State University of New York
Integrated Clinical Trials Infrastructure

2014-15 Campus Reports:
  University at Buffalo
  Downstate Medical Center
  Optometry
  Stony Brook University
  Upstate Medical University

Kathryn Richdale, OD, PhD
Research Foundation Presidential Fellow

Version date: 28 Jul 2015
# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>4</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>5</td>
</tr>
<tr>
<td>SUNY University at Buffalo</td>
<td>6</td>
</tr>
<tr>
<td>- Overview</td>
<td>6</td>
</tr>
<tr>
<td>- Software/systems</td>
<td>6</td>
</tr>
<tr>
<td>- Sponsored project intake, review and approval process</td>
<td>6</td>
</tr>
<tr>
<td>- IRB, ethics training, compliance, clinical trials registration</td>
<td>6</td>
</tr>
<tr>
<td>- Statistical support and data management</td>
<td>7</td>
</tr>
<tr>
<td>- Study start-up and conduct</td>
<td>7</td>
</tr>
<tr>
<td>- Outreach and recruitment</td>
<td>7</td>
</tr>
<tr>
<td>- Billing, reconciliation, study close-out</td>
<td>7</td>
</tr>
<tr>
<td>- Future aims and needs</td>
<td>8</td>
</tr>
<tr>
<td>- Campus Org Chart</td>
<td>9</td>
</tr>
<tr>
<td>SUNY Downstate Medical Center</td>
<td>10</td>
</tr>
<tr>
<td>- Overview</td>
<td>10</td>
</tr>
<tr>
<td>- Software/System</td>
<td>10</td>
</tr>
<tr>
<td>- Sponsored project intake, review and approval process</td>
<td>10</td>
</tr>
<tr>
<td>- IRB, ethics training, compliance, clinical trials registration</td>
<td>10</td>
</tr>
<tr>
<td>- Statistical support and data management</td>
<td>11</td>
</tr>
<tr>
<td>- Study start-up and conduct</td>
<td>11</td>
</tr>
<tr>
<td>- Outreach and recruitment</td>
<td>11</td>
</tr>
<tr>
<td>- Billing, reconciliation, study close-out</td>
<td>11</td>
</tr>
<tr>
<td>- Future aims and needs</td>
<td>11</td>
</tr>
<tr>
<td>- Campus organizational chart</td>
<td>12</td>
</tr>
<tr>
<td>SUNY Optometry</td>
<td>13</td>
</tr>
<tr>
<td>- Overview</td>
<td>13</td>
</tr>
<tr>
<td>- Software/System</td>
<td>13</td>
</tr>
<tr>
<td>- Sponsored project intake, review and approval process</td>
<td>13</td>
</tr>
<tr>
<td>- IRB, ethics training, compliance, clinical trials registration</td>
<td>13</td>
</tr>
<tr>
<td>- Statistical support and data management</td>
<td>14</td>
</tr>
<tr>
<td>- Study start-up and conduct</td>
<td>14</td>
</tr>
<tr>
<td>- Outreach and recruitment</td>
<td>14</td>
</tr>
<tr>
<td>- Billing, reconciliation, study close-out</td>
<td>14</td>
</tr>
</tbody>
</table>
Introduction

The SUNY Research Foundation (RF) expenditure reports from fiscal year 2013-14, showed nearly 550 open sponsored clinical research accounts for the campuses with the greatest activities (Stony Brook University, Upstate Medical University, University at Buffalo, Downstate Medical Center, and Optometry). More than 250 unique sponsors were reported in the database (see appendix). Due to limitations in the current RF reporting system the sponsor listing is not always accurate, as it is not possible to fully list primary and subcontracts and contract research organizations for clinical trials. It is also not possible to determine from the current RF system if the open accounts are associated with actively enrolling studies, projects in long term follow-up, or closed projects. Nor is the type of clinical research study (i.e. observational study, disease registry, interventional clinical trial) included in the current database. There was nearly $10 million in clinical research trials expenditures across these five campuses in fiscal year 2013-14, but there is no readily available information on the actual value of all sponsored clinical research contracts, nor the ability to reconcile differences in funds based on actual enrollment and completion of subjects.

A 2012 Research Foundation (RF) Risk Assessment demonstrated a need to strengthen compliance and risk management for clinical trials. Risk exists in areas including, but not limited to, budgeting and contract negotiation, effort reporting, conflict of interest, and invoicing and reconciling of sponsored projects. SUNY also lacks some of the basic infrastructure, at the system level, to support clinical trials. There is no clear online presence to introduce SUNY faculty and facilities to potential sponsors, connect sponsors to our investigators, or recruit and retain patients for clinical trials. There are also increasing federal demands for increased training for clinical research personnel (faculty, staff, residents, students).

For these and other reasons the RF chartered an Integrated Clinical Trials Infrastructure Project charter in the Summer of 2014. The project began by seeking input from the five campuses with the most active sponsored clinical research programs. The vice-presidents of research (VPR) and/or operating managers (OM) were invited to appoint a campus lead for the project. This person coordinated an on-campus day-long meeting with key administrative personnel and faculty conducting sponsored trials. Participants were asked to provide an overview of current procedures and future goals and needs for sponsored clinical research at their campus. All participants were encouraged to share both what was working well, and what areas were in need of improvement. The campus reports were designed to be brief (2-3 page), factual representations of the overall process, and not to layout individual steps or processes. All campus reports were routed for review and approval, by the campus lead.

This report provides an overview of the current conduct of and stated needs for sponsored clinical research at the five campuses (pages 6-21). Organizational charts were provided by campuses to support continued communication and development across the system. A summary of the current systems and plans for implementation of new software are provided at the end of the campus reviews (page22). Finally, recommendations for the development of system-wide clinical trials infrastructure are summarized at the end of the report (pages 23-24).
Acknowledgements

Thanks to the following VPRs and OM for their support of this project and to the campus leads who coordinated visits with key personnel and assisted with the development of campus reports.

