HRP-596 - Protocol for Human Subject Research - Chart Review and/or Analysis of Existing Restricted Data Set Study

Protocol Title:

A Patient-Centered PaTH to Addressing Diabetes: Impact of State Health Policies on Diabetes Outcomes and Disparities

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Important Instructions for Using This Protocol Template:

1. Add this completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page, item 7.
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3. **Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.**
4. **For research being conducted at Penn State Hershey or by Penn State Hershey researchers only, delete the instructional boxes from the final version of the protocol prior to upload to CATS IRB** (http://irb.psu.edu)**. For all other research, do not delete the instructional boxes from the final version of the protocol.**
5. When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the Study Submission Guide available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.

If you need help…	
University Park and other campuses: Office for Research Protections Human Research Protection Program The 330 Building, Suite 205 University Park, PA 16802-7014 Phone: 814-865-1775 Fax: 814-863-8699 Email: irb-orp@psu.edu	**College of Medicine and Hershey Medical Center:** Human Subjects Protection Office 90 Hope Drive, Mail Code A115, P.O. Box 855 Hershey, PA 17033 (Physical Office Location: Academic Support Building Room 1140) Phone: 717-531-5687 Fax number: 717-531-3937 Email: irb-hspo@psu.edu

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1.0 Objectives

The overarching goal of this proposal is to understand the comparative effectiveness of obesity counseling as covered by Centers for Medicare and Medicaid Services (CMS) in improving weight loss for adults either with or at high risk of type 2 diabetes. CMS and most insurers now include obesity screening and counseling benefits, with no cost sharing to patients.[1] Since overweight patients are at highest risk for diabetes, improved weight management services could prevent diabetes and its negative health outcomes. Beneficiaries with obesity are eligible for up to 20 face-to-face visits for weight counseling in the primary care setting. We propose comparing weight and diabetes outcomes in three states using electronic health record (HER) and claims data before and after this policy was implemented. The PaTH network brings together six academic health systems – the University of Pittsburgh/University of Pittsburgh Medical Center, Penn State College of Medicine/Hershey Medical Center, Temple University School of Medicine/Temple Health, and the Johns Hopkins University/Johns Hopkins Health System/Johns Hopkins Health Care, Geisinger Health Systems, and The University of Utah – to function as an integrated research network and learning health system, providing an infrastructure for observational studies, such as the one proposed here, that require populations beyond a single health system to answer important patient-centered health services questions (www.pathnetwork.org). Using the PaTH Clinical Data Research Network (CDRN) infrastructure, we propose the following specific aims:

Aim 1: Evaluate the impact of universal preventive service coverage for obesity screening and counseling on weight loss, diabetes incidence, and diabetes outcomes, in patients with diabetes or at high risk for diabetes (defined by body mass index (BMI) ≥ 25). We will determine how the annual probability of receiving obesity and/or nutritional counseling (as defined by Current Procedural Terminology (CPT) code) changed pre- and post-policy across all insurers in a cohort of patients with diabetes and at high risk for diabetes. We hypothesize that individual patients are more likely to receive counseling following coverage implementation. Further, we hypothesize that patients who receive a greater number of face-to-face visits will have greater weight loss compared to those who receive fewer visits.

Aim 2: Compare patient weight loss and diabetes-related outcomes among those who receive obesity screening and counseling to those who do not, following implementation of preventive service coverage. We will examine post-policy impact of obesity screening and counseling in a cohort of patients with diabetes and at high risk for diabetes. Specific outcomes to be examined include weight loss, diabetes incidence, and diabetes outcomes (including hemoglobin A1c, controlled blood pressure, use of a statin medication). Further, we will determine patient characteristics, including demographics (age, race/ethnicity, rurality), and practice characteristics, including provider type, and their impact on receiving/providing obesity screening and counseling. Understanding patient and practice characteristics most likely to engage in obesity counseling can identify best practices and inform how to increase engagement by both patients and providers.

2.0 Background

2.1 Scientific Background and Gaps

Overweight and obesity are America's number one health concern. The prevalence of obesity in the US is greater than 36%,[1] which is far above the Healthy People 2020 objective of less than 30.5%.[2] Perhaps most concerning is the rate that obesity has increased, having doubled since 1970.[3] As the second most preventable cause of death,[4] obesity is a risk factor for diabetes, cardiovascular disease, stroke, and cancer, all major causes of death in the US.[5] Addressing obesity through lifestyle interventions decreases the risk of developing type 2 diabetes, a disease which affects over 29 million people (9.3% of the US population).[6] Diabetes is associated with serious complications, including cardiovascular disease, blindness, renal failure and lower extremity amputation. Although complications are preventable with proper medical and lifestyle management, including weight loss, nearly half of patients with diabetes do not have adequate glycemic control.[7]

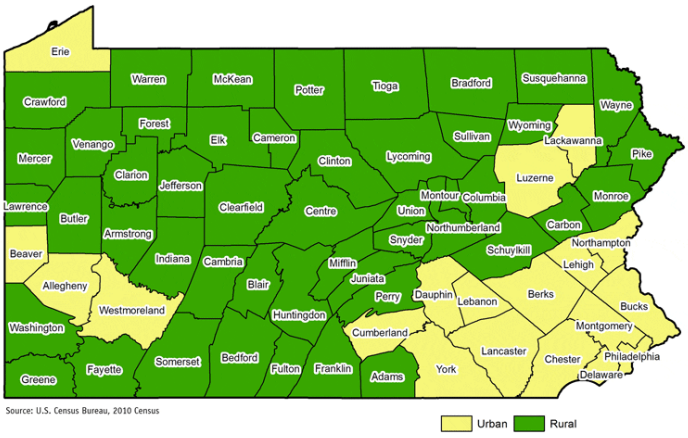
Primary care clinics may be an ideal setting for weight control interventions. Greater than 80% of Americans see a PCP regularly and access to primary care is expected to increase with health care reform.[8,9] Further, as PCPs identify and treat the multitude of conditions affected by being overweight, including diabetes, they are ideally positioned to best engage their patients in weight management. The Centers for Medicare and Medicaid Services (CMS) implemented a healthcare procedure coding system code for intensive behavioral therapy (IBT) for obesity within primary care settings in 2012 to facilitate payment for addressing obesity, which was followed by universal coverage by insurers for IBT for adults of all ages in 2013.[10] However, the impact of this coverage on patient-centered outcomes is largely unknown.

The proposed work leverages the novel infrastructure of the Patient-Centered Outcomes Research Institute-funded PaTH Clinical Data Research Network (CDRN), a partnership of four Mid-Atlantic academic health systems (Penn State Hershey Medical Center, University of Pittsburgh Medical Center, Temple Health System, and Johns Hopkins Health System) that have established governance to operate as an integrated research network. In 2015, the University of Utah and Geisinger Health System also joined PaTH, creating an electronic health record (EHR)-based data infrastructure across three states (Maryland, Pennsylvania, and Utah).

We have additionally added a focus on rural/urban differences in provision of obesity screening and counseling and the resultant impact on weight loss and diabetes incidence. Rural populations have a 17% higher prevalence of diabetes when compared to their urban counterparts.[11,12] As a result, diabetes is the second highest priority for Rural Healthy People 2020.[13] Additionally, rural populations have lower rates of guideline-concordant diabetes services, although this has been inadequately investigated.[14] Studies report adults with diabetes living in rural communities are less likely to receive adequate diabetes-related care than non-rural residents, but are limited in study design (i.e., reliant on patient self-report or medical expenditure data).[11,15] We propose leveraging the novel infrastructure of the Patient-Centered Outcomes Research Institute-funded PaTH CDRN to understand the rural and urban effects on diabetes and its complications. The integration of six large health institutions spanning a diversity of rural and urban populations has the unique opportunity to overcome limitations of prior studies by using health record data.[14] In this way, our proposed study will address important gaps in our understanding of rural/urban differences in diabetes outcomes and guide future approaches to address and eliminate disparities.

Utilizing the PaTH CDRN offers an opportunity to study rural/urban effects, given that the 6 health institution network (University of Pittsburgh Medical Center, Penn State Hershey Medical Center, Temple Health System, Johns Hopkins Health System, University of Utah Health Care, and Geisinger Health System) covers significant populations in both rural and urban counties. For example, PaTH CDRN's service area includes more than 85% of the population of Pennsylvania, including coverage in nearly every one of Pennsylvania's 67 counties (48 rural and 19 urban, see map below). Further, 27% of Pennsylvania's residents live in rural counties, which is higher than the national average of 20%, offering opportunity to better understand diabetes care in this setting.[13] The addition of the University of Utah also offers a different geographic location with similar opportunities to study rural/urban effects. This system provides care for Utahns and residents of five surrounding states in a referral area encompassing more than 10% of the continental US, the vast majority of which is rural. Johns Hopkins Health System, Temple Health System, and the University of Pittsburgh Medical Center offer three different urban populations for comparison.

Rural Pennsylvania Counties



2.2 Previous Data

Preliminary Studies

<u>PaTH Clinical Data Research Network</u>

Overview. The PaTH Clinical Data Research Network (CDRN) brings together four Mid-Atlantic academic health systems—the University of Pittsburgh/University of Pittsburgh Medical Center (UPMC), Penn State College of Medicine/Hershey Medical Center, Temple University School of Medicine/Temple Health, and the Johns Hopkins University/Johns Hopkins Health System/Johns Hopkins Health Care to function as an integrated research network and learning health system, providing an infrastructure for pragmatic clinical trials and observational studies that require populations beyond a single health system to answer important patient-centered clinical and health services questions (www.pathnetwork.org). Funded by the Patient-Centered Outcomes Research Institute (PCORI) in March 2014, the PaTH CDRN is one of 11 CDRNs across the country. Along with 18 Patient-Powered Research Networks (PPRNs), these 11 CDRNs form PCORnet—the National Patient-Centered Clinical Research Network—a national network for conducting clinical outcomes research (www.pcornet.org). The goal of PCORnet is to improve the nation's capacity to conduct comparative effectiveness research by a creating large, highly representative network from which to draw data, while protecting patient privacy and ensuring data security.

PaTH's mission during its initial funding period is to create the technical, governance, and patient- and clinician-engagement infrastructure to conduct clinical and health services research across diverse health systems.[42] For this proposal, we will include all four of the PaTH institutions (Pittsburgh, Penn State, Johns Hopkins, and Temple), thus representing patients from Pennsylvania and Maryland. The University of Utah will join the PaTH network in 2015, which is an exciting new partnership for our network (see Table 3). The addition of the University of Utah greatly strengthens the proposed project by adding a state that has not adopted Medicaid expansion.

The University of Pittsburgh is the lead site for the PaTH Network, with Rachel Hess, MD, MS as the PaTH Network PI. The overall operations of the PaTH Network are run by the PaTH Steering under Dr. Hess' lead. Dr. Hess and the PaTH Steering Committee enthusiastically support this Penn State application to RFA-DP-15-001 (see Dr. Hess' letter of support), which will leverage the data infrastructure, established governance and regulatory policies related to data security, data sharing and human subjects protection of the PaTH Network.

Table 3. Population Overview at Proposed Clinical Sites

	Penn State Hershey	Pitt/UPMC	TUHS	Hopkins	University of Utah
EHR platform	Cerner	Cerner (inpatient) Epic (outpatient)	Epic	Epic	Epic
Distinct patients with at least one encounter or record in EHR	615,012	5,537,583	457,388	4,800,000	1,602,245
Active patients with data in EHR	520,310	1,880,457	323,682	1,764,221	581,568

PaTH Patient Population. The patients in the PaTH network are diverse—22% are aged 17 years or younger and 20% are aged 65 years or older. Over 25% are non-white and 20% have public insurance (excluding Medicare) or no insurance. The organizations are also diverse with many affiliated community-based hospitals and outpatient practices in addition to their academic hospitals. Other facilities include rehabilitation hospitals, dialysis centers, fitness and wellness centers, psychiatric hospitals, ambulatory surgery centers, and home healthcare support.

PaTH Data Sources. PaTH leverages health-related data from: 1) electronic health records (EHR), 2) patient-reported outcomes (PROs), 3) insurance claims data, and 4) biospecimen data. The PaTH data that will be used in the proposed work will be limited to EHR data and claims data.

PaTH Governance and Regulatory Issues. A significant challenge of multi-institutional research networks is managing the governance and regulatory issues that arise when different institutions have their own procedures for conducting research and managing their clinical health records. Perhaps the largest tasks to date for the PaTH CDRN have been the establishment of several governance policies that were required in order for the network to function.

Thus, the proposed research not only builds on the PaTH data infrastructure, but also on its established governance and regulatory policies. The most important agreements that have been executed are: 1) the PaTH network's **data use agreement (DUA)** and the 2) PaTH network's **reliance agreement for a central Institutional Review Board (IRB)** to oversee the protection of human subjects. The PaTH DUA establishes a secure environment for sharing and handling patient data for the purposes of research within the PaTH network. These policies describe data standardization, data privacy standards, and sharing of data within the CDRN. Under the PaTH DUA, we will be able to conduct the research described in this proposal without delays due to need to establish such agreements.

The PaTH network has also established a centralized process for IRB reviews. Creating separate IRB protocols with different formats and procedures to be reviewed by separate IRBs would be an inefficient and ineffective process. This problem has been recognized by the National Institutes of Health (NIH), who is promoting the use of a single IRB in multi-site clinical research studies to reduce duplication of effort, speed-up the initiation of important research, and save time and resources.[43] To this end, the PaTH network has established a reliance agreement naming Johns Hopkins IRB as our central IRB of record. Under the reliance agreement, the other institutions agree to allow the Johns Hopkins IRB to review the study protocol, and to honor the approval of the protocol. To ensure that each PaTH institution would have input into the review process, we convened the PaTH Network Protocol Review Committee, or PNPRC. Two IRB members from each institution serve on the PNPRC, an IRB member and a community member, currently totaling 8 members. Only after the PNPRC approves a PaTH protocol, does it then get submitted to the Johns Hopkins IRB for centralized review.

2.3 Study Rationale

The proposed project is significant for several reasons. First, diabetes is a leading public health concern and associated with significant economic burden. Recent health policies changes (e.g., CMS coverage) are expected to impact diabetes and pre-diabetes outcomes and the proposed project will capture differences in these outcomes through a broad region. Understanding the uptake of the CMS weight counseling benefit and its effect on diabetes and pre-diabetes outcomes can inform future policies to improve overall care for patients.

3.0 Inclusion and Exclusion Criteria

3.1 Inclusion Criteria

Patients with Diabetes

- Ages 18 and older
- Indication of Type 2 Diabetes as defined using a clinically validated algorithm: type 2 diabetes mellitus on the problem list, diabetes-specific medications, hemoglobin A1c (HbA1c) results > 7.0%, or one inpatient diagnosis code or two out-patient diagnosis codes for type 2 diabetes (ICD-9 codes 250.xx)
- patients who have either: (1) had at least 2 outpatient primary care visits in one of the PaTH health systems in the past 3 years (since January 1, 2012), or (2) for whom claims data are available

Patients with Pre-Diabetes (At risk):

- Ages 18 and older
- BMI $\geq$ 25 kg/m^2
- patients who have either: (1) had at least 2 outpatient primary care visits in one of the PaTH health systems in the past 3 years (since January 1, 2012), or (2) for whom claims data are available

3.2 Exclusion Criteria

- Patients under the age of 18

4.0 Sample Selection

4.1 Source of the charts/existing restricted data set

The proposed project will utilize the PaTH Network's existing infrastructure for sharing EHR data across our network. The PaTH Network population represents real-world populations of patients, reducing the likelihood of selection biases that occur with clinical trial data or data from individuals within the same insurance plan. This, in turn, enhances the generalizability of our results. While research records residing at each site will retain identifying information, research records will be de-identified (i.e., personal health information (PHI) will be removed from individual records) prior to making data from the local sites available to Penn State.

PaTH Patient Population. The patients in the PaTH network are diverse—22% are aged 17 years or younger and 20% are aged 65 years or older. Over 25% are non-white and 20% have public insurance (excluding Medicare) or no insurance. The organizations are also diverse with many affiliated community-based hospitals and outpatient practices in addition to their academic hospitals. Other facilities include rehabilitation hospitals, dialysis centers, fitness and wellness centers, psychiatric hospitals, ambulatory surgery centers, and home healthcare support.

PaTH Data Sources. For this study, we will leverage PaTH's : 1) electronic health records (EHR), 2) patient-reported outcomes (PROs), and 3) insurance claims data.

4.2 Identification of subjects/charts/existing data

The University of Pittsburgh is the lead site for the PaTH Network. The overall operations of the PaTH Network are run by the PaTH Steering Committee, which will leverage the data infrastructure, established governance and regulatory policies related to data security, data sharing and human subjects protection of the PaTH Network.

We will use the PaTH Network to identify potential patients who meet our eligibility criteria. PaTH's infrastructure enables and allows for the development, validation, and deployment of electronic algorithms for identifying patients with the conditions of interest. PaTH will continue to follow the guidance of the NIH Health Systems Collaboratory's work on EHR-based phenotyping to create computable phenotypes for the proposed diabetes and pre-diabetes cohorts. Phenotypes will be based on the above inclusion/exclusion criteria.

5.0 Consent Process and Documentation

5.1 Consent Process

Check all that apply:

☒ **Informed consent will not be obtained – request to completely waive or alter the informed consent requirement. *[Complete Section 5.1.1]***
[Review the "CHECKLIST: Waiver or Alteration of Consent Process (HRP-410)" to ensure you have provided sufficient information for the IRB to make these determinations. HRP-410 can be accessed by clicking the IRB Library link in CATS IRB (http://irb.psu.edu). Waiver of consent is the most frequently requested type of consent for both retrospective and prospective chart reviews and existing restricted data sets.]

☐ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.1.2, 5.2.1 and 5.3 (when 5.3 is applicable)]***
[Review "SOP: Written Documentation of Consent (HRP-091)" for information about the process to document the informed consent process in writing. HRP-091 can be accessed by clicking the IRB Library link in CATS IRB (http://irb.psu.edu).]

☐ **Implied or verbal consent will be obtained – subjects will not sign a consent form *[Complete Sections 5.1.2, 5.2.2 and 5.3 (when 5.3 is applicable)]***
[Review "CHECKLIST: Waiver of Written Documentation of Consent (HRP-411)" to ensure that you have provided sufficient information. HRP-411 can be accessed by clicking the IRB Library link in CATS IRB (http://irb.psu.edu). If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.]

5.1.1 Waiver or alteration of the informed consent requirement

The research poses no more than minimal harm to subject (i.e., loss of confidentiality/privacy). The waiver will not adversely affect the rights and welfare of subjects because the research results will not affect the care of the subjects. Given the number of subjects and the possibility that subjects may no longer be living or lost to follow-up, this research would not be practical without this waiver. No information which would be pertinent to the on-going care of individual subjects is expected to result from this study.

5.1.2 Obtaining Informed Consent

N/A

5.2 Consent Documentation

5.2.1 Written Documentation of Consent

N/A

5.2.2 Waiver of Documentation of Consent (Implied consent, Verbal consent, etc.)

The proposed research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context.

5.3 Consent – Other Considerations

5.3.1 Non-English Speaking Subjects

N/A

5.3.2 Cognitively Impaired Adults

N/A

5.3.2.1 Capability of Providing Consent

N/A

5.3.2.2 Adults Unable To Consent

N/A

5.3.2.3 Assent of Adults Unable to Consent

N/A

5.3.3 Subjects who are not yet adults (infants, children, teenagers)

5.3.3.1 Parental Permission

N/A

5.3.3.2 Assent of subjects who are not yet adults

N/A

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☐ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☒ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Information is included in the "Confidentiality, Privacy and Data Management" section of this protocol.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Data will be de-identified.

6.2.2 Explanation for why the research could not be practicably conducted without access to and use of PHI

Retrieval of study data necessitates access to patient charts through their MRNs. Once this information is obtained, it will be identified with code numbers linked to patient MRN's

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Given the number of subjects and the possibility that subjects may no longer be living or have current contact information, this research would not be practical without waiver. No clinical information which would be pertinent to the care of individual subjects is expected to result from this study

6.2.4 Waiver or alteration of authorization statements of agreement

Protected health information obtained as part of this research will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other permitted uses and disclosures according to federal regulations. The research team will collect only information essential to the study and in accord with the 'Minimum Necessary' standard (information reasonably necessary to accomplish the objectives of the research) per federal regulations. Access to the information will be limited, to the greatest extent possible, within the research team. All disclosures or releases of identifiable information granted under this waiver will be accounted for and documented.

7.0 Study Design and Procedures

7.1 Study Design

Check all that apply:

☐ **Analysis of an existing restricted data set. Existing means that all of the data to be used in this study are already in existence when the study is initially submitted to this IRB for review.**

☒ **Retrospective chart/record review – A retrospective chart/record review study means that all of the data to be used in this study are already in existence when the project is initially submitted to this IRB for review.***

*Provide date range of chart/record review (mm/dd/yyyy to mm/dd/yyyy):
2009-2019

☒ **Prospective chart/record review – A prospective chart/record review study means that all of the data are not in existence when the project is initially submitted to this IRB for review.**

7.2 Study Procedures

For the specific needs of this proposal, we will define 2 patient cohorts using the PaTH Network: (1) Diabetes cohort and (2) At-risk for diabetes cohort. As demonstrated in the table below, there are over 328,000 patients with a diagnosis of diabetes (defined as age 18 and older with a diagnosis of diabetes mellitus – ICD9 250.xx) and over 2 million patients at risk for diabetes (defined as age 18 and older with a BMI of ≥ 25) within the PaTH network.

Patient Characteristics	Penn State University (N=25,219)	University of Pittsburgh (N=150,589)	Johns Hopkins University (N=60,324)	Temple University (N=40,536)	University of Utah (N=51,787)	PaTH Total (N=328,455)
Patients with Diabetes						
Insurance type						
Private	9,874 (38%)	60,223 (40%)	32,371 (54%)	5,261 (13%)	21,264 (41%)	**128,993 (39%)**
Medicaid	1,890 (8%)	10,165 (7%)	727 (1%)	21,759 (54%)	4,189 (8%)	**38,730 (12%)**
Medicare	12,998 (52%)	54,675 (36%)	22,826 (38%)	10,916 (27%)	23,997 (46%)	**125,412 (38%)**
Uninsured	457 (2%)	11,625 (8%)	485 (1%)	2,599 (6%)	2,337 (5%)	**17,503 (5%)**
Race						
White	21,780 (86%)	116,056 (77%)	32,544 (54%)	14,347 (35%)	39,580 (76%)	**224,307 (68%)**
African-American	1,679 (7%)	15,336 (10%)	20,053 (33%)	14,656 (36%)	944 (2%)	**52,668 (16%)**
Other	1,760 (7%)	19,197 (13%)	7,727 (13%)	11,533 (29%)	11,263 (22%)	**51,480 (16%)**
Hispanic Ethnicity	1,054 (4%)	697 (0.5%)	2,002 (3%)	7,356(18%)	6,077 (12%)	**17,186 (5%)**
Female Gender	12,014 (48%)	70,623 (47%)	30,912 (51%)	22,485 (55%)	25,727 (50%)	**161,761 (49%)**
Patients At-Risk for Diabetes						
	(N=167,799)	**(N=950,020)**	**(N=471,860)**	**(N=212,314)**	**(N=260,506)**	**(N=2,062,499)**
BMI						
25-29.9	69,353 (30%)	433,799 (31%)	226,113 (32%)	92,807 (31%)	122,583 (31%)	**944,655 (32%)**
30-34.9	48,353 (21%)	268,236 (19%)	128,799 (18%)	60,330 (20%)	87,023 (22%)	**592,741 (20%)**
35-39.9	25,388 (11%)	128,113 (9%)	58,072 (8%)	29,930 (10%)	70,774 (18%)	**312,277 (10%)**
40+	24,705 (11%)	94,550 (7%)	43,377 (6%)	23,321 (8%)	25,410 (7%)	**211,363 (7%)**

Diabetes Cohort Definition. During year 1 of the proposed project, the investigative team, in collaboration with the PaTH Network, will identify a valid cohort of patients with type 2 diabetes. The cohort of patients under study will be defined as all patients age 18 and older with an indication of type 2 diabetes during the proposed study time frame. Patients will be classified as having diabetes using a clinically validated algorithm: type 2 diabetes mellitus on the problem list, diabetes-specific medications, hemoglobin A1c (HbA1c) results > 7.0%, or one inpatient diagnosis code or two out-patient diagnosis codes for type 2 diabetes (ICD-9 codes 250.xx). The diabetes cohort will be further limited to patients who will likely be captured in the PaTH EHR records or claims data so that outcome assessments can occur. Thus, we will further limit the diabetes cohort to patients who have either: (1) had at least 2 outpatient primary care visits in one of the PaTH health systems in the past 3 years (since January 1, 2012), or (2) for whom claims data are available. The cohort will be dynamic, with new patients added into the cohort after 2015 as they meet the diabetes cohort definition prospectively. The observational period for the outcome variables will be for the 10-year period from 2009-2019, thus including 3 years of data prior to the first policy change (CMS instituting coverage for intensive behavioral therapy for obesity) and 3 years after the last policy change (Pennsylvania Medicaid expansion) under study.

Following the definition of the diabetes cohort and key diabetes outcomes and covariates as described above, an initial extraction of variables will be conducted in Year 2 of the proposed project for years 2009-2015. This early data extraction from the PaTH Network will allow for cohort validation and data cleaning and editing, as well as required programming and determination of the analysis models. We will utilize this initial data extraction in Years 2 and 3 to analyze the impact of early health policy changes, as well as to prepare a manuscript of both the protocol and early findings of policy impact. The final data extraction will occur during the final quarter of Year 4 of the proposed project, allowing for completion of a ten-year time period (2019).

At-risk Cohort Definition. The cohort of patients under study will be defined as patients age 18 and older who are at risk for the development of diabetes, based on being overweight. Patients seen at one of the four PaTH institutions will be included in the at-risk cohort if they have a BMI ≥ 25 kg/m^2, based on most recent recorded weight and at least one recorded height. The at-risk cohort will be further limited to patients who will likely to be captured in the PaTH EHR records or claims data so that outcome assessments can occur. Thus, we will further limit the at-risk cohort to patients who have either: (1) had at least 2 outpatient primary care visits in one of the PaTH health systems in the past 3 years (since January 1, 2012), or (2) for whom claims data is available. The cohort will be dynamic, with new patients added into the cohort after 2015 as they meet the at-risk cohort definition prospectively. Patients will not be removed from the cohort, even if they are no longer overweight. The observational period for the outcome variables will be for the 10-year period from 2009-2019, thus including 3 years of data prior to the first policy change (CMS instituting coverage for

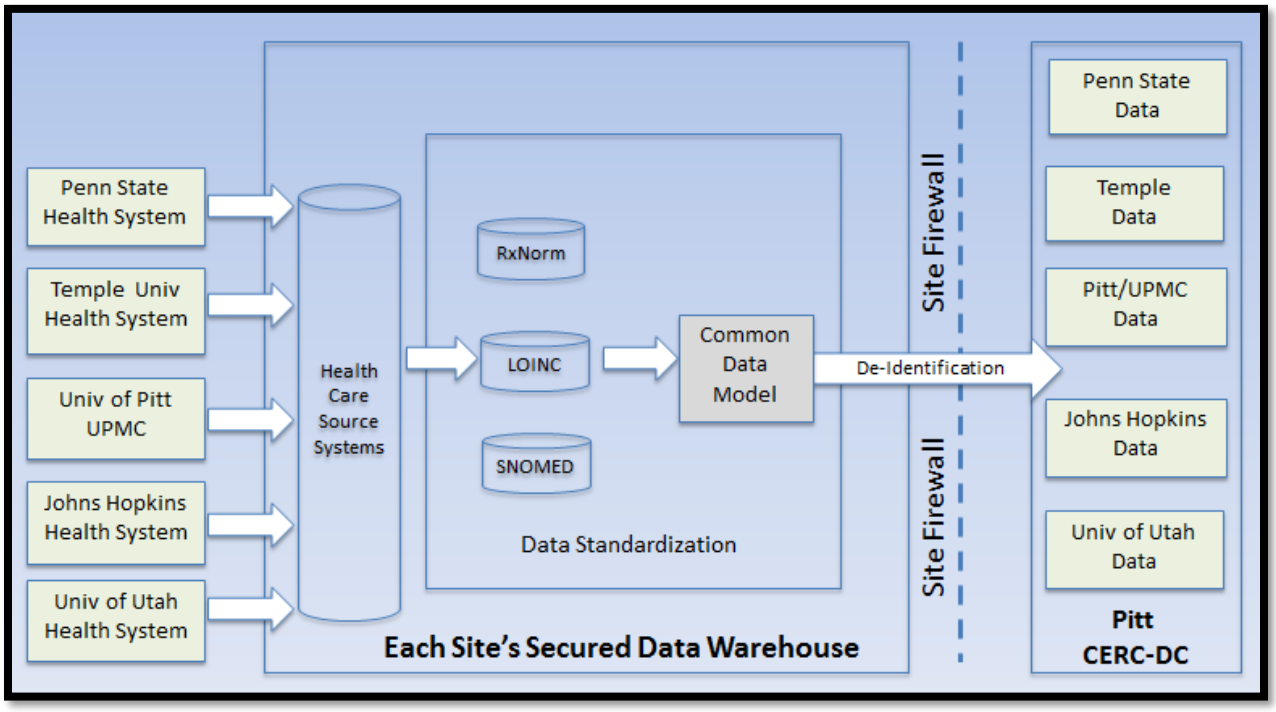
intensive behavioral therapy for obesity) and 3 years after the last policy change (Pennsylvania Medicaid expansion) under study.

Table 1. Proposed Outcomes for the Pre-diabetes and Diabetes Cohorts

Outcomes	Definition	Notes
Pre-diabetes cohort		
Weight loss during counseling	Weight lost from first IBT visit to final IBT visit	Available at all PaTH sites
Weight loss maintenance	% of weight lost during program and maintained over remaining time period, reported by year	Available at all PaTH sites
Diabetes incidence	% of patients who develop diabetes per year following weight counseling	Available at all PaTH sites
Patient-reported outcomes	-SF-12 -PHQ-2, PHQ-8, PHQ-9 -Physical function -sleep -fruit and vegetable consumption -social support -physical activity -PROMIS (PROMIS 29, physical function, depression) -healthy lifestyles -patient reported medication reconciliation	Available at some sites – Formal inventory of PROs will be collected at each institution at the beginning of the project, to be included as secondary outcomes
Diabetes cohort		
Weight loss during counseling	Weight lost from first IBT visit to final IBT visit	Available at all PaTH sites
Weight loss maintenance	% of weight lost during program and maintained over remaining time period, reported by year	Available at all PaTH sites
Patient reported outcomes	-SF-12 -PHQ-2, PHQ-8, PHQ-9 -Physical function -sleep -fruit and vegetable consumption -social support -physical activity -PROMIS (PROMIS 29, physical function, depression) -healthy lifestyles -patient reported medication reconciliation	Available at some sites – Formal inventory of PROs will be collected at each institution at the beginning of the project, to be included as secondary outcomes
Uncontrolled diabetes	Average A1c > 9 or no A1c	Available at all PaTH sites
Controlled blood pressure	SBP < 140, DBP < 90, averaged across values over year	Available at all PaTH sites
On a statin medication	Evidence of a statin medication on current EHR medication list	Available at all PaTH sites
Receiving annual eye exam	Documentation of eye exam once in past year	Available at all PaTH sites
Receiving annual urinary microalbumin test	Documentation of lab testing for urinary microalbumin at least once in past year	Available at all PaTH sites
Lower extremity amputations	Documentation of procedure for lower extremity amputation or billing code through health plans in past year	Available at all PaTH sites
Diabetes Service Use	-Clinic visit with primary or secondary diagnosis of diabetes -Emergency department visit with primary or secondary diagnosis of diabetes -Hospitalization with primary or secondary diagnosis of diabetes	Available at all PaTH sites
Exposure variables		
Individual level	-Sociodemographics (e.g., age, sex, race, insurance status, rural vs. urban) -Medical co-morbidities	Available at all PaTH sites
Provider/practice level	-Practitioner type (advanced practice vs. MD/DO) -Practitioner specialty -Practice size (# of providers) -Practice type (multispecialty, academic) -Practice setting (rural vs. urban)	To be determined

Data Transfer. The PaTH network has established an operational data infrastructure with the necessary technical safeguards as agreed upon in the PaTH Data Use Agreement (DUA) for sharing and analyzing data while addressing data confidentