Minutes of the meeting of the Audit and Compliance Committee of the Board of Directors of the Cook County Health and Hospitals System held Tuesday, June 7, 2011 at the hour of 9:30 A.M., at John H. Stroger, Jr. Hospital of Cook County, 1901 W. Harrison Street, in the fifth floor conference room, Chicago, Illinois.

I. Attendance/Call to Order

Chairman Muñoz called the meeting to order.

Present: Chairman Luis Muñoz, MD, MPH and Directors Benn Greenspan, PhD, MPH, FACHE and Heather O'Donnell, JD, LLM (3)

Gerald Bauman, CPA (non-Director Member)

Absent: None (0)

Additional attendees and/or presenters were:

Michael Ayres – System Chief Financial Officer
Cathy Bodnar – System Chief Compliance Officer
Claudia Fegan, MD – System Interim Chief Medical Officer
Tracey Guidry – Deloitte & Touche, LLP
Elizabeth Reidy – System General Counsel
Trisha Routh – Deloitte & Touche, LLP
Deborah Santana – Secretary to the Board
Thomas Schroeder – System Director of Internal Audit

II. Public Speakers

Chairman Muñoz asked the Secretary to call upon the registered speakers.

The Secretary responded that there were none.

III. Report from System Corporate Compliance Officer (Attachment #1)

A. Activity Report

Cathy Bodnar, System Corporate Compliance Officer, presented the Activity Report and an update on the following: Compliance Issues (Reactive); Compliance Work Plan – Proposed Proactive Activity FY 2011; Compliance E-Learning; and the Business Associate Project. The Committee reviewed and discussed the information.

During the Committee's discussion of Reactive Compliance Issues, Director Greenspan requested that additional information be provided on this subject at the next Committee meeting that shows which issues were resolved, by category, and whether the complaint/allegation was validated.

IV. Report from System Director of Internal Audit (Attachment #2)

A. Activity Report

Tom Schroeder, System Director of Internal Audit, presented the following report: update on the 2011/2012 Internal Audit Plan; the PricewaterhouseCoopers invoice review; and information regarding Internal Audit's involvement in the preparation of Cook County's Fiscal Year 2010 Comprehensive Annual Financial Report. The Committee reviewed and discussed the information.

Additionally, Mr. Schroeder introduced and welcomed Kin Chan, who recently joined his staff as Information Technology Auditor.

V. Recommendations, Discussion/Information Items

A. Minutes of the Audit and Compliance Committee Special Meeting, May 4, 2011

Director Greenspan, seconded by Director O'Donnell, moved to accept the minutes of the Audit and Compliance Committee Special Meeting of May 4, 2011. THE MOTION CARRIED UNANIMOUSLY.

B. Report from Deloitte & Touche, LLP (Attachment #3)

Tracey Guidry and Trisha Routh, of Deloitte & Touche LLP, provided a report on the ongoing activities to finalize the Cook County FY2010 Comprehensive Annual Financial Report; they presented an overview of this information as it relates to the Cook County Health and Hospitals System.

Ms. Guidry stated that they are wrapping up the activities, and indicated that they may be completed by the end of the month. She noted that her colleague, Don O'Callaghan, will soon be assuming her role in reporting to the Committee, as she will be transferring to Texas.

C. Approval of draft Corporate Compliance Policy - Conflict of Interest (Attachment #4)

Ms. Bodnar presented the draft Conflict of Interest Policy for the Committee's consideration and approval.

Director Greenspan, seconded by Director O'Donnell, moved to approve the draft Conflict of Interest Policy. THE MOTION CARRIED UNANIMOUSLY.

D. Update on Special Earnings (Attachment #5)

Dr. Claudia Fegan, System Interim Chief Medical Officer, provided an update on Special Earnings. The information included the following: response to Internal Audit report dated March 4, 2011; review of "high" usage clinical areas; drivers behind special earnings; and go-forward policies.

During the presentation of the information, Chairman Muñoz noted that the information on Special Earnings should include a delineation of activities under each category of usage. Director Greenspan indicated that this information could be presented as part of the budget process. Following discussion, Michael Ayres, System Chief Financial Officer, responded that he can provide this information; he stated that he will analyze a pay period and provide a breakdown of the different categories of Special Earnings.

E. Update on Grants Management Program (Attachment #6)

Mr. Ayres provided an update on the Grants Management Program. He stated that a request for information (RFI) has been sent out to look for alternative administrative services organizations. He added that discussions are ongoing with representatives of Hektoen regarding the System's expectations and whether Hektoen wishes to move forward. Through these efforts, the System is moving forward towards the establishment of an infrastructure to secure greater transparency and direction of resources to programs, and towards creating the framework for better coordination and collaboration with the System's academic neighbors.

The Committee discussed the information. Following discussion, Mr. Ayres stated that he can provide an index of current CCHHS grants.

VI. Action Items

A. Any items listed under Sections V, VI and VII

VII. Closed Session Discussion/Information Items

A. Discussion of Personnel Matters

Director Greenspan, seconded by Director O'Donnell, moved to recess the regular session and convene into closed session, pursuant to the following exception 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." THE MOTION CARRIED UNANIMOUSLY.

Chairman Muñoz declared that the closed session was adjourned. The Committee reconvened into regular session.

VIII. Adjourn

The Committee discussed the possibility of convening a special Committee meeting between now and the next scheduled Committee meeting in September. The July 1st Committee Meeting will be canceled, as this is a designated shut down day; this meeting was scheduled prior to the County's determination of the FY2011 shut-down days. Chairman Muñoz stated that he will follow-up on the possibility of holding a Committee meeting before September.

Chairman Muñoz and Director Greenspan thanked the Internal Audit and Finance staff for their efforts and success in the past year in addressing deficiencies and weaknesses identified in the management letter relating to last year's Comprehensive Annual Financial Report.

As the agenda was exhausted, Chairman Muñoz declared the meeting ADJOURNED.

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

XXXXXXXXXXXXXXXXXXXXXX
Luis Muñoz, MD, MPH, Chairman

Attest:

XXXXXXXXXXXXXXXXXXXXXX
Deborah Santana, Secretary

ATTACHMENT #1

JUNE 7, 2011 REPORT
to the
AUDIT AND COMPLIANCE COMMITTEE
from the
CHIEF COMPLIANCE OFFICER

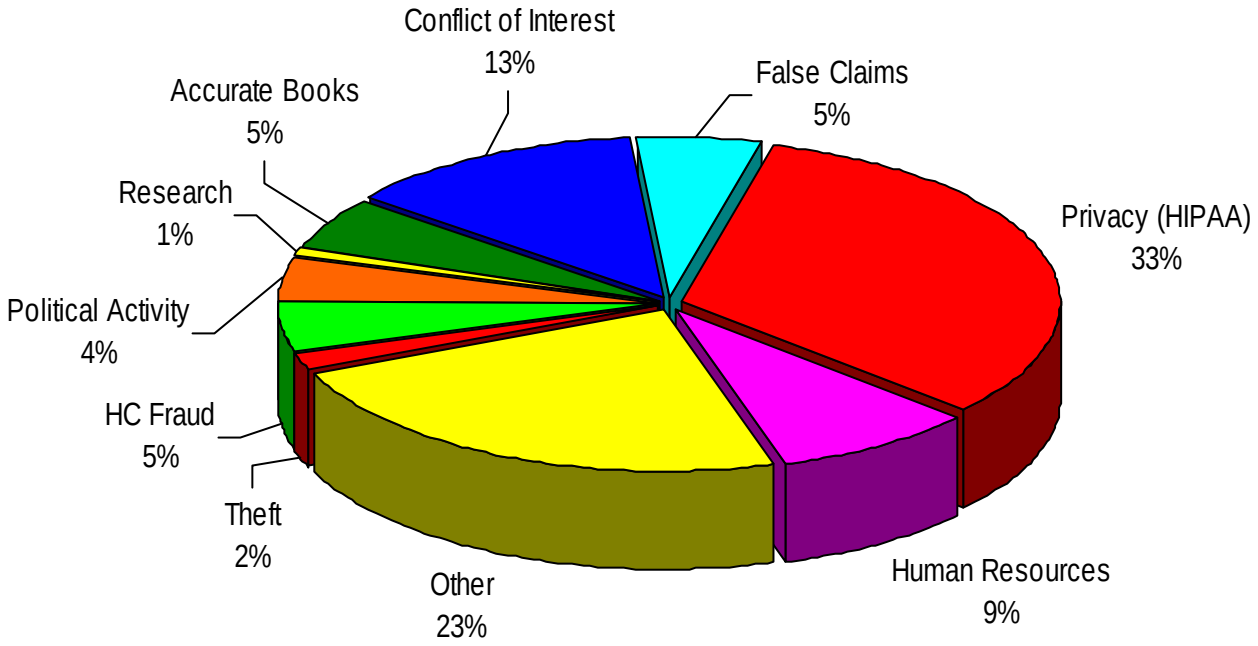
III A
ACTIVITY REPORT

COMPLIANCE ISSUES (REACTIVE)
BY CATEGORY

2nd Quarter F-YTD 2011 Statistics

12/01/2010 – 05/31/2011

116 Issues



Total F-YTD Issue Count by Category

Privacy (HIPAA)	38	Accurate Books	6
Conflict of Interest	15	Political Activity	5
Human Resources	10	Theft	2
False Claims	6	Research	1
Healthcare Fraud	6	Other	27

COMPLIANCE WORK PLAN
PROPOSED PROACTIVE ACTIVITY
FY 2011

Identified System Goals

1. Update and disseminate CCHHS Standards of Conduct/ Code of Ethics
   Initial projection: 2nd Quarter FY 2011
   Modified projection: Update 3rd Quarter FY 2011
   Modified projection: Dissemination 4th Quarter FY 2011

2. Initiate compliance e-learning on a platform that can benefit the system as a whole
   Initial projection: 2nd Quarter FY 2011 (Vendor Identified)
   System implementation: 3rd Quarter FY 2011

3. Develop system-wide guidance for record retention that is recognized as the authoritative source reference document
   Initial projection: 4th Quarter FY 2011

Additional Identified Projects

4. Conflict of Interest policy development with the establishment of a CCHHS disclosure survey.
   Policy completion: 2nd Quarter FY 2011
   Approvals and Dissemination: 3rd Quarter FY 2011
   Survey development: 4th Quarter FY 2011

5. Business Associate Agreements; compliance with federal regulations.
   Assessment: 1st Quarter FY 2011
   Project planning and development: 2nd Quarter FY 2011
   Completion: 3rd Quarter FY 2011

6. Service Animal policy update with distribution.
   Policy completion: 3rd Quarter FY 2011
   Approvals and Dissemination: 3rd Quarter FY 2011

7. Assessment of Emergency and Trauma facility coding with the operational areas and external consultants.
   Initiation: 2nd Quarter FY 2011
   Projected completion: 3rd Quarter FY 2011

8. Assessment of procedure coding and billing.
   Initial projection: 3rd Quarter FY 2011

9. Assessment of compliance with Dual Employment policy.
   Initial projection: 4th Quarter FY 2011

10. Professional fee review.
    Initial projection: 4th Quarter FY 2011

COMPLIANCE E-LEARNING PRESENTATION

BUSINESS ASSOCIATE PROJECT

Work Plan Activity: Business Associate Agreements; compliance with federal regulations.

Status: Assessment: 1st Quarter FY 2011
Project planning and development: 2nd Quarter FY 2011
Projected completion: 3rd Quarter FY 2011

Board Action: Review

Summary:

- Required by both HIPAA Privacy and Security Rules and amended in the HITECH Act of the ARRA, it is the policy of CCHHS to execute Business Associate Agreements with all the vendors and suppliers meeting the HIPAA definition of Business Associate.

- As of February 18, 2010, the administrative, physical, and technical standards and implementation specifications of the HIPAA security rule apply to the Business Associate in the same manner that it applies to CCHHS. CCHHS requires updated Business Associate Agreements with all Business Associates to reflect this rule.

- In conjunction with the General Counsel, Corporate Compliance will complete a mailing to all vendors, suppliers, and others having received a payment, requesting the return of a signed Business Associate Agreement or an Affidavit in lieu of the Business Associate Agreement. Corporate Compliance will track the return of these documents.

- Going forward, Business Associate Agreements must be provided to all new vendors that are identified as Business Associates.

    → Supply Chain will ensure the execution of Business Associate Agreements for all Purchased Contracts.

    → The department securing the service/product will provide each new vendor with a Business Associate Agreement or include the terms in their agreements.

HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

COMPLIANCE TODAY

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the Co-chairs of HCCA's Upper North East Regional Conference, Caron Cullen and Eric Sandhusen
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CMS shifts from "pay and chase" to proactive fraud prevention
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feature focus

What your board needs to know about compliance and ethics

By Frank J. Navran

Editor's Note: Frank J. Navran is the Founder and Principal Consultant of Navran Associates. Frank has worked with clients in more than twenty countries, reducing their risk of ethics and/or compliance failures and contributing to their success in developing and sustaining strong ethical cultures. Frank has authored five books and more than two hundred articles and book chapters. He may be reached at frank@navran.com, or for more information, www.navran.com.

The hospital's Vice President–Ethics and Compliance had been waiting outside the conference room for about ten minutes. The board had been in closed session for almost two hours and she was next on the agenda. The door opened and she was invited in to get ready for her presentation while the board took a short break. As she went into the conference room, she heard three of the board members in heated discussion.

> "We can't let him get away with this. We have a strict policy against this kind of conflict of interest."
>
> "We have no choice. He's the only doctor on staff that has his level of certification and experience. If we run him off just because he owns a bunch of shares in the company that supplies our cardio machines, we lose him. And that would be a disservice to the community. Those machines are as good as any others on the market. It's not like he's having an adverse effect on patients."
>
> "But, how can we apply our Conflict of Interest policy to everyone else and not apply it to him?"
>
> "We just do. We make an exception. This is a special case. To lose him would be a disaster, both in terms of community service and our bottom line. No harm, no foul. And, if it comes back to haunt us, we can always blame the manufacturer."

You can't believe what you just heard. The company has strict conflict of interest guidelines that are supposed to apply to everyone and the board is choosing to violate these policies. What are you to do? Later that day you take your concern to the Chief Operations Officer. After listening to your story he says,

> "This is none of your business. What you heard was not intended for your ears. It was board members discussing board business. We have to trust that they know what they are doing. As far as I'm concerned, no harm, no foul. As far as you're concerned, it never happened. Do I make myself clear?"

The behavior of the board members and the COO in this example relies on two preconditions: the ability of people to rationalize, and a weak ethics culture.

Rationalization

Rationalizations are one of the most powerful mechanisms used by "good" people to justify doing "bad" things. Over the years, I have come to define a rationalization as, "A lie we tell ourselves to give us permission to do what we know is wrong."

Consider the lies in this case:

1. **This is none of your business.**
   a. Actually, as the hospital's Ethics Officer, it was precisely her "business."
      i. Here is a clear instance of the hospital's purchasing agent being pressured by a member of the board of directors to do business with a vendor with whom the board member has a significant financial interest—a clear violation of hospital policy.
      ii. The conversation suggests an implicit (if not explicit) threat from that doctor that changing vendors would result in him leaving the hospital, thus harming the hospital's ability to

serve both the community and its shareholders. Such threats also violate hospital policy.

iii. The conversation also implies that the board has just knowingly chosen to ignore this conflict of interest, rather than risk the anticipated consequences, thereby violating the explicit prohibitions in the board bylaws that address this specific type of conflict.

iv. And perhaps most significantly, this conversation is symptomatic of a board that does not believe that the organization's ethics standards apply to them and their decisions. This suggests that the decision in question might not be an isolated case, but rather indicative of a board that routinely chooses to operate outside the company's proscribed ethics standards.

2. What you heard was not intended for your ears.

a. The implication is that if you hear something that was not intended for your ears, you have no responsibility to act. That is not true.

i. As an ethics officer, you have both a fiduciary obligation to serve the best interests of the organization and a duty to do so in a manner consistent with all applicable policies and procedures—and that includes the hospital's Code of Ethics.

ii. As an employee, irrespective of position or title, you should have a copy of the Employee Code of Ethics. If that is well written, it should state that you have "…an affirmative obligation to report any observed or suspected ethics violation. Failure to do so is an ethics violation in its own right."

3. We have to trust that they know what they are doing.

a. There is no such obligation to trust.

i. Trust must be earned.

ii. It cannot simply be conferred by virtue of title or position.

b. In this instance, trust is not deserved.

4. "No harm, no foul."

a. There is harm

i. In this case the organization was harmed when potentially important data was suppressed. Without that data, the board cannot make informed decisions.

ii. The reputation of the board and the company was put at risk.

b. There is a foul

i. Implicit in the overheard conversation is a problem with the board applying a double standard.

ii. "If it comes back to haunt us, we can always blame the manufacturer" suggests it is serious enough that a plan to deflect responsibility is warranted.

5. As far as you're concerned, it never happened.

a. Unfortunately, it did happen.

b. Once that is the case, you have no ethical alternative but to act.

These rationalizations were necessary for the decision to "do nothing" to be justified. In this instance, rationalizing both legitimized and forgave an ethical breech. By extension, it also created a precedent for tolerating future misconduct, thus helping create and/or sustain a board culture based on lowered ethical standards.

Ethical culture

Culture, in this context, can be understood as the commonly held beliefs about "how things really work around here"—what we often call the unwritten rules. These are rules we need to know about, but won't find written down anywhere. Please note, "culture" is different from compliance, because it is based on unpublished standards (i.e., rules that cannot be researched, printed, distributed, and read).

Ethical culture is that aspect of culture that defines what is "right" and what is "wrong" in an organization. It sets boundaries and defines limits. It is the response to my favorite "diagnostic" question:

> "If I were a new employee here and you wanted to help me succeed, what one or two things would you tell me that I need to know, but won't find written down anywhere?"

I have been asking this question for more than 15 years, in dozens of organizational assessments and culture reviews. Among the thousands of interviewees, no one, irrespective of seniority, function or level, has ever said, "We don't have any unwritten rules." Quite the contrary. Every respondent has had several examples, and all agree that in a clash between the written rules and these unwritten rules, the unwritten rules always prevail.

In this case the board "expects" that conflicts of interest will be avoided and, if observed, will be reported. Abiding by that expectation creates a "climate of trust" in the organization, a belief that decisions will be made on their merit, in accordance with company policies and procedures, and consistent with the organization's stated values, principles, and standards.

Continued on page 30

 ...continued from page 29

To violate that standard breaches a trust. This breach, as detailed above, may be a unique circumstance or symptomatic of a pattern. Either way, these board members have chosen to act unethically. An organizational culture that encourages and/or tolerates this kind of breach is a "weak" ethical culture. A strong ethical culture neither encourages nor tolerates ethical misconduct.

What has this to do with ethics training for my board?

How is this hypothetical case related to the argument that ethics training for boards is necessary? According to *The Board Book*,[1] one of the duties of a board is "…ensuring legal and ethical conduct." I would characterize that duty as including the need for creating and sustaining a strong ethical culture.

Given that duty, is it reasonable to expect a board to sustain the ethical standards of a strong ethical culture even if/when those standards have not been formally communicated to the board? Some have argued that the answer is "yes" because ethical standards, the definitions of what is right and wrong in the boardroom, are nothing more than "common sense." But, can we be confident that is the case? If not, then ethics training for boards becomes necessary.

I have been making the argument for ethics training for boards for several years, based on a belief that board ethics is not common sense. That position "crystallized" for me early on, after working with the boards of directors and trustees of a state medical association, a combined group of about 45 working professionals and academics. I was invited to facilitate a one-day session on how best to go about revising their Code of Professional Ethics for their members. I was also advised that I was the third consultant so engaged. The other two had been fired, mid-session.

Forewarned, I used a "pre-session" questionnaire regarding the current Code and discovered that there were two separate "camps" within the board. Most supported the decision to revise the Code. About a third of the board thought that revising the Code was "hooey," and that ethics is simply common sense.

I started my presentation with a simple exercise[2]:

> "Raise your hand if you consider yourself to be an ethical person."

Naturally, every hand went up. (Having done this countless times since, I can report that in every instance, nearly every hand always goes up. The exceptions are those reluctant to participate, and those "testing" me, wanting to see what I might say/do if they do not raise their hand).

Then I said,

> "Take one minute and, in no more than 50 words, define what that means: What is an ethical person? What does an ethical person do?"

One minute later, I randomly selected five people in the room and asked that they read what they had written. I recorded their replies on a flipchart. As expected, the five replies were each different from the others.

> Ethical people don't lie, cheat, or steal.
> They do the right thing, even when no one is looking.
> They treat others according to set of principles such as respect, fairness, and integrity.
> They follow policies and procedures.
> They tell the truth, even when it is difficult.

Without commenting on the responses, I addressed the group, saying:

> "My assumption is that we are all ethical. Unethical people typically do not seek nor rise to the positions represented in this room. But, as you can see from the posted responses, we are all "ethical" differently. We embrace common values and principles, but interpret and apply them uniquely. A Code of Ethics is not a tool to teach bad people how to be good. Rather, it fulfills the obligation of the organization to clearly define for its members that, in this group, this is what it means to be ethical."

Substitute "ethics training" for "Codes of Ethics" and this same activity effectively overcomes the reluctance of many boards to engage in ethics training.

Your board may not need "compliance" training to teach them the rules, but they would benefit from a process that helps them reach consensus regarding the principles used to guide their discourse, decisions, oversight, and governance activities. They would benefit from a process that explicitly defines their ethical culture, describing "how things work on our board" so that a true common sense – a common understanding about the ethical underpinnings of the board – can be developed and sustained.

Boards that take the time to deliberate and reach consensus on the values upon which their operational culture rests have an advantage. Once the values are agreed upon, the board can then go on to explore:

> how those values will manifest regarding how decisions get made;
> operational guidelines, such as what constitutes a "conflict of

interest" and how such conflicts ought be resolved; and,
how the board will balance the requirements of law, regulation, shared values, individual values, societal expectations, and organizational effectiveness in their collective decision-making.

That is the ethics training for boards that I am proposing. Provide your board the opportunity to develop and then articulate a consensus–based set of principles, an "ethic" for their unique set of obligations.

Two additional questions for your consideration:

1. At a practical level, how do I, as an ethics/compliance professional, make the case to my board that ethics training is prudent; and,
2. If my argument is successful, just what kind of ethics training do my board members need?

The argument in support of ethics training could begin with the "ethical person" exercise, described above. It can help in making the case that ethics is not simply a matter of applying one's "common sense." It can surface the advantages to your board of agreeing on the governing values and ethical standards that will define their dialog and decision-making. Finally, it can facilitate them agreeing on (and defining in concrete, behavioral language) the values/principles that ought to define their individual and collective actions as a board.

The training could then explore how, individually and collectively, they might integrate that common sense into those actions and how that common ethic will affect their choices. Simple cases could illustrate how a values-based board addresses disagreements, potential conflicts of interest, and pressures for the board and those they govern to perform to expectations, such as those imposed by the media, shareholders, and financial markets.

The training can conclude with an action planning session where the facilitator takes them through the process of applying their agreed-upon principles to real-life decisions.

The outcome of this kind of training is a board that shares a common vocabulary for discussing the ethics of their decisions and actions. They will also have a framework for assessing the ethics of those decisions (i.e., the degree to which a decision conforms to their stated values and principles). Finally, they will have a context for assessing the ethics of the organization they are responsible for overseeing and agreed-to standards for describing what constitutes a strong ethical culture against which to measure those actions. But….

There is always a "but…"

What your board needs to know about compliance and ethics, first and foremost, is that they are not one and the same. Irrespective of whether the board chooses to engage in compliance training, ethics training is absolutely necessary—and not just so they can "check the box." Every board is at risk if they are not clearly focused on the ethical aspects of their working culture and if they are not absolutely certain that they are meeting all of their ethical obligations. Relying on the assumption that, "We are ethical people so we don't need ethics training" is both foolish and dangerous.

Among my favorite colleagues are some who have gone on record as suggesting that board ethics training is not needed. I contend that their remarks may apply to "compliance-oriented" training, but do not apply to training aimed at strengthening the ethical culture of the board itself. In the above, I argue that ethics training (aimed at helping boards facilitate and sustain a strong, values-based culture) makes a significant contribution to the board, its members, and the organization as a whole. I also suggest a process for making that activity both palatable to and effective for your board.

