

ABSTRACT: 2015 ELAM Institutional Action Project Poster Symposium

Project Title: Integration of Clinical Trials Between PSU/HMC and the Community Health System Pinnacle During a Planned Merger

Name and Institution: Barbara A. Miller, MD
Pennsylvania State University College of Medicine

Collaborators: Ray Hohl, MD, Director
Eugene Lengerich, VMD, MS, Interim Director, Population Sciences
Penn State Hershey Cancer Institute

Background:

The Pennsylvania State University College of Medicine is a premier academic health system which provides state-of-the-art health care, medical education, and performs innovative research. Pinnacle Health is a leading community healthcare system. The two systems are proposing a merger.

Objective:

The objective of this project is to develop a plan for integration of research at PSU and Pinnacle following a planned merger. Initial goals (6 months) will be to identify and meet key administrative personnel, delineate clinical trial infrastructures, identify active research projects, and identify barriers to an interactive clinical research environment at each institution. We will initiate research collaborations in 1-2 key areas. The long term goals (6-24 months) are to establish a process for joint clinical trials pre-merger and post-merger to increase trial enrollment, reduce redundancy, and maintain quality.

Approach:

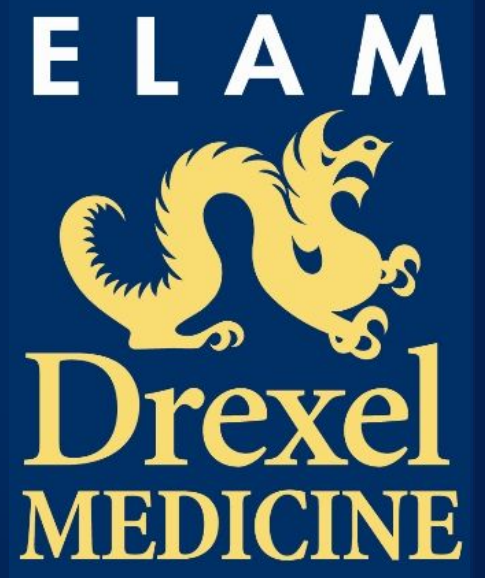
The approach was: (1) to delineate current research infrastructures by meeting with the Directors of the Clinical Trials Offices and IRB at PSU/HMC and Pinnacle; (2) to identify the type and number of trials currently active at each; (3) during these meetings, to assess support for and barriers to joint clinical trial enrollment; and (4) to initiate the joint clinical trial process by focusing on therapeutic and preventative cancer trials.

Outcomes:

(1) Met with Directors of Clinical Trial Offices and IRB at PSU and with the CMO, Director of Research and Cancer Services, and Vice President of Oncology Services at Pinnacle. The clinical trial infrastructures at each institution were delineated. (2) Determined the clinical trials currently open:

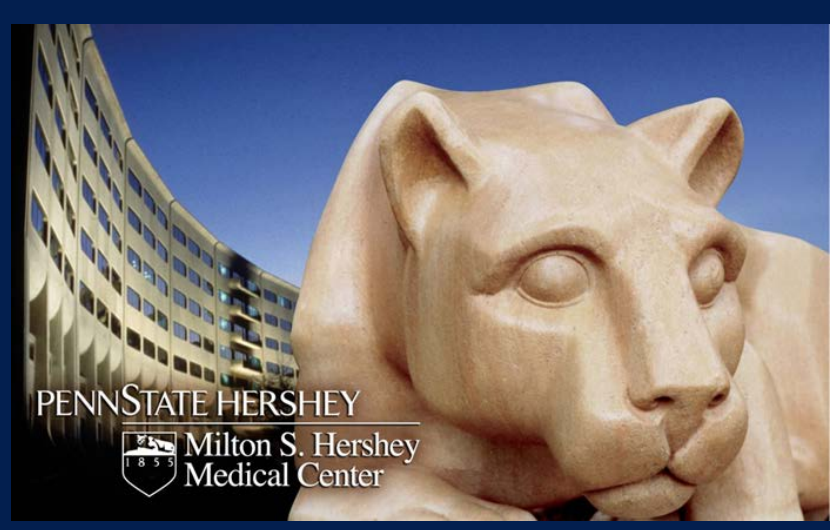
	Cardiology		Cancer		Internal Medicine		Other*		TOTAL
	No	(%)	No	(%)	No	(%)	No	(%)	
PSU/HMC	103	(5%)	348	(16%)	296	(14%)	1371	(65%)	2118
Pinnacle	71	(39%)	51	(28%)	16	(9%)	45	(24%)	183