University at Buffalo (UB)

VPR: Venu Govindaraju
Campus lead: Michelle Van Gheem, Betty Smith

Downstate Medical Center

OM: Astra Bain-Dowell
Campus lead: Joseph Barabino

Optometry

VPR/OM: Stewart Bloomfield
Campus lead: Eric Samonte

Stony Brook University (SBU)

VPR: David Conover
Campus lead: Lydia Chabza

Upstate Medical University

VPR/OM: David Amberg
Campus lead: Jennifer Rudes

A sincere thanks to Tim Killen for the opportunity to participate in this project as the 2014-15 Presidential Fellow, and to Hao Wang and Cathy Kaszlug for their support throughout the year. Finally, thanks to Judy Burns and Lisa LeBlanc for their assistance with the campus visits.
SUNY University at Buffalo

Overview
Buffalo is undergoing major campus-wide initiatives to support the growth and development of sponsored clinical research. They currently share some CTSA resources (i.e., Research Match) through the Rochester CTSA and re-submitted a CTSA grant application January 2015. Clinical research is conducted in individual practice plans and area hospitals and health centers as well as through a new university-wide Clinical Research Office (CRO). A new medical school building and children’s hospital building are slated to open in 2017. Buffalo is a decentralized campus and operates mostly independently with consultation to the RF central office as needed.

Software/systems
- COEUS and Oracle for pre and post award
- IRBnet
- CITI program for ethics
- There are four different EMR platforms in use across the UB systems (Kaleida, Erie County Medical Center, individual practice plans).
- Buffalo will be one of the first sites to use the CLICK system (preaward, IRB, IACUC, COI, safety, export controls). IRBnet will no longer be used once CLICK is in place (potentially as soon as October 2015).
- Buffalo reviewed and vetted multiple CTMS systems and has purchased and is currently implementing the Forte OnCore system (implementation is expected to last one full year until it is fully operational, with an expected completion date of summer 2016). OnCore, CLICK and Oracle will interface to provide a comprehensive clinical research management system.

Sponsored project intake, review and approval process
Department level approval is now required for all projects. All studies (investigator or industry initiated), must go through the CRO for registration and review/negotiation/approval. The process begins with a confidentiality agreement, signed by UB RF personnel and reviewed/acknowledged by the PI. The CRO works with study PIs and coordinators to review feasibility and budgeting. The IRB application and review/approval process occurs concurrently with contract/budget negotiations. This speeds the process and is financially feasible because a separate MOU is in place to designate that start-up and IRB fees must be paid even if the final contract/project isn’t completed. The CRO has compiled a fee schedule and works within the templates provided/required by sponsors to make sure that the budgets are appropriate and costs will be covered. Internal budgets are kept to clarify costs (i.e., if study coordinator time is wrapped into procedure costs or a separate line item).

IRB, ethics training, compliance, clinical trials registration
The Buffalo IRB is AAHRPP accredited and currently staffed by eight administrative staff. IRB committees meet weekly. Buffalo currently has about 200 active drug/device/biomedical research studies across campus. PRIMR guidelines suggest that, based on the ~4,000 total IRB applications reviewed annually, about 12-15 staff are needed. The Office of Research Compliance (in which the IRB function falls) is growing the staff size to be more in line with benchmarks and to meet national standards. Buffalo works with NIH IRBs as required. They do not generally work with external/central IRBs but may consider it on a case-by-case basis and only with approval from the IO. Studies were not historically being monitored for compliance, but the CRO is developing plans to monitor open protocols, especially in high risk areas.

Investigators are required to complete the CITI course basic human subject, ethics, social/biomedical and COI modules. Additional Responsible Conduct of Research and Good Clinical Practices modules and other training program are
available, but not required campus-wide. Good Clinical Practice (GCP) training is also required for all clinical research using human subjects. The first in-person training was conducted by Huron, but is being run by the Office of Research Compliance moving forward. As of March, 2015, over 2,000 investigators and members of their research teams have gone through GCP training.

Moving forward, clinical trials registration for IIS studies will be registered through CRO. There will be a review to determine if trials need to be registered.

**Statistical support and data management**
The Statistical and Data Management Center of the Gynecological Oncology group provides statistical consultation for study design, data analysis. They have the ability to develop electronic source documents and other electronic study support systems. They collaborate with Frontier for database development and management.

**Study start-up and conduct**
The process and support available vary widely across study sites. Much of the human subjects research is currently conducted within the departments/hospitals.

The CRO has SOPs in place for study conduct and is staffed with 10 FTE to work with UB’s clinical researchers to optimize their research efforts. The CRO offers the following services:

- Feasibility assessment
- Protocol and consent writing assistance
- Regulatory and IRB application assistance
- Contract negotiation (Confidentiality Agreement, CTA, MTA etc.)
- Budget negotiation and approval or consistent budgeting across university programs
- Coverage Analysis (CA) review and approval
- Study Coordinator support (if requested)
- Invoicing and accounts payable and receivable
- Study closure and budget reconciliation

**Outreach and recruitment**
Communication about enrolling studies varies across sites. Some PIs report no problems with recruitment and have been very successful in getting physician referrals within their department and from the surrounding community. Some have had success with Research Match and local paid advertising methods. Others have cited major problems with recruitment and low enrollment numbers. The CRO is working with PIs to assist in recruitment efforts, in order to increase enrollment and participation in clinical trials.

**Billing, reconciliation, study close-out**
Coordinators are responsible for preparing and submitting invoices. The CRO hired a full time staff member to manage invoicing and accounting for industry studies within that center.

There are significant challenges with tracking and managing funds received at Albany that do not allow timely and accurate internal accounting of funds received.

There is currently no formal process to reconcile and close out projects.
After funds are charged by the various entities the balance goes to the department and PI. When funds are transferred to non-sponsored accounts to close a grant there is concern that indirects are not charged.

The CRO is updating policies/practices to ensure that all billing and charges of expenses are timely. The CRO would prefer the ability to have payments from industry sponsors be issued to the campus (to the CRO), identified by the CRO as to what study the payment is for, and then proactively assign the payment to the appropriate account (it is felt that this would reduce the uncertainty of payments, i.e., determining what campus, what PI, what project a payment is for).

