

Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is “None”, please specify “None” as your response. “Not applicable” is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

- 1. Grantee Institution:** The Pennsylvania State University
- 2. Reporting Period (start and end date of grant award period):** 1/1/2010- 12/31/2013
- 3. Grant Contact Person (First Name, M.I., Last Name, Degrees):** John Anthony, MPA
- 4. Grant Contact Person’s Telephone Number:** 814-935-1081
- 5. Grant SAP Number:** 4100050904
- 6. Project Number and Title of Research Project:** 4. Impact of the Penn State Diabetes Patient Registry
- 7. Start and End Date of Research Project:** 05/01/2010 to 12/31/2011
- 8. Name of Principal Investigator for the Research Project:** Robert A. Gabbay, MD, PhD
- 9. Research Project Expenses.**

9(A) Please provide the amount of health research grant funds spent on this project for the entire duration of the grant, including any interest earned that was spent:

\$ 232,650.00

9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project	Cost
Gabbay	Principal Investigator	4%	\$10,408.42
Ulbrecht	Co-PI	1%	\$1,528.58
Mincemoyer	Co-Investigator	50%	\$39,892.13
Mulfinger	Co-Investigator	15%	\$33,063.63
Kipp	Research Assistant	50%	\$20,766.17
Bricker	Research Assistant	15%	\$12,596.45
Grant	Research Assistant	10%	\$2,639.69
Harris, A.R.	Research Assistant	10%	\$10,376.12
Harris, P.D.	Research Assistant	10%	\$3,503.54
Wyman	Research Assistant	10%	\$1,800.58
Yoo	Research Assistant	10%	\$1,550.69

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project
Baloh	Research Assistant	10%
Mauger	Co-Investigator	10%
Curry	Co-Investigator	3%

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost
None		

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes _____ No X

If yes, please indicate the source and amount of other funds:

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you

able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes X No _____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert “not funded” in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
Identifying Best Practices of Diabetes Self-Management: A Mixed-Methods Approach. (Stuckey H. 1K01DK090403-02 - 04)	<input checked="" type="checkbox"/> NIH <input type="checkbox"/> Other federal (specify: _____) <input type="checkbox"/> Nonfederal source (specify: _)	10//2011	\$363,102	\$363,102
A Multi-payer Patient Centered Medical Home Initiative in Pennsylvania 5 R18 HS019150-02	<input type="checkbox"/> NIH <input checked="" type="checkbox"/> Other federal (specify: <u>Agency for Health Research and Quality</u>) <input type="checkbox"/> Nonfederal source (specify: _)	05/ 2011	\$294,704	\$294,704

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes X No _____

If yes, please describe your plans:

Implementing the registry is difficult but it can help improve outcomes for chronic diseases. Expanding the research will allow us to see how the registry improved health outcomes in other healthcare settings.

12. Future of Research Project. What are the future plans for this research project?

Dr. Cynthia Chuang is planning on submitting a R01 NIH grant that is aimed towards understanding pre-conception counseling in women with Diabetes Mellitus. She will use the registry to identify patients for her research. The findings from this research project have led to this being a more useful resource for research and clinical activities. The registry is an essential supporting infrastructure for multiple other grants being submitted by investigators at Penn State including Heather Stuckey, DEd, Robert Gabbay, MD, PhD, Nazia Raja-Khan and Alan Adelman, MD, MS.

Note: Dr. Gabbay left Penn State in 2013.

13. New Investigator Training and Development. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes No

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male	3		3	
Female				
Unknown				
Total	3		3	

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic	3		3	
Unknown				
Total	3		3	

	Undergraduate	Masters	Pre-doc	Post-doc
White	3		2	
Black				
Asian			1	
Other				
Unknown				
Total	3		3	

14. Recruitment of Out-of-State Researchers. Did you bring researchers into Pennsylvania to carry out this research project?

Yes No

If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. Impact on Research Capacity and Quality. Did the health research project enhance the quality and/or capacity of research at your institution?

Yes X No _____

If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

The subject recruitment infrastructure will help improve the registry for new established investigation.

16. Collaboration, business and community involvement.

16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

Yes X No _____

If yes, please describe the collaborations:

The University of Pittsburgh through a PRISM grant.

16(B) Did the research project result in commercial development of any research products?

Yes _____ No X

If yes, please describe commercial development activities that resulted from the research project:

16(C) Did the research lead to new involvement with the community?