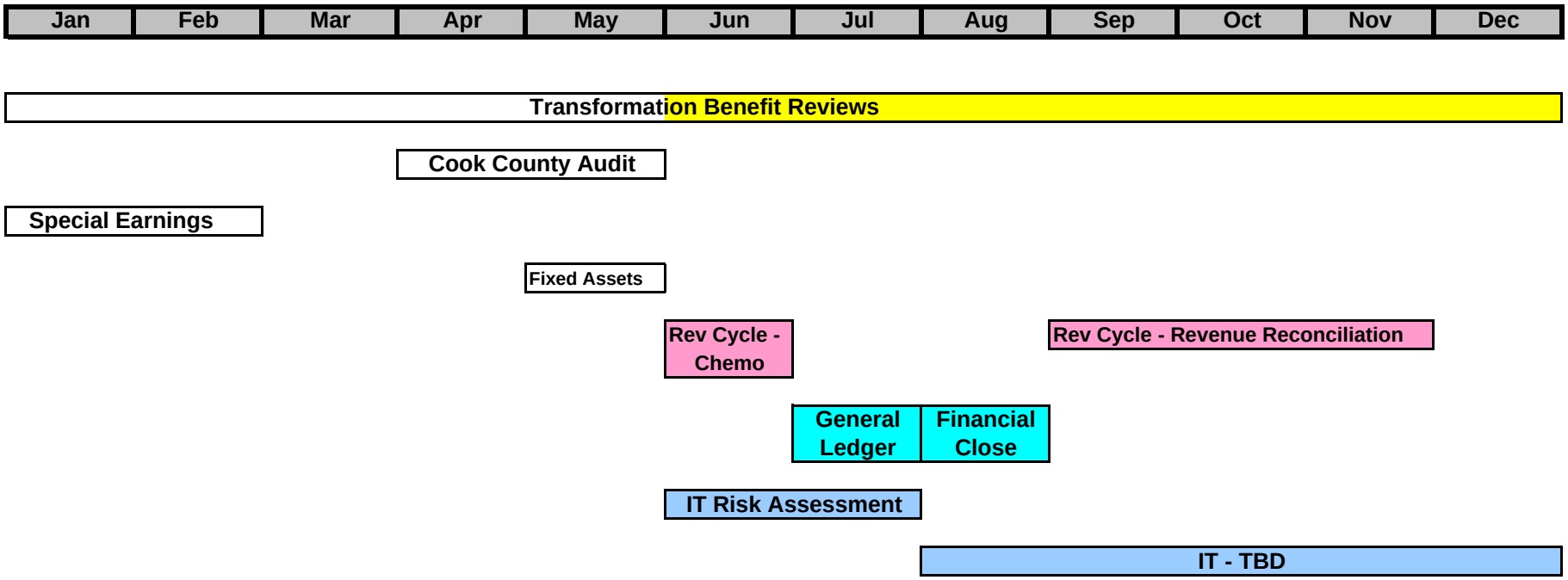
My own experience, as the Chair of a small NGO and advisor to numerous boards (including large, small, local, global, corporate, charitable and professional entities), strongly supports the contention that creating a strong ethical culture in a board ought not be trusted to chance. It requires a deliberate and conscientious effort of leadership to communicate and establish the values-basis for actions and decisions in the boardroom. In all but the rarest of cases, that outcome is more likely when the process is deliberate and facilitated.

We call that "board ethics training."

1. Susan Schultz: *The Board Book: Making Your Corporate Board a Strategic Force in Your Company's Success*. AMACOM, 2000, page 6
2. I include the details of the activity for any readers who would like to use this design in their own organization or practice. Acknowledging its origin would be appreciated.

ATTACHMENT #2

2011 Internal Audit Plan
Status at May 31, 2011



MEMO

Date: 6/01/2011

To: Tom Schroeder

From: John Dalen

RE: CCHHS Internal Audit Dept. Involvement in Preparation of Cook County's Fiscal Year 2010 Comprehensive Annual Financial Report

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Per a request from President Preckwinkle's Office, CCHHS Internal Audit assisted members of the County Comptroller's and County Auditor's staff in preparing the County's Comprehensive Annual Financial Report. Specifically, the following assistance was provided from 4/4/11 through 5/27/11 by CCHHS Internal Audit Dept. staff:

- Compilation of combining agency fund financial statements.
- Preparation of General Purpose Preparer Checklist for attainment of GFOA Certificate of Achievement for Excellence in Financial Reporting.
- Review of above checklist with County Comptroller and follow-up with various County departments.
- Compilation and review of CAFR Notes to Basic Financial Statements.
- Compilation and review of CAFR Management Discussion and Analysis (MD&A).
- Various reviews and troubleshooting of Comptroller's general ledger and trial balance entries and adjustments.

Date: June 2, 2011

To: Michael Ayres

From: Internal Audit

Cc: Jackie Edwards (PwC)
Larry Patrick (PwC)

Subject: PwC Invoice Review

INTRODUCTION

Internal Audit completed certain procedures relating to PwC's November and December 2010 invoices and PwC's January 2011 invoice. The PwC invoices relate to their performance improvement efforts at CCHHS.

Cumulative benefits as reported by PwC from August 2010 through January 2011 equal $57.7 million for revenue cycle and $4.9 million for supply chain for a total of $62.6 million.

1. REVENUE CYCLE

The CCHHS CFO requested that Internal Audit validate PwC involvement in creating their reported economic benefit. In order to accomplish this, Internal Audit's review was designed to provide reasonable assurance cash balances collected on CCHHS patient accounts:

1. Are consistent between PwC's benefit tracker report and CCHHS's patient accounting system,
2. Resulted from involvement by PwC,
3. Resulted in actual cash receipts by CCHHS.

Sample Selection

Internal Audit sampled 53 patient accounts from PwC's benefit tracker report detail. We judgmentally selected accounts to ensure our sample included transactions from all backlog sources identified by PwC. The entire sample covered $2.5 million (8.6%) of the $28.9 million benefit created between October 20, 2010 and January 31, 2011. Internal Audit's sample did not include benefits created prior to October 20, 2010. Our previously completed review of PwC's October 2010 invoice included a sample test of benefits reported by PwC up to October 20th.

Internal Audit Procedures and Results

Procedure 1
Compare the benefit in PwC's benefit tracker report to the cash collected on CCHHS patient accounts as detailed in CCHHS's patient accounting system.

Results: Internal Audit compared the amounts reported in the benefit tracker report to cash collected on patient accounts in CCHHS's patient accounting system. We found all amounts agreed without exception.

Procedure 2
Verify PwC involvement in the billing and collection activities related to patient accounts.

Results: As noted below, Internal Audit identified evidence PwC performed a role in collecting the patient accounts, without exception.

Internal Audit identified 40 patient accounts totaling $2.4 million (96% of sampled benefit) where notes in the CCHHS patient accounting system contained documentation indicating PwC involvement with collecting the account.

For the remaining 13 patient accounts, Internal Audit reviewed minutes from the weekly revenue cycle steering committee meetings and found documentation at the backlog source level indicating PwC involvement in collecting the respective accounts. The weekly revenue cycle steering committee meetings are attended by PwC revenue cycle and CCCHHS leadership teams.

Procedure 3
Verify CCHHS received cash remittances for the sampled patient accounts.

Results: Internal Audit confirmed remittances were received, and the remittances matched the amounts indicated in the CCHHS patient accounting system without exception.

2. SUPPLY CHAIN

PwC's January 2011 invoice reported nine supply chain initiatives with aggregate benefits totaling $4.9 million. Internal Audit's review was designed provide reasonable assurance the reported benefits were:

1. Supported by adequate documentation, and
2. Computationally accurate.

Sample Selection

Internal Audit judgmentally selected three PwC supply chain initiatives for review as follows ($ indicates PwC reported benefit):

1.	Pharmacy initiatives	$3.2 million
2.	Specialty beds	$0.5 million
3.	Suture conversion	$0.1 million

Procedure 1

Obtain PwC documentation supporting the supply chain benefits and discuss with CCHHS management.

For specialty beds and suture conversion, PwC provided Internal Audit with amended vendor agreements.

Internal audit reviewed the documents and discussed the initiatives with CCHHS Office of Performance Improvement. Internal Audit agrees with the conclusions without exception.

For pharmacy initiatives, PwC provided Internal Audit with a spreadsheet listing prescription drug benefits by individual drug.

Internal Audit reviewed the documents and discussed the initiatives with CCHHS Pharmacy management and CCHHS Office of Performance Improvement. At the time of Internal Audit's review, CCHHS management and PwC management were in the process of evaluating the method used to measure pharmacy-related performance improvement benefits. PwC management and CCHHS management subsequently worked together to refine the pharmacy benefit measures. PwC presented CCHHS management with a measure indicating pharmacy benefits of $2.3 million are attributable to PwC efforts.

Subsequent to the conclusion of Internal Audit's review of pharmacy benefits, PwC provided Internal Audit with documentation in support of the $2.3 million pharmacy benefit. Internal Audit will perform additional review procedures around the $2.3 million of claimed benefit and report back to CCHHS management.

Procedure 2
Re-compute the reported benefit using the documentation provided in Procedure 1 above.

Internal Audit re-computed the benefit for specialty beds and suture conversion without exception.

We were unable to re-compute the pharmacy benefit using the documentation provided. As noted above, Internal Audit will re-compute the benefit with the revised documentation and report back to CCHHS management.

3. HOURLY FEES

Pursuant to CONTRACT FOR SERVICE DOCUMENT No. H10-25-113 PERFORMANCE IMPROVEMENT IMPLEMENTATION SERVICES FOR COOK COUNTY HEALTH AND HOSPITALS SYSTEM WITH: PRICEWATERHOUSECOOPERS LLC (the "Master Agreement"), after the Initial Benefit Threshold of $10 million is achieved, the Master Agreement allows PwC to bill CCHHS at an hourly rate of $150 subject to the Maximum Monthly Fee and the Carry Forward provisions. The $10 million threshold was achieved as noted in the October 2010 PwC invoice.

Internal Audit reviewed PwC's accumulated project hours in PwC's project management time keeping system through December 31, 2010 for six work streams. The hours reported in the December invoice submitted by PwC to CCHHS matched the hours in PwC's project management time keeping system. We computed the product of the monthly project hours and the hourly rate and noted the results match the December invoice.

Internal Audit notes PwC has invoiced CCHHS $12.5 million through January 2011 under the Master Agreement. Realized benefits per the January 2011 invoice total $62.6 million (which may be subject to adjustment for reported pharmacy initiatives) generating a performance fee due PwC of $10.4 million. The Master Agreement allows hourly invoicing to exceed performance fees. However at the termination or expiration of the Master Agreement, any payments by CCHHS to PwC in excess of the performance fee earned must be refunded by PwC to CCHHS.

The CCHHS Chief Financial Officer indicated invoices are not paid until performance fees achieved based on realized benefits are sufficient to cover the invoice.

Internal Audit reviewed invoices paid by CCHHS to PwC through January 31, 2011 and noted the payments made by CCHHS to PwC did not exceed the performance fee earned by PwC through this time period.

4. ADDITIONAL CONSIDERATIONS

PwC Master Agreement

Pursuant to the Master Agreement Section I(4)(j)(2), PwC is to provide CCHHS with a credit of $3.2 million amortized over a period of 24 months against Performance Fees for work where it is difficult to separately identify benefit attributable to PwC's work and that is attributable to prior work.

Internal Audit was not able to identify the subject credits on PwC invoices submitted to CCHHS.

CHHHS's CFO indicated he will apply cumulative monthly credits of approximately $1 million to the March 2011 invoice and he directed PwC to ensure subsequent invoices reflect the monthly amortized credit until the total $3.2 million credit is fully amortized.

RC18 SOW: CCHHS Quick Hit Priorities and Reduction of Backlogs

The subject SOW indicates the baseline metrics that will be used to measure performance related to this SOW will vary depending on the nature of the backlog or quick hit improvement and will include one or more of the following:

- If process not operational when backlog or quick hit identified, the baseline will be zero;

- If process was operational when identified, then the baseline metric will be the average historical monthly cash collections for each specific area as identified.

Based on Internal Audit's review of revenue cycle benefits thus far, PwC indicates the benefits identified on the benefit tracker report relate to non-operational processes and thus the baseline in these cases should be zero. If CCHHS management concurs, both parties should consider documenting this in a memo of understanding.

CONCLUSION

Based on the procedures Internal Audit performed, we conclude:

With respect to the revenue cycle, for the November and December 2010 invoices and the January 2011 invoice, PwC's subject benefit tracker report can be relied upon to measure benefits achieved by PwC from their effort to collect amounts due CCHHS from outstanding patient accounts.

With respect to the supply chain initiatives listed on the January 2011 invoice, Internal Audit will perform additional procedures around the proposed $2.3 million benefit attributed to pharmacy initiatives.

Finally, since the PwC invoices submitted to CCHHS to date do not reflect the contractual credits due CCHHS, CCHHS management should note these credits and ensure final benefit computations reflect these amounts.

ATTACHMENT #3

Deloitte.

Cook County Health and Hospitals System
Status Meeting
Fiscal Year Ended November 30, 2010

June 7, 2011

Deloitte & Touche LLP

This report is intended solely for the information and use of management and the Audit Committee of Cook County Health and Hospitals System and is not intended to be, and should not be, used by anyone other than these specified parties.

Cook County Health and Hospitals System Audit

- Cook County Health and Hospitals System significant audit areas
  - Patient accounts receivable
  - Contractual allowance and bad debt reserves
  - Patient revenue cycle
  - Deferred revenue
  - Sales tax revenue
  - Third-party reimbursement

- Additional significant audit areas tested at the County
  - Self-insurance liabilities
  - Pension obligation
  - Cash and investments
  - Payroll expenditures and related liabilities
  - Debt transactions
  - Capital transactions
  - JD Edwards Financial System

Cook County Health and Hospitals System Audit con't

- Audit specialists used
  - Information technology — Understand Siemens system controls as well as Lawson implementation (and JD Edwards at County)
  - Third-party reimbursement — Analyze cost report settlement activity
  - Actuaries — Review outside actuary's report on medical malpractice and pension

- Management judgments and accounting estimates related to CCHHS
  - Revenue recognition and related allowances for patient care receivables
  - Third-party reimbursements

Remaining open audit areas

Open areas:

- Health
  - Capital asset testing
  - Journal entry testing
  - Contractual expenses
  - Sales tax
  - Reporting
  - Quality control review
- County*
  - Accrued salaries and accrued vacation
  - Pension liability and expense — received actuarial report
  - Manager and partner reviews
  - Reporting
  - Quality control review

* Tested by the County audit team as records are with the County.

Management recommendations on internal control

- Topics as of June 7, 2011:
  - Improvements from prior year:
    - Accounts receivable and bad debt allowances – documented processes for determining valuation allowances
    - Timely review of cash reconciliations
  - Financial reporting:
    - Accounts payable cutoff
    - Fixed asset cutoff
    - Capitalization of Lawson
    - Oversight and review of Oak Forest accounting estimates (contractual allowance and assessment tax accruals)
  - Inventory management
  - Information technology — system access

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Member of Deloitte Touche Tohmatsu

ATTACHMENT #4

	Category: SYSTEM-WIDE POLICY	
Subject: ADMINISTRATIVE OPERATIONS	Page 1 of 5	Policy #: <<TBD>>
Title: CONFLICT OF INTEREST	Approval Date:	Posting Date:

PURPOSE

The purpose of this policy is to help ensure that the business and professional activities of the Cook County Health & Hospitals System (CCHHS) are conducted free of actual conflicts of interest, or the appearance of any conflicts of interest, and to protect the interests of CCHHS when it is contemplating entering into a transaction or arrangement.

AFFECTED AREAS

This policy affects Covered Persons within all CCHHS affiliated operating units including: John H. Stroger, Jr. Hospital of Cook County, Oak Forest Hospital of Cook County; Provident Hospital of Cook County; Cermak Health Services of Cook County, Ruth M. Rothstein CORE Center; Ambulatory & Community Health Network and Cook County Department of Public Health.

DEFINITIONS

A. Conflict of Interest: A conflict of interest may exist when:
   a. a Covered Person, or his/her Personal Relationships, is doing business with CCHHS or any of its operating units;
   b. a Covered Person, or his/her Personal Relationships, has an interest in any issue, item, matter or transaction that involves CCHHS or its operating units or that is under consideration by CCHHS or its operating units;
   c. a Covered Person, or his/her Personal Relationships, is in a position to influence business or other decisions including patient access or care of CCHHS in ways that could lead or appear to lead to the personal gain or advantage of such person, his/her Personal Relationships, or outside entities.

B. Covered Person: All officers, directors, Board committee members, advisory councils, employees, members of the CCHHS medical staff or house staff, researchers, students and contractor personnel carrying out the business or professional activities of the CCHHS.

C. Doing Business: Having or negotiating the creation of a contract or agreement, whether verbally or in writing, that involves the commitment of (either in a single transaction or a combination of transactions) $2,500 or more of CCHHS funds or funds controlled by CCHHS.

D. Gift: Any gratuity, discount, entertainment, hospitality, loan, forbearance, or other tangible or intangible item having monetary value including, but not limited to, cash, food and drink, and honoraria for speaking engagements related to or attributable to a person's status as a Covered Person.

E. Interest: Any legal or equitable economic interest (whether or not subject to an encumbrance or a condition), activity, arrangement, or relationship, which is owned or held, either directly or indirectly, by a Covered Person (or through a Personal Relationship or Person of Influence) with any entity with which

CCHHS has or may in the future be doing business. The term "Interest" includes, but is not limited to the following examples,

a. An ownership interest; serving as a member, officer, director, committee member, partner, paid consultant, or employee of the same or a related business, or having a financial interest in the same or a related business;
b. Participation in any outside activity that could interfere significantly with the Covered Person's work time obligation;
c. Receipt of fees, or other compensation or remuneration from an entity as a result of professional services, consulting, speaking engagements, royalties, patents, copyrights, or other intellectual property rights.

F. Personal Relationships: Covered Person's spouse, children, parents, siblings, grandchildren, and their spouses; the Covered Person's spouse's parents, siblings, children, grandchildren, and their spouses; and any Person of Influence.

G. Person of Influence: a person with a close personal or business connection with a Covered Person who would likely influence the decisions of the Covered Person.

POLICY

Covered Persons shall not be involved in any situation or circumstance that would cause the Covered Person to have a conflict of interest. This prohibition includes the Personal Relationships of the Covered Person.

No Covered Person shall accept any gift from any entity, or an employee, contractor or agent of an entity, with which CCHHS or its operating units is doing business or with which CCHHS has done business within the past three years.

Covered Persons are responsible for addressing conflicts of interest, whether actual or those that have the appearance of a conflict of interest. Covered Persons must comply with the provisions of this policy.
The CCHHS Conflicts of Interest Policy covers the following areas:

1. Conflicts of Interest in Day-to-Day Business Operations of CCHHS Affiliates
2. Conflicts of Interest in Patient Care
3. Conflicts of Interest in Research Activities
4. Conflicts of Interest in Educational Activities

All Covered Persons shall preserve and protect the interests and assets of CCHHS. The business and professional activities of CCHHS must be conducted in the best interests of CCHHS, without favoritism or preference based on personal considerations. Accordingly, each Covered Person must avoid situations, which may give rise to a Conflict of Interest or the appearance of a Conflict of Interest.

CCHHS has adopted a Standard of Conduct (Code of Ethical Conduct) that supplements the Cook County Ethics Ordinance. This defines CCHHS' standards for ethical behavior by CCHHS Personnel in carrying out CCHHS operations. Among other things, the Code of Ethical Conduct is designed to protect the integrity of clinical decision-making. Patient care decisions must be based on the health care needs of the patient, independent of compensation, financial arrangement or favor that may benefit the health care provider or CCHHS.

Research activities at CCHHS must be carried out with the utmost integrity. All research activities must be approved in advance by the Institutional Review Board of the Cook County Health and Hospital System and by CCHHS management.

Educational activities (including professional and public education) at CCHHS must be free from bias and carried out in a manner that serves the educational component of CCHHS' Mission and responsibilities as a public health system, and not the personal interests of any Covered Person.

Duty to Disclose: Covered Persons have a duty to disclose the existence of a possible Conflict of Interest and all material facts relating to the possible Conflict of Interest, as provided in this policy. No Covered Person who has or may have a Conflict of Interest with respect to a transaction or decision shall participate in the transaction or decision unless authorized to participate by Corporate Compliance.

PROCEDURE

A. The Conflict of Interest process for CCHHS, including Disclosure Statements and conflict resolution, shall be coordinated by the System Corporate Compliance Office, in consultation with the Office of General Counsel. Questions regarding the Conflict of Interest Policy should be directed to the Corporate Compliance Office.

B. Required Reporters. The following Covered Persons are required to complete disclosure forms on an annual basis:
    1. Board of Directors members and committee members appointed by the Board
    2. Management and individuals in leadership positions
    3. Supply Chain Management personnel, members of committees charged with selection of products or services to be purchased and anyone in a position to influence purchasing decisions
    4. Any CCHHS personnel who have commitments or relationships with competing organizations
    5. Any CCHHS personnel who have outside employment relationships with businesses that seek to do business with CCHHS
    6. Any CCHHS personnel who previously had a conflict identified.

C. Disclosure Statement (Conflict of Interest Disclosure Statement): Annually a Covered Person who is a Required Reporter must accurately complete a Disclosure Statement and affirm that they: (i) have received a copy of this Conflict of Interest Policy; (ii) have read and understand this Policy; and (iii) agree to comply with this Policy. Covered Persons will submit the Disclosure of Interests Statement on a timely basis to the CCHHS Corporate Compliance Office.

D. Duty to Update Disclosure Statement: It will be the continuing duty of each Covered Person who is sent such a Disclosure Statement to advise the Chief Compliance Officer within 10 business days of the occurrence of any event that would have been described in the COI Disclosure Statement had it occurred or been known at the time the COI Disclosure Statement was originally completed.

E. Addressing a Potential Conflict of Interest:

    1. If the Covered Person who may have a Conflict of Interest is a Board or Board Committee member or a member of executive management, the Covered Person shall report the Conflict to the Chief Compliance Officer. The Chief Compliance Officer, in consultation with the CCHHS Office of General Counsel, will review the facts of the situation and make a recommendation to the Chief

Executive Officer (or his/her designee), or in the case of a Board member, the Chairman of the Board (or his/her designee), as to whether a potential Conflict exists.

2. The CEO (or his/her designee), for those Covered Persons who are subject to his/her supervision, shall decide whether the potential conflict of interest that has been disclosed amounts to an actual conflict of interest. If it is determined that an actual conflict of interest exists then the following procedures shall be taken:

   a. The CEO (or his/her designee), shall direct that the Covered Person refrain from participating in the transaction or decision.

   b. The CEO (or his/her designee), may impose additional safeguards concerning the transaction or decision in order to protect CCHHS' interests. These may include, without limitation, (i) appointing a disinterested person or committee to oversee or review the proposed transaction or arrangement, or (ii) deciding not to pursue the transaction or arrangement.

3. In the case of a Board member, the Chairman of the Board shall allow the Board member to disclose the facts surrounding the potential conflict of interest to the Board of Directors in executive session if he/she so desires. Thereafter, the Board member with the potential conflict shall leave the room while the Board of Directors decides whether an actual conflict of interest exists. If it is determined that an actual conflict of interest exists then the following procedures shall be taken:

   a. The Chairman of the Board shall direct that the Board member refrain from participating in the transaction or decision.

   b. The Chairman of the Board may impose additional safeguards concerning the transaction or decision in order to protect CCHHS' interests. These may include, without limitation, (i) appointing a disinterested person or committee to oversee or review the proposed transaction or arrangement, or (ii) deciding not to pursue the transaction or arrangement.

F. Complete and accurate records shall be maintained of all investigations and determinations under this Policy.

POLICY UPDATE SCHEDULE
At least every three (3) years, or more often as appropriate.