(3) Determined both institutions supported research integration, but a general approach needed to be delayed until FTC approval of merger. There was agreement that following approval of the merger, a Clinical Research Review Committee would be formed with representatives from both institutions to work on details of pre and post award processes. Barriers to strong research collaborations included: (a) cultural differences between the two institutions. PSU goals were to increase enrollment while increasing referrals, whereas Pinnacle's were to increase regional recognition and patient retention. (b) Financial issues exist. How will Pinnacle physicians be reimbursed for research effort? Who will pay for research coordinators? (c) Legal nature of merger needs clarification prior to redesign of research infrastructure. (4) In cancer, met with Director of PSHCI and Director and Vice President of Oncology Services at Pinnacle. All were interested in opening therapeutic and preventative cancer trials at Pinnacle. **As a first step, an Affiliation Agreement to open joint trials was proposed by PSHCI and is under review by Pinnacle. This will facilitate opening of the first cancer trials.** Long Term Measures of Successful Outcomes will include: (1) Formation of the Clinical Research Review Committee, (2) increase in number of clinical trials opened, (3) increase number of patients enrolled, and (4) shorter time to open clinical trials.



INTEGRATION OF CLINICAL TRIALS BETWEEN PSU/HMC AND THE COMMUNITY HEALTH SYSTEM PINNACLE DURING A PLANNED MERGER

Barbara A. Miller, MD, Pennsylvania State University College of Medicine
Presented at the 2015 ELAM® Leaders Forum



BACKGROUND

The Pennsylvania State University College of Medicine/Milton S. Hershey Medical Center is a premier academic health system which provides state-of-the-art health care, medical education, and performs innovative research. Pinnacle Health is a leading community healthcare system. The two systems are proposing a merger. The purpose of this project is to develop a plan for integration of clinical research at PSU/HMC and Pinnacle following the merger.

OBJECTIVES

- Initial (6 months):**
1. Delineate current research trial infrastructures of each institution, including identification of key administrative personnel.
 2. Determine active clinical trials at each institution.
 3. Assess support for and barriers to joint trial enrollment.
 4. Initiate clinical trials in 1-2 key areas.

Long Term (6-24 months):
Establish process for joint clinical trials pre-merger and post-merger to increase enrollment and efficiency, reduce redundancy, and maintain quality.

APPROACH

- ❖ Delineate current research infrastructures by meeting with Directors of the Clinical Trials Offices and IRB at PSU/HMC and Pinnacle.
- ❖ Utilize these contacts to identify the type and number of trials currently active.
- ❖ Use these meetings to assess support for and barriers to joint clinical trial enrollment.
- ❖ Initiate joint therapeutic and preventative cancer trials.
- ❖ Begin discussion of clinical trial support infrastructure changes post merger.

Collaborators:

Raymond Hohl, MD, Director, Penn State Hershey Cancer Institute

Eugene Lengerich, VMD, MS, Interim Associate Director, Population Sciences, PSHCI, Public Health Sciences Community Outreach Coordinator

OUTCOMES

1. Clinical Trial Infrastructures at PSU/HMC and Pinnacle:

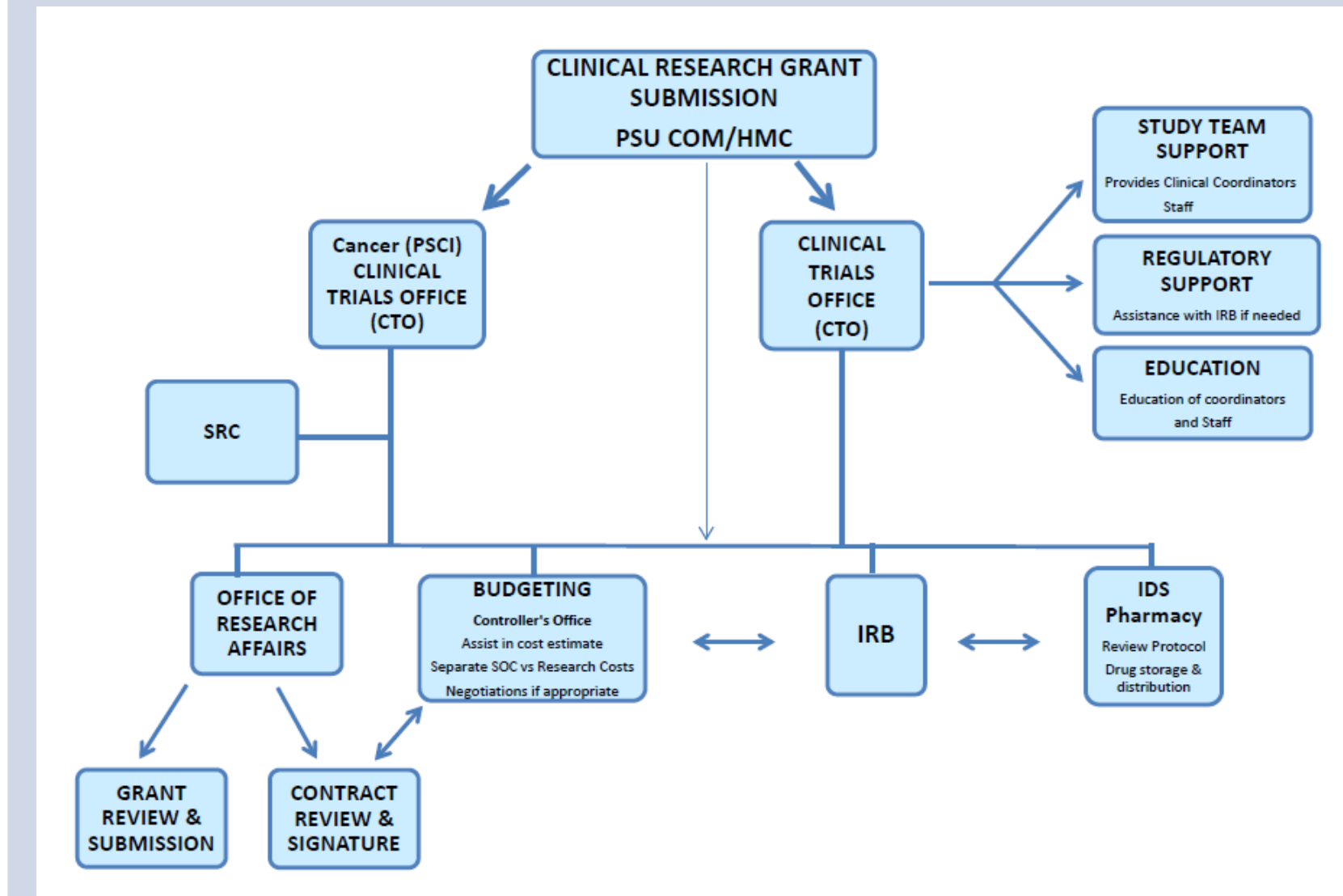


Figure 1: Research Infrastructure at PSU/HMC.