**Future aims and needs**

There are significant ongoing efforts to build and support the campus CRO to provide greater infrastructure for efficient and compliant growth. Looking at SUNY-wide potential for improvements in shared support services, Buffalo cited a need for more research education and training. There are also needs to increase recruitment/enrollment. There are challenges to working with local hospitals, VAs and other SUNY campuses who have their own research review/approval and IRB processes and thus a clear need for MOUs across facilities. And, there are continued challenges to appropriate financial oversight with remote fund receipt.
Campus Org Chart

June 2015
SUNY Downstate Medical Center

Overview
Downstate Medical Center is actively developing new procedures and policies to support the conduct of clinical trials. Downstate had about 40-45 active clinical trials, the majority being industry sponsored drug trials. The most active areas of research are rheumatology and endocrinology. Downstate collaborates extensively with Kings County Hospital across the street. Downstate is a centralized campus and works closely with the Research Foundation for many pre and post award needs.

Software/Systems
- Oracle for pre- and post-award
- IRBNet
- CITI programs and Health Care Compliance Strategies for ethics
- Allscripts/Healthbridge EMR
- PIs/coordinators keep their own research records. There is no clinical trials management system software currently in use.

Sponsored project intake, review and approval process
Downstate utilizes a multilevel review and approval form for all research. Their Proposal Tracking Sheet requires PI certifications and conflict of interest documentation as well as departmental and institutional review and sign off (Chair, Dean, IO, OM). Downstate requires submission of an internal budget and is in the process of developing standard fee schedules (standard of care services, research pharmacy, etc.). Following review and approval of IRB protocols at the department level using a department-based Scientific Review Committee and Chair’s sign-off, PIs then submit their protocols for IRB review. The IRB submission may be done at the same time as the contract and budget review.

Confidentiality agreements can be signed on campus, but all contracts are reviewed and signed by the Research Foundation. The contract review process takes about 4 weeks.

IRB, ethics training, compliance, clinical trials registration
Human subjects applications generally go through the local Downstate IRB. Extensive work has been done to establish policies and procedures for working with the Downstate IRB and other IRBs. A memorandum of understanding is in place for working with Kings County and the central BRANY IRB and is currently being updated. Downstate also works with NIH-mandated IRBs and has procedures in place for PIs to request approval to work with other central/external IRBs or seek reciprocity with other academic centers. The Downstate IRB meets monthly and reviewed about 650 full board, 750 expedited and 160 exempt studies in the past year.

Every new study member must complete CITI (basic modules) and Health Care Compliance (COI) training before starting on a study. CITI re-training is required every 2 years and COI every 4 years.

A compliance office was established in 2000 and oversees all campus compliance issues, not just research. The office ensures ethics and COI certifications are complete/current. There is no formal campus study monitoring/auditing program beyond these reviews.

Although generally done by the sponsor, PIs are responsible for ensuring applicable clinical trials information is submitted to Clinical Trials.gov. Submissions are reviewed and approved by the pre-award office.
**Statistical support and data management**
Two full time statisticians are available to consult with faculty on clinical trials and other projects. There are no costs associated with support for protocol development. If the work is to be ongoing with support from a funding agency, the project is expected to include support for the biostatistician. Biostatisticians are also members of the IRB and can provide support for faculty in need of statistical consultation.

**Study start-up and conduct**
Study support varies by the PI/department. Some PIs have well-established coordinators while others have limited research staff support/experience. PIs operate relatively independently. There was interest in setting up a network of study coordinators across the campus and in developing more standardized procedures across the campus.

**Outreach and recruitment**
There is no general campus advertising or recruitment system in place. Some PIs reported no problem with recruitment for disease studies where patients are enrolled through the practice, but there may be some challenge to recruiting healthy controls. Recruitment/enrollment was not Downstate’s primary concern at this time.

**Billing, reconciliation, study close-out**
Study coordinators are responsible for generating, sending and following up on sponsor invoices. There is no formal reconciliation process at study close-out, but processes are being established to ensure certain funds were appropriately charged (i.e., IRB, pharmacy). After the PI confirms that the study is completed and funds received, the account is closed and the balance goes to the PI’s discretionary account.

**Future aims and needs**
Downstate would like to develop a clinical trials office with dedicated staff. There were significant concerns from faculty about the lengthy review/approval process at the RF. There were also concerns that the since accounts receivable go to Albany, that they are not easily reconciled. It was thought that having more pre- and post-award services directly available on campus would provide better support and oversight for clinical trials.

The SUNY-wide shared systems of interest include a clinical trials management software system, and potentially some educational programs (i.e., junior faculty, study coordinators).
Campus organizational chart

Note: grey boxes indicate vacant positions.
**SUNY Optometry**

**Overview**

Optometry has about 50 active clinical research projects, including roughly 10 active sponsored clinical trials. They are a centralized campus and utilize the RF for grants/contracts, tech transfer, and cash management. The College founded the Clinical Vision Research Center (CVRC) in 2013 to support sponsored clinical research. Other human subjects research is run through individual labs.

**Software/Systems**

- Oracle for pre- and post-award
- IRBNet
- CITI and Responsible Conduct of Research programs for ethics
- NextGen EMR
- Optometry uses Quickbooks for internal bookkeeping for sponsored projects. Greenphire ClinCards are used for electronic subject payment for projects in the CVRC. There is currently no clinical trials management system software in use.

**Sponsored project intake, review and approval process**

Optometry utilizes a Research Authorization Form (RAF) for administrative review and approval for all research conducted at the college. The RAF requires PI certifications and conflict of interest documentation as well as a PI- or sponsor-proposed budget to be submitted. Institutional sign off includes the VPR/OM (for all), Dean (if requests personnel effort changes), VP of the Clinic (if patients are recruited from clinic), and Director of CVRC (if sponsored clinical research). The CVRC has a standardized list of minimum expected reimbursements for clinical trials.

Confidentiality agreements can be signed at the campus level, but all contracts must be reviewed and signed by the Research Foundation. The contract review process takes up to 4 weeks.

**IRB, ethics training, compliance, clinical trials registration**

Human subjects research goes through the local Optometry IRB, unless it is a multicenter sponsored trial. Policies are in place for expectations in working with a central IRB, and a memorandum of understanding with the central IRBs stipulates that the college will retain oversight of compliance on campus. The IRB is in the process of seeking AAHRPP accreditation. The IRB meets biweekly and reviewed about 50 expedited applications in the last year.