Yes _____ No X

If yes, please describe involvement with community groups that resulted from the research project:

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant application's strategic plan). Summarize the progress made in achieving these goals, objectives and aims

for the entire grant award period. Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha (α) and beta (β) should not print as boxes (\square) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

There were three specific aims for this research project studying the effectiveness and implementation of the Penn State Diabetes Registry (PSDR). All three aims were achieved as described below:

The specific aims as contained in the grant application's strategic plan:

Aim #1. Evaluate the impact of introducing a chronic disease registry (Penn State Diabetes Registry) to improve clinical care. Patient registries, such as PSDR, are used to identify and track patients with particular chronic diseases or preventive needs. The PSDR helps practices identify and track all of their patients with diabetes. Provider care teams use the registry to assure patients receive the laboratory tests and services they need at and between each visit. The registry also provides reports showing which patients are overdue for tests or services and which patients are not meeting evidence-based measures for diabetes control.

We collected longitudinal clinical data from 18 practices using the PSDR to evaluate whether or not PSDR implementation improved clinical outcomes for diabetes patients. Several factors impeded our analysis. We had difficulty compiling and analyzing the data that were collected under an earlier version of the PSDR with the current version of the PSDR. We had

to account for missing data elements and variation in data collection among the practices. We also needed to consider the dramatic increase in use of the PSDR between 2007 and 2009. Registry use increased from less than 20% usage at the beginning of 2007 to 70% usage at the end of 2009, as providers realized the value of capturing and tracking patient data. Statistical analyses were conducted in SAS to determine whether the PSDR use was correlated with a change in clinical outcome measures. We found a significant correlation between blood pressure levels and registry use. As the level of the registry use increased, patient blood pressure levels improved. This is an important finding as blood pressure control among patients with diabetes is the most important determinant in preventing long-term morbidity and mortality.

Our analyses did not find similar correlation between registry use and A1C levels (blood sugar control) at the clinic level. Nor did we find a similar correlation between registry use and LDL-cholesterol control, but this analysis was limited due to many fewer LDL data points being collected (annual vs. quarterly for blood pressure and A1C).

Patient registry tools such as the PSDR are increasingly important in today's increasingly accountable health care system, where providers and their care teams must be tracking and measuring individual and population-level patient outcomes. One important finding in this study was the nearly quadruple growth in registry usage in recent years. In July 2011, the Penn State Hershey Medical Center hired the former director of the PSDR to work more closely with the practices in using the PSDR and other population management tools to achieve federal "meaningful use" standards for health information technology.

Improved blood pressure control correlated with increased PSDR usage is another important finding that is consistent with aggregate blood pressure outcomes reported by 140 practices using registries to manage their diabetes patients as part of the statewide Pennsylvania Chronic Care Initiative between 2008 and 2011. This finding is especially noteworthy because it typically takes longer to see evidence of improvement in patient outcomes, such as blood pressure control, compared to process measures, such as the ordering of tests that are more fully controlled by health care providers.

It is heartening that providers appear to be using the tracking and trending tools in the PSDR to overcome tendencies to hold off on intensifying treatment for blood pressure control (clinical inertia). Blood pressure management is the most important preventer of micro- and macro-vascular diabetes complications and is arguably even more important than A1C and LDL management. It is helpful that blood pressure is routinely assessed at patient visits, while A1C and LDL levels (which require laboratory tests) may not be.

Aim #2. Evaluate the impact of the PSDR for subject recruitment for research trials. The Penn State Institute for Diabetes and Obesity provides researchers with two ways to recruit subjects for research projects: (1) the PSDR and (2) a volunteer database containing information on nearly 700 adults who have volunteered to participate in research projects. We aimed to evaluate use of the PSDR compared to use of the volunteer database by comparing four studies using each method for participant recruitment. For each study, we

analyzed the contact rate, response rate, and enrollment rate as well as the study design, extent of subject involvement, and sample population characteristics (see Table 1 below).

We found that the recruitment rates for both groups of studies were positive and compared favorably to other studies using patient registries to recruit individual chronic care patients. However, we found a number of difficulties with the analysis. Wide variation in sample populations and study methodologies clouded qualitative judgments about the relative recruitment efficacy of either database. All of the studies that used the volunteer database screened criteria match before contact was made with potential enrollees; none of the studies using the PSDR pre-screened enrollees. Data for our study also were limited because we included in it only studies that had completed their enrollment phase.