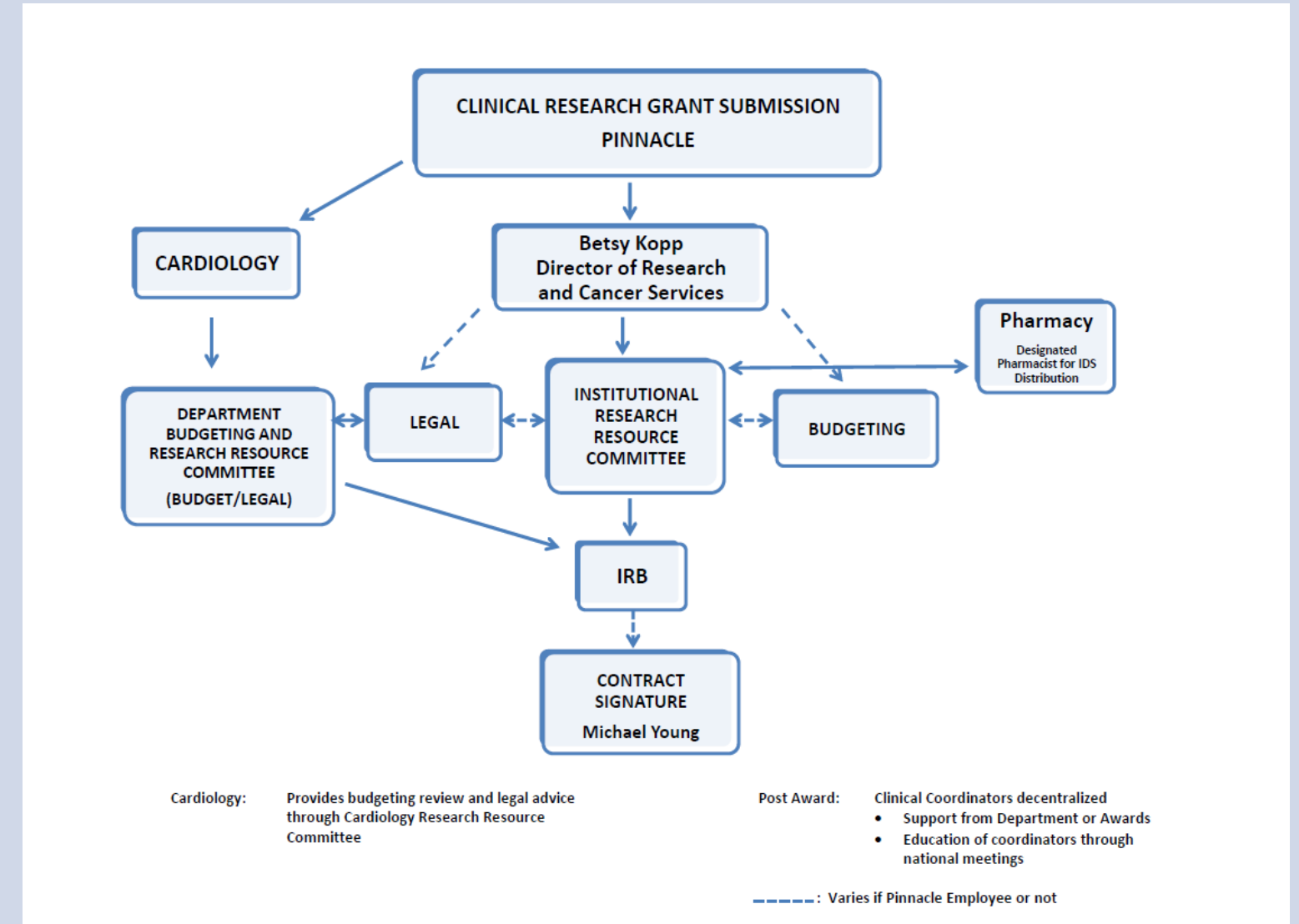


Figure 2: Research Infrastructure at Pinnacle.

2. Number and type of clinical trials at PSU/HMC and Pinnacle (Table I):

	Cardiology		Cancer		Internal Medicine		Other*		TOTAL
	No	(%)	No	(%)	No	(%)	No	(%)	
PSU/HMC	103	(5%)	348	(16%)	296	(14%)	1371	(65%)	2118
Pinnacle	71	(39%)	51	(28%)	16	(9%)	45	(24%)	183

*Other includes education, humanities, surgical specialties, dermatology, anesthesia, etc.

3. A. Both institutions support goal to streamline joint clinical trial process post merger.
B. Anticipated Barriers to joint clinical trials:
 1. Cultural differences. Fewer Pinnacle physicians are currently research-oriented.
 2. Some clinical goals are currently in competition. Example: PSU may want to increase enrollment while increasing referrals. Pinnacle may want to increase regional recognition and patient retention.
 3. Financial issues exist. Example: How will Pinnacle physicians be reimbursed for research effort? Who will pay for research coordinators?
 4. Legal nature of merger needs clarification prior to redesign of research infrastructure.
4. Affiliation Agreement between PSH Cancer Institute and Pinnacle Oncology Services proposed and under review. This will facilitate opening of cancer trials.

DISCUSSION

1. FTC approval of merger required followed by details of merger structure before generalized combined infrastructures can be designed.
2. Merger of cultures will be easier after institutional priorities established in final merger agreement.
3. Cost bearing and reward structure also needs to be established.
4. Affiliation Agreement best way to move therapeutic and preventative cancer trials forward at present. Joint therapeutic and preventative cancer trials will begin once Affiliation Agreement signed.

SUMMARY

Significant interest in sharing of clinical trials among physicians in specific areas, for example cancer and cardiology, which represent ~70% of Pinnacle trials.

Merger of research infrastructures requires formal agreements to clarify responsibilities, cost, and benefits. Affiliation Agreement for cancer trials underway.

Once the merger is finalized, optimization to facilitate shared clinical trials and efficiency will involve appointment of joint Clinical Research Review Committee to include individuals in the following areas:

- Regulatory: IRB
- Clinical Trials Office
- ORA
- Legal Review
- Investigational Drug Services Pharmacy
- Budgeting/Compliance
- Contract Review and Signature
- Study Team Support: Clinical coordinator education, support, and monitoring
- Quality Assurance: Research auditing to assure compliance and quality data

Final Outcome measures of success will be:

1. Establishment of Clinical Research Review Committee with representatives from both institutions to work on details of pre and post trial processes.
2. Increase in number of clinical trials opened.
3. Increase in number of patients enrolled.
4. Shorten time to open clinical trials.