POLICY LEAD	Cathy Bodnar, MS, RN, CHC CCHHS, Chief Compliance Officer
REVIEWERS	Office of General Counsel
APPROVAL PARTY	Terry Mason, MD CCHHS, Interim Chief Executive Officer Electronically Approved <<INSERT>> Audit & Compliance Committee of the Board of Directors

Electronically Approved <<INSERT>>

REVIEW HISTORY
Supersedes:
Written:

REGULATORY REFERENCES:

Cook County Ethics Ordinance, Section 2-578 (*Conflicts of Interest*)
Federal Sentencing Guidelines
Federal Anti-Kickback Statute (Stark)
National Institute of Health Guidance
American Medical Association Guidance
PhRMA Code on Interactions with Healthcare Professionals
OIG Self Disclosure Protocol
Physician Payment Sunshine Act
Fraud Enforcement and Recovery Act of 2009
Joint Commission Standard LD.04.02.01

POLICY REFERENCES:

CCHHS Code of Conduct

ATTACHMENT #5

Special Earnings

CCHHS Interim Chief Medical Officer Update

Special Earnings
CCHHS Interim Chief Medical Officer Update

CMO Overview:

- Response to Internal Audit report dated March 4, 2011
- Review of “high usage” clinical areas
- Drivers behind special earnings
- Go-forward policies

Special Earnings
"High Usage" Clinical Areas

CMO Overview:

• Five practice areas represent 50% of special earnings paid to physicians:

Critical Care	$0.9mm
NICU/Neonatal	0.7
Cermak	0.6
RHS	0.3
ASC	0.2
Total "Top Five"	$2.7mm

Special Earnings
"High Usage" Clinical Areas - Details

Clinical Area	Clinical Need
Critical Care	Coverage for six physician vacancies at Provident and Oak Forest. Special earnings will trend down with strategic plan implementation.
Cermak	Coverage for staff shortage (approx. 4 FTEs) for evenings and weekends.
ASC	Coverage for reduced staff.
NICU/Neonatal	Primarily for reimbursed services at three non-CCHHS hospitals.
RHS	Per-procedure compensation.

Special Earnings
Summary of Policy Provisions

- Compliance with work-related provisions of Collective Bargaining Agreements
- Limits on consecutive hours worked when the shift includes hours worked for special earnings
- Limits on cumulative special earnings hours in a pay period
- Management not eligible (exception may be granted with CMO approval)
- Swipe in, swipe out for shifts where work is eligible for special earnings
- Per-procedure fee restricted to RHS only
- Department Chair:
  - Approval of work schedules when work eligible for special earnings is planned/incurred
  - Approval of special earnings pay rates when not specified in collective bargaining agreement
  - Review of budget and actual spend

Date: June 1, 2011

To: Dr. Terry Mason
Michael Ayres

From: Dr. Claudia Fegan

Subject: **Special Earnings**

Background

On March 4, 2011, CCHHS Internal Audit issued a report to CCHHS management regarding Internal Audit's review of special earnings paid to CCHHS clinical staff.

Briefly, at the November, 2010 meeting of the CCHHS Board of Directors, Director Carvalho inquired of the CCHHS Chief Financial Officer if special earnings were paid to physicians in 2010. Director Carvalho also inquired if special earnings were included in the 2011 budget. Subsequent to the November Board meeting, Director Carvalho requested a list of physicians who earned special earnings in 2009 and 2010 and explanations of the reasons for the special earnings. Director Greenspan requested Internal Audit collect the information requested by Director Carvalho and that Internal Audit also conduct a review of special earnings practices at CCHHS.

Internal Audit's report contained recommendations for management to consider. The recommendations primarily focused on; (1) adoption by management of formal policies and procedures around the payment of special earnings, (2) including in subsequent physician collective bargaining agreements terms for administering physician work subject to special earnings, and (3) benefits which might be obtained from a more robust time and attendance system when applied to managing work subject to special earnings.

Interim Chief Medical Officer Review

I believe the first Internal Audit recommendation falls under my responsibility as Interim Chief Medical Officer, while issue #2 belongs to Human Resources and issue #3 belongs to Humans Resources and Finance.

Before developing the policies and procedures to be used to administer special earnings for CCHHS physicians, I completed a detailed review of physician staffing practices which give rise to special earnings.

Based on my review, I conclude roughly 50% of special earnings paid to physicians in 2010 occurred in five clinical practice areas, as follows:

(See next page)

Practice Area	Special Earnings Incurred ($ million)
Critical Care	$0.9
NICU/Neonatal	$0.7
Cermak	$0.6
RHS	$0.3
ASC	$0.2
Total “Top Five” Practices	$2.7

Critical Care, Cermak, and ASC represent physicians filling in for staff shortages.

About 90% of the Critical Care dollars are paid to Stroger, Provident, and Oak Forest physicians for services performed at Provident and Oak Forest. We have six critical care physician vacancies at these two locations. We decided not to fill these positions due to the strategic repositioning of services to be provided at Provident and Oak Forest. The need to incur special earnings at these two locations will wind down as we transform these locations to regional outpatient centers.

Cermak is statutorily required to maintain specific physician coverage 24/7. Clinical management at Cermak estimates they would need an additional four FTEs to meet evening and over night clinical requirements. Cermak utilizes both Cermak and Stroger physicians to backfill for required coverage needs. To date, this additional work burden has been handled by a small number of physicians who volunteer to work additional shifts. While I don’t feel we need to hire additional staff at Cermak at this time, I would recommend the work load be spread over a greater number of physicians to ensure a consistent level of high quality care to Cermak patients. We would thus continue to incur special earnings for these services.

ASC has lost 6 physicians in the past year. Special earnings have been incurred to supplement for these staff shortages, although nowhere near the extent of the capacity of the lost staff. As you know, the volume of patients coming through ASC is directly related to the ASC staff. We could reduce special earnings by further cutting back ASC hours. Alternatively, we could increase patient volumes by increasing physician coverage by either moonlighting (e.g. special earnings) or new hires. I believe this is a strategic issue which we will need to discuss further.

NICU/Neonatal is primarily (90%) for physician services provided to three hospitals outside of CCHHS and for which CCHHS receives reimbursement from the respective non-CCHHS hospital.

RHS represents per-procedure payments to our physicians. Procedure rooms are only available from 4:00 pm to 7:00 pm, Monday through Thursday. RHS management feels this physician compensation arrangement is the best way to incent efficient use of resources. This is the only instance for which I am aware where such a compensation agreement exists within CCHHS. As a side note, patients pay a co-payment equal to 50%

of the per-procedure rate paid to the physician. Additionally, the Department of Gynecology is the recipient of a number of grants, some of which support the work of RHS. I am recommending we allow this compensation practice to continue going forward.

Policies and Procedures

Based on what I learned from my review, I have drafted policies and procedures for CCHHS management's review. These policies and procedures will enable management to strengthen administrative and monitoring controls around situations where we believe special earnings pay is warranted.

Highlights of the proposed policy include:

- Attending and House Staff physician compliance with provisions of their respective collective bargaining agreements.
- Limits on consecutive work hours where the consecutive hours include time subject to special earnings.
- Limits on cumulative work hours eligible for special earnings in a given pay period.
- Exclusion of physicians who occupy management positions (exceptions may be granted by CCHHS Chief Medical Officer).
- Department Chair review and approval of physician's work schedule when such physician is scheduled to work hours eligible for special earnings.
- Department Chair approval of special earning pay rates, when such rates are not consistent with respective collective bargaining agreements.
- Physician swipe in and swipe out of the time and attendance system for shifts where work is eligible for special earnings.
- Department Chair review and approval of annual special earnings budget as well as periodic review of actual special earnings incurred compared to budget.
- Per-procedure special earnings limited to RHS only.

Conclusion

In the clinical areas examined, I conclude special earnings were primarily incurred to cover staff shortages. Lesser amounts were used to compensate physicians for work performed outside of CCHHS and for which reimbursement is made to CCHHSS. Finally, one practice area provides a per-procedure form of compensation in addition to base pay.

Given the varying circumstances in which physicians are eligible for special earnings, I have developed policies and procedures to effectively administer and monitor the work effort. These policies will be communicated to respective Department Chairs and their staff with an effective operational compliance date of December 1, 2011.

	Category: System-Wide Policy	
Subject: Payroll	Page 1 of 4	Policy #:
Title: SPECIAL EARNINGS	Approval Date:	Posting Date:

PURPOSE

From time to time, certain Cook County Health and Hospitals System ("CCHHS") employees perform work in addition to, or outside of their current job responsibilities and for which they are entitled to receive compensation, either pursuant to a collective bargaining agreement ("CBA") or absent a CBA, at the discretion of Hospital Administration. Because this work is often times outside of an employee's current job responsibilities, and given existing limitations on CCHHS's time and attendance system, it is necessary to schedule work time, track work time, apply pay rates, and facilitate calculation of certain earning types in a unique category in the payroll system. This unique category is referred to as special earnings. The purpose of this policy is to provide standards under which an employee is eligible for special earnings and to set forth the requirements for documenting, authorizing, and approving special earnings.

AFFECTED AREAS

This policy applies to CCHHS:

- Nurses, technicians, therapists, clinicians, and trades covered by CBAs,
- House Staff Physicians (fellows and residents) and Attending Physicians covered by CBAs,
- Attending Physicians who are not covered by a CBA.

POLICY

1. CCHHS nurses, technicians, therapists, clinicians, and trades covered by CBAs are eligible for special earnings for shift differentials, on-call pay, and coverage for in-charge staff. Any payment of special earnings must be consistent with provisions of the employee's respective CBA.

2. House Staff Physicians are eligible for special earnings when they work additional shifts or perform clinical procedures outside of their regularly scheduled rotations and consistent with the CBA covering House Staff. Opportunities to earn special earnings shall not be offered to House Staff Physicians until all House Staff Physicians qualified to perform the work subject to special earnings are scheduled to work their minimum required work week specified in the CBA, or as specified by the respective Resident Review Committee ("RRC").[1]

3. Attending Physicians are eligible for special earnings when they work additional shifts or perform clinical procedures outside of their regularly scheduled rotations and consistent with their CBA.[2]

[1] The CBA defines moonlighting as; *"when Hospital administration decides that house staff physicians are needed to perform additional work within the Hospital for extra compensation"*. The Collective Bargaining Agreement further states *"House staff physicians will receive a minimum of $57.22 per hour of moonlighting work"*.

[2] The CBA covering Attending Physicians states; *"the normal work week will consist of up to fifty (50) hours per week, but as professionals in the health care industry, Attending Physicians will work such hours as are necessary to fulfill their patient care responsibilities, as well as being on call as needed, by rotation as needed"*.

Physicians may not work more than 12 hours per week and may not work more than 24 hours per pay period for work entitled to special earnings.

4. Employees deemed by Hospital administration to be management are not eligible for special earnings. This includes, but is not limited to Department Chairs, Division Chairs, and nursing and clinical management. An exception to this policy #4 may be granted in writing by the CCHHS Chief Medical Officer.

5. With respect to House Staff Physicians and Attending Physicians, when the need to incur special earnings is predictable due to physician staffing levels or clinical needs, the respective affiliate Chief Medical Officer must review and approve physician work schedules in advance to ensure the minimum required work week is adhered to. In other situations, the respective Department Chair is responsible for approving work eligible for special earnings on a case-by-case basis. The Department Chair must retain documentation indicating his/her approval of work for which special earnings are paid.

6. With respect to House Staff Physicians and Attending Physicians, pay rates for work eligible for special earnings must be consistent with the respective CBA. When the CBA is not specific as to the pay rate for work eligible for special earnings, the CCHHS Chief Medical Officer and the CCHHS Chief Financial Officer will approve such rates as submitted by the respective affiliate Chief Medical Officer. These rates should generally be consistent with hourly pay rates for CCHHS physicians performing similar work. The rates must be updated and approved at least annually. All pay rates represent hourly rates, with the exception of Reproductive Health Services, which will be at a per-procedure rate and subject to the approval process described above.

7. All employees receiving special earnings must swipe in and swipe out of the time and attendance system for shifts when work is performed and such work is eligible for special earnings. An employee receiving special earnings must ensure a record of his/her hours worked is maintained.

8. The annual budget for special earnings must be reviewed and approved by the respective affiliate Chief Medical Officer, affiliate Chief Nursing Officer, as well as the CCHHS Chief Medical Officer and the CCHHS Chief Clinical Officer.

9. On a quarterly basis, the CCHHS Chief Medical Officer will review and compare actual special earnings incurred to date to the pro-rata year to date budget. Differences of +/- 5% or more will be reported to the CCHHS Chief Financial Officer.

Full compliance with the above policies will be complete by December 1, 2011. This will ensure sufficient transition time for practice areas that will require significant adjustments to existing staff schedules to meet policy requirements.

DEFINITIONS

1. Attending Physician – a physician or dentist employed by the County of Cook.

2. Collective Bargaining Agreement – a bargaining agreement between a bargaining unit and the County of Cook. Please refer to the section below titled REFERENCES.

3. Hospital Administration – an employee of CCHHS or any of its affiliates, including Chief Operating Officer, Chief Medical Officer, Chief Clinical Officer, or Chief Nursing Officer.
4. House Staff Physician – post graduate level physician or dentist (e.g. interns, residents, and fellows).

PROCEDURE/PROCESS

Nurses, technicians, therapists, clinicians, and trades

1. Supervisors prepare staff schedules and complete time sheets.
2. Employees swipe in and swipe out at the conclusion of his/her shift.
3. Supervisors forward time sheets to departmental time keepers.
4. Timekeepers compute on-call and in-charge pay. If differential is due to an employee for working outside of his/her regularly scheduled shift, the timekeeper also computes amounts due the employee.
5. Timekeepers compute the total amounts noted above and enter the amounts for each employee into the tima and attendance system according to bi-weekly payroll processing cycles.
6. Payroll Department processes bi-weekly payroll.

Attending Physicians and House Staff Physicians

1. Department Chairs or their designees prepare bi-weekly physician schedules.[3]
2. Department Chairs or their designees identify the need for clinical coverage which would require physicians to work beyond the normal work week requirements specified in the collective bargaining agreement. The proposed staffing plan is forwarded to the respective Department Chair.
3. The Department Chair approves the staffing plan and retains a copy.
4. At the conclusion of the bi-weekly period, the Department Chair verifies physician hours worked, computes the amount due each physician for work beyond the normal work week, and forwards a signed request to the Payroll Department requesting amounts computed are reflected in the next payroll run.
5. In situations where unplanned need for physician coverage is required, the Department Chair may authorize the work and compensate physicians accordingly, provided best efforts are made to adhere to the minimum work week requirements.
6. On a quarterly basis, Department Chairs will review and compare actual special earnings incurred to date to the pro-rata year to date budget. Differences of +/- 5% or more will be reported to the CCHHS Chief Medical Officer.

[3] The CBA covering Attending Physicians states*; "Attending Physician schedules shall be posted for the upcoming month at least two weeks in advance of the beginning of the month, including the schedule for moonlighting, rounds, and holidays"*.

CROSS REFERENCES <<insert relevant CCHHS policies or procedures>>

REFERENCES

Collective Bargaining Agreement Between Housestaff Association of Cook County and County of Cook

Collective Bargaining Agreement Between Licensed Practical Nurse Association of Illinois, Division I and County of Cook

Collective Bargaining Agreement Between National Nurses Organizing Committee and County of Cook

Collective Bargaining Agreement Between Service Employees International Union, Local 20, CTW/CLC and County of Cook Ambulatory Community Health Network (ACHN) (Representing Attending Physicians)

Collective Bargaining Agreement Between Service Employees International Union, Local 20, CTW/CLC and County of Cook Cermak Health Services (Representing Attending Physicians)

Collective Bargaining Agreement Between Service Employees International Union, Local 20, CTW/CLC Formally Service Employees International Union, Local 73-HC, AFL-CIO, CLC and County of Cook (Oak Forest Hospital Physicians)

Collective Bargaining Agreement Between Service Employees International Union, Local 20, CTW/CLC and County of Cook Provident Hospital (Representing Attending Physicians)

POLICY UPDATE SCHEDULE
At least every three (3) years, or more often as appropriate.

POLICY LEAD	Dr. Claudia Fegan CCHHS Interim Chief Medical Officer
REVIEWER(S)	CCHHS Office of the General Counsel CCHHS Chief Financial Officer
APPROVAL PARTY(IES)	Dr. Terry Mason CCHHS Interim Chief Executive Officer

REVIEW HISTORY
Supersedes:
Written:

ATTACHMENT #6

BRIEFING NOTE

Development of Extramural Funding:
Proposal to Establish a Centralized Sponsored Programs Administration at CCHHS

Background

CCHHS currently conducts programs funded by approximately $50 million a year from outside sources to provide clinical care and undertake clinical research programs at CCHHS facilities. These extramurally sponsored programs enable CCHHS to deliver care outside of the fee-for-service reimbursement model for example to HIV/AIDS patients at CORE Center, for public health programs and to provide our patients with access to cutting edge novel therapeutics and diagnostics through clinical research programs.

CCHHS does not provide centralized financial oversight, development or support for extramural sponsored programs. The vast majority of these functions are currently provided by an outside organization, the Hektoen Institute of Medical Research. Although the relationship with Hektoen is long-standing, it has become strained due to a lack of transparency and accountability. Internally, the Cook County Department of Public Health and the CORE Center have developed capabilities to allow them to make applications, monitor and issue reports on sponsored grant awards. Neither the external arrangement nor the internal structure provides adequate support to individual clinicians at CCHHS who wish to be involved in clinical research. Lastly, other than CCHHS's highly effective Institutional Review Board which monitors human subject protection, CCHHS lacks central oversight, or clear knowledge at the executive level, of the financial and operational parameters of the grants that are being operated at CCHHS.

As part of the transformation project started in the second half of 2010 a workgroup was established comprising several senior clinical faculty and administrators. Their charge was to look at the way extramurally sponsored programs are currently conducted at CCHHS and to make recommendations for improvements.

Infrastructure Enhancement for Targeted Revenue Opportunity

The workgroup examined the current internal and outsourced infrastructure of the administration of extramural sponsored programs. The workgroup determined that while Hektoen provided meaningful benefits that reduce certain administrative and bureaucratic burdens, Hektoen operates at a level of independence and indifference to CCHHS' objectives of establishing greater financial responsibility and accountability and to fostering aligned growth. Hektoen's behaviour also creates jeopardy of regulatory and grant compliance problems for CCHHS.

The workgroup conducted an analysis of current grant availability and discovered that, from the main federal sources alone, there were over 1,300 active RFAs (Request For Applications) on offer, of which at least 1/3 rd were appropriate for CCHHS. This list was refined further by consideration of CCHHS's current strengths and centers of excellence. The result was a targeted list of 100 grant opportunities worth over $200 million in total over the lifetime of the awards equating to $50 million a year in additional revenue to CCHHS. Since conducting that analysis several more highly relevant RFAs have been published and a number of RFAs have expired and been reissued. The availability of suitable grants should not be a limiting factor to growing CCHHS's portfolio of sponsored programs.

Proposed Future Operating Model

The recommendations made by the workgroup of clinicians and administrators were directed to achieving a future operating model that would facilitate the pursuit of these targeted grants and ease their operation once awarded, without impinging on the current processes that are succeeding and without being burdensome to faculty.

The future model adds two new management entities that represent a strong collaboration between the administrative and medical professionals at CCHHS that will be focused on acquiring and operating new sponsored grants.

1) Sponsored Programs Committee: SPC will comprise of medical faculty and senior administrators. Their mission is to encourage, and actively support extramurally funded projects, to foster collaboration, and to ensure alignment of activities with the mission and values of CCHHS.
2) Office of Sponsored Programs: OSP will provide day to day financial and operating oversight for sponsored programs conducted at CCHHS. The OSP will report to the CFO and will comprise of a three person team with the following primary functions;

- Manage internal and outsourced grant accounting and administration.
- Work with external fiscal agents and collaborators on pre-award and post-award responsibilities.
- Assist investigators in writing non-technical portions of grants
- Develop and maintain a repository of needed demographic data on CCHHS facilities / patients, proformas and precedent documents to facilitate grant writing.
- Derive budgets for protocols/programs.
- Streamline internal approvals.
- Facilitate the operation of institutional research policies such as protected time and distribution of Indirect Costs recovered from sponsors.

These additional resources will be funded from incremental indirect cost recoveries generated from more efficient revenue capture on existing grants and the increased volume of extramural sponsorship.

In support of these new procedural elements the existing policies relating to research at CCHHS will be reviewed and updated if necessary.

A full analysis of the business case for the centralized administration of sponsored programs, along with the draft mission and charter of the proposed committee and draft policies are available for board review.

Collaborations

The workgroup also identified the need for creating an improved framework for collaboration with academic institutions locally, regionally and nationally. CCHHS already participates in a number of national cooperative research programs and this is a trend that is actively encouraged by grant sponsoring institutions. We are exploring the expansion of a number of our existing collaborations.

Fiduciary Agents

It is anticipated that for the foreseeable future it will be necessary to continue using third party fiscal agents to interface with extramural sponsors. We will continue to investigate ways to improve this element of sponsored programs management through identifying efficiencies and securing greater transparency and control of external agents. To this end we anticipate issuing a Request For Interest to test alternative avenues, locally, that might fulfil these critical interface functions.

Next Steps

We are in the process of combining the physician-led workgroup with the legal and financial workgroup to finalize the operational details and are proceeding with:

i. Implementing the physician workgroup recommendations to permit the pursuit and operation of a significantly increased level of sponsored grants.
ii. Seeking improved relationships with fiscal agents to secure greater managerial and financial efficiencies in the operation of sponsored programs.

The Business Case for a Centralized Sponsored Programs Administration at CCHHS

CONTENTS

Date:

Introduction

As part of the major transformation being undertaken at CCHHS a workgroup was established to review sponsored program activities and to make recommendations that will increase the amount of extramural sponsorship as well as improve the efficiency of current programs.

Among the recommendations made by the workgroup were the establishment of an internal centralized support function and a committee to give oversight and support to CCHHS investigators who are, or would like to, conduct programs funded by extramural sponsors. Additionally, review of the current fiduciary agent relationship revealed a need to increase the transparency of its current relationship, create resources within CCHHS to assist in management of fiduciary relationships and evaluate of potential alternatives to the current state.

This document describes the way sponsored programs are currently organized at CCHHS and establishes a case for making specific improvements.

Landscape of federally sponsored grants

Sponsored programs fall into two different categories: project grants and research grants. Project grants typically provide funding for clinical services that are not reimbursed by insurers (including Medicare and Medicaid) under the usual fee-for-service system. Ryan White HIV/AIDS program grants as well as most other public health programs are considered project grants. Research grants typically provide funding for discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies. Sponsorship of a novel therapeutic protocol that is not part of the usual standard of care and therefore not reimbursable by insurers would be an example of a research grant.

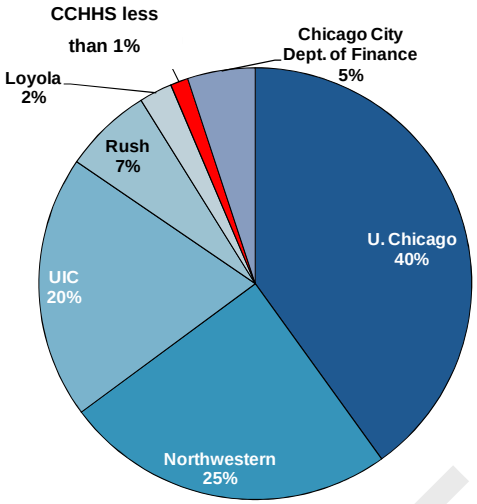
The largest sponsor of healthcare in the US is the Department of Health and Human Services which has a total budget of almost $1 trillion. Other sources of health related grants include federal departments such as Federal Emergency Management Agency (FEMA), Department of Defense (DoD), State of Illinois and philanthropic foundations.

Within the total HHS budget the four main agencies that sponsor the programs at CCHHS have an overall budget across the United States of $50 Billion a year.