Table 1: Research Participant Recruitment Using the PSDR vs. Volunteer Database

Source	Name	Sessions	Procedures	Criteria	Criteria Matches	Letters Sent	Contact Rate	Replies	Response Rate	Enrollees	Enrollment Rate
PSDR	SHADE	11	BG, A1C, Physical, Interview	4	844	844	100%	32	3.79%	15	1.78%
PSDR	Making Meaning of Diabetes Mellitus	9	3x A1C & BP, Interview	5	83	83	100%	8	9.64%	5	6.02%
PSDR	DYNAMIC	10	A1C, LDL, Lifestyle Intervention, Motivational Interviewing	4	1778	1778	100%	1012	56.92%	550	30.93%
PSDR	Diabetes Mellitus Values and Preferences	1	Telephone Interview	2	127	127	100%	40	31.50%	40	31.50%
Volunteer	Endometrial Hyperplasia	1	Physical, Transvaginal Ultrasound, Uterine Biopsy	5	60	10	16.67%	10	100%	5	50.00%
Volunteer	Incorporating Comorbidities	1	Focus Group	3	130	21	16.15%	13	61.90%	13	61.90%
Volunteer	Food: Focused Ethnographic Interview	1	Interview	1	34	11	32.35%	8	72.73%	8	72.73%
Volunteer	PDA	6	Height, Weight, 2x FG, Seminar, Interview	4	157	32	20.38%	24	75.00%	8	25.00%

Aim #3. Evaluate facilitating factors and identify barriers for the adoption and implementation of the PSDR within individual clinics.

This study aimed to identify the factors that facilitate and hinder adoption and implementation of the PSDR by understanding how providers and staff in practices using the PSDR have used and benefitted from it. We employed a mixed methods approach involving surveys and semi-structured individual interviews and focus group sessions. Purposeful sampling was used to recruit participants who had used it.

The survey examined five domains: (1) time efficiency, (2) clinician-system interaction, (3) quality of patient care, (4) research, and (5) improvements. Separate web-based surveys were distributed to 52 providers (physicians, NPs, and PAs) and 51 staff (MAs, LPNs, RNs, clerical). Surveys included 38 Likert-type scale questions (0= total disagreement, 10=total agreement); 12 questions were excluded from the staff survey due to the specificity of providers' experiences. The surveys were anonymous, but respondents were given the opportunity to share their identity for follow-up with an interview or focus group.

Individual interviews were conducted with 10 providers, and there were 4 focus groups of staff. The interviews and focus groups explored four domains: (1) general perspectives of registries, (2) quality and efficiency of care using a registry, (3) research applicability of registries, and (4) orientation and feedback from a registry.

The provider survey response rate was 49.5%. As shown in Table 2, overall provider satisfaction with the PSDR was positive, with a median (min, max) of 7 (2, 10). The providers felt that the PSDR increased the efficiency of the diabetes patient visit (8 (1, 10)) and facilitated better adherence to evidence-based guidelines (8.5 (2, 10)). They felt that the PSDR patient profile was easy to understand and complete (8 (3, 10)), and 88.5% reported filling out the profile and 76.9% reported distributing the profile to their patients.

Providers were less pleased with the increased time needed for documentation (6 (0, 10)), inadequate training in the use of the registry (5, (1, 10)) and inadequate IT help with the registry (5, (1, 10)). The providers who were satisfied with the PSDR believed that it did not increase documentation time and that it increased the efficiency of the diabetes patient visit and improved the health of their patients. Specific aspects of the PSDR that were highly correlated with satisfaction were the helpfulness of reminder prompts and the increased ability to follow evidence-based guidelines.

The staff survey response rate was 26.2%. Like providers, staff were overall satisfied with the PSDR (7 (3, 10)). They thought the patient profile was easy to understand and complete (8 (4, 10)) and that the online user interface was intuitive and easy to use (7 (0, 10)). Fewer staff than providers reported filling out the PSDR profile (54.9%, $p < 0.001$), but more reported having signed into the online system for data entry or printing of the patient profiles (64.7% for staff vs. 32.7% for providers, $p < 0.01$).

Like providers, staff were not very positive about PSDR system training (5 (0, 10)) or about the adequacy of available IT help (5 (0, 10)). As with providers, staff who were most satisfied with

the registry believed that it increased the efficiency of the diabetes patient visit.

The qualitative data from the interviews and focus groups were combined in analysis. Many participants remarked about the registry's ability to provide comprehensive evidence-based care. They appreciated the ability to display patient data graphically as a tool to explain clinical significance. They also viewed performance reports from the registry positively and noted using them to identify and set specific interventions to improve care and for intra-office benchmarking and sharing of best practices. Most providers said that having data available regarding a chronic condition ready for the patient visit was a time-saving feature that can increase time for patient counseling, improve coordination of care, and facilitate clinic teamwork.

The most prevalent challenge associated with implementation of the PSDR was dealing with "double documentation" and the preconception of the registry being "more work." Some mentioned the lack of integration with an electronic medical record to be problematic. One physician said, "The registry needs to be coordinated with my note. So right now, it's a separate piece of paper, a separate thing that I've got to circle and put information on, or take information off of, and I've got to redo it for my note." Another said, "There is a hump to get over with the staff because ... we were asking our staff with the registry to do things differently than they've always done them. It's perceived frequently as more work and there's always a limited amount of time to do the job." However, there were also providers and staff who recognized that the work gets easier and that it comes with returns.