Every new study member must complete CITI (basic modules) and COI training before starting on a study. Students are also required to complete RCR training. GCP training is required for those conducting drug or device trials. A CITI refresher course is required every 3 years and the full course must be repeated every 9 years. COI training is required every 3 years.

A compliance office was established in 2014 and oversees all human subjects research at the College. The office ensures ethics and COI certifications are complete/current. The CVRC has additional support for monitoring of clinical trials prior to sponsor visits.

PIs are responsible for ensuring applicable clinical trials information is submitted to Clinical Trials.gov. Submissions are reviewed and approved by the compliance office.
**Statistical support and data management**
A part-time statistician is available to consult with faculty. There are currently no costs for faculty to utilize statistical consulting, but if the work is to be ongoing the project proposal is expected to include biostatistician support.

**Study start-up and conduct**
The CVRC has two full time study coordinators and about 1.5 FTE of clinical research optometrist time available on a fee-for service schedule. The CVRC also has SOPs in place for study conduct. There is a part-time associate director who oversees regulatory and outreach for sponsored studies. Projects conducted outside the CVRC are run by the PIs with their own lab staff.

**Outreach and recruitment**
The CVRC works with PIs to develop “advertising packages” for each project that includes website and newsletter language, flyers, dear doctor letter, and TV or radio ads, as project funding allows. The CVRC also conducts regular “in-service” education for faculty, staff and students to educate them on all currently enrolling sponsored studies. The CVRC has a profile on Center Watch. Projects run outside the CVRC manage their own recruitment/advertising. In general, recruitment/enrollment remains a challenge, with the majority of studies closing without meeting contracted enrollment numbers.

**Billing, reconciliation, study close-out**
In the CVRC, study coordinators are responsible for creating invoices based on study mile markers and enrollment. They are reviewed and signed off on by the PI and then submitted by the college’s sponsored research office, with a copy to the RF. Optometry is in the process of implementing Quickbooks to prepare and track invoices and accounts receivable for sponsored trials. Projects are reconciled at least twice a year, and a final review at study completion ensures funds were charged appropriately (e.g., faculty offset, IRB, CVRC). The balance goes to the PI’s discretionary account.

**Future aims and needs**
Optometry has interest in shared clinical trials management software, a web database for subject recruitment. There is also interest in shared policies for human subjects research conduct, training, and compliance. There remain challenges with using the central RF office for grants/contracts, study invoicing/accounts receivable, etc. but the campus believes that these services can remain centralized as long as they are done efficiently and with improved communication.
Campus organizational chart

Associate Dean for Research and Graduate Studies
Dr. Stewart Bloomfield

Clinical Vision Research Center
Director
Dr. Kathryn Richdale

Sponsored Research

Program Coordinator
Mr. Canh Tran

Administrative Assistant

Associate Director of Regulatory and Clinical Affairs
Dr. Kristen Fry

Clinical Research Doctors

Clinical Research Staff
Ms. Valerie Leung
Mrs. Alex Stormann

Sponsored Programs Director
Mr. Eric Samonte

Sponsored Research Officer/Institutional IRB Administrator
Vacant

Senior Staff Assistant
Ms. Debra Berger
SUNY Stony Brook University

Overview
Stony Brook has a significant and growing clinical trials program. They initiate about 75 new studies a year and have about 500 active sponsored clinical research projects. Their largest area for clinical trials is hematology/oncology, but there are also active programs in cardiology, neuro, surgery, and emergency medicine. Stony Brook is a de-centralized campus and operates mostly independently.

Software/Systems

- COEUS and Oracle for pre- and post-award
- IRBNet
- CITI programs for ethics
- Cerner EMR
- SBU has been using Clinical Conductor CTMS (Bio-Optronics), for the past three years. They will pilot the OnCore CTMS in oncology soon and hope to eventually transition to one CTMS for the entire campus. While all sponsored projects are entered and tracked in the CTMS system, only about 20 projects use the full management system for tracking enrollment, invoicing, etc. based on the size and scope of the project.

Sponsored project intake, review and approval process
The protocol, budget and contract are reviewed by the Clinical Trials Office (CTO). General feasibility of the project is discussed with the PI before proceeding. Oncology has an additional formal departmental review. The CTO has a standard fee schedule for sponsored projects and reviews and negotiates budgets with the sponsor on behalf of the PI. The only exception is for investigator-initiated projects where the PI determines the budget. IRB proposals can be submitted while contracts are being finalized.

Confidentiality agreements and contracts are reviewed and signed at the campus level and the campus has a number of master trial agreements in place. The process for new projects can take about 4-6 months from initial submission to study start-up.

IRB, ethics training, compliance, clinical trials registration
Industry sponsored (either investigator or sponsor initiated) studies are reviewed by Chesapeake Research Review, Inc. (central) IRB. The exception is if the sponsor is not willing/able to pay Chesapeake directly, then the local Stony Brook IRB will review the project. The Stony Brook IRB was accredited by AAHRPP in 2010. Stony Brook has procedures in place to work with other AAHRPP accredited IRBs and NIH IRBs (cancer, pediatrics, etc). There are approximately 1000 active studies involving human subjects at Stony Brook.

Every study team member must complete CITI (human subjects basic modules) and COI training before starting on a study. CITI re-fresher courses are required every 3 years and COI every 4 years.

The Office of Research Compliance ensures ethics and COI certifications are complete/current. They also conduct random and for-cause audits on open projects, and well as witness study procedures (i.e. consent process). Oncology recently hired their own additional monitor to conduct QA reviews on active projects.

The Compliance Office oversees Stony Brook submissions to clinicaltrials.gov.
Statistical support and data management
The Biostatistics consulting core has statisticians available as a fee for service. Stony Brook also has epidemiologists and statisticians who can collaborate on investigator initiated trials. Oncology also has a statistician on their Data Safety Management Committee.

Study start-up and conduct
Some PIs support their own study coordinators, but there are also two full time experienced coordinators available on a fee for service schedule through the CTO. Trials may be conducted within a department or at the Clinical Research Center. The Clinical Research Center has two nurses available, but is not currently equipped to handle in-patient studies. There was some faculty interest in developing an in-patient clinical research center.

