and updated as necessary to be effective.

Education and Training

As has been stated before, the Research Compliance Program leverages the existing compliance education structure to ensure that all individuals performing research activities on behalf of CCH receive adequate compliance related training upon hire and on an annual basis. Subject areas related to CCH Compliance, the Code of Ethics, Fraud, Waste and Abuse (FWA) and Health Insurance Portability and Accountability Act (HIPAA) Privacy are addressed in training materials.

Additionally, Principal Investigators and their staff are required to complete human subject protection training modules as outlined in the application for research that is reviewed by the CCH IRB, which includes formal research ethics training. Ongoing efforts are underway to identify subject areas for enhanced, ad hoc education that will be developed by Research Compliance.

Element 4

The creation and maintenance of an effective line of communication between the compliance officer and all employees, that includes a process to receive complaints or questions and allows the option to report issues in a manner that protects the anonymity of complainants and protects whistleblowers from retaliation.

Receiving and Responding to Complaints

Similar to other elements already addressed, Research Compliance leveraged existing CCH Compliance mechanisms for communicating with workforce members regarding research related issues, including:

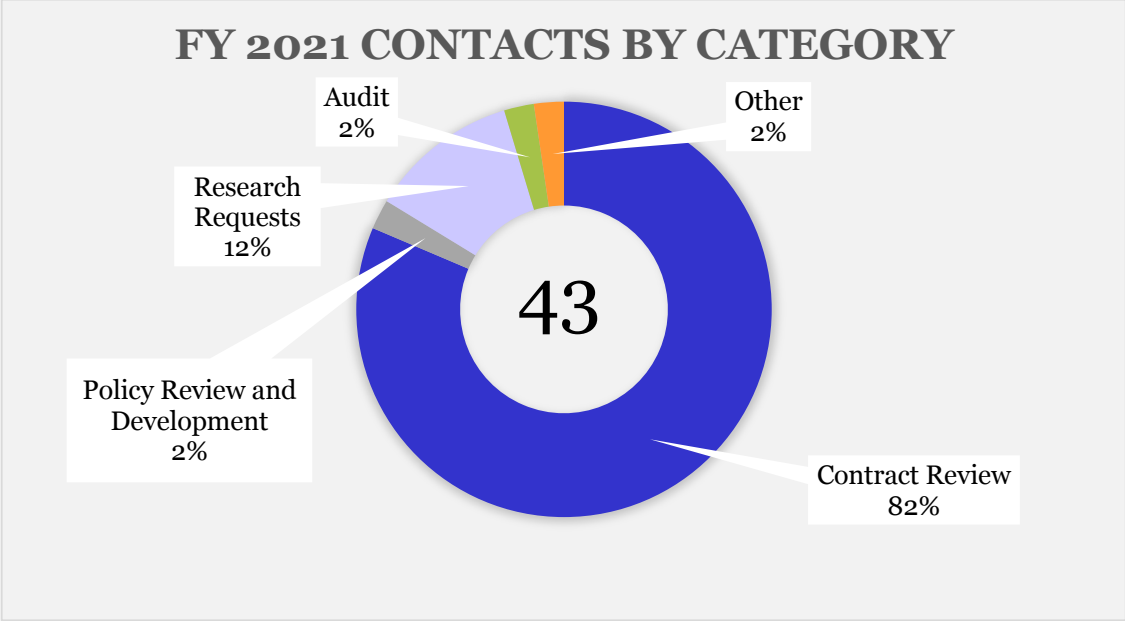
- A hotline service provided by an independent, contracted third-party to preserve caller anonymity if desired. The individual is given a code number related to their report and can call back or check the website using that code number to review comments and updates. In FY21, 51 calls or internet/online inquiries were received on the hotline.
- Maintained two email addresses for departmental notices and communications:
  - Compliance (compliance@cookcountyhhs.org) and
  - Privacy (privacy@cookcountyhhs.org).
- Collaboration with operational areas, including but not limited to General Counsel, Human Resources, HIS, Finance, CCH IRB, Research & Regulatory Affairs, and the Centers for Health Equity & Innovation to assist in resolving Research compliance-related issues.

The process for responding to compliance contacts related to Research also followed the SBAR workflow, an acronym for **S**ituation, **B**ackground, **A**ssessment, **R**ecommendation, which is identical to that as followed by CCH Compliance and CountyCare Compliance.

The diagram included here illustrates the approach to incident investigation and ensures that all the causes are discerned and addressed by appropriate actions, including detection, reporting and correction of inappropriate actions, as well as monitoring for issues post mitigation.

Research Contact Volume for FY 2021

In its first year of operation in FY 2021, 43 identified contacts were received and documented for the CCH Research Compliance Program.



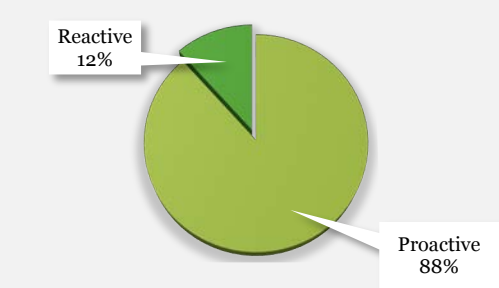
Contacts related to research included requests for the below listed activities:

Categories	Count
Review of contracts or agreements related to research (including clinical trial agreements, study contracts, grants, non-disclosure agreements, data transfer and/or sharing agreements, etc.)	35
Research or regulatory review requests	5
Policy review and / or development	1
Audits	1
Other	1

FY 2021 Proactive vs. Reactive

It has been a longstanding goal of CCH Compliance to balance to the number of proactive versus reactive contacts that come into the department.

Of the 43 Research compliance contacts managed during FY 2021, 5 contacts or 12% were reactive. Reactive contacts occur in response to an action that has already been initiated. On the proactive side, 88% or 38 contacts were classified as proactive. The proactive category is defined as questions brought to the attention of Research Compliance by individuals seeking guidance prior to the occurrence of an event or activity.



Compliance continues to be encouraged by the positive trend towards individuals seeking guidance prior to embarking upon an action.

Element 5

The development of policies and procedures to investigate identified instances of non-compliance or misconduct and implementing a prompt and proper response to detected offenses through the initiation of appropriate corrective action and preventive measures.

Enforcing Standards

The Research Compliance Program leverages existing CCH policies and standards of enforcement for its activities to ensure that prompt and proper response to detected offenses is taken through the initiation of appropriate corrective action and preventive measures, in close collaboration with the Human Resources department.

In its inaugural year of operations, Research Compliance relied upon the following standards of enforcement, in collaboration with the CCH Privacy Officer and Compliance department:

- Breach Assessments. Reviewed investigations and provided remediation guidance to the Research department to minimize and/or eliminate breaches in the future and utilized the CCH Sanction Policy and Personnel Rules, to provide leadership guidance for disciplinary action. Where necessary, the Privacy Officer completes breach notification requirements for confirmed HIPAA breaches. A breach occurs where there is an impermissible access to, use, or disclosure of research participant PHI. Notification involves drafting a letter to each impacted participant, explaining what happened, what information was compromised, and what CCH is doing to mitigate further harm. Research Compliance received one (1) report of a potential HIPAA breach in FY 2021. This occurred when a researcher used the "CC" line instead of the "BCC" line to send a communication to research participants, thereby allowing participants to see each other's phone numbers. In total, 112 participants were impacted.

- Breach Notification. Investigated all instances of lost or stolen PHI, including paper and electronic. For all instances in which the data loss constitutes a breach as defined by the Breach Notification Rule, the breach notification requirements to the patient, the Secretary of HHS, and the media are completed. Corrective action plans are

created and executed to improve the processes and counsel the physicians and employees involved.

Element 6

The use of audits and/or other techniques to evaluate risks to monitor compliance and identify problem areas

Risk Assessment

As part of the initial implementation of the Research Compliance Program, an informal risk assessment was conducted that focused on key risk areas for research, as observed nationally and as identified internally at CCH. The following focus areas were identified in FY 2021:

- Financial Conflict of Interests
- Accurate Billing for Research
- Processes in Place for Legal/Compliance Study Review and Approval
- Privacy/Security Concerns for Information Sharing
- Potential Research Misconduct (plagiarism, fabrication, and falsification)
- Allocation of Research/Grant Funding
- Informed Consent Management

Efforts are currently underway to document and finalize the Risk Assessment process. Formal documentation will be available in FY 2022.

Auditing and Monitoring

Research Compliance initiated two audits during FY 2021, as described below:

- Discovery audit of the existing research compliance billing process for a randomly selected study, designed to learn more about how services related to clinical studies are billed for at the study and organization level at CCH; and
- Initiation of a CMS Open Payments audit, including the review of conflict-of-interest information for CCH personnel (including those involved in research studies) against publicly available information on the CMS Open Payments website.

Notably, no external audits were conducted during FY 2021 related to research activities by government regulators or third-party sponsors.

As the Research Compliance Program was newly developed, a formal auditing and monitoring plan has yet to be developed. Upon completion of the Risk Assessment, a formal auditing and monitoring plan will be developed based on the project outcome.

Element 7

The enforcement of appropriate disciplinary action against employees or contractors who have violated Federal requirements and/or institutional policies and procedures in relation to the use of Federal research dollars.

The Research Compliance Program leverages existing CCH policies and disciplinary processes for its activities, in close collaboration with the Human Resources department. Notably, the following sanction screening check procedures apply to all individuals conducting research activities at CCH:

Sanction Screening Checks

- A policy and procedure paralleling the requirements set forth by the Department of Health and Human Services, Office of Inspector General, is in place to ensure the screening of all contractors and workforce members.
- The policy is placed to avoid employing, engaging, contracting or agreeing with any individual or entity that is excluded or "sanctioned" from participation in a federal health care program or who is debarred from participation in federal procurement or non-procurement programs for the provision of goods or services.
- CCH screens all employees prior to hire and vendors prior to contracting.
- Delegated vendors attest to screening of all workforce members upon hire and routinely thereafter.
- CCH Compliance, through an independent third party, is responsible for subsequent screenings. The third-party screens workforce members, employees of delegated vendors that work at CCH locations or have contact with a patient or CountyCare member, monthly and annually.

No excluded or sanctioned workforce members or vendors who conduct research at CCH were identified throughout this fiscal year.

Element 8

The clear definition of roles and responsibilities within the institution's organization and ensuring that oversight responsibilities are effectively assigned

As part of the Risk Assessment process outlined above, Research Compliance actively gathered information related to the volume and types of research and grant funded activities conducted by various CCH departments, including the Research & Regulatory Affairs department, the Center for Health Equity & Innovation and the Finance department. In the coming year, Research

Compliance will continue to collaborate with key stakeholders to help build out more formal research office functionalities, including a structure for appropriate oversight.

V. Looking Ahead to 2022

In FY 2022, Research Compliance plans to continue collaborating with the various departments conducting research at CCH to assess potential risk areas, identify areas of potential non-compliance and work toward strengthening and improving research compliance at CCH.

Other notable priorities for FY 2022 include:

- Continued Implementation of the Research Compliance Program: As the Research Compliance Program was newly initiated in FY 2021, many initiatives to strengthen the program will continue in FY 2022, including identification of a permanent CCH Research Compliance Officer.
- Financial Conflict of Interest audit: Completion of the CMS Open Payments audit and identification of areas for improvement related to existing disclosures processes.
- Audit Collaboration: In collaboration with the CCH Research & Regulatory Affairs department, review the current schedule of audits conducted and determine where Research Compliance may be leveraged for support for internal and external audit activities.
- Focused Review of Clinical Trial Billing Processes: Review and identify areas of improvement related to uniform clinical trial billing processes at CCH, including how CCH patients may be flagged as participating in a research study within the electronic medical record and whether enhanced bill review processes are needed for charges related to research studies.
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