When implementing the PSDR, there was a lack of knowledge about the importance and purpose of the registry as well as using the features to the fullest extent. Some providers and staff said they didn't initially understand the importance of completing the patient profiles, but later learned the features and powerful tools of the registry. There were also concerns about the accuracy of the data in the registry.

In addition, participants mentioned the value of using the registry to identify research subjects and as a data pool for retrospective data. Even so, there was recognition of the potential risk of soliciting patients for participation in research based on their health status.

The results of this study were published in the *Journal of Clinical Outcomes Management* in July 2011. *J Clin Outcomes Manage* 2011 Jul;18(7):303-312; *The perspectives of health care providers and staff on the usefulness of a diabetes registry*; Stuckey HL, Yoo F, Curry WJ, Gabbay RA. As reported in the paper, there are many advantages to using a chronic disease registry in the clinical care setting. Registries such as the PSDR can improve adherence to evidence-based guidelines, increase visit efficiency, and clinical organization of health care delivery, and result in clinical quality improvement. But practices need adequate training and IT support to realize the full potential of registries and to get to the point where registries are seen as valuable patient care tools and not just "more work." (Due to an oversight the acknowledgement of the Tobacco CURE program as a funding agency was omitted.)

Table 2: Comparison of Averages and Standard Deviation of Provider and Staff Surveys

Question	Provider Survey Median (Min, Max)	Staff Survey Median (Min, Max)	P value*
The PSDR increases time needed for documentation.	6 (0, 10)	5 (0, 10)	0.4876
The PSDR increases the efficiency of the patient visit.	8 (1, 10)	8 (4, 10)	0.7054
Do you fill out the PSDR form?***			
YES	46 (88.5%)	28 (54.9%)	0.0003
NO	6 (11.5%)	23 (45.1%)	
If yes to previous question, the PSDR form is easy to understand and complete.	8 (3, 10)	8 (4, 10)	0.8417
The adoption process of the PSDR into everyday practice was overall positive.	7 (0, 10)	6 (1, 10)	0.2205
There was adequate training in using the PSDR.	5 (0, 10)	5 (0, 10)	0.2812
There is adequate IT help in dealing with the PSDR.	5 (1, 10)	5 (0, 10)	0.0468
Have you ever signed into the PSDR system?			
YES	17 (32.7%)	33 (64.7%)	0.0017
NO	35 (67.3%)	18 (35.3%)	
If yes, the user interface is intuitive and easy to use.	7 (1, 10)	7 (0, 10)	0.5446
Do you receive feedback for population disease management from the PSDR?			
YES	24 (46.2%)	14 (27.5%)	0.0535
NO	28 (53.8%)	37 (72.5%)	
The reminder prompts for patient care from the PSDR are helpful.	8 (3, 10)	7 (0, 10)	0.0333
The PSDR helps to follow evidence-based guidelines for diabetes care.	8.5 (2, 10)	n/a	

The PSDR patient profiles present all the information necessary for effective management of diabetic patients.	7 (0, 10)	n/a	
Do you distribute the patient version of the PSDR patient profile to your patients? YES NO	40 (76.9%) 12 (23.1%)	32 (62.7%) 19 (37.3%)	0.1226
If yes, the PSDR patient sheet provides support to patients for self-management of their disease.	7 (2, 10)	n/a	
If yes, the patients seem satisfied with the information given to them in the patient profile.	7 (5, 10)	n/a	
Are you satisfied with the PSDR overall?	7 (2, 10)	7 (3, 10)	0.4779

18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be “No.”

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes
 No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

Yes
 No

If “Yes” to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both “No.”)

18(C) How many hospital and health care professionals were involved in the research project?

_____ Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

_____ Number of subjects originally targeted to be included in the study
_____ Number of subjects enrolled in the study

Note: Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached, the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:
_____ Males
_____ Females
_____ Unknown

Ethnicity:
_____ Latinos or Hispanics
_____ Not Latinos or Hispanics
_____ Unknown

Race:
_____ American Indian or Alaska Native
_____ Asian
_____ Blacks or African American
_____ Native Hawaiian or Other Pacific Islander
_____ White
_____ Other, specify: _____
_____ Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.)

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involve, in any capacity, human embryonic stem cells?
_____ Yes
_____ X No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?

_____ Yes
 _____ No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication, listed in the table, in a PDF version 5.0.5 format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI Smith for the “Cognition and MRI in Older Adults” research project (Project 1), and two publications for PI Zhang for the “Lung Cancer” research project (Project 3), the filenames should be:

- Project 1 – Smith – Publication 1 – Cognition and MRI
- Project 1 – Smith – Publication 2 – Cognition and MRI
- Project 3 – Zhang – Publication 1 – Lung Cancer
- Project 3 – Zhang – Publication 2 – Lung Cancer

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
None				<input type="checkbox"/> Submitted <input type="checkbox"/> Accepted <input type="checkbox"/> Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes X No _____

If yes, please describe your plans:

We plan to submit an article that describes the value of a Diabetes Mellitus registry to improve clinical outcomes to the premier diabetes journal, Diabetes Care.