Outreach and recruitment
The CTO maintains a website with active clinical trials information. The office uses information from the contract and IRB submission to create profiles and updates information monthly. Departments communicate new studies through grand rounds programs, department newsletters, etc. The EMR system allows alerts to be generated based on study criteria (i.e., age, diagnosis). Faculty reiterated that there is significant manpower required to identify and enroll eligible subjects, and that further support in this area would be welcomed.

Billing, reconciliation, study close-out
Study coordinators are responsible for generating and sending invoices to sponsors. A limited number of projects utilize the full CTMS platform for registering study visits and thus can use this to generate study visit specific invoices. But all projects are registered in the CTMS and it is used to manage invoicing of startup costs (IRB, pharmacy, CTO, etc). Like all campuses, there are challenges with incoming funds and identification of the appropriate account, but Stony Brook feels that they have an experienced team that is capable of working with key people at the RF to identify and assign unappropriated funds. PIs have up to one year after the close of a study to use any remaining study funds. After the one-year extension any remaining funds are transferred to the department.

Future aims and needs
Stony Brook aims to grow their clinical research presence, especially in the area of oncology and they are actively investing in those areas. They have CTMS systems in place. The primary concerns from faculty centered around personnel effort (investigator and study coordinator time) and space. The campus did not believe that they had any need for shared campus infrastructure at this time.
SUNY Upstate Medical University

Overview
Upstate is conducting major government and industry funded clinical trials as well as a variety of other sponsored clinical research studies. They are working to expand their research infrastructure. Much of their research is conducted in individual departments, but some projects are coordinated through their Clinical Research Unit (CRU). There are significant faculty research strengths in neuroscience/neurology, psychiatry, cancer, pharmacology, global health, and diabetes research, among others. Upstate is a decentralized campus and operates mostly independently with consultation with the RF as needed.

Software/Systems
- COEUS and Oracle for pre- and post-award
- IRBNet
- CITI programs for education
- EPIC EMR system.
- Upstate is currently trialing a Patient Identification Platform (Untangled Health Care Innovations) to identify potential study participants. No clinical trials management system is currently in use. PIs/coordinators keep their own records for trials.

Sponsored project intake, review and approval process
The process varies somewhat by department and PI, with some departments conducting an internal review before deciding whether or not to conduct the study and others allowing PI discretion. A master CPT code list is available for budget planning but rates can vary across departments. The CRU has guidelines for review and budgeting of clinical trials. The review and approval process takes about 6-8 weeks from beginning to final sign-offs and study start. Confidentiality agreements and contracts are reviewed and signed at the campus.

IRB, ethics training, compliance, clinical trials registration
All projects conducted at Upstate are generally required to use the Upstate IRB. The campus participates in NIH-mandated IRBs (i.e. National Cancer Institute’s Adult and Pediatric Central IRB’s, NeuroNext) and has participated in NY State and SUNY IRB initiatives (UNYCHRQ, UNYTE, SUNY REACH) but does not work with other central/external IRBs. The Upstate IRB meets once a month and reviewed 73 full board and 39 expedited studies in the past 12 months. The IRB administrator reviews each application for compliance with federal and state regulations, institutional policies and ethical considerations and a faculty member (not participating in the study) conducts a scientific merit review. Comments and questions raised by the reviewer(s) and/or IRB administrator are provided to the Principal Investigator. Following that, applications requiring full board review are added to the IRB meeting agenda for committee review. Applications that qualify for expedited review are reviewed by the chair, vice-chair or a designated member of the IRB.

The IRB has not sought accreditation. The Quality Assessment and Improvement Program (QAIP) coordinator (full time NP) conducts about three project audits a month. The audit reports are made available to the PI, VPR and IRB committee. QAIP also offers start-up/initiation support/training, coordinates the “hot topics in research” lecture series, training for investigators and CRA’s, and other support services as requested.

All study investigators are required to complete the human subjects curriculum, responsible conduct of research (RCR) and conflict of interest (COI) modules in CITI. Other modules are available, and requirements for training depend on the type of projects being conducted. Upstate is looking into mandatory in-person research education training.
Training for residents and fellows in research and scholarship is currently managed by the department and varies across departments. Interest was expressed in having centralized support for this.

Upstate has a policy and procedures in place for registering trials with clinicaltrials.gov and PIs are supported in the submission process.

**Statistical support and data management**
Upstate’s Center for Research Evaluation provides statistical support for grant writing, study design, and data analysis. Some faculty concern was expressed that the statistical support is a fee-for-service and not institutionally supported. Faculty expressed a need for large database development and management support.

**Study start-up and conduct**
The process and support available varies across department/PIs. Some departments have little to no research staff and others have multiple well-established coordinators and investigators. Some departments/PIs, and the Clinical Research Unit have SOPs in place for study conduct. There is an interest in more standardized procedures/systems across the campus and across SUNY.

A clinical research professionals group was formed which meets quarterly to share best practices and provide training for newer coordinators. Many of the coordinators have SOCRA certification. There are over 60 coordinators across campus.

**Outreach and recruitment**
The Upstate research office has a volunteer recruitment form that can be completed to post information on their website. Investigators have utilized various methods for recruitment from internal and external physician referrals, to flyers and newsletters, to paid external advertising. Enrollment is considered good to excellent for some studies, but other studies have closed with zero enrollment and some PIs site major challenges with meeting enrollment expectations.

There is currently no system-wide research database, Upstate recently began trialing the Patient Identification Platform software that works through the EMR to identify potential research participants.

**Billing, reconciliation, study close-out**
Coordinators are responsible for generating and sending invoices for studies. A copy is sent to the accounting office and the coordinator is expected to follow up once on the invoices and then let the business office know whether funds have been received. There is currently no formal audit or reconciliation process at study close-out. Upstate is working to standardize expectations for billing/reconciling of accounts via quick reference guide/checklists. After costs are charged, the account is closed and the balance goes to the department for further allocation.

**Future aims and needs**
Upstate would like to provide a “one stop shop” where faculty could be identified and matched with sponsors, and a team could help develop grants and budgets, training, study support, etc. There is a need for handling big database management and data analytics. Other general clinical research needs include increasing subject recruitment, recovering/analyzing clinical research costs, establishing best practices and providing education across the campus, and incentivizing clinicians to conduct research.
Campus organizational chart

Research Administration
SUNY Upstate Medical University
Summary of Systems/Software
Overview of current systems (June 2015). The pre and post award and IRB systems will be updated with the new PACS implementation (see below).