Department of Health and Human Services	2010 outlay $ Millions
Food & Drug Administration:	2,429
Centers for Disease Control and Prevention:	6,491
Centers for Medicare & Medicaid Services:	781,713
Indian Health Service:	4,612
Health Resources and Services Administration:	8,532
Agency for Healthcare Research and Quality:	317
Substance Abuse and Mental Health Services:	3,457
National Institutes of Health:	37,189
Administration for Children and Families:	58,472
Administration on Aging:	1,583
Office of the National Coordinator:	851
	905,646

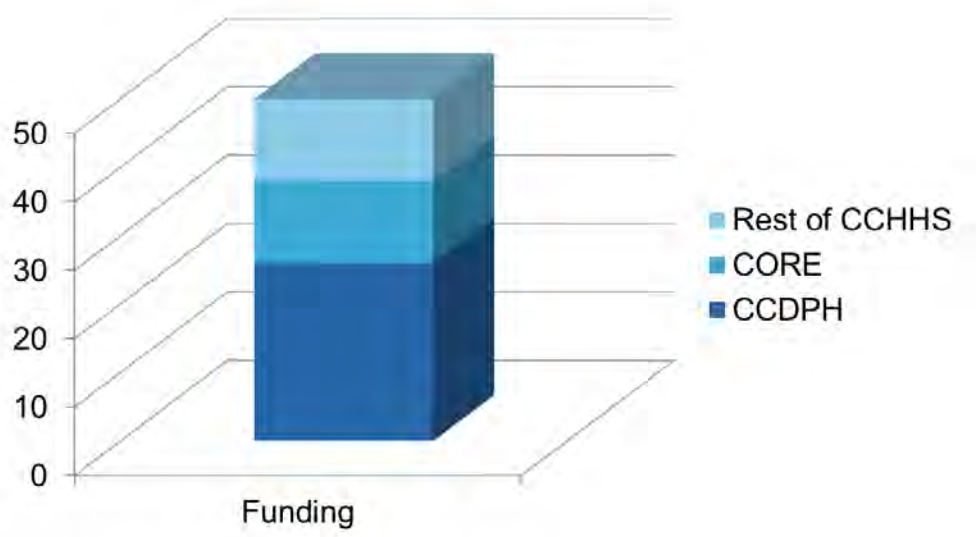
$50 Billion

In FY2009, major Chicago area institutions received **$826 million** in federal healthcare sponsorship from these four agencies, of which CCHHS received less than 1%.



Current sponsored program activities at CCHHS

CCHHS currently has approximately $50 million of extramural funding sponsorship annually. Programs are conducted throughout CCHHS and managed by multiple fiduciary agents. The Cook County Department of Public Health (CCDPH) has approximately $26 million of extramural sponsorship annually, plus the recently won Communities Putting Prevent to Work (CPPW) program worth $15.9 million over 2 years. (Note, some of these funds are distributed to external agencies for programs that fulfil targeted requirements) The Ruth M. Rothstein CORE Center, focused on prevention, care, and research of HIV/AIDS and other infectious diseases has approximately $12 million of extramural sponsorship, in addition to the support provided to the CORE Center's facilities through the CORE Foundation's philanthropic development activities. Across the hospitals & clinics there is a further $12 million of sponsorship, primarily of research protocols, longitudinal studies and interventional programs.



Opportunity to increase grant portfolio

In November 2010, the NIH, HRSA and AHRQ had over 1,300 open RFAs (Requests For Applications) with a total value exceeding $900 million over grant periods ranging from 1 to 5 years - equivalent to $311 million annually. Each of these opportunities was ranked by its relevance to CCHHS's clinical mission. The top 100 of

these had a total award value $156 million equivalent to $50 million annually. The breakdown of these 'Top 100 Targets' based on applicability to CCHHS included the following areas:

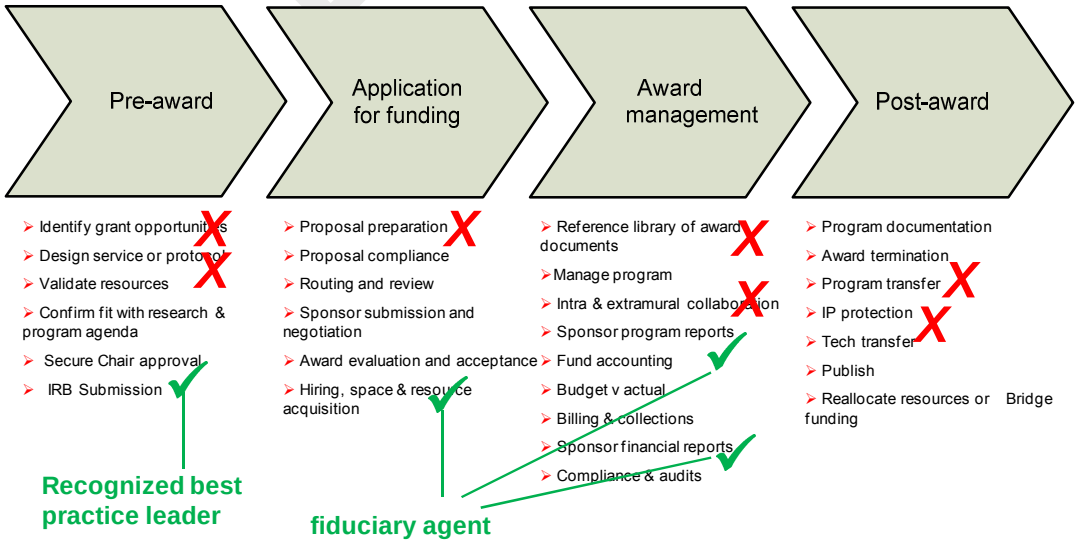
Diabetes	$ 5.1M
Behavioral	$ 20.2M
HIV	$ 9.5M
Maternal	$ 2.5M
Disparities	$ 7.0M
Operations/other	$ 5.7M

These additional sources of funding not only include opportunities for CCHHSs' investigators individually, but also include many grants that require collaboration with other institutions. CCHHS has not fully leveraged its potential collaborations. While CCHHS currently has a research affiliation agreement with Rush University Medical Center, the full potential of this affiliation has yet to be realized. For example, in March 2010 Rush University Medical Center was awarded a major grant to establish a Center for Urban Health Equity. Additionally, UIC was a awarded a major grant to establish a Center for Population Health and Health Disparities in addition to their existing Center of Excellence in Eliminating Health Disparities.

Current operating structure

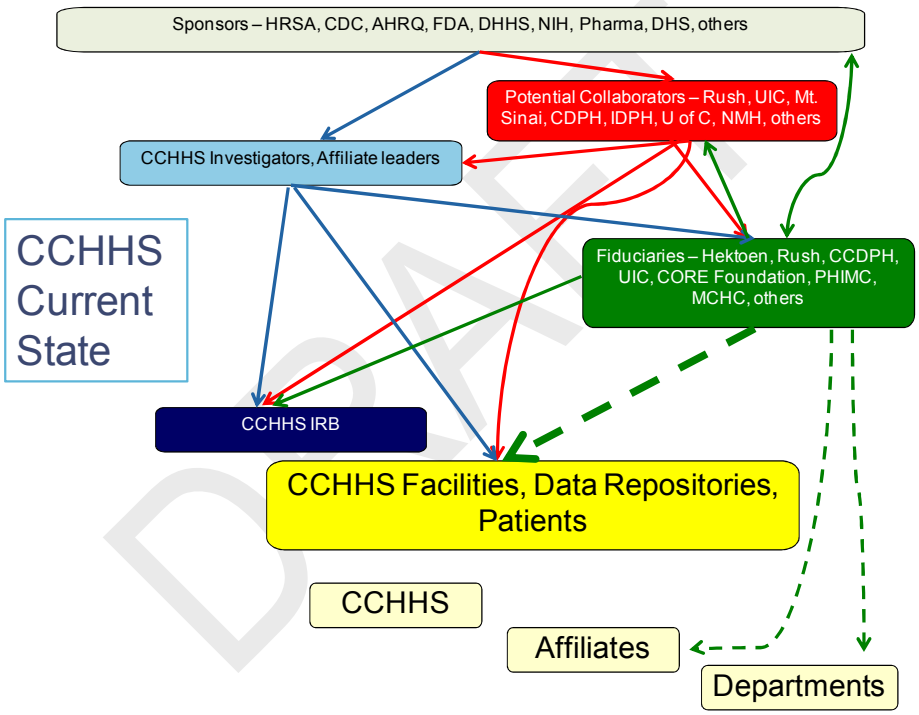
Successful research infrastructures provide resources, whether internal or external, for all aspects of grant management. The life cycle of a grant includes four key stages: pre-award, application for funding, award management, and post-award. Typically, most of these services are located within the primary institution. However, at CCHHS, many of these functions are either not fulfilled or they are outsourced to other institutions. While outsourcing should not be an impediment, the current state of outsourcing grants management has been challenging for CCHHS because of the lack of transparency with external agents and centralized research administration within CCHHS.

The figure below outlines the resources needed for each stage. CCHHS is lacking key support in areas that are needed for successful growth of its research enterprise including assistance in the following areas: identifying grant opportunities, designing services and protocols, preparation of proposals, reference libraries, collaboration, program documentation, and IP and tech transfer. However, CCHHS is a recognized best practice leader in its IRB services. CCHHS's primary fiduciary agent, Hektoen Institute, provides assistance with human resource functions, fund accounting, sponsor financial reports, and compliance and audit. In the past, Hektoen has provided grant identification and writing assistance; however, as reported by many investigators this function is no longer provided.



The current operating structure for CCHHS sponsored programs is fragmented reflecting the multiple players at all levels in the chain from sponsor down to service/program delivery. The key aspects of the current state operating structure consist of the following:

- Sponsors -agencies, foundations, or industry that provide money and support
- Fiduciary Agents -institution that submits and receives grants on behalf of CCHHS. Hektoen Institute serves as the primary fiduciary for CCHHS; however, other agents can also be used.
- Centralized management -does not currently exist
- Compliance -Institutional Review Board (IRB) and Office of Research Affairs (ORA)
- Investigators -faculty/staff executing grants
- CCHHS Facilities, Data Repository and Patients -currently patients receive benefit from services provided; however, there are no funds dedicated to directly benefit facilities and cultivate a data repository
- CCHHS Affiliates and Departments -interaction with specific affiliates such as Ambulatory and Community Network (ACHN) and departments at CCHHS such as Department of Medicine.
- CCHHS Administration -leadership of CCHHS



The arrows in the figure indicate direct interaction between the stakeholders. Because CCHHS lacks a centralized structure and utilizes an outside fiduciary agent who serves as the grantee, direct interaction between the investigators, collaborators, sponsors and fiduciary agents can occur without CCHHS leadership's knowledge. The only source of capturing grant services and activities in a centralized manner is through the IRB; however, IRB only captures grants/services that require human subject approval which does not include program grants such as Ryan White grants.

The diagram also illustrates the funds flow from the fiduciary agents shown through the green arrows. It is important to note that currently CCHHS administration does not receive any funds from grants to assist in supporting the infrastructure.

Strengths and weaknesses of current operations

Strengths:

- Cook County Department of Public Health (CCDPH) and the CORE Center have the administrative structure and resources that are experienced in working with sponsors
- Highly dedicated faculty & staff
- CCHHS IRB has a fast decision turnaround, works with investigators to identify and address shortcoming in applications and has been very effective in protecting CCHHS's patient population.
- No significant hospital services (lab, imaging etc) left unbilled to sponsor
- Patient volume and demographics are attractive to researchers due to the availability of funding targeted toward this population

Weaknesses:

- Complexity, fragmentation, lack of central visibility of sponsored program operations
- Faculty noted barriers to increasing the volume of grants including:
  - Lack of time/resources to write grant applications
  - Increasing need for multidisciplinary approach requires external collaborations
  - Clinical pressures limit the time available to conduct programs when grant is awarded
  - Mentorship, training and development of faculty in research
- CCHHS and investigators lack cohesive project development and operating guidelines
- Inadequate financial and program operating controls expose CCHHS to compliance risks

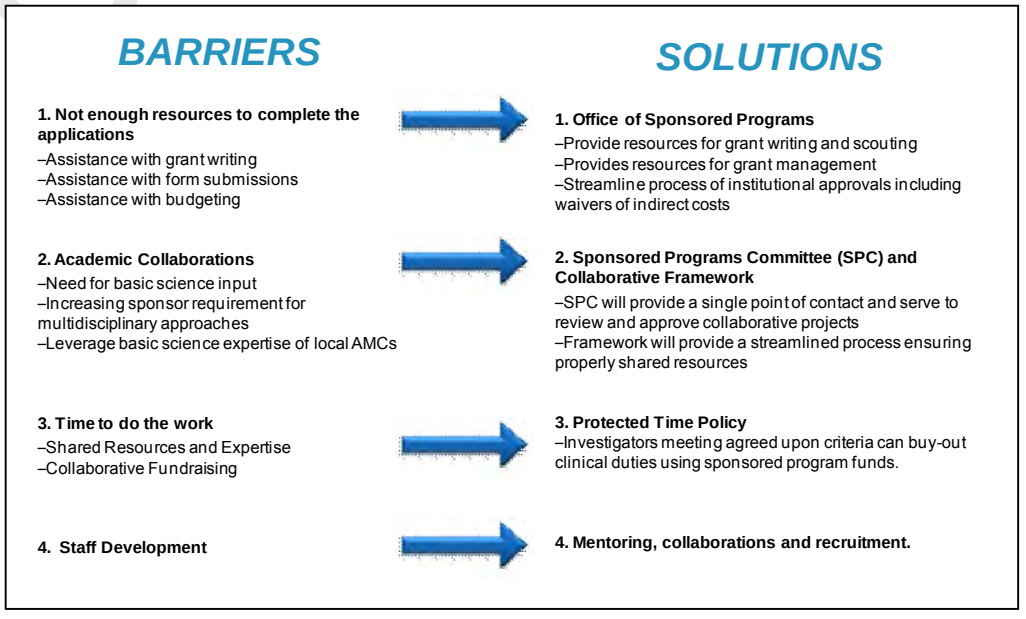
Opportunity to improve operating effectiveness and efficiencies

In order to increase and diversify its grant portfolio, CCHHS should address the operating inefficiencies identified in the current structure. The key operating inefficiencies include:

- Barriers for investigators pursuit of additional grant funding
- Challenges in its relationships with its current fiduciary agents
- Lack of a centralized structure to support and integrate management of research activities

Barriers for investigators

To develop recommendations, the investigators from the research workgroup collected benchmark data from peer institutions, reviewed known industry best practices and evaluated possible improvement options against the reported barriers indentified during the diagnostic interviews. The workgroup identified four key barriers to growing the portfolio of sponsored programs at CCHHS and propose the following solutions.



Challenges with fiduciary agents

Currently CCHHS's primary fiduciary agent is the Hektoen Institute, a institution that was created 1943 to support research and educational programs designed to train physicians and other health professionals in the County of Cook. Its relationship with Hektoen has occurred for a number of years; however, no formal affiliation agreement has been established. For the past two years, CCHHS has worked to create a suitable affiliation agreement for both parties. While Hektoen provides much needed services to CCHHS, CCHHS does not receive any portion of the indirect costs recovered from its sponsored programs.

Based on the lack of progress to date with Hektoen, alternative options for fiduciary agents are recommended. The proposed new entity, Office of Sponsored Programs, encompasses knowledgeable grant accounting resources to assist with the oversight of the fiduciary agent. The potential options for fiduciary agents include and are not mutually exclusive:

1. Renegotiate the arrangement with **Hektoen Institute**.
2. Negotiate with **Rush** for them to provide a more comprehensive fiduciary and research administration services. This is already anticipated and allowed for under the existing Master Affiliation Agreement with Rush University.
3. Find another **third party** with existing federal recognition to be fiduciary agent.
4. The **CORE Foundation** already acts as fiduciary on a handful of pharmaceutical industry grants and could be built into a federally recognized fiduciary with its own F&A rate.
5. **Establish a new entity** to act as fiduciary for grants – could be combined with responsibility for developing philanthropy for CCHHS programs

The relationship of a new or different fiduciary agent should not have an impact on the future operating structure since this structure already includes grant accounting resources to play a larger role in the management of the fiduciary agents.

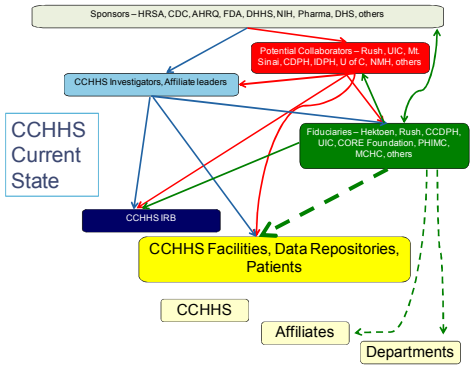
Lack of centralized structure

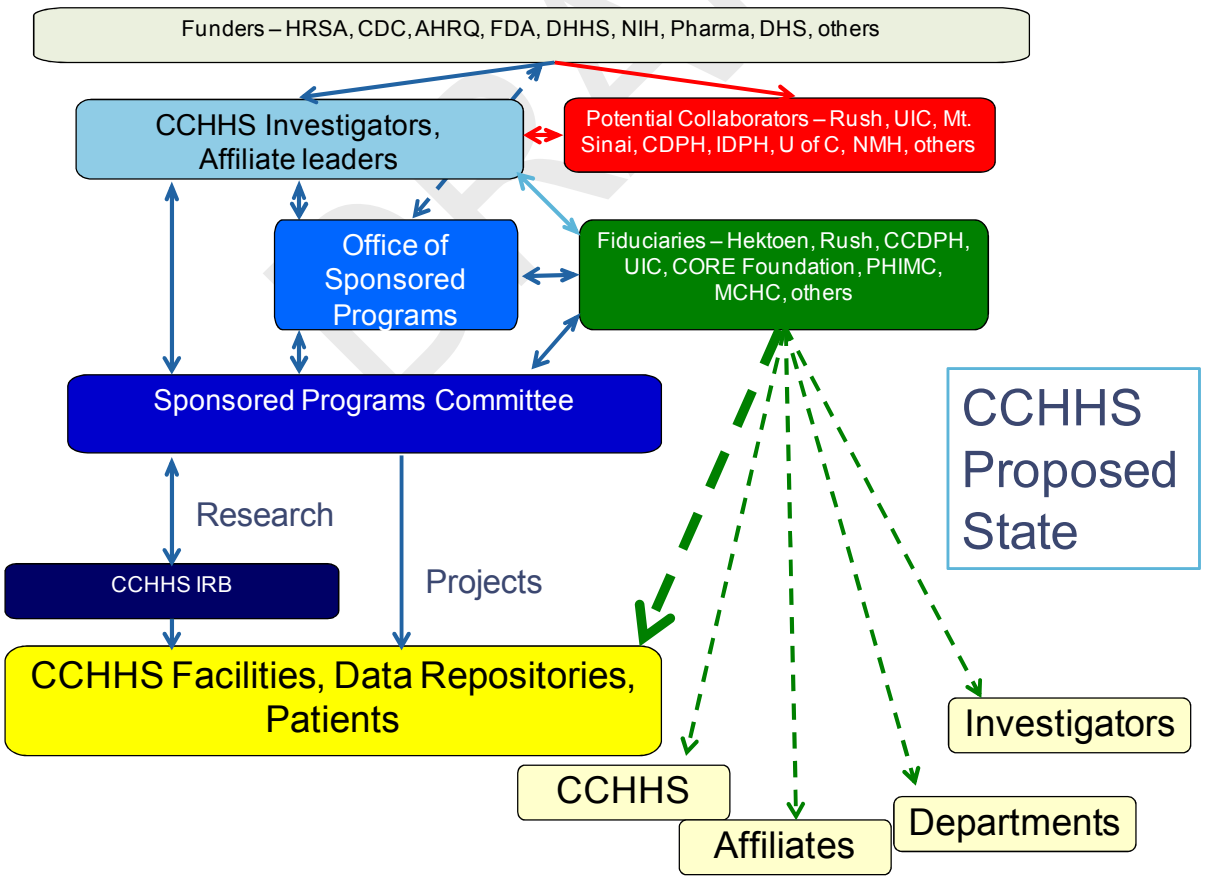
Currently, the lack of a centralized structure to support and integrate management of grant activities has created challenges across many different aspects of the grant life cycle. As CCHHS takes on more responsibility and liability with grants management, it also takes on the added compliance risks. The new entities will need to incorporate mitigations of these risks into their procedures and policies.

Changes proposed for future operating model

Two key recommendations are highlighted in the proposed future operating model: establishment of a new office, Office of Sponsored Programs, and creation of a new committee, Sponsored Programs Committee.

In addition to the creation of these entities, relationships between the current key areas have been modified as indicated by the arrows. These recommendations help to address inefficiencies in the current model by providing a centralized administration function. Additionally, funds flow from fiduciary agents to CCHHS administration, affiliates, departments, and investigators have been improved such that there is more streamlined approach to providing funds.





Future model and proposed structure

The future model has two key additional functions added: Office of Sponsored Programs and Sponsored Programs Committee.

The Office of Sponsored Programs (OSP) will serve as the centralized research office for CCHHS. Its activities will include, but are not limited to the following:

- Assist investigators in writing non-technical portions of grants
- Develop and maintain a repository of needed data on CCHHS facilities / patients for writers
- Provide biostatistician and design assistance to the protocol/program design
- Derive budgets for the protocol/program
- Streamline internal approvals
- Operate/monitor institutional policies on protected time and distribution of Indirect Costs recovered from sponsors
- Work with fiduciaries pre-award and post-award
- Assist fiduciary with grant accounting, costing, and indirect recovery

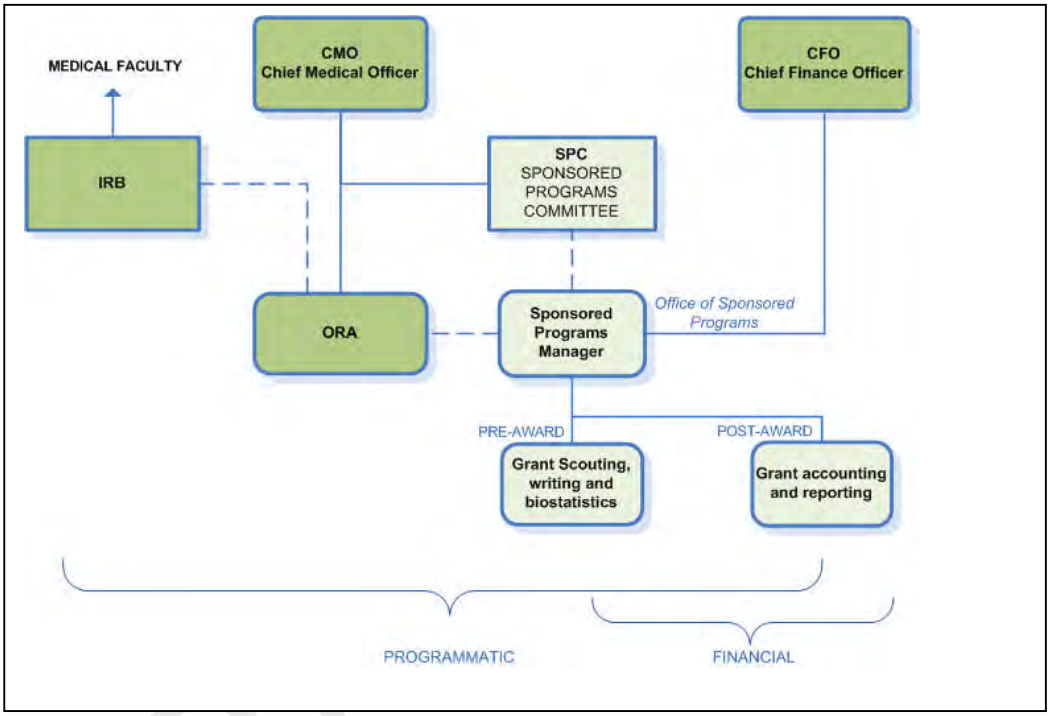
The OSP is specifically designed to have both pre-award and post-award assistance. Through the evaluation process, it was identified that CCHHS should have more internal knowledge and control over distribution of funds and reporting to sponsors. Through the creation of internal resources for grant accounting, CCHHS will have leverage and knowledge to request increased oversight of grant management from its external fiduciary agents.

The Sponsored Programs Committee will ensure congruency with CCHHS's mission, develop external collaborations, encourage internal cooperation and allocate the support resources. Additionally, one of its key aims is to encourage research among existing and new investigators. Operational procedures of the SPC have been designed to ensure that the operational processes will not create additional work for faculty seeking extramural funding. In addition to providing resources to assist faculty in preparing their applications, the SPC will have the resources to expedite the approval process and a degree of delegated approval authority. Its activities include, but are not limited to the following:

- Brief review of all proposed extramurally funded projects
- Prioritize projects for OSP assistance when limited
- Prevent competition between CCHHS investigators for same funds
- Facilitate collaboration within CCHHS and with outside groups
- Create registry of all projects for CCHHS Board, Management, public
- Recommend waivers of Indirect Costs for meritorious projects
- Streamline approvals in concert with CCHHS CFO and CMO

Proposed structure:

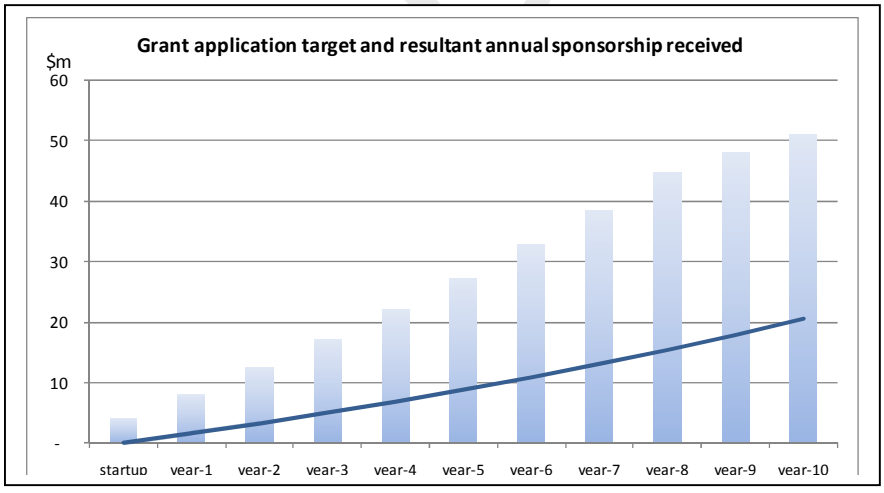
By adding these additional functions, the reporting structure and its interaction with existing functions will be more clearly defined. The SPC will work in parallel with the Institutional Review Board which ensures compliance with human subject protection, by encouraging and supporting other aspects of sponsored programs.



Similarly, the OSP will support and facilitate the SPC in its mission, similar to how the Office of Research Affairs supports and facilitates the IRB in its mission. While it may be possible to combine the ORA and OSP into a single administrative office, initially they will be distinct in order not to interrupt the smooth operation of the IRB and to ensure the OSP has a strong focus on its role.

Working capital needed and return on investment

Typically, grants are awarded over the course of three to five years and may be renewable depending on the specific type of grant. Because grant submission is a rolling process, once a grant is announced there may only be a short window, sometimes only four to six weeks, to prepare the application. While it may have a short preparation time, it can take up to six months or more before the grant is awarded and the project can be initiated. Thus there is often a year or more between preparing the grant application and receiving funds from the sponsor.



This timeline means that the benefits from grant applications accrue over a long period of time.

The cumulative incremental revenue benefit over this time period is $103 million and requires an initial investment of $700,000 to establish the needed infrastructure in year 1. The following ROI calculation conservatively does not include the revenue from direct cost reimbursement, only the incremental indirect costs recovered.

Return on Investment in Extramural Funding Administration

		startup	year-1	year-2	year-3	year-4	year-5	year-6	year-7	year-8	year-9	year-10
	$000s	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
INCREMENTAL EXPENSES								additional staff for increased volume year 6 onwards				
Salaries	base											
sponsored programs manager	$ 105,000	105	108	111	115	118	122	125	129	133	137	141
grant scout	$ 65,000	49	67	69	71	73	75	78	80	82	85	87
grant writer	$ 60,000	30	62	64	66	68	70	143	148	152	157	161
statistician	$ 65,000	49	67	69	71	73	75	78	80	82	85	87
grant budget & finance specialist	$ 55,000	55	57	58	60	62	64	131	135	139	144	148
contracting coordinator	$ 55,000	28	57	58	60	62	64	131	135	139	144	148
grant accountant	$ 60,000		31	64	66	68	70	143	148	152	157	161
grant accountant	$ 55,000		28	58	60	62	64	131	135	139	144	148
base salaries		315	476	552	568	585	603	961	990	1,020	1,050	1,082
composite fringe benefits	30.0%	95	143	166	170	176	181	288	297	306	315	325
total salaries		571	921	1,088	1,121	1,155	1,189	2,008	2,068	2,130	2,194	2,260
oncost -office expenses	15.0%	86	138	163	168	173	178	301	310	320	329	339
occupancy costs 1,500ft² at $30/ft²	$ 45,000	45	46	48	49	51	52	81	83	86	88	91
Total incremental cost of EFA		**701**	**1,105**	**1,299**	**1,338**	**1,379**	**1,420**	**2,390**	**2,461**	**2,535**	**2,611**	**2,689**
INCREMENTAL INCOME												
additional grants		-	3.0	6.0	9.0	12.0	15.0	18.0	21.0	24.0	27.0	30.0
Total income from award		-	1,568	3,230	4,991	6,854	8,825	10,908	13,107	15,429	17,879	20,461
less Direct costs incurred	$ 350,000	-	(1,082)	(2,228)	(3,442)	(4,727)	(6,086)	(7,523)	(9,040)	(10,641)	(12,330)	(14,111)
Indirect Costs Recovered	45.0%	**-**	**487**	**1,003**	**1,549**	**2,127**	**2,739**	**3,385**	**4,068**	**4,788**	**5,549**	**6,350**
Net cashflow		**(701)**	**(618)**	**(297)**	**210**	**749**	**1,319**	**996**	**1,607**	**2,253**	**2,937**	**3,661**

Internal rate of return	**38.6%**	per annum over 10 years

In addition to the financial benefit flowing from our increased capacity to apply for and win more sponsored grants, the proposed structure will also;

- Increase patient access to novel therapies
- Increase funding for innovative service programs
- Improve assessment and fulfilment of community health needs
- Increase the number of research and pilot programs directed towards health disparities, access to care, cost effectiveness and delivery models in line with the national agenda on healthcare.
- Fair internal allocation of IDCs recovered from sponsors
- Protect time that is fair to institution and faculty
- Discharge regulatory obligations to ACGME for residents and fellows to conduct research
- Reduce risk of non-compliance with Federal and state agencies, and private grant funders
- Enhance staff recruitment/motivation
- Improve recognition as a site for clinical service and research programs, which will also enhance CCHHS standing as a worthy recipient of philanthropic gifts
- Improve ability to collaborate with academic institutions and leverage off their grant management track record with sponsors.
- Improve control over more aspects of grant financial management which will bring CCHHS independence from the intermediary fiduciary agents and to retain more of the IDCs recovered. (A proposal in regard to the structure of fiduciary agents will be the subject of a separate business case).

In addition to the financial benefit flowing from our increased capacity to apply for and win more sponsored grants, the proposed structure will also:

- Increase patient access to novel therapies
- Increase funding for innovative service programs
- Improve assessment and fulfilment of community health needs
- Increase the number of research and pilot programs directed towards health disparities, access to care, cost effectiveness and delivery models in line with the national agenda on healthcare and CCHHS priorities.
- Achieve fair internal allocation of IDCs recovered from sponsors
- Protect time consistent with institutional and faculty needs
- Discharge regulatory obligations to ACGME for residents and fellows to conduct research
- Reduce risk of non-compliance with FDA and TJC
- Enhance staff recruitment/motivation
- Improve recognition of CCHHS as a site for clinical service and research programs, which will also enhance CCHHS' standing as a worthy recipient of philanthropic gifts
- Improve ability to collaborate with academic institutions and leverage off their grant management track records with sponsors.
- Gain greater control over grant financial management which will allow CCHHS to retain more of the IDCs recovered.

Draft proforma for budgeting the allocation of indirect cost recoveries

Background

In Fall 2010 a workgroup was established to recommend improvements in the way that sponsored programs are sought and operated at CCHHS. The assessment and design phases of the workgroup activities resulted in specific recommendations and a meeting was held on April 26, 2011 to discuss the implementation of these recommendations.

Present at the meeting were: M.Ayres, Dr.S.Martin, Dr.R.Weinstein, Dr.J.Watts, Dr.D.Barker, Dr.A.French, Dr.W.Trick, K.Braswell, H.Haynes, L.George, R.Myers and A.Armstrong.

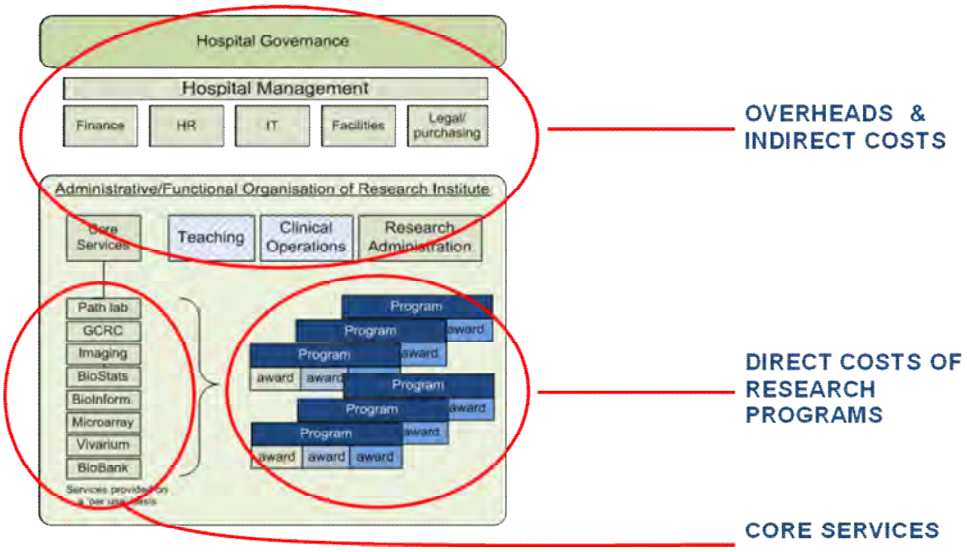
Several actions were proposed:

1. Finalise SPC Mission & Charter.
2. **Form sub-group for drafting IDC policy**
3. Finalise RFI for third party fiduciary agent
4. Draft presentation to wider audience of faculty
5. Review workplan and timetable
6. Set up future meetings

This note relates to action item #2 and should be considered in conjunction with the IDC Allocation Discussion Document that was distributed at the last meeting.

Overview:

When conducting research in a hospital setting there are three broad areas where costs can be recovered and financial efficiencies obtained:



This note focuses on one aspect of indirect cost recovery - budgeting for internal allocation of IDCs in order to support an institutional IDC allocation policy at CCHHS.

Purpose of IDCs:

Sponsors recognize that their programs of clinical care or research are conducted within an institution that provides facilities and administrative support to the medical staff who are delivering the sponsored care or research protocol. The federal government's Division of Cost Allocation within the HHS is designated by the Office of Management and Budget (OMB) as the cognizant federal agency for reviewing and negotiating facility and administrative (indirect) cost rates, fringe benefit rates, special rates as determined to be

appropriate, research patient care rates, statewide cost allocation plans and public assistance cost allocation plans. These indirect cost rates and cost allocation plans are used by grantee institutions to charge Federal programs for administrative and facility costs associated with conducting Federal programs.

The agreed F&A rate is, as the name suggests, meant to contribute to the facilities and administrative costs of conducting research.

Locus of indirect costs:

Like all other institutions conducting research, CCHHS's indirect costs occur largely outside of the departments and programs that actually conduct the research. It is standard practice for the Dean, or other institutionally appointed authority to collect the indirect cost payments from the sponsor because it is their budget, not the researcher's or department's, that bears the cost of the physical facilities and general administration.

It is also customary for an institution to pass through some of the IDCs recovered to the department conducting research when the department is incurring some of the administrative burden related to the sponsored program. However, as the IDC Allocation Discussion Document distributed earlier demonstrate, there is no precise, standardized formula for this distribution and therefore it is up to the workgroup to determine the appropriate models to be used at CCHHS. The general pattern is approximately ⅓ - ⅓ - ⅓ between Central facilities & overheads - overall program administration - department hosting program.

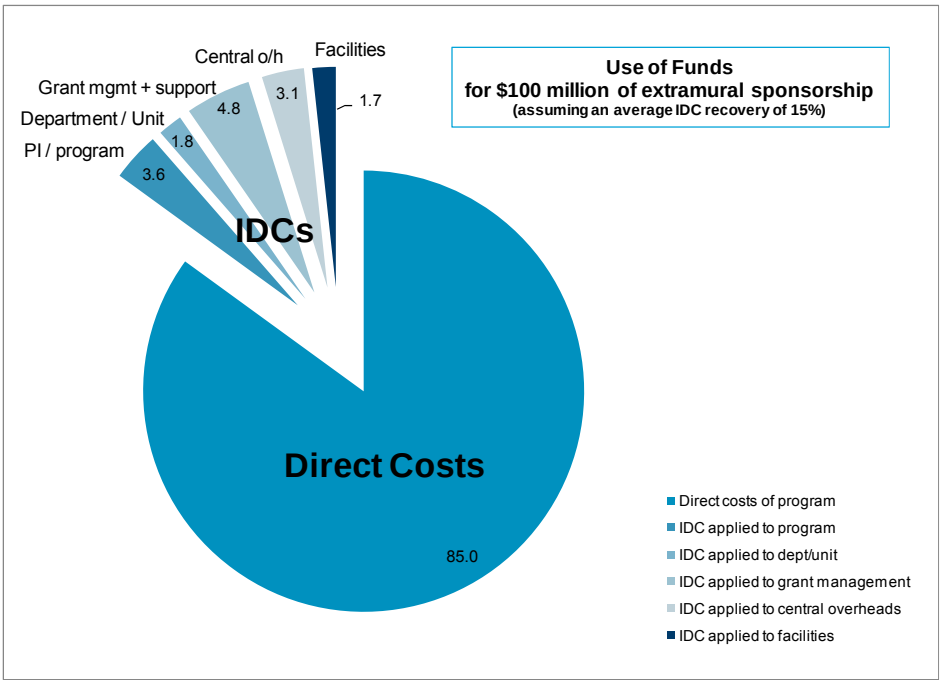
There are likely to be multiple models because different program types use different amounts of space and indirect support. Also the F&A rate differs depending on the specific sponsor.

The task of the IDC Allocation Subgroup is to decide on the number of different IDC allocation models that CCHHS needs and to propose a proforma budget for each model.

Generalized proforma allocation model:

The attached spreadsheet has 4 sections:

A. The various activities undertaken in managing sponsored programs.
B. An attribution of what percentage of the total indirect cost base is consumed by each activity
C. An estimate of the area at CCHHS (or fiduciary agent) where the activity occurs
D. An example of how the total cost budget might appear for the total portfolio of all sponsored programs



Your comments on this approach and the analysis tool would be much appreciated

Appendix: Proforma cost allocation model for sponsored programs

Attibution of Grant Management Costs

AVERAGE ACROSS WHOLE PORTFOLIO

Section A: activities undertaken	Section B: % of recovered IDC	Section C: Domain where activity occurs				Section D: Example sponsored program portfolio of $100 million per annum				
		Central	Grants Mgmt/ fiscal agent	Medical Dept / Unit	PI / Program	Total IDC recovered $000s	Central	Grants Mgmt/ fiscal agent	Medical Dept / Unit	PI / Program
Infrastructure										
Space lease/bond service	10.0%	100%	-	-	-	1,500	1,500	-	-	-
other facilities related costs, maintenance, utilities etc	1.5%	100%	-	-	-	225	225	-	-	-
general overheads for HR, IT, marketing, executive etc	10.0%	100%	-	-	-	1,500	1,500	-	-	-
Pre-Award (project identification and design)										
Identify grant opportunities	2.0%	-	50%	25%	25%	300	-	150	75	75
Design service or protocol	1.5%	-	-	-	100%	225	-	-	-	225
Validate resources	1.0%	-	10%	65%	25%	150	-	15	98	38
Confirm fit with research & program agenda	0.5%	-	10%	80%	-	75	-	8	68	-
Devise budget	1.0%	-	10%	45%	45%	150	-	15	68	68
Secure internal approvals	0.5%	20%	40%	40%	-	75	15	30	30	-
IRB Submission (unless paid as direct cost)	1.0%	-	50%	-	50%	150	-	75	-	75
Pre-Award (proposal preparation and submission)										
Proposal preparation	3.0%	-	50%	-	50%	450	-	225	-	225
Review proposal compliance with sponsor terms	3.0%	-	100%	-	-	450	-	450	-	-
Routing and review	3.0%	10%	30%	30%	30%	450	45	135	135	135
Sponsor submission and negotiation	3.0%	10%	50%	-	40%	450	45	225	-	180
Award evaluation and acceptance	3.0%	20%	20%	30%	30%	450	90	90	135	135
Hiring, space & resource acquisition	3.0%	-	-	50%	50%	450	-	-	225	225
Post-Award (grant management)										
Reference library of award documents	1.0%	-	50%	25%	25%	150	-	75	38	38
Manage program	8.0%	-	10%	10%	80%	1,200	-	120	120	960
Intra & extramural collaboration	1.0%	-	10%	10%	80%	150	-	15	15	120
Sponsor program reports	6.0%	-	50%	10%	40%	900	-	450	90	360
Fund accounting system	8.0%	50%	50%	-	-	1,200	600	600	-	-
Fund reporting eg Budget v actual	6.0%	-	80%	10%	10%	900	-	720	90	90
Billing & collections	9.0%	40%	40%	10%	10%	1,350	540	540	135	135
Sponsor financial reports	5.0%	-	80%	10%	10%	750	-	600	75	75
Compliance & audits	3.0%	10%	40%	25%	25%	450	45	180	113	113
Post-Award (grant closing)										
Program documentation	1.0%	-	10%	10%	80%	150	-	15	15	120
Award termination, reallocate resources	1.0%	-	20%	80%	-	150	-	30	120	-
Tech transfer & IP protection	1.0%	50%	25%	10%	15%	150	75	38	15	23
Publish, deliver conference papers etc	1.0%	-	-	-	100%	150	-	-	-	150
Reallocate resources	0.5%	35%	5%	60%	-	75	26	4	45	-
Build fund to bridge staff between grants	1.5%	50%	-	50%	-	225	113	-	113	-
Indirect Cost allocation	**100.0%**	**32%**	**32%**	**12%**	**24%**	**15,000**	**4,819**	**4,804**	**1,815**	**3,563**
Pus: Direct Cost allocation										**85,000**
Total Funding support from extramural sponsors							**4,819**	**4,804**	**1,815**	**88,563**

SUMMARY DOCUMENT

Mission and Charter of CCHHS Sponsored Programs Committee and Operations of the Office of Sponsored Programs

June 2011

Preamble

CCHHS wishes to enhance the health system's capabilities to perform programs of clinical care, health education outreach and medical research that are sponsored extramurally in order to better serve the long-term health interests of Cook County residents. CCHHS recognizes that externally funded programs of service and projects of research are powerful levers for improving and protecting the health of the public and the patients we serve.

CCHHS is establishing a two interrelated groups the Sponsored Programs Committee (SPC) and the Office of Sponsored Programs (OSP), which will have with four main goals:

i. **Increase** extramurally sponsored programs within CCHHS
ii. **Support** staff and clinicians creating grant applications and executing sponsored programs.
iii. **Understand** the breadth of extramurally sponsored programs throughout CCHHS
iv. **Align** new endeavours with the mission and capabilities of CCHHS and its affiliates.

The SPC will be charged to provide oversight and direction in the conduct of sponsored programs at CCHHS. The SPC will endeavor to optimize programmatic objectives and the allocation of resources through the issuance of policies and the provision of other guidance.

The OSP will have a more operational charge, which will help clinicians and staff navigate the process of seeking and securing funding for health initiatives and research projects that are aligned with the CCHHS Strategic Plan, receives progress and financial reports on ongoing efforts, and produces reports for the SPC, CCHHS Administration, and outside sponsors. Appendix A shows the proposed organizational structure

Mission Statement

The Sponsored Programs Committee (SPC) is to encourage, and actively support extramurally funded projects, to foster collaboration, and to ensure alignment of activities with the mission and values of the Cook County Health and Hospitals System (CCHHS).

The SPC does not create the strategic plan or mission for CCHHS, nor the System's research plan but seeks to maximize the utility and benefit of the resources of the OSP and ensure that all projects and programs are compatible with the aims and values of CCHHS.

Purpose

- **Actively support new grant applications and sponsored program opportunities.** The SPC will give practical, tangible support to CCHHS clinicians and administration by:
    - Allocating resources from the Office of Sponsored Programs (OSP) to assist in assembling grant applications, writing non-technical sections, program budgeting,

liaison with external collaborators, securing internal approval and completing the submission processes at the IRB and sponsoring agencies.

  - Providing feedback and recommendations regarding the fit of a given proposal to the mission(s) of CCHHS and its affiliates
  - Identifying other areas within CCHHS that could add strength to projected programs and to encourage internal collaborative efforts to win grants.
  - Assisting the identification of potential external collaborators for specific programs.

- **Protect & enhance current programs**: The SPC is committed to supporting existing programs. Through the OSP and other resources it will try to provide assistance to current investigators and programs.
- **Enhance the organizational understanding of sponsored programs**: The SPC / OSP will act as a central repository of knowledge about all of the sponsored programs undertaken by CCHHS and within CCHHS facilities.
- **Act as an internal advocate of sponsored programs:** The SPC, through the OSP, will provide clinicians and senior management of CCHHS and its Affiliates with information regarding funding opportunities.
- **Establish standards:** The SPC will create general standards in collaboration with the clinical chairs, CCHHS CFO, and other senior leaders for the fair allocation of funds to cover CCHHS costs in conducting projects. Funds should be equitably shared between investigators, fiduciary agencies, clinical departments, and affiliate administrations depending on project type and expenses incurred.
- **Ensure the highest standards of ethical, regulatory and sponsor compliance:** The CCHHS IRB has final authority regarding compliance issues. The SPC can serve as an initial sounding board for ethics or performance issues that may arise and help resolve potential problems. The SPC in collaboration with the OSP and IRB will complete the required reports on Research Integrity.
- **Present coordinated institutional response to sponsors:** Particularly to avoid having multiple CCHHS investigators competing for the same funding rather than collaborating.
- **Foster collaboration with other institutions:** The SPC will also support CCHHS as it looks to increase collaborations with other institutions. SPC will create the framework within which CCHHS faculty and facilities collaborate with others, It can provide advice and feedback related to research with potential collaborations. IRB can refuse to allow collaborators access to CCHHS facilities to be used in projects which do not adhere to the framework for collaboration for Research.
- **Support system leadership:** The SPC is to support decisions (i.e. strategic planning) made by CCHHS and clinical department leaders and work with staff seeking extramural funding. SPC will only influence directions taken by its prioritization of OSP resources to various projects. SPC is responsible to the System CMO.

<u>Structure & Composition</u>

- **Number:** The SPC will be composed of no less than nine and no more than eleven members.
- **Committee Membership**: The SPC will contain members primarily associated with at least 3 separate affiliates of CCHHS. Up to nine members including the Chair and Vice-Chair will be

clinicians fully qualified by the CCHHS IRB as investigators. Membership will be limited to those with a primary appointment at CCHHS. Members may not concurrently serve on the SPC and IRB. These members will be appointed by the CCHHS CMO with the approval of the CEO. The CCHHS CFO will appoint one member with the concurrence of the CEO. The CCHHS CEO may appoint one additional administrative representative with the concurrence of the Chair of the SPC. The Director of the Office of Research Administration will serve as the liaison between the IRB and SPC.

Membership on the SPC is expected to include representation from leading researchers, department chairpersons, and senior CCHHS administrative leadership.

- **Meetings:** The committee will meet at least monthly. The SPC may endow the Chair or Vice Chair with the authority to grant preliminary approval between meetings for urgent matters. The SPC may seek input from Affiliate Administrations, the Chair of the IRB, Department Chairs, other faculty, CCHHS administration or outside experts when needed. Staff from the OSP will perform the functions of secretary for the SPC.

Description of Activities

The SPC and OSP will coordinate operations to conduct the following activities:

- **Directing the use of support resources:** The SPC will direct the use of resources of the Office of Sponsored Programs. This will include:
    - **Resource prioritization:** The demand from faculty for support of grant scouting, application editing and submission, is likely to exceed the resources available to the OSP. Therefore, the committee will devise transparent criteria for prioritizing the use of CCHHS extramural support services, driven by goals established by CCHHS clinical, and administrative leadership.
    - **Information gathering:** The OSP gathers and analyzes, and the SPC disseminates information relevant to sponsored programs at CCHHS. The OSP is authorized to gather information by means of direct requests to a CCHHS clinician, department, or affiliate and by the development and use of questionnaires and surveys. The OSP / SPC will also receive copies of financial reports from fiduciary agents. OSP will also be the recipient of progress reports (along with IRB for research studies) for all extramurally funded projects.
    - **Data Repository:** The OSP will act as a central repository for data and pro-forma content needed for applications (such as example budgets, as well as clinical and demographic data regarding CCHHS and the communities we serve).
    - **Cost of resources:** Projects which receive funding will be expected to allocate a portion of indirect costs to offset costs incurred by CCHHS affiliates for the conduct of research. Projects which were funded with the assistance of the OSP will repay this assistance with a percentage of indirect costs (IDC) which will be negotiated with the fiduciary agent to facilitate future operations of the OSP.
- **Internal reports:** The SPC will make periodic [quarterly] internal reports to CCHHS senior management. The content and nature of this report will be determined at the discretion of the SPC chair and CCHHS CMO. The prime purpose of these reports is to allow senior CCHHS management to discharge their duties of oversight required by their governance obligations.
- **Annual report:** The SPC will make an annual report that will contain non-confidential descriptions of sponsored program activities at CCHHS, to the degree permitted by sponsors.

The prime purpose of the annual report is to generate interest and answer questions about sponsored programs at CCHHS to a broad audience and to create publicity & awareness among CCHHS's wider stakeholders.

- **Dissemination of guidelines and policies:** The OSP can act as a central repository for the organization's policies with regard to the application, operation and closing of sponsored awards. The SPC creates and reviews procedures such as the Policy for Protected Time for Investigators and the Framework for Collaboration between CCHHS and external organizations.
- **Training & guidance:** As part of its support of research, when needed, the SPC shall arrange seminar(s) for CCHHS clinicians, investigators, and other professionals to answer questions on the conduct of research & other sponsored programs at CCHHS in collaboration with the IRB. This may include instruction on how to write grant proposals, how to submit grant applications and information about CCHHS sponsored programs support resources. Other training and guidance channels, such as publications and intranet websites will also be used where appropriate.
- **Notice:** In order to discharge its duties with regard to fostering collaborations internally & externally, maximising use of CCHHS resources, ensuring alignment with CCHHS priorities and maintaining the repository of sponsored programs data, the SPC will receive notification of intent to apply for extramural funding. This notice will be submitted to SPC as early in the application process as possible. Such notice shall include all applications for funding of research, programmatic projects, demonstration projects, and quality improvement projects. Generally this submission may take the form of a brief memorandum or whatever documentation is determined as appropriate by SPC.
- **Review and recommendations:** The SPC will review all proposals and respond to the originator with regard to alignment with CCHHS strategic priorities and mission, and conformity to CHHS policies. The SPC is particularly concerned with the selection of an appropriate fiduciary agents, whether protected time is being sought, external collaborators roles, whether fair reimbursement for CCHHS costs (e.g. laboratory and radiology) will be sought, whether internal cooperation between departments, affiliates, and investigators is assured; and adherence to CCHHS operating procedures. After discussion with the originator, the SPC will make a recommendation to the CMO to grant institutional approval for the application to external sponsors. The SPC's mode of operation will be "permissive" for all beneficial efforts that align with the mission of CCHHS. The CCHHS IRB will be relied upon to be the final arbiter of the merit of research proposals with regard to human subject protection and the CMO to be the final arbiter with regard to the clinical and research agenda for CCHHS.
- **Absence of burden:** The SPC will conduct its reviews in whatever manner is needed to prevent delays and so as to not place additional burdens on investigators. See Appendix D for an illustration of the form of notification that the SPC will request of program managers & PIs. Submissions to SPC will not entail cost or "taxes" on investigators.
  The SPC's mode of operation will be to facilitate all beneficial efforts that align with the mission of CCHHS.
- **Other considerations:** The SPC Charter covers items such as the meeting calendar, individual privacy & confidentiality, faculty autonomy, feedback to faculty on SPC decisions regarding granting of resources to support them and rules for amending the charter.

<u>Operational Procedures</u>

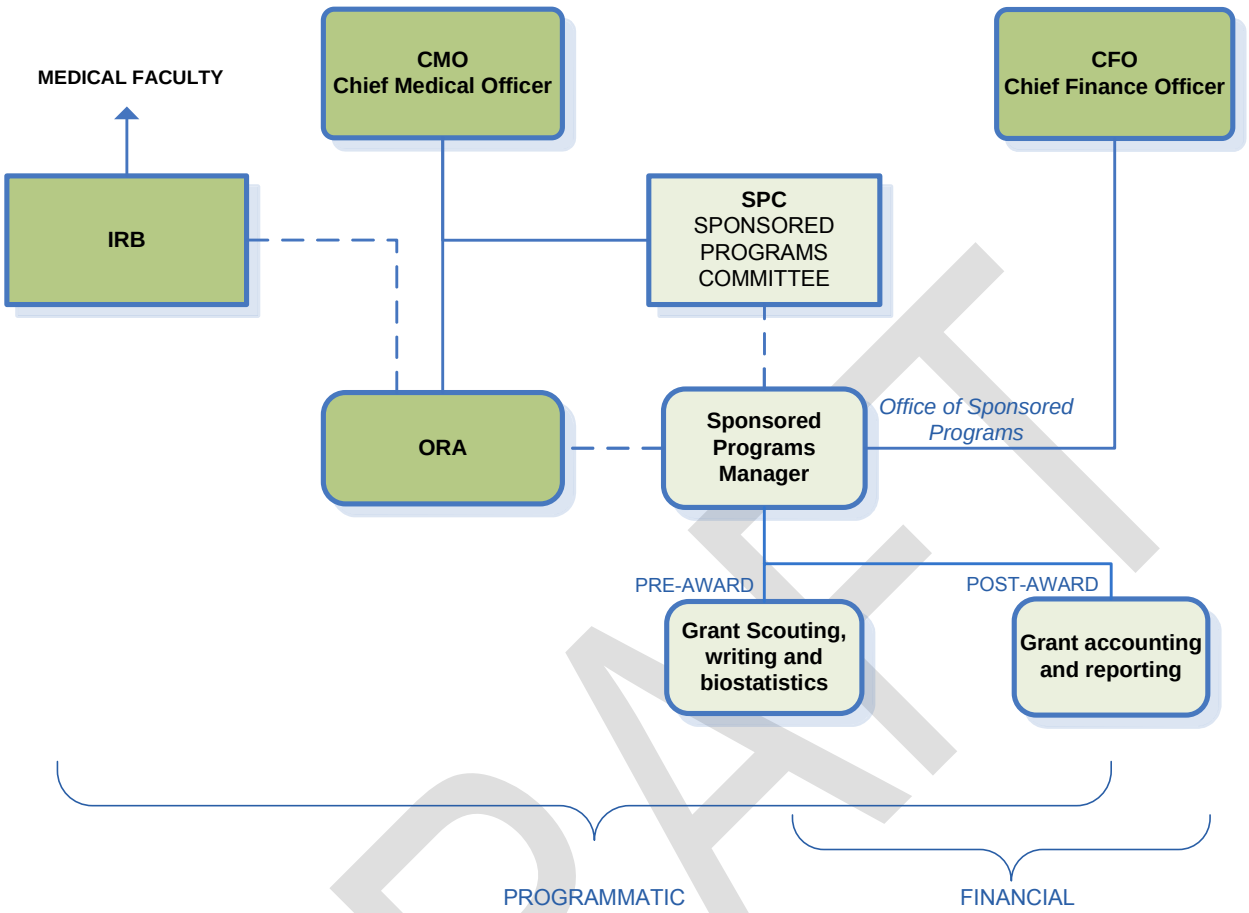
Appendices B, C and D illustrate the process that the SPC and OSP will adopt.

Implementation

- **Formation of SPC:** Once this mission statement and charter are adopted by the System CEO and Governing Board, the System CMO, CFO, and CEO in consultation with key clinical stakeholders, CCHHS leaders, and the existing research bodies will appoint the SPC.

  Formation of OSP: The establishment of the SPC and OSP will be in at least two phases. The first phase would be to employ pre-award resources to assist with grant scouting, editing, assembly and submission. The second phase would be to create permanent personnel resources for post-award grant support.

APPENDIX A Proposed Organizational Structure Diagram



The Office of Research Administration supports the operations of the IRB and therefore is tightly focused on compliance with human subjects protection.

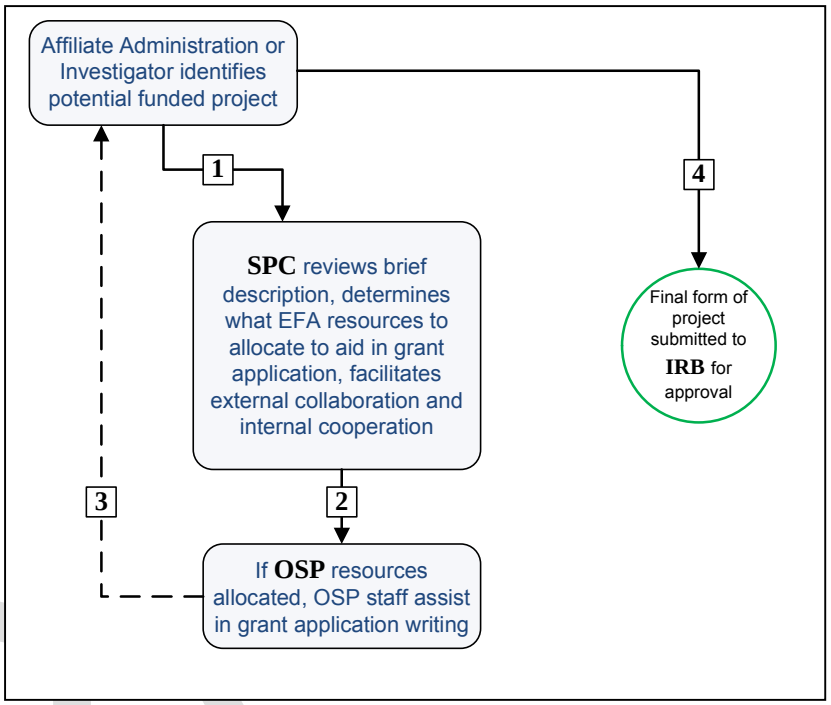
The Office of Sponsored Programs will be focused on developing CCHHS portfolio of sponsored programs by giving tangible support to program managers and principal investigators.

The OSP will work closely with the ORA and wherever possible share information, proforma documents, internal communications & training, systems development (such as updating the precursor Office of Research Development webpages at http://www.cchil.org/irb/sitemap.html).

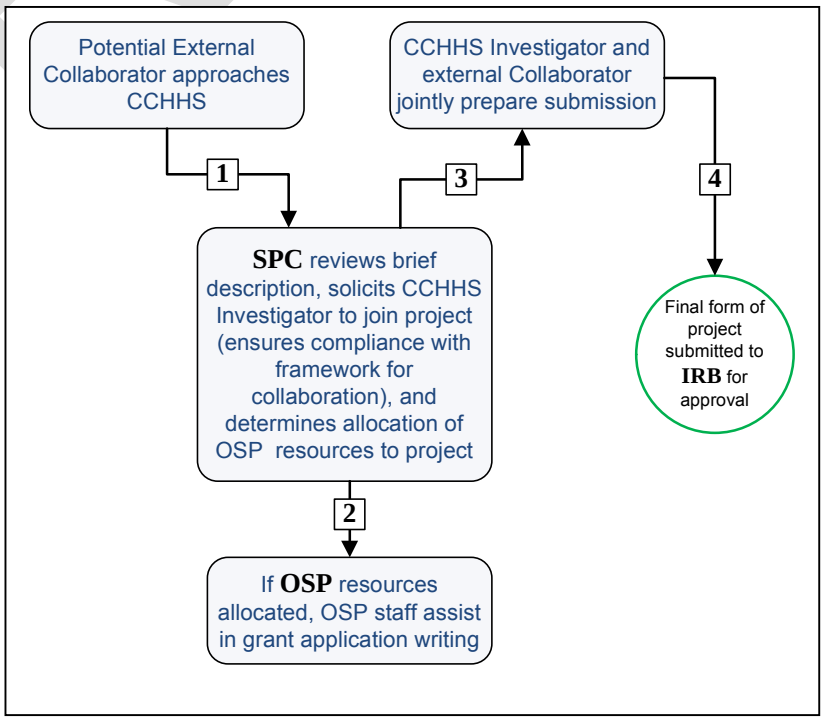
APPENDIX B Process Flows for Grant Initiation

A prime requirement is that faculty notify the SPC, through the OSP, of their intent to apply for extramural funding as early as possible in the process so that the SPC can allocate resources to assist the faculty in developing the grant application. It is anticipated that potential grants are initiated in one of three ways.

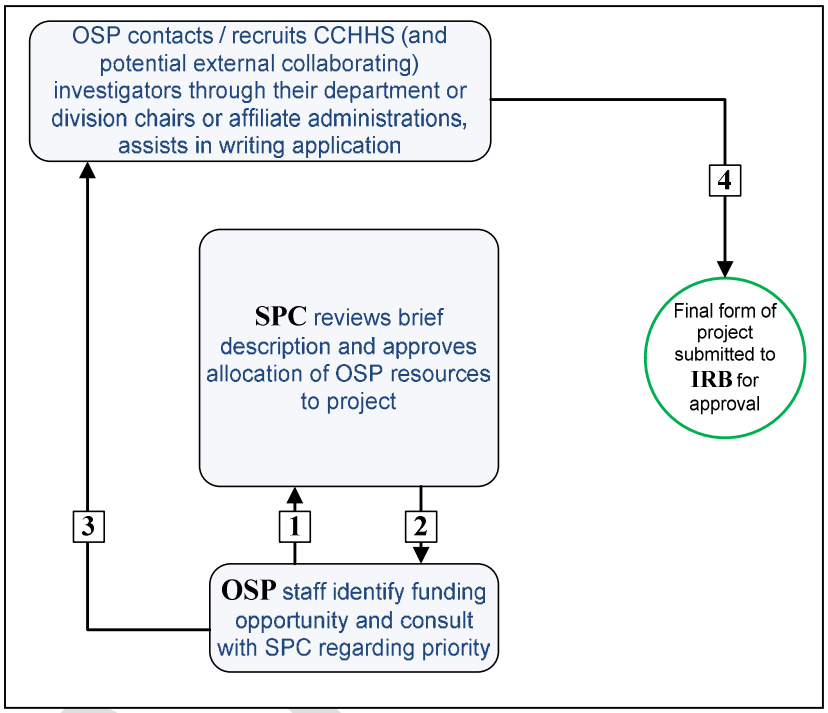
1. CCHHS faculty initiated



2. Initiated by a CCHHS collaborating institution

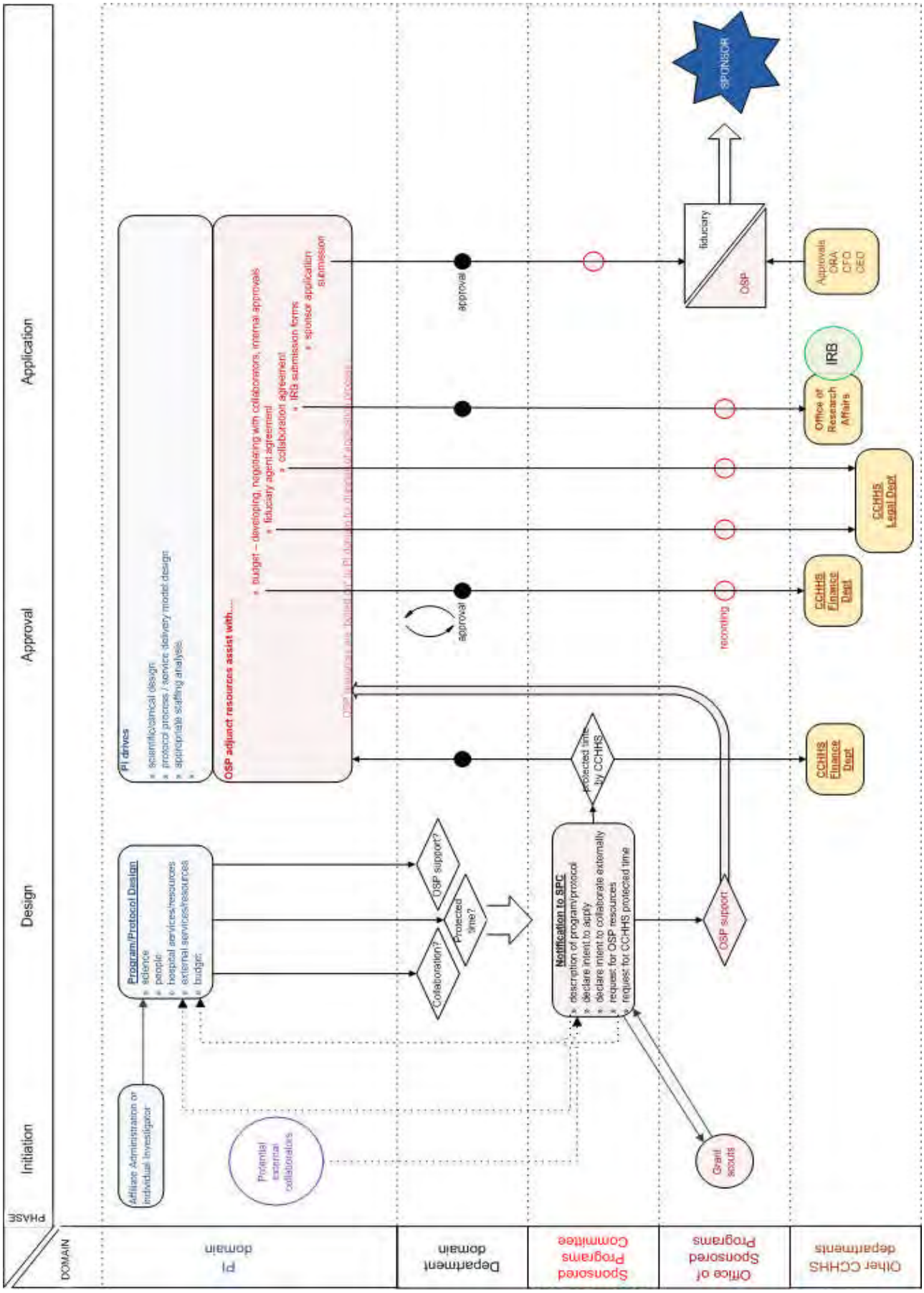


3. Initiated by CCHHS 'grant scouting' activities



Regardless of the source of the initiation, it is anticipated that the remainder of the application process will be the same. An overview of the role of the SPC and OSP in the full process of application is illustrated in Appendix C

APPENDIX C Full Process Flow for Grant Application Phases



APPENDIX D Proposed SPC / OSP Notification form

NOTIFICATION OF INTENT TO APPLY FOR EXTRAMURAL SPONSORSHIP

This form is a statement of intent and does not create an obligation. Please send this notification to the Sponsored Programs Committee who will review and assign resources to assist in building your application to the sponsoring agency and obtaining internal approvals

Principal Investigator(s) Click here to enter PI name(s).

Dept. contact name: Click here to enter text. email: Click here to enter email phone: Click to enter phone#.

Program Title: Click here to enter text.

Sponsoring agency: Click here to enter name of sponsoring agency Due date: click to pick date from dropdown

Sponsor reference: Click here to enter name of sponsor's reference eg RFA, RFP, internet URL etc

Description of program or protocol:

Click here to enter description of the program or protocol. If cutting & pasting from another document please paste as unformatted text and then click outside of the box before saving the document

CCHHS Resources Requested:

- ☐ I request assistance with preparing the application and securing internal approvals
- ☐ I anticipate requesting protected time to conduct program/protocol
- ☐ I anticipate requesting additional space to conduct program/protocol
- ☐ The program/protocol will use CCHHS pathology labs (If non-standard test needed please comment below)
- ☐ The program/protocol will use CCHHS imaging resources
- ☐ The program/protocol will use CCHHS pharmacy resources
- ☐ The program/protocol will use other CCHHS clinical resources. (Please specify in comments box below)

Collaboration Assistance:

- ☐ Does this program/protocol involve collaboration with external institutions (other than the sponsor)? if so, please indicate collaborators name & affiliation: Click here to enter name of collaborating institution
- ☐ Would you like assistance in finding collaborators?

Financial Impact:

- ☐ Will you be able to budget for full recovery of indirect cost at full F&A rate?
- ☐ Does the sponsor require CCHHS cost sharing? (i.e. in order to complete the protocol CCHHS will have to provide resources that will not be reimbursed by the sponsor, including clinical resources noted above if not directly reimbursed)

Anticipated Fiduciary Agent Choose from dropdown list. Or enter agent name Click here to enter name of fiduciary

Additional Comments: Click here to make additional comments or requests.

If cutting & pasting from another document please paste as unformatted text and then click outside of the box before saving the document

When complete please email to spcinbox@ccbhs.org

SPC Follow-up…

This box to be completed by SPC/OSP

Form received
date

Advanced Notifications sent to:
Department Chair
date
CCHHS labs, imaging, pharmacy, IT
date
CMO's office
date
CFO's office
date
ORA/IRB
date
Fiduciary agent
date

SPC/delegate review
date
ORA resources assigned
name
Date assigned

Progress checked with OSP and confirm back to PI
date

Approvals requested
Department Chair
date
CCHHS labs, imaging, pharmacy, IT
date
CMO's office
date
CFO's office
date
ORA/IRB
date
Fiduciary agent
date
IRB
date

Report back to PI on approvals received
date

Additional comments & guidance from SPC..
Click here to enter text.

SPC Notification Form Feb-2011 for up to date forms and other resources to support your sponsored programs please go to http://www.cchil.org/irb/handbook.html

Protected Time Policy For CCHHS Clinical Staff Engaged In Extramurally Sponsored Programs

Purpose:

Complex, multiyear funded projects often require considerable time investment by investigators. CCHHS seeks to recruit, retain, and develop internally outstanding investigators. Therefore CCHHS wishes to introduce a protected time policy for those staff engaged in extramurally sponsored programs which provide sufficient salary support to offset their usual County paid duties.

Introduction:

CCHHS recognizes the pressures faced by clinicians and other staff to complete their assigned clinical and other duties. Some large, long term projects provide specific salary support in sufficient amounts to allow CCHHS to defray the System's employee related expenses and hire others to carry out the investigator's usual duties. This creation of "protected time" for the activities of the funded project will further the research and public health service missions of CCHHS. CCHHS pledges to utilize these funds from extramural sponsors for coverage that will release funded staff from their clinical and administrative obligations to allow them to fulfil the programmatic responsibilities to their sponsor without adverse impact on CCHHS activities.

CCHHS expects its clinicians to keep abreast of developments in their field, and the wider health landscape. Such continuing education and scholarship are required for licensure and do not constitute 'research'. Thus reading journals, attending conferences, etc. are considered usual for an active clinician and fall outside the realm of protected time for research.

Qualification for receiving protected time:

CCHHS will grant 'protected research time' for Staff who meet the following criteria.

i) The Staff is a recipient of an extramurally funded grant that includes explicit time obligations to the extramural sponsor that were approved by the SPC.

ii) The funder provides sufficient monies to cover the amount of clinical or other duties time called for in (i) above, according to the formulae stated below;

Or

The Sponsored Programs Committee and the Staff's Departmental Chair both agree that CCHHS should provide protected time even in the absence of sufficient external funding due to the importance of the project.

The provisions in this policy for CCHHS protected research time are in addition to the existing discretionary powers available to department chairs. However when a funded project which has been approved by the SPC and the Department Chair receives sufficient funding to pay for "protected time" the Chair is obligated to find ways to cover the clinical or other work duties of the investigator to the extent funded.

Amount of protected time:

Funding for less than **20%** time will not trigger any obligation by the Chair to provide protected time.

In general funding should be sought by investigators in 10% increments. The cost for each 10% will be 10% of the of the investigator's annualized salary plus 45% to pay for benefits and other expenses associated with recruiting and engaging replacement staff. Thus a clinician earning $100K per year would have to set aside $14.5K for each 10% increment of protected time sought. The cost to provide protected time are thus linked to the costs to CCHHS of that investigator and the likely cost of another provider taking over those activities.

The exact type and scope of duties relieved from the funded investigator shall be fairly negotiated between the Chair and the investigator. In the case of an impasse the SPC chair or SPC committee's input can be sought with recourse to the System CMO (or other appropriate "C-level" officer).

The Chair shall be given a reasonable amount of time to identify, recruit, and if needed credential replacement staff. In no case shall the Chair be required to begin the period of protected time in less than 90 days. In general the Chair will be expected to begin providing protected time in less than 180 days. Disputes can be referred to the SPC and if needed the System CMO. Funding from salary reallocation for protected time can be used via having the fiduciary agent pay the replacement staff directly as their employee subject to the direction of the Chair, or funnelled to CCHHS to pay its own current or new replacement employees. Ten (10) percent of these funds shall accrue to the clinical department, business unit, or affiliate depending on the organizational level responsible for finding and hiring replacement staff.

The SPC discourages Chairs from reassigning duties from “protected time” investigators to existing full time staff as such reassignment is likely to cause resentment within the department. In the rare circumstances where existing staff are already available and are underutilized the Chair needs to clearly articulate the current situation and understand the potential difficulties if / when the external funding ends.

Process for award of CCHHS protected time:

- Staff should discuss their proposal for protected time with their department chair (business unit or affiliate leadership as appropriate) at an early stage in the design of the research protocol or program parameters and receive approval.
- The approximate amount of protected time that will be sought (and for which existing staff members) should be disclosed in the initial submission to SPC – although this initial estimation will not be binding since grant budgeting requires flexibility in reallocation of funding.
- Protected time allocations become binding at the time of submission to the IRB, on both the submitting authors and the Chairs (business unit / affiliate leaders if appropriate). These allocations are subject to adequate final funding from the sponsor.
- If the department chair anticipates the use of current full time CCHHS resources to provide coverage then the chair should include an explanation along with the request for CCHHS protected time in the initial notification to the Sponsored Programs Committee.

Process for operation of CCHHS protected time:

- The Sponsored Programs Committee informs the Office of Sponsored Programs that it has agreed to CCHHS protected time for a specific Staff and grant award.
- The OSP grant accountant will liaise with the fiduciary agent for the grant to ensure that funds received from the sponsor are made available for 'buying' clinical coverage
- The department chair (or other existing authority responsible for managing the clinical staffing) will be responsible for sourcing and selecting personnel to cover for the project staff's protected time.

NOTIFICATION OF INTENT TO APPLY FOR EXTRAMURAL SPONSORSHIP

This form is a statement of intent and does not create an obligation. Please send this notification to the Sponsored Programs Committee who will review and assign resources to assist in building your application to the sponsoring agency and obtaining internal approvals

Principal Investigator(s) Click here to enter PI name(s).

Dept. contact name: Click here to enter text. email: Click here to enter email phone: Click to enter phone#.

Program Title: Click here to enter text.

Sponsoring agency: Click here to enter name of sponsoring agency. Due date: click to pick date from dropdown.

Sponsor reference: Click here to enter name of sponsor's reference eg RFA, RFP, internet URL etc

Description of program or protocol:

Click here to enter description of the program or protocol. If cutting & pasting from another document please paste as unformatted text and then click outside of the box before saving the document

CCHHS Resources Requested:

- ☐ I request assistance with preparing the application and securing internal approvals
- ☐ I anticipate requesting protected time to conduct program/protocol
- ☐ I anticipate requesting additional space to conduct program/protocol
- ☐ The program/protocol will use CCHHS pathology labs (If non-standard test needed please comment below)
- ☐ The program/protocol will use CCHHS imaging resources
- ☐ The program/protocol will use CCHHS pharmacy resources
- ☐ The program/protocol will use other CCHHS clinical resources. (Please specify in comments box below)

Collaboration Assistance:

- ☐ Does this program/protocol involve collaboration with external institutions (other than the sponsor)? if so, please indicate collaborators name & affiliation: Click here to enter name of collaborating institution
- ☐ Would you like assistance in finding collaborators?

Financial Impact:

- ☐ Will you be able to budget for full recovery of indirect cost at full F&A rate?
- ☐ Does the sponsor require CCHHS cost sharing? (i.e. in order to complete the protocol CCHHS will have to provide resources that will not be reimbursed by the sponsor, including clinical resources noted above if not directly reimbursed)

Anticipated Fiduciary Agent Choose from dropdown list. Or enter agent name Click here to enter name of fiduciary

Additional Comments: Click here to make additional comments or requests.

If cutting & pasting from another document please paste as unformatted text and then click outside of the box before saving the document

When complete please email to spcinbox@ccbhs.org

SPC Follow-up…

This box to be completed by SPC/OSP

Form received
date

Advanced Notifications sent to:
Department Chair
date
CCHHS labs, imaging, pharmacy, IT
date
CMO's office
date
CFO's office
date
ORA/IRB
date
Fiduciary agent
date

SPC/delegate review
date
ORA resources assigned
name
Date assigned

Progress checked with OSP and confirm back to PI
date

Approvals requested
Department Chair
date
CCHHS labs, imaging, pharmacy, IT
date
CMO's office
date
CFO's office
date
ORA/IRB
date
Fiduciary agent
date
IRB
date

Report back to PI on approvals received
date

Additional comments & guidance from SPC..
Click here to enter text.

Improving the Operation of Extramurally Sponsored Programs at CCHHS

Internal CCHHS Presentation
June 2011

Confidential – For internal use only

Agenda

I. Why should CCHHS be in the *Research Business*

II. Sponsored programs funding – a landscape of opportunity

III. Current operations

IV. Recommendations

V. Future State Operating Model

Goals

- Grow sponsored programs to provide more clinical services and to enhance professional life at CCHHS
- Build supportive infrastructure and secure greater transparency and direction of resources to programs
- Create framework for better coordination and collaboration with academic neighbors

Why Research at CCHHS ?

- Most training programs require research opportunities for trainees
- Doing research attracts high quality students and faculty
- Research and project funding pays for innovations in clinical care, in some cases helping reduce disparities in access, and providing patients their only access to leading edge therapeutics.
- Research can defer costs for tests and treatments and provide evidence of the necessity and cost effectiveness of new tests / treatments
- Research can return money to CCHHS, Departments, and investigators to fund both clinical and routine costs, grants flexible and fast alternatives to County purchasing system
- Creates alternative avenues to hire part time and sometimes full time staff to meet clinical and other departmental needs.

Sponsored Programs: Definition

Sponsored programs fall broadly in two different categories which we will call :

- **Project Grants** deliver clinical services that are not reimbursed by insurers (including Medicare and Medicaid) under the usual fee-for-service system, but instead are funded by federal or state agencies to deliver specific clinical services to defined populations (as in the Ryan White programs and most public health programs). These sometimes study innovations in healthcare quality, technology, or processes (e.g. SPNS grants). These programs are of particular benefit in addressing health disparities. Many, but not all, are waived from review by the IRB. Most CCHHS grants are currently this type.

- **Research grants** where the sponsor agrees to fund a novel therapeutic protocol that is not part of the usual standard of care and therefore not reimbursable by insurers. These programs typically require more stringent assessments of outcomes, and are formally reviewed by the IRB.

Federal Funding actual outlays

Department of Health and Human Services	2010 outlay
	$ Millions
Food & Drug Administration:	2,429
Centers for Disease Control and Prevention:	6,491
Centers for Medicare & Medicaid Services:	781,713
Indian Health Service:	4,612
Health Resources and Services Administration:	8,532
Agency for Healthcare Research and Quality:	317
Substance Abuse and Mental Health Services:	3,457
National Institutes of Health:	37,189
Administration for Children and Families:	58,472
Administration on Aging:	1,583
Office of the National Coordinator:	851
	905,646

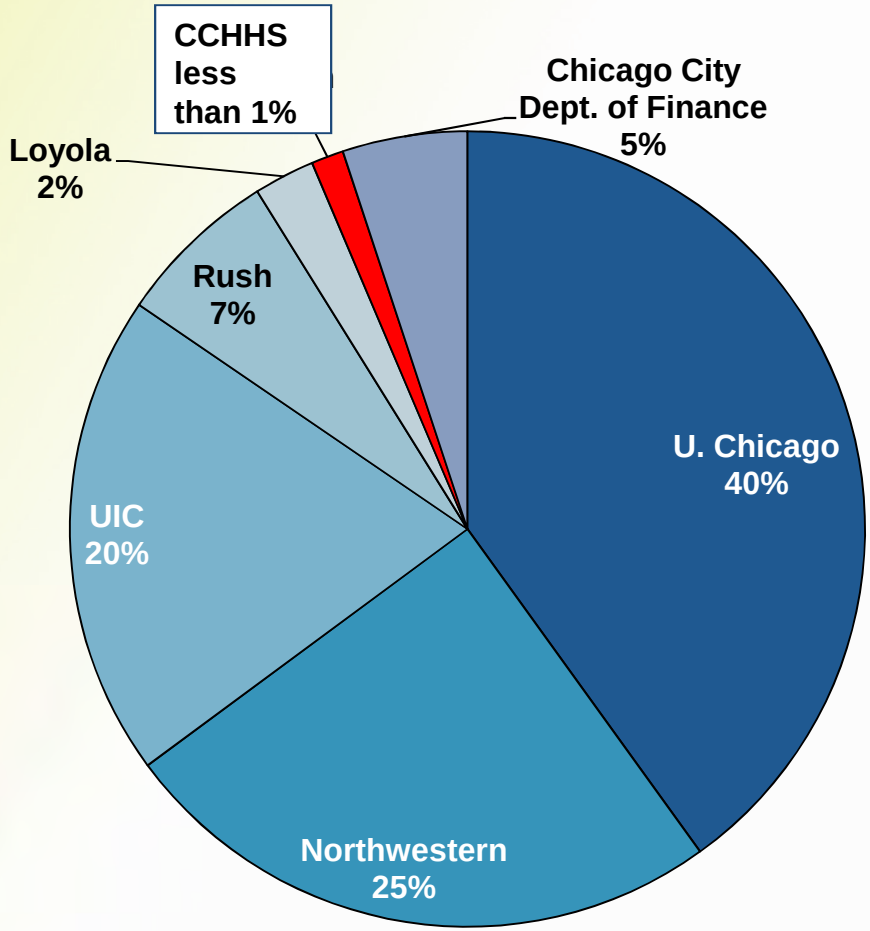
$50 Billion

$826 million to Chicago area

HHS only. Excludes opportunities from FEMA, DoD or other government agencies

Chicago Institutions Federal Healthcare Funding: $826 M

FY 2009 Total Funding: $826 M



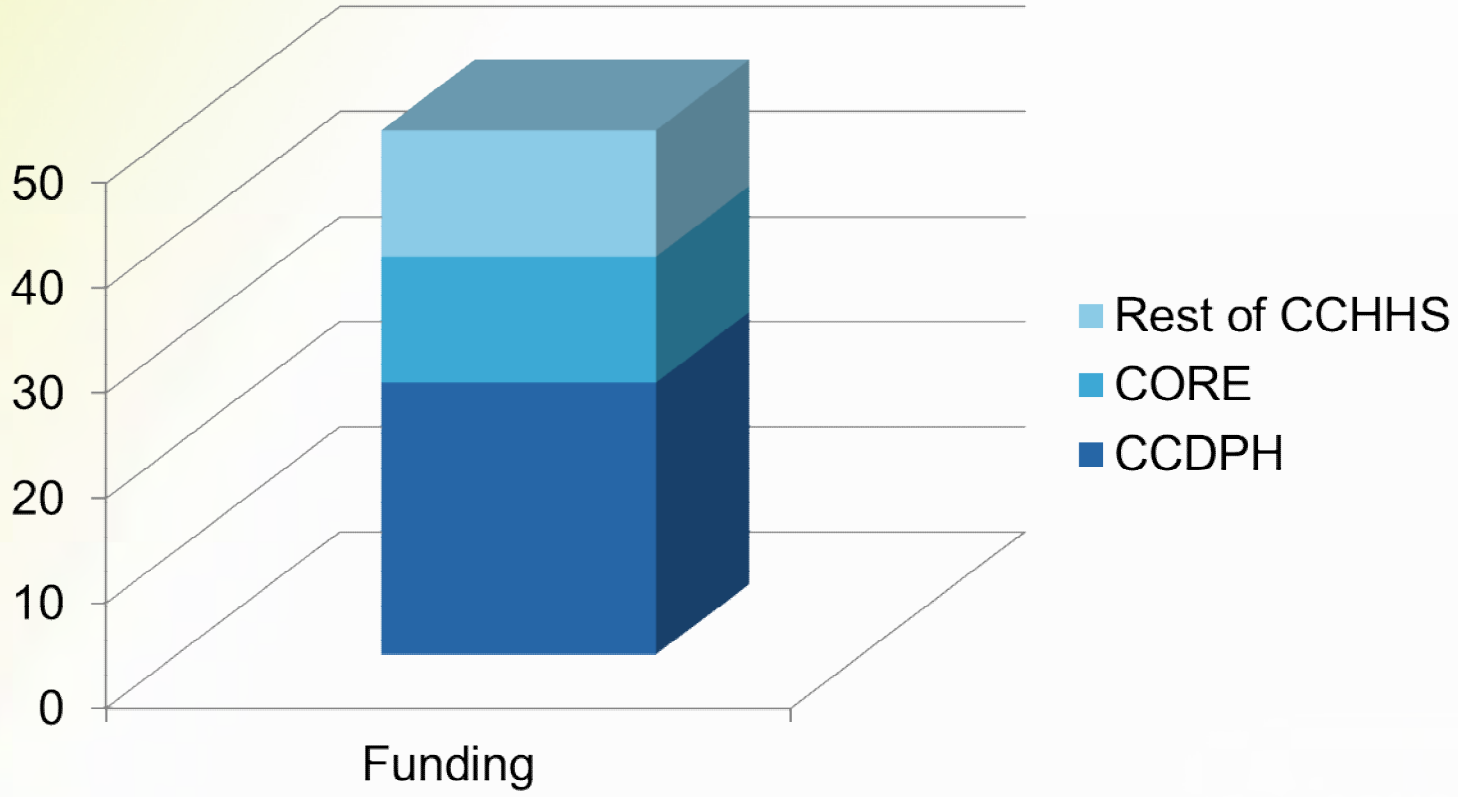
- This includes federal funding relating to health care research and programs for major Chicago institutions involved in healthcare.
- Agencies include: Dept. of Defense, Dept. of Navy, Dept. of Army, SAMSHA, CDC, NIH, FDA, HRSA, AHRQ, NSF

Source: usaspending.gov, includes reported amounts of expenditures from federal sources. Data shows expenditures specifically related to healthcare research and programs.

CCHHS share of Chicago area funding

Sponsored programs are conducted throughout CCHHS, at Cook County Department of Public Health, the Ruth M Rothstein CORE Center and at the hospitals & clinics.

CCHHS receives $50 million from extramural sponsors, our hospitals plus Cermak plus ACHN conduct less than one quarter of these projects by $ value.

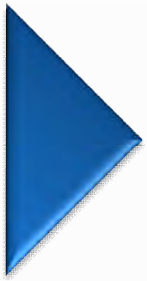


Sources: A-133, IRS Form 990, NIH RePorter & other public documents

Growth Target for Research and Sponsored Programs

- Based on snapshot of federal funding opportunities as at Nov 2010
- Over 1300 grants identified, total value of $311M annually
- Top 100 –identified applicable to CCHHS $50M annually

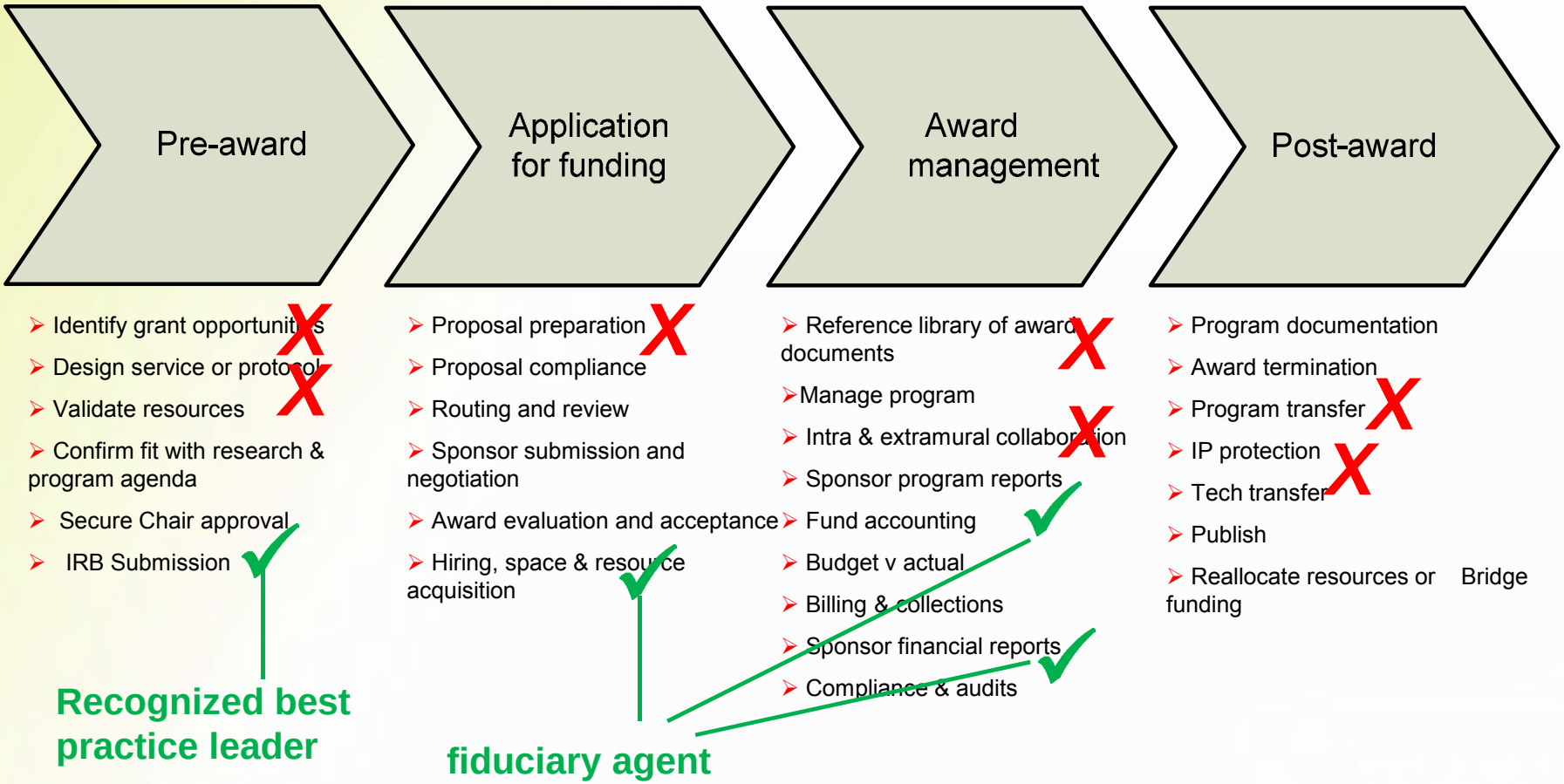
Top 100 for CCHHS*		
Diabetes	→	$ 5.1M
Behavioral	→	$ 20.2M
HIV	→	$ 9.5M
Maternal	→	$ 2.5M
Disparities	→	$ 7.0M
Operations & other	→	$ 5.7M

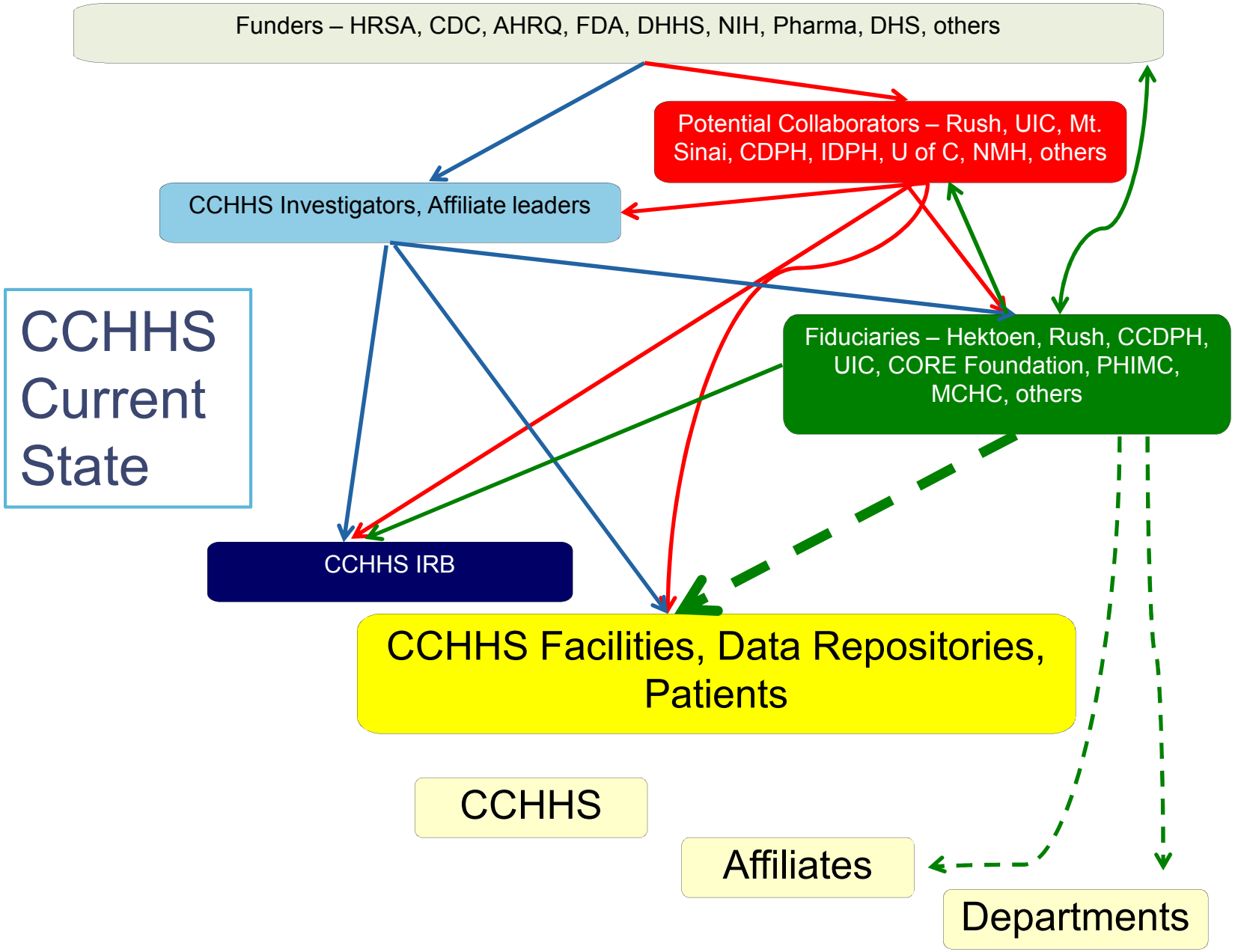


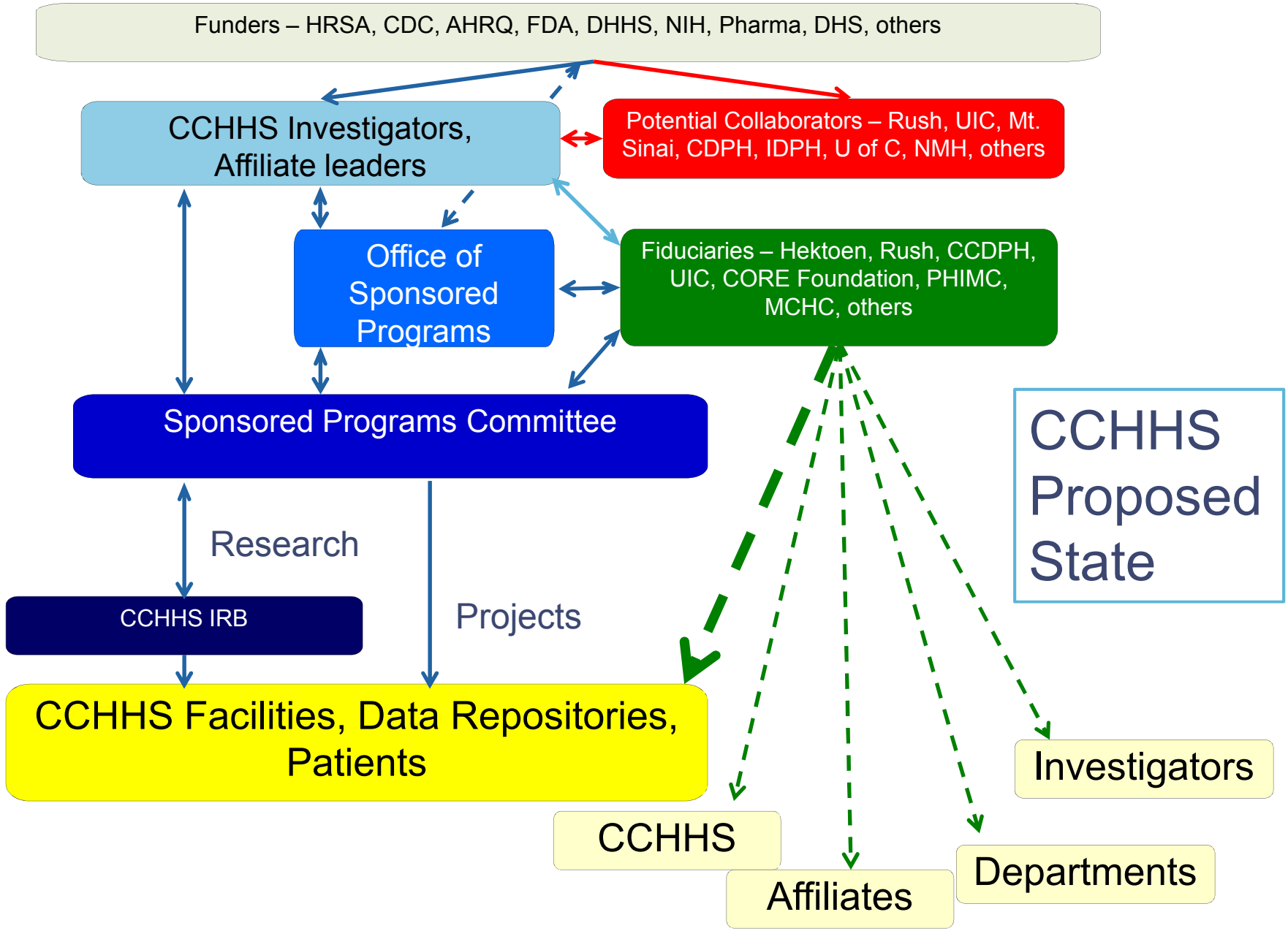
Target
$50M annually

Current Model: Strengths and Weaknesses

- Highly dedicated staff
- Organized program administrative support at CCDPH and CORE Center
- No significant hospital services (lab, imaging etc) left unbilled to sponsor
- Effective patient protection
- Patient volume and demographics attractive to researchers




Funders – HRSA, CDC, AHRQ, FDA, DHHS, NIH, Pharma, DHS, others
Potential Collaborators – Rush, UIC, Mt. Sinai, CDPH, IDPH, U of C, NMH, others
CCHHS Investigators, Affiliate leaders
CCHHS Current State
Fiduciaries – Hektoen, Rush, CCDPH, UIC, CORE Foundation, PHIMC, MCHC, others
CCHHS IRB
CCHHS Facilities, Data Repositories, Patients
CCHHS
Affiliates
Departments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Office of Sponsored Programs
Fiduciaries – Hektoen, Rush, CCDPH, UIC, CORE Foundation, PHIMC, MCHC, others
Sponsored Programs Committee
CCHHS Proposed State
Research
CCHHS IRB
Projects
CCHHS Facilities, Data Repositories, Patients
Investigators
CCHHS
Departments
Affiliates

11

Removing impediments,

BARRIERS

1. Not enough resources to complete the applications

–Assistance with grant writing
–Assistance with form submissions
–Assistance with budgeting

2. Academic Collaborations

–Need for basic science input
–Increasing sponsor requirement for multidisciplinary approaches
–Leverage basic science expertise of local AMCs

3. Time to do the work

–Shared Resources and Expertise
–Collaborative Fundraising

4. Staff Development

SOLUTIONS

1. Office of Sponsored Programs

–Provide resources for grant writing and scouting
–Provides resources for grant management
–Streamline process of institutional approvals including waivers of indirect costs

2. Sponsored Programs Committee (SPC) and Collaborative Framework

–SPC will provide a single point of contact and serve to review and approve collaborative projects
–Framework will provide a streamlined process ensuring properly shared resources

3. Protected Time Policy

–Investigators meeting agreed upon criteria can buy-out clinical duties using sponsored program funds.

4. Mentoring, collaborations and recruitment.

Future State: Recommendations

- Management & Compliance
  - Sponsored Programs Committee
  - CCHHS Board Reports
  - Facilitating collaborations
- Operational Resources
  - Office of Sponsored Programs
  - Faculty mentoring, recruitment
- Operational Procedures
  - Protected Time Policy
  - IDC Allocation Policy
- Collaborative Framework
  - Policies clarified
  - Processes communicated
  - Facilitate through Departments / Affiliates
- Fiduciary Agents
  - Secure greater transparency
  - Focus more resources into program support
- Philanthropic Development
  - Comparable to peers

SPC and OSP

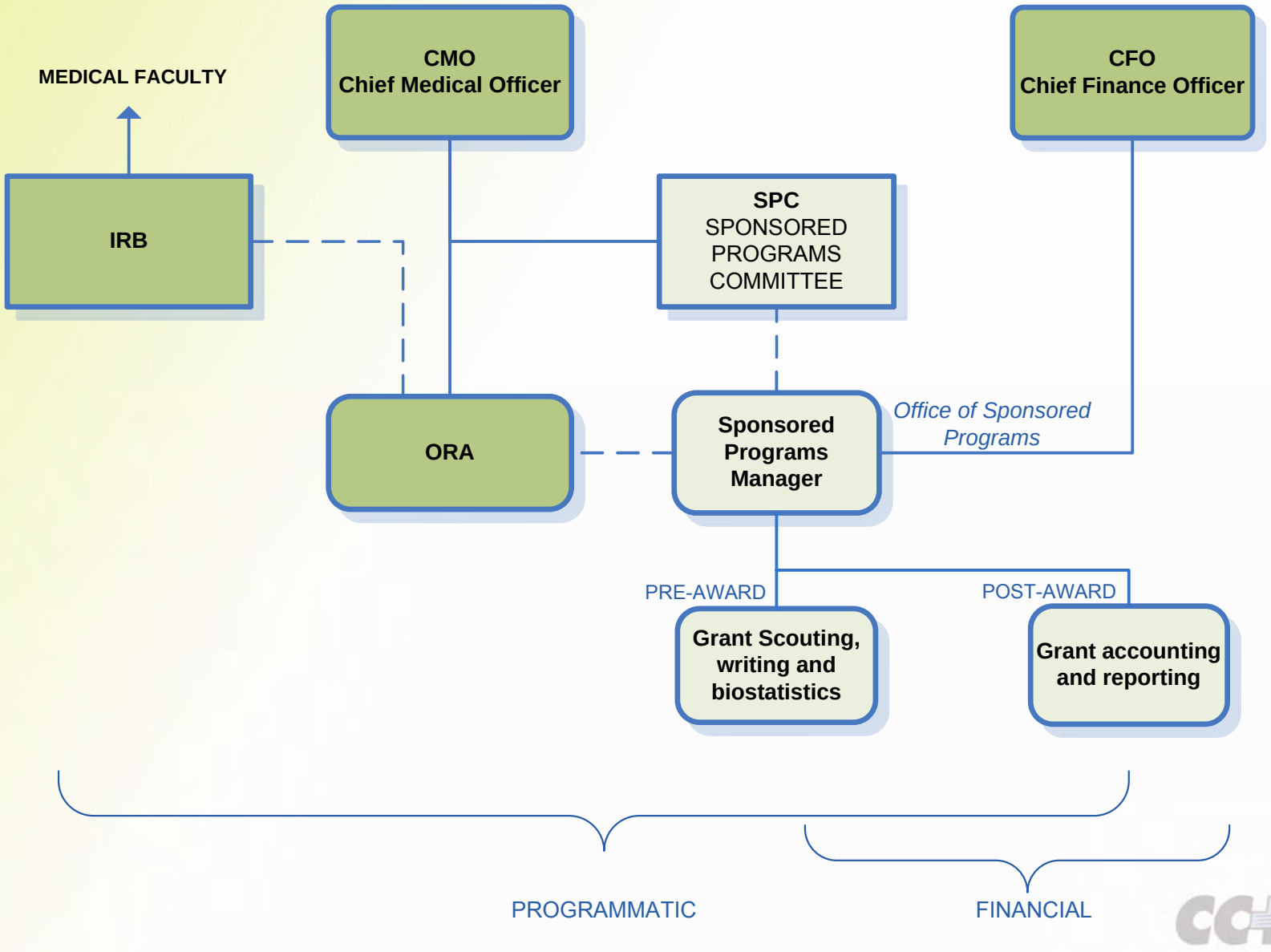
Sponsored Programs Committee

- Brief review of all proposed extramurally funded projects
- Prioritize projects for OSP assistance when limited
- Prevent competition between CCHHS investigators for same funds
- Facilitate collaboration within CCHHS and with outside groups
- Create registry of all projects for CCHHS Board, Management, public
- Recommend waivers of Indirect Costs for meritorious projects
- Streamline approvals in concert with CCHHS CFO and CMO

Office of Sponsored Programs

- Assist investigators in writing non-technical portions of grants
- Repository of needed data on CCHHS facilities / patients for writers
- Biostatistician and design assistance, feasibility exploration
- Work with fiduciaries pre-award and post-award
- Assist fiduciary with grant accounting, costing, and indirect recovery

SPC and OSP


MEDICAL FACULTY
CMO
Chief Medical Officer
CFO
Chief Finance Officer
IRB
SPC
SPONSORED
PROGRAMS
COMMITTEE
ORA
Sponsored
Programs
Manager
Office of Sponsored
Programs
PRE-AWARD
POST-AWARD
Grant Scouting,
writing and
biostatistics
Grant accounting
and reporting
PROGRAMMATIC
FINANCIAL

3rd Party Fiduciary Agents

- Provide valuable management services, finance, admin, HR,
- Will continue to be needed for the foreseeable future
- Need to be aligned closer to CCHHS strategy and operations
- Need to be more supportive of CCHHS staff in grant writing
- Greater financial transparency & control is essential for success

Future State: Benefit Analysis

- Capacity to win more grants
- Increased patient access to novel therapies
- Increased funding for innovative service programs
- Achieve “critical mass” self sustaining research infrastructure
- Improved assessment and fulfillment of community health needs
- Fair allocation of IDC on grants to CCHHS, Investigator, Department / Affiliate
- Increase access to highly flexible funds to fund research and programs
- Protected Time system that is fair to faculty, chairs, and institution
- Develops and retains investigators
- Fulfill RRC requirements for residents and fellows to conduct research
- Funds Quality Improvements in care via demonstration projects
- Improves data infrastructure and analysis capabilities
- Improve ease of staff recruitment / increase motivation, morale
- Improved recognition as a site for clinical innovation and research programs
- Improved ability to collaborate fairly with other institutions

CCHHS

Your comments, observations, suggestions…….

Dr. David Barker
Chief Medical Officer, The Ruth M. Rothstein CORE Center
dBarker@corecenter.org

Mr. Mike Ayres
Chief Financial Officer, CCHHS
mayres@ccbhs.org

Additional slides:

Notification to SPC one-page form

NOTIFICATION OF INTENT TO APPLY FOR EXTRAMURAL SPONSORSHIP

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Program Title:

Sponsoring agency: Due date:

Sponsor reference:

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Anticipated Fiduciary Agent Or enter agent name

Additional Comments:

When complete please email to spcinbox@ccbhs.org

SPC Follow-up...

Form received

Advanced Notifications sent to:
Department Chair
CCHHS labs, imaging, pharmacy, IT
CMO's office
CFO's office
ORA/IRB
Fiduciary agent

SPC/delegate review

ORA resources assigned

Progress checked with EFA and confirm back to PI

Approvals requested
Department Chair
CCHHS labs, imaging, pharmacy, IT
CMO's office
CFO's office
ORA/IRB
Fiduciary agent
IRB

Report back to PI on approvals received

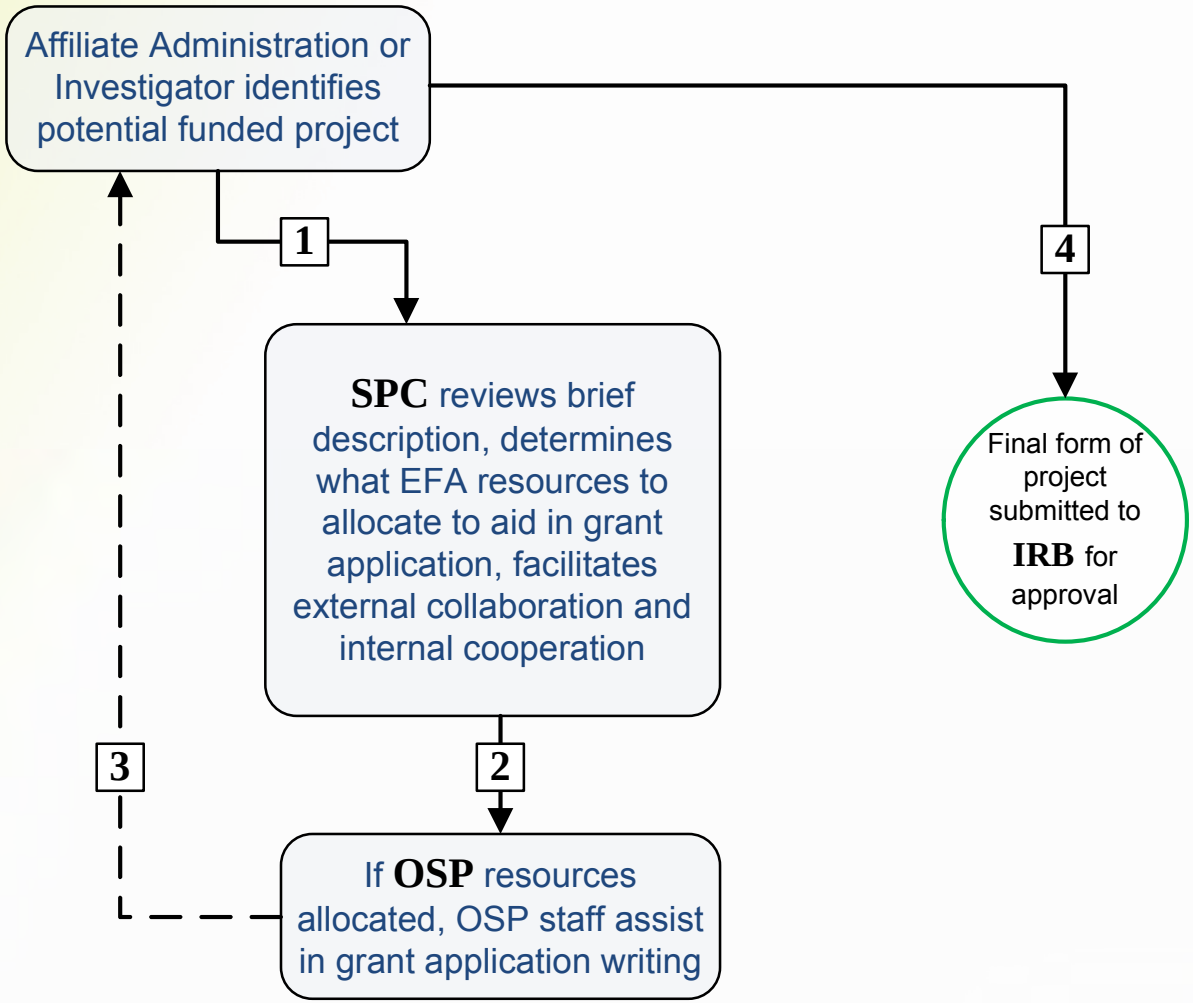
Additional comments & guidance from SPC..

SPC Notification Form Feb-2011

CCHHS

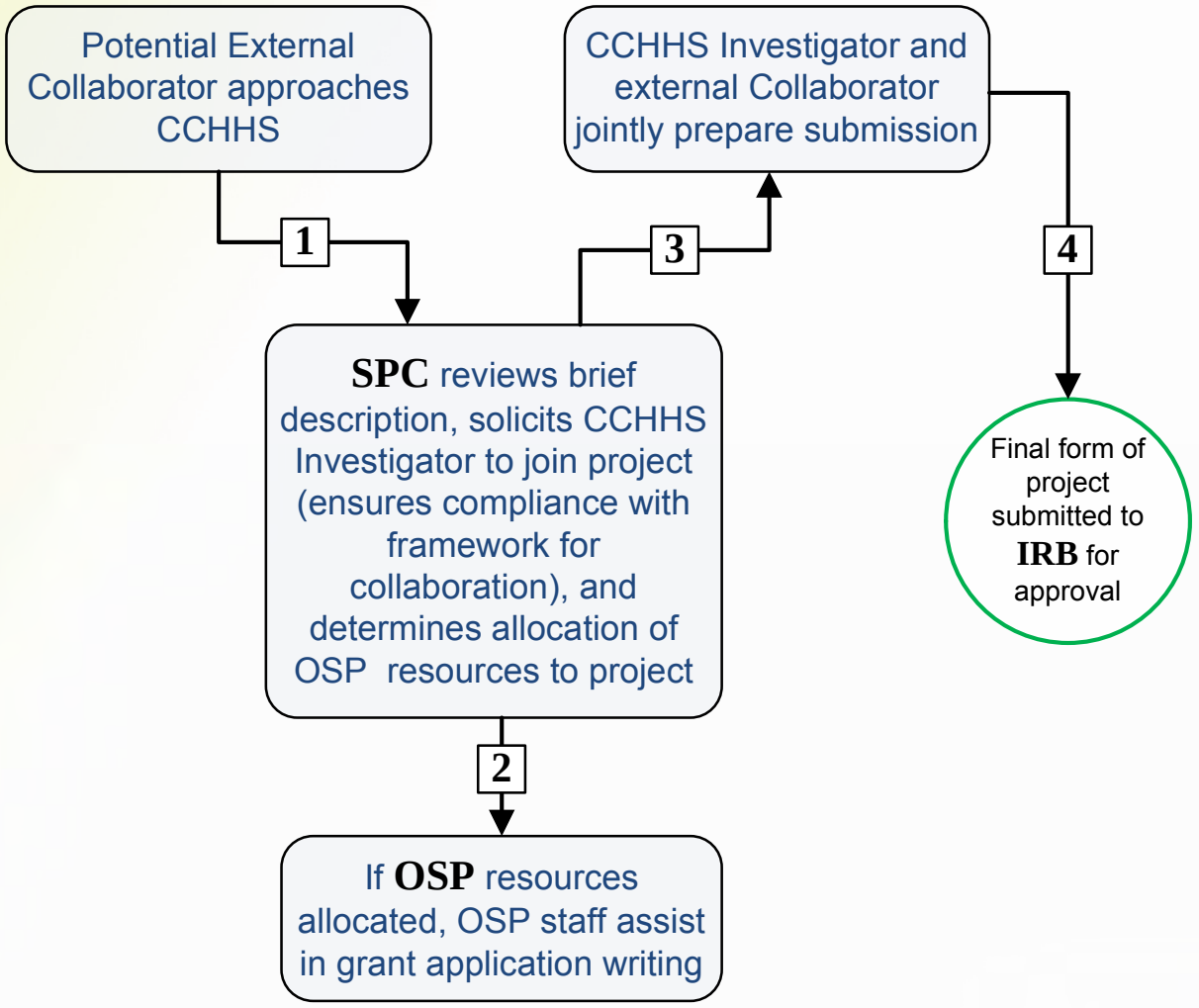
SPC/OSP process

Affiliate administration or individual investigator initiated

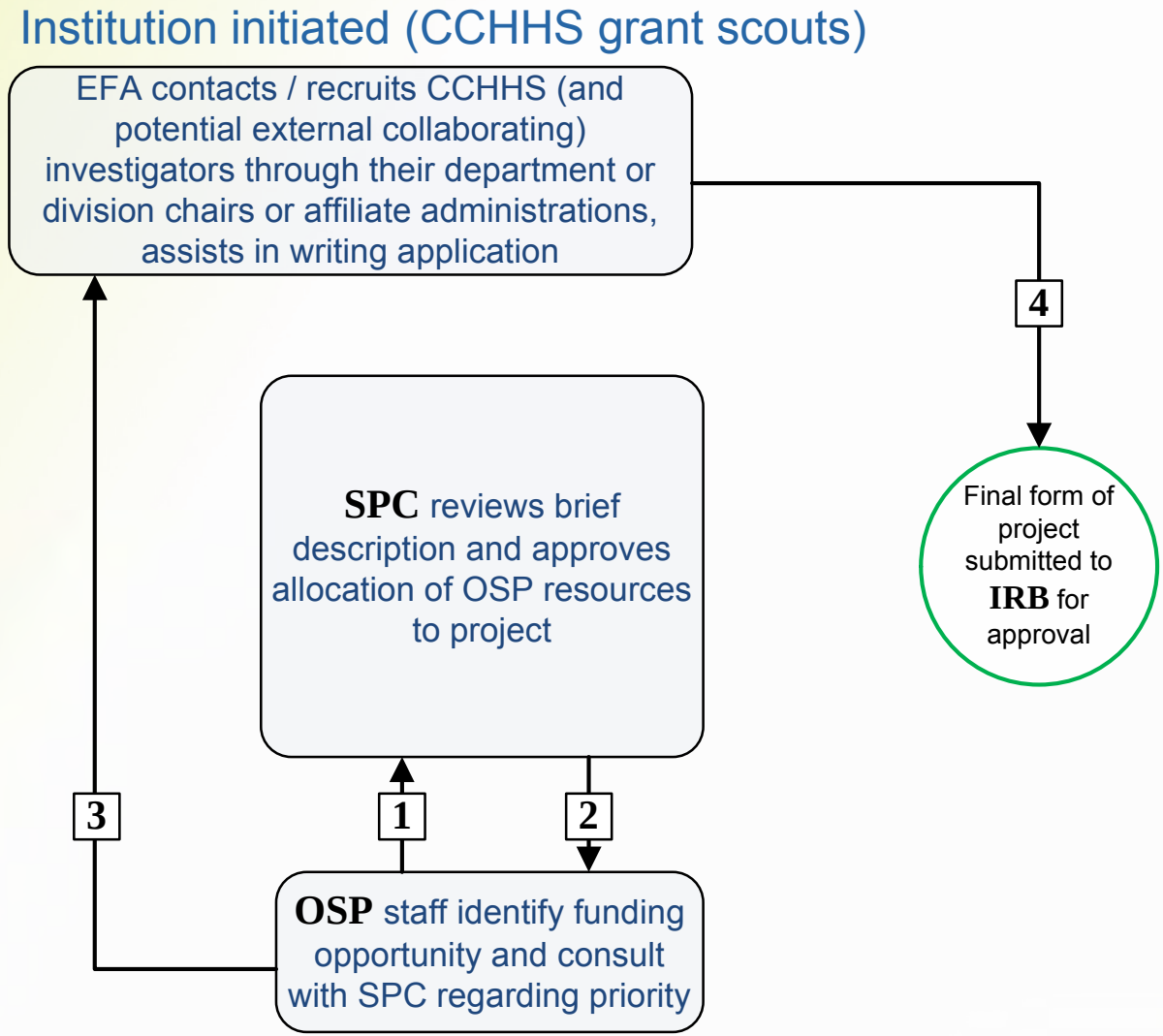


SPC/OSP process

External collaborator initiated



SPC/OSP process



SPC/OSP process during application phases