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project.

Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

The Penn State Diabetes Registry (PSDR) is a previously underutilized tool to improve diabetes patient outcomes, increase office visit efficiency, facilitate patient care teamwork and communications, and facilitate benchmarking and the sharing of best practices. We found a correlation between registry use and improved blood pressure control among diabetes patients. This is significant because blood pressure control is a key determinant of diabetes complications, cardiovascular events, and mortality among diabetes patients. We found substantial growth in the use of the PSDR since 2007, as providers began to realize its potential to help them track and improve patient care. Our research showed that providers and their care teams wanted and needed more training and IT assistance than initially provided to adopt and implement the PSDR. The Penn State Hershey Medical Center recently hired the former PSDR director to work more closely with the practices in leveraging the PSDR and other health information technology for data reporting and quality improvement under the new federal “meaningful use” standards. We further found the PSDR to be an acceptable tool to use for human subjects recruitment for research.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert “None”; do not use “Not applicable.” Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance

of work under this health research grant? Yes _____ No X _____

If “Yes” to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is “No.”)

a. Title of Invention:

b. Name of Inventor(s):

c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):

d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?

Yes _____ No _____

If yes, indicate date patent was filed:

e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?

Yes _____ No _____

If yes, indicate number of patent, title and date issued:

Patent number:

Title of patent:

Date issued:

f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes _____ No _____

If yes, how many licenses were granted? _____

g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes _____ No _____

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes _____ No X _____

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here.

BIOGRAPHICAL SKETCH

NAME Robert A. Gabbay	POSITION TITLE Professor of Medicine		
eRA COMMONS USER NAME (credential, e.g., agency login)			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
McGill University, Montreal, Canada	B.Sc.	1978	Biochemistry
University of Wisconsin, Madison, Wisconsin	Ph.D.	1985	Biochemistry
S.U.N.Y. Health Sciences Center, Brooklyn, NY	M.D.	1990	Medicine

A. Positions and Honors**Positions and Employment**

1992	Associate Physician, Rockefeller University Hospital, New York, NY
1998	Director, Diabetes Program; The Milton S. Hershey Medical Center, The Pennsylvania State University College of Medicine, Hershey, PA
2002-	Associate Professor of Medicine (tenured); The Pennsylvania State University College of Medicine, The Milton S. Hershey Medical Center, Hershey, PA
2002-	Co-Director, Penn State Diabetes Center, The Milton S. Hershey Medical Center, Pennsylvania State University, University Park and Hershey, PA
2007-2013	Professor of Medicine and Director, Penn State Hershey Diabetes Institute, The Pennsylvania State University, Hershey, PA and University Park, PA
June 24, 2013 -	Robert A. Gabbay, M.D., Ph.D., has been appointed as Chief Medical Officer and Senior Vice President of Joslin Diabetes Center. Joslin Diabetes Center is an independent institution affiliated with Harvard Medical School and the world's largest diabetes clinic, diabetes research center and provider of diabetes education.

Other Experience and Professional Memberships

2004 – 2008	Co-Chair, Steering Committee, Pennsylvania Department of Health Diabetes Prevention and Control Program Stakeholders Group
2004 – 2005	Co-Author, Diabetes White Paper for the Commonwealth of Pennsylvania
2005 – present	Advisory Committee, Penn State Clinical Research Training Program (K30 NIH program)
2005 – present	Editorial Board, Diabetes Forecast
2006	Juvenile Diabetes Research Foundation Grant Review, Artificial Pancreas Program
2007 – present	International Diabetes Federation, Broadening Research in Diabetes to Global Environmental Systems (BRIDGES)
2007 – present	Appointed Member, Governor's Commission on Chronic Care Steering Committee
2007	Co-Author, Pennsylvania Diabetes Action Plan
2009 – present	Study Section, National Institutes of Health, NHLBI Special Emphasis Panel/Scientific Review Group ZHL1 CSR-Z
2010-2012	American Diabetes Association Professional Practice Committee

Honors

2001 – present Best Doctors in America

2002 – present Provider Recognition, American Diabetes Association, National Committee on Quality Assurance

B. Selected peer-reviewed publications (in chronological order – last 5 years).

Most relevant to the current application

1. Gabbay, RA, Bailit M, Mauger D, Wagner E, Siminerio L. Multipayer Patient-Centered Medical Home Implementation Guided by the Chronic Care Model. The Joint Commission Journal on Quality and Patient Safety. 37(6):265-273. June 2011.