<table>
<thead>
<tr>
<th>Software type</th>
<th>Buffalo</th>
<th>Downstate</th>
<th>Optometry</th>
<th>Stony Brook</th>
<th>Upstate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre and post award management</td>
<td>COEUS, Oracle</td>
<td>Oracle</td>
<td>Oracle</td>
<td>COEUS, Oracle</td>
<td>COEUS, Oracle</td>
</tr>
<tr>
<td>IRB</td>
<td>IRBnet</td>
<td>IRBnet</td>
<td>IRBnet</td>
<td>IRBnet</td>
<td>IRBnet</td>
</tr>
<tr>
<td>Ethics certifications</td>
<td>CITI Programs</td>
<td>CITI Programs, Health Care Compliance Strategies</td>
<td>CITI Programs, Responsible Conduct of Research</td>
<td>CITI Programs</td>
<td>CITI Programs</td>
</tr>
<tr>
<td>EMR</td>
<td>Allscripts/ Healthbridge</td>
<td>NextGen</td>
<td>Cerner</td>
<td>EPIC</td>
<td></td>
</tr>
<tr>
<td>Subject payment</td>
<td>--</td>
<td>--</td>
<td>Greenphire</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Subject recruitment</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>Patient Identification Platform</td>
</tr>
<tr>
<td>CTMS</td>
<td>OnCore</td>
<td>--</td>
<td>--</td>
<td>Clinical Conductor, OnCore</td>
<td>--</td>
</tr>
</tbody>
</table>

DRAFT overview of implementation of Huron PACS system (courtesy of Hao Wang).
Recommendations for continued development

To support the expansion of clinical trials, improve risk management, and coordinate with other related SUNY initiatives (Networks of Excellence, SUNY AIR, etc.), it is clear that both the RF and SUNY campuses would benefit from the development of centralized support services via an RF central clinical trials office (RF-CTO). The primary areas in need of greater system-wide support can be categorized as: Clinical Trials Management, Outreach, and IRB/Ethics education and compliance. An overview of current limitations and future considerations are provided below.

Clinical Trials Management

CTMS software can help to lower costs, increase productivity, and support compliance. Specifically, CTMS systems support appropriate budget development, invoicing, and reconciliation, tracking of subject visits and database development, documentation of regulatory information, and may even interface with other systems (IRB, COI, contracts, etc.) to allow continuity across the life of a sponsored trial. Incorporating the same CTMS system across all campuses would allow standardized reporting of metrics and support the development of multi-campus trials. Buffalo and Stony Brook have already begun implementation of the OnCore CTMS, which can be integrated with Huron’s other pre- and post-award systems. Thus, it would be beneficial if the other SUNY campuses also adopt OnCore CTMS. Both RF-CTO and campus levels efforts will be needed to establish a plan for implementation of the system and training on its use.

To be successful in attracting industry-sponsored trials and ensuring long-term financial viability, SUNY must also significantly decrease turn-around time and improve accounting practices. Currently, the time to review, approve and start-up new clinical trials takes from 2 to 6 months. Campuses and the RF are working to develop master clinical trials agreements (MCTA) that can be used across all campus and the CLICK “Agreements” module should help facilitate the process. While some sponsors are not willing to enter into master agreements, many are and MCTAs can decrease the time for review/approval of new trials. Most campuses also cited many delays and challenges to sponsor invoicing and tracking of accounts receivable. An RF-CTO could help speed the development of new MCTAs, better assist some campuses in the review and approval of contracts, and increase support for invoicing and reconciling of funds. In the longer term, the RF-CTO could work towards allowing a sponsor to contact a single source and have access to a broad demographic patient base across multiple SUNY campuses. The RF-CTO could also work with campuses to develop standardized research budget guidelines which could be scaled for location costs or other campus-specific requirements.

Outreach

SUNY lacks a strong online presence to introduce faculty and facilities to potential sponsors, connect investigators across fields/campuses, and recruit patients for clinical trials. Multiple campuses expressed concerns about poor enrollment and highlighted the need for better recruitment methods. Under enrollment is the largest source of lost revenue in clinical trials. Previous effort was made by the SUNY REACH group to develop research faculty profiles, but the maintenance of the website required a significant amount of manpower and is not currently supported at a system level.

Development and maintenance of a comprehensive SUNY research website could be led by an RF-CTO in partnership with campus personnel to ensure that information is current and accurate. So as to avoid duplication of efforts, information would need to be easily entered by clinical research staff at the campus level and drawn into a comprehensive SUNY-wide system. Ideally, the central RF-supported system would be easily searchable by potential study subjects, collaborators and sponsors. “Sponsor/Collaborator” focused webpages would: highlight faculty expertise; document availability of equipment and resources; describe the diversity of clinic patients and the surrounding community for entry into trials; and clearly layout the process for conducting sponsored research at SUNY. “Community” focused webpages would: provide information to the SUNY and general New York community about the
clinical research being conducted at SUNY; educate potential participants about what clinical research is and why they should participate; provide information on how to participate in open (enrolling) studies at SUNY; provide a means for people to register to be contacted for future studies looking for either specific populations (i.e., by diagnosis) or healthy control subjects.

**IRB, Ethics, Education and Compliance**

All five campuses will be implementing the Click IRB system over the next 15 months. The CITI training programs will also be integrated in the new preaward system. Many campuses are actively working to improve their internal IRBs (establishing SOPs, beginning accreditation, etc.), and developing agreements to work with central/external IRBs. In order to facilitate multi-campus clinical research projects, campuses should have agreements in place to cede review of IRB protocols across the SUNY system. Many sponsors preferentially select sites that are able to work with a single central/external IRB. To maintain appropriate compliance, policies and procedures must be established to ensure proper oversight of both internally and externally reviewed/approved protocols. Monitoring for research compliance should generally be maintained at the campus level, but having central RF-CTO monitors who could be tapped for large projects or at campuses with fewer resources could be a consideration for future growth.

Because regulatory and ethics policies are based on federal/international guidelines, many of the campus have very similar Human Subjects Research Policies. An additional goal of an RF-CTO could be to work with campuses to develop a single SUNY-wide Human Subjects Policy. Similarly, all campuses utilize the CITI programs as the basic ethics training requirement to conduct human subjects research (although the amount of time between re-training varies). A single policy for ethics requirements would also support the use of shared/central monitors and multi-site trials.

There is a growing push from government and industry sponsors to have in-person ethics training. Some campuses have already begun developing programs for their faculty, residents and students. Since the information presented is not campus-specific, this could also be another resource provided by an RF-CTO. Campus presentations could be provided quarterly or semi-annually based on campus size and activity.

**Summary**

SUNY is a diverse system with great strengths and opportunities in the clinical trials arena. To fully realize this potential, greater infrastructure is needed at both the campus and system levels. Much of the ground work could be laid by an experienced and appropriately staffed clinical trials office at the RF. Short-term goals of an RF-CTO should include implementation of a SUNY-wide CTMS system. From there, specific goals for outreach and ethics and compliance could be developed. Working together, SUNY campuses and the RF could position themselves to be a strong and unique entity and a national leader in the conduct of clinical trials.
Appendix

Current clinical trial sponsors in RF system

Note: many entities are actually CROs and subcontracts due to current system reporting limitations

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M Company</td>
<td>Beckman Coulter Inc</td>
</tr>
<tr>
<td>Aastrom Biosciences Inc</td>
<td>BioControl Medical Inc</td>
</tr>
<tr>
<td>Abbott</td>
<td>Biodex Inc</td>
</tr>
<tr>
<td>AbbVie Inc</td>
<td>Biogen Idec</td>
</tr>
<tr>
<td>Abraxis Bioscience LLC</td>
<td>BioMarin Pharmaceutical Inc</td>
</tr>
<tr>
<td>Academic and Community Cancer Research</td>
<td>Biotronik Inc</td>
</tr>
<tr>
<td>Acorda Therapeutics</td>
<td>Trustees of the University of Alabama Birmingham</td>
</tr>
<tr>
<td>Actelion</td>
<td>Boehringer Ingelheim Pharmaceutical</td>
</tr>
<tr>
<td>Agensys Inc</td>
<td>Boston Scientific Corp</td>
</tr>
<tr>
<td>Alcon Laboratories</td>
<td>Boston Scientific CRM</td>
</tr>
<tr>
<td>Alder Biopharmaceuticals Inc</td>
<td>Bracco Diagnostics Inc</td>
</tr>
<tr>
<td>Alere San Diego Inc</td>
<td>BRAHMS GmbH</td>
</tr>
<tr>
<td>Alexion Pharmaceuticals Inc</td>
<td>Brigham and Womens Hospital</td>
</tr>
<tr>
<td>Alpha Oncology</td>
<td>Bristol Myers Squibb Company</td>
</tr>
<tr>
<td>Amarex LLC</td>
<td>BTG International Limited</td>
</tr>
<tr>
<td>Amedica Corp</td>
<td>Celator Pharmaceuticals Inc</td>
</tr>
<tr>
<td>American College of Radiology</td>
<td>Celgene Corp</td>
</tr>
<tr>
<td>American College of Surgeons</td>
<td>Celldex Therapeutics Inc</td>
</tr>
<tr>
<td>Oncology Group</td>
<td>CEM-102 Pharmaceuticals Inc</td>
</tr>
<tr>
<td>Amgen Inc</td>
<td>Centocor Ortho Biotech Services</td>
</tr>
<tr>
<td>Amorcyte Inc</td>
<td>Centre Hospitalier De L'Universite</td>
</tr>
<tr>
<td>Ampio Pharmaceuticals Inc</td>
<td>De Montreal</td>
</tr>
<tr>
<td>Amyotrophic Lateral Sclerosis Association</td>
<td>Cephalon Inc</td>
</tr>
<tr>
<td>Angel Medical Systems</td>
<td>Cerexa Inc</td>
</tr>
<tr>
<td>Angion Biomedical Corp</td>
<td>Cervitech Inc</td>
</tr>
<tr>
<td>Aptus Endosystems Inc</td>
<td>Chestnut Medical Technologies Inc</td>
</tr>
<tr>
<td>Arcon Group Inc</td>
<td>Childrens Hospital of Boston</td>
</tr>
<tr>
<td>Argos Therapeutics Inc</td>
<td>Children's Hospital of Philadelphia</td>
</tr>
<tr>
<td>ARIAD Pharmaceuticals Inc</td>
<td>CoDa Therapeutics Inc</td>
</tr>
<tr>
<td>Arthrex Inc</td>
<td>Codman and Shurtleff Inc</td>
</tr>
<tr>
<td>Astellas Pharma Global Development Inc</td>
<td>Columbia University</td>
</tr>
<tr>
<td>Astex Pharmaceuticals Inc</td>
<td>Comprehensive Research Associates</td>
</tr>
<tr>
<td>AstraZeneca Pharmaceuticals Inc</td>
<td>Concentric Medical Inc</td>
</tr>
<tr>
<td>Asubio Pharmaceuticals Inc</td>
<td>Connecticut Children's Med Ctr</td>
</tr>
<tr>
<td>Augmentix Inc</td>
<td>Cook Medical</td>
</tr>
<tr>
<td>Auris Medical AG</td>
<td>Corthera Inc</td>
</tr>
<tr>
<td>Auxilium Pharmaceuticals</td>
<td>Cougar Biotechnology Inc</td>
</tr>
<tr>
<td>Avanir Pharmaceuticals</td>
<td>Covance</td>
</tr>
<tr>
<td>Axio Research Corp</td>
<td>Covidiend</td>
</tr>
<tr>
<td>Bayer Healthcare Pharm Inc</td>
<td>Cyberonics Inc</td>
</tr>
<tr>
<td>BD Diagnostic Systems</td>
<td>Cytokinetiscs Inc</td>
</tr>
<tr>
<td>Daiichi Sankyo Pharma Development Inc</td>
<td>Dainippon Sumitomo Pharma</td>
</tr>
<tr>
<td>Development</td>
<td>America Inc</td>
</tr>
<tr>
<td>Dainippon Sumitomo Pharma</td>
<td>Debiopharm S A</td>
</tr>
<tr>
<td>America Inc</td>
<td>DePuy Spine</td>
</tr>
<tr>
<td>Debiopharm S A</td>
<td>Dialysis Clinic Inc</td>
</tr>
<tr>
<td>E Ink Corp</td>
<td>Duke University</td>
</tr>
<tr>
<td>Eisai Inc</td>
<td>EMM Serono Inc</td>
</tr>
<tr>
<td>Eisai Medical Research Inc</td>
<td>Emmaus Medical Inc</td>
</tr>
<tr>
<td>Eleven Biotherapeutics Inc</td>
<td>Emes Corp</td>
</tr>
<tr>
<td>Eli Lilly and Company</td>
<td>Emory University</td>
</tr>
<tr>
<td>EMD Serono Inc</td>
<td>Essilor International</td>
</tr>
<tr>
<td>Ev3 Endovascular Inc</td>
<td>Excited States Limited Liability</td>
</tr>
<tr>
<td>Forest Research Institute</td>
<td>Garnett McKeen Laboratory Inc</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>GE Healthcare</td>
</tr>
<tr>
<td>Genentech Inc</td>
<td>General Electric Company</td>
</tr>
<tr>
<td>General Electric Company</td>
<td>Genzyme Corp</td>
</tr>
<tr>
<td>Geron Corp</td>
<td>Gilead Sciences Inc</td>
</tr>
<tr>
<td>Gilead Sciences Inc</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Greenwich Hospital</td>
<td>Hansen Medical Inc</td>
</tr>
<tr>
<td>Gynecologic Oncology Group</td>
<td>Harvard Clinical Research Institute</td>
</tr>
<tr>
<td>Gyne Oncology Group</td>
<td>Health Research Inc</td>
</tr>
<tr>
<td>H Lundbeck AS</td>
<td>Helsinn Therapeutics</td>
</tr>
<tr>
<td>Halozyme Inc</td>
<td>Hoffmann Laroche Inc</td>
</tr>
<tr>
<td>Hamamatsu Photonics KK</td>
<td>Howmedica Osteonics Corp</td>
</tr>
<tr>
<td>Hamilton Health Sciences Corp</td>
<td>Human Genome Sciences</td>
</tr>
</tbody>
</table>
HyperBranch Medical Technology
Icon Clinical Research
Ikaria
INC Research Inc
INC Research LLC
Intarcia Therapeutics Inc
Integrium LLC
InterMune Inc
Ivoclar Vivadent Inc
Ivoclar Vivadent Inc
Jaeb Center for Health Research
Janssen Research and Development LLC
Jewish General Hospital McGill University
John Wayne Cancer Institute
Johns Hopkins University
Johnson & Johnson Vision Care Inc
Joslin Diabetes Center
Juvenile Diabetes Research Foundation Intl
Kiadis Pharma Netherlands B V
Lifecell Corp
Lilly Research Laboratories
Lilly USA LLC
Lupus Clinical Trials Consortium
Massachusetts General Hospital
Mayo Clinic Rochester Minnesota
McMaster University
MED Institute Inc
Medical University of South Carolina
Medicines Company
MedImmune Inc
Medline Industries Inc
Medpace Inc
Medtronic Inc
Melinta Therapeutics Inc
Merck and Company
MethylGene Inc
MicroTransponder Inc
MicroVention Inc
Millennium Pharmaceuticals Inc
Miriam Hospital
Mount Sinai School of Medicine
Npex Pharmaceuticals Inc
National Cancer Inst of Canada
National Childhood Cancer Found

National Institute of Dental & Craniofacial Res
Neurocrine Biosciences Inc
New England Research Institute
NexBio Inc
Northwest Biotherapeutics
Nostrum Pharmaceuticals LLC
NOVA Southeastern University
Novadaga Technologies Inc
Novartis Pharmaceuticals Corp
Novo Nordisk Inc
NPS Pharmaceuticals Inc
NSABP Foundation Incorporated
OBI Pharma Inc
Omnyx LLC
OncoGenex Technologies
Opexa Therapeutics
Optimer Pharmaceuticals Inc
OptumHealth Care Solutions
Orexigen Therapeutics
Ortek Therapeutics Inc
Ortho McNeil Janssen Scientific Affairs LLC
Orthovita Inc
Osiris Therapeutics Inc
Otsuka Pharmaceutical Development
Otto Bock Health Care
Parexel International Corp
Penumbra Inc
Pfizer Inc
Pharmaceutical Research Associates
PLC Medical Systems
PPD Development LP
PSMA Development Company
Puma Biotechnology Inc
Questcor Pharmaceuticals Inc
Quintiles Inc
Regents of the University of California
Registat Inc
RTI Health Solutions
Salix Pharmaceuticals Inc
Sanofi US Services Inc
SARcode Bioscience Inc
Schering Corp
Schering Plough Research

Schwarz BioSciences Inc
Seattle Childrens Hospital
Shire Development Inc
Siemens Medical Solutions USA
Silk Road Medical
St Lukes Roosevelt Institute f
St. Jude Medical CRMD
Sunesis Pharmaceuticals Inc
Sunovion Pharmaceuticals Inc
Synapse Biomedical Inc
Tactile Systems Technology Inc
Temple University
Teva Neuroscience Inc
THD America Inc
Third Wave Technologies
Topcon Corp
Townsend Design
Tragara Pharmaceuticals Inc
Translation Research Oncology
Trubion Pharmaceuticals Inc
Trustees of Columbia University
Tyco Healthcare Group LP
U S Biotest Inc
UCB Biosciences Inc
United BioSource Corp
University Neurology Inc
University of Florida
University of Florida
University of Miami
University of Pittsburgh
University of Rochester
University of Rochester
University of South Florida
University of Texas
US Army Medical Research
VentiRx Pharmaceuticals Inc
Ventrus Biosciences
Versartis Inc
Vertex Pharmaceuticals Inc
VertiFlex Inc
Vertos Medical Inc
Volcano Corp
VPS 1 Inc
WL Gore and Associates Inc
Welch Allyn
Wyeth Pharmaceuticals
Yale University
ZetrOZ LL