C. Research Support. List selected ongoing or completed (during the last three years)

Ongoing Research

Role: Principal Investigator Duration: 2005-2010
Effort: 5% Total funding: \$3,011,856
Source: NIH (R18-DK067495)

Title: *Impact of Nurse Case Management on Diabetes Co-Morbidity, DYNAMIC*
The DYNAMIC (Diabetes Nurse Case Management and Motivational Interviewing for Change) study was a 3-year, randomized, controlled trial comparing enhanced nurse case management with usual care for high-risk patients with diabetes with focus on an underserved, Hispanic population. Enhanced nurse case management includes motivational interviewing to foster behavior change, basic diabetes self-management education, tracking of patient outcomes and implementation of standing orders for process measures.

Role: Principal Investigator Duration: 2010-2012
Effort: 16.5% Total funding: \$599,189
Source: Agency for Healthcare Research and Quality (AHRQ)

Title: *A Multi-payer Patient Centered Medical Home Initiative in Pennsylvania*
The proposed research will look at the impact of the implementation of the chronic care model with the Patient Centered Medical Home Initiative on diabetes outcomes and the cost of care in the Philadelphia region.

Role: Principal Investigator Duration: 2011-2013
Effort: 20% Total Funding: \$961,586
Source: AHRQ

Title: *Spreading Primary Care Enhanced Delivery Infrastructure (PA SPREAD)*
PA SPREAD aims to enhance Pennsylvania's Medical Home initiative by integrating lessons learned in teaching the Medical Home model, facilitating practices, and leveraging IT resources and then testing these innovations in partnership with the PA Area Health Education Center (AHEC) network of preceptor practices. Lessons learned will also be packaged for dissemination to at least three other states through multi-stakeholder engagement

Role: Principal Investigator Duration: 2010-2012
Effort: 16.5% Total funding: \$599,189
Source: AHRQ

NAME ULBRECHT, Jan S.		POSITION TITLE	
eRA COMMONS USER NAME JULBRECHT		Professor of Biobehavioral Health and Medicine	
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Worcester College, Oxford University, England	B.A.	1976	Physiology
University College Hospital Medical School, University of London, England	M.B., B.S.	1979	Medicine
Stafford & Basingstoke, England Upstate Medical Center, Syracuse, NY		1983	IM Residency
University of Pittsburgh		1986	Endocrinology Fellowship

A. Positions and Honors. List in chronological order previous positions, concluding with your present position. List any honors. Include present membership on any Federal Government public advisory committee.

1986 – present Endocrinologist, Center Medical and Surgical Associates of State College, PC
1987 – present Medical Director, Diabetes Foot Clinic, Mount Nittany Medical Center, State College, PA
2000 – present Medical Consultant, DIApedia LLC
2000 – present Associate Medical Director, General Clinical Research Center, Penn State University, University Park, PA
2001 – present Co-Director, Penn State Institute for Diabetes and Obesity
2007 – present Professor of Biobehavioral Health and Medicine, Penn State University, University Park and Hershey, PA

Special Certification:

1983 ABIM - Internal Medicine
1986 ABIM - Endocrinology and Metabolism

Medical Licensure:

1983 Commonwealth of Pennsylvania and the Department of Health of the State of New York

Professional Associations:

1984 American Diabetes Association

Professional Service:

2005 – 2008 Member, Research Grant Review Panel, American Diabetes Association

B. Selected peer-reviewed publications (in chronological order). Do not include publications submitted or in preparation.

Diabetes foot:

McCrary JL, Morag E, Norkitis AJ, Barr MS, Moser RP, Caputo GM, Cavanagh PR, Ulbrecht JS. Healing of Charcot Fractures: Skin Temperature and Radiographic Correlates. The Foot. 1998; 8: 158-165.

Gabbay RA, Kaul S, Ulbrecht JS, Scheffler, Armstrong DG. Motivational Interviewing by Podiatrists: A Method for Improving Patient-Self Care of the Diabetic Foot . Journal of the American Podiatric Medical Association 2009, accepted.

Diabetes and behavioral issues:

Garcia-Dominic OA, Wray LA, Trevino RP, Hernandez AE, Yin Z, Beverly EA, Ulbrecht JS. Identifying Barriers That Hinder On-Site Parental Involvement in a School-Based Health Promotion Program. Health Promotion Practice, Epub April 1, 2009.

C. Research Support. List selected ongoing or completed (during the last three years) research projects (federal and non-federal support). Begin with the projects that are most relevant to the research proposed in this application. Briefly indicate the overall goals of the projects and your role (e.g. PI, Co-Investigator, Consultant) in the research project. Do not list award amounts or percent effort in projects.

1. NIH 5 M01 RR010732 04/01/05 – 03/31/10
Associate Director, General Clinical Research Center

2. NIH/NCAM R01 AT002477 10/01/04 – 06/30/09
Co-investigator
Expressive Writing: Complementary Treatment for Diabetes
The goal of this 5 year project is to explore whether emotional expression through directed writing can reduce stress among patients with diabetes, thereby improving both QOL and glucose control.
3. Western Pistachio Association 6/15/09 – 6/14/2011
Co-PI
Effects of Pistachios on Cardiovascular Responses to Stress in Type 2 Diabetes: A Novel Intervention for a High Risk Population.
This study will assess cardiovascular and metabolic effects of pistachios in otherwise healthy adults with type 2 diabetes.

4. NIH/NIDDK 2 R44 DK062547-05A1 to DIApedia, LLC 10/01/08 – 09/30/11
Co-investigator
CAD-CAM Technology for Diabetic Footwear (Phase II SBIR)
The goal of this 3-year project is to test the efficacy of a CAD-CAM designed and manufactured orthotic against standard orthotics on the market in a RCT.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Curry, William J.		POSITION TITLE Professor, Department of Family & Community Medicine and Public Health Sciences, Penn State College of Medicine; Associate Vice-Chair for Research	
eRA COMMONS USER NAME WICurrv			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Washington University	B.S.	1979	Chemical Engineering
Penn State University College of Medicine	M.D.	1983	Medicine
Penn State University College of Medicine	M.S.	2005	Health Evaluation Sciences

C. Positions and Honors.

Positions and Employment

1986 – 1992	Flight Surgeon, Family Physician – United States Air Force
1992 – 1995	Staff Family Physician, Private Practice, Easton, Maryland
1995 – 2003	Assistant Professor of Family & Community Medicine, Penn State College of Medicine, M.S. Hershey Medical Center
2003 – 2009	Associate Professor, Department of Family & Community Medicine, Penn State College of Medicine, M.S. Hershey Medical Center
2009 – Present	Professor, Department of Family & Community Medicine and Public Health Sciences, Penn State College of Medicine, M.S. Hershey Medical Center
1995 – Present	Family Practice Physician, University Physician Group Middletown
1995 – 2004	Medical Director, University Physician Group Middletown
2004 – Present	Associate Vice Chair for Research, Department of Family & Community Medicine, Penn State College of Medicine, M.S. Hershey Medical Center
2007 – Present	Director of Quality, Department of Family & Community Medicine, Penn State College of Medicine, M.S. Hershey Medical Center.

Honors

2003 – Present	Best Doctors in America Recognition
2005	Mark J. Young Award for Outstanding Scholarship in Health Evaluation Sciences Graduate Program

D. Selected peer-reviewed publications.

1. Curry WJ, Kulling DL. “Newer Antiepileptic Drugs: Gabapentin, Lamotrigine, Felbamate, Topiramate and Fosphenytoin.” In American Family Physician, Feb 1998; 57(3):513-520 [PMID: 9475899].
2. Curry W, Lewis P. “Bacteremia and Sepsis.” In Taylor R (Ed) Textbook of Family Medicine 6th Edition, Springer Verlag, 2002; 368-374.
3. Curry WJ, Lengerich EJ, Kluhsman BC, Graybill MA, Liao JZ, Schaefer EW, Spleen AM, Dignan MB. “Academic Detailing to Increase Colorectal Cancer Screening by Primary

Care Practices in Appalachian Pennsylvania.” In BMC Health Services Research, May 2011; 11:112-120

4. Stuckey HL, Yoo F, Curry WJ, Gabbay RA. “*The Perspectives of Health Care Providers and Staff on the Usefulness of a Diabetes Registry.*” In Journal of Clinical Outcomes Management, July 2011; 18(7):303-312.

E. Research Support.

Current Research

Curry (Co-Investigator) 2008 – 2012
National institute of Allergy and Infectious Diseases 1 R15 A1076933-01A1
(Debra L. Wohl, PhD, Elizabethtown College – PI) “Hospital Practices and Early Childhood Health.”

This purpose is to study the correlation of intra-partum antibiotics and subsequent development of eczema in children.

Curry (Co-Investigator) 2008 – 2014
A.T. Still University of Health Sciences 5 R25AT003579 (Alan M. Adelman, MD – PI)
“Curriculum and Faculty Development in Evidence-based Medicine”
This work is developing faculty skills in evidence-based care, with emphasis towards teaching students.

Curry (Co-Investigator) 2010 – 2012
UPMC Health System, subcontract from DoD Prime FA7014-10-BAA-10-01 (Robert A. Gabbay, MD – PI)
“Implementing and Assessing a National Model for Diabetes Prevention and Treatment: Task 3”
This is a randomized clinical trial to determine if patients who receive Diabetes Self-Management Education who are enrolled in a specific Self Management Support follow up program will maintain and/or improve behavioral and clinical outcomes at 6 months and be more satisfied as compared to those in other SMS program interventions.

Curry (Co-Investigator) 2010 – 2015
DHHS, HRSA D5DHP20521 (Shou Ling Leong, MD – PI)
“Building Work Force Capacity: Patient Centered Medical Home”
This is an educational program to institute longitudinal training in concepts and implementation of PCMH in primary care. There is an evaluative component for the education that seeks to evaluate gains in chronic care management skills in medical students.

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.

NAME Lorraine M Mulfinger, PhD	POSITION TITLE Associate Director of Strategic Initiatives and Research Program Development & Research		
eRA COMMONS USER NAME LMULFINGER	Associate Professor		
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
The Pennsylvania State University	PhD	1977	Microbiology
The Pennsylvania State University	MS	1989	Veterinary Science
The Pennsylvania State University	BS	1990	Veterinary Science

A. Positions and Honors.**Positions and Employment**

1977-1982	Research Aide & Instructor, Departments of Biochemistry & Microbiology, The Pennsylvania State University
1982-1990	Quality Control/Research & Development Coordinator, Vespa Laboratories, Inc., Spring Mills, PA (a subdivision of ALK/Christian Hansen, Denmark)
1990-1994	Compliance Coordinator, PSU Research and The Graduate School, The Pennsylvania State University
1994-2000	Program Coordinator, The Center for Locomotion Studies (CELOS), The Pennsylvania State University
2000-2003	Visiting/Assistant Professor of Chemistry and Science Outreach Director, Department of Chemistry, Juniata College
2003-2007	Associate Professor of Chemistry and Science Outreach Director, Department of Chemistry, Juniata College
2007-2010	Associate Professor of Medicine and Associate Director, Penn State Institute for Diabetes and Obesity, The Pennsylvania State University
2010-present	Associate Director of Strategic Initiatives and Research Program Development, Research Associate Professor of Health and Human Development

Honors and Memberships (selected)

1977-present	American Society for Microbiology; National Registry of Microbiologists
1995-2000	International Society of Biomechanics
1999-present	American Chemical Society
2003	Council of State Governments Innovation Award for Science In Motion Outreach Program
2004	Department of Energy ORISE (Oak Ridge Institute for Science and Education) Reverse Site Visit for the Human Genome Project Website
2005-2007	Pennsylvania Governor's Commission for College and Career Success, Science Benchmarking Subcommittee Chair, 2007

NAME Richard Scott Mincemoyer	POSITION TITLE Associate Director for the Penn State Hershey Diabetes and Obesity Institute
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EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Pennsylvania State University	MS	2011	Nursing
Pennsylvania State University	BS	2006	Nursing
Robert Packer Hospital School of Nursing	Diploma-RN	1984	Nursing

Positions and Honors.

- 1984-1985 Robert Packer Hospital, Sayre, PA – Staff Nurse, Medical/Surgical Unit
- 1985-1985 Travelcorp - Staff RN
- 1986-1990 Geisinger Medical Center, Danville, PA – Staff Nurse Critical Care Float Pool
- 1990-1995 Geisinger Medical Center, Danville, PA – Clinical Instructor, Cardiac Care, Nursing Education Department
- 1996-1997 Susquehanna Health System, Williamsport, PA – Clinical Practice Coordinator, Intensive Care Unit
- 1997-2002 HealthSouth Corporation, Nittany Valley Rehabilitation Hospital, Pleasant Gap, PA – Director of Patient Care Services
- 2002-2003 HealthSouth Corporation, Dubois Regional Medical Center, Dubois, PA – Rehab Program Administrator
- 2003-2005 Community Health Systems, Inc., Lock Haven Hospital, Lock Haven, PA - Director of Emergency Services/Assistant Chief Nursing Officer
- 2005-2007 Community Health Systems, Inc., Lock Haven Hospital, Lock Haven, PA – Director of Quality Management and Regulatory Compliance
- 2007-Present Pennsylvania State University, University Park, PA - Associate Director for the Penn State Hershey Diabetes and Obesity Institute

Other Experience, Licensure, Certifications and Professional Memberships (select).

- 1984-present Professional Nursing License, Pennsylvania
- 1986-2007 Advanced Cardiac Life Support Provider
- 1988-2000 National American Association of Critical Care Nurses (AACN)
- 1988-2007 Advanced Cardiac Life Support Instructor
- 1994-1996 President/President-Elect of the North Central Pennsylvania Chapter of AACN
- 1998-2002 National Association of Rehabilitation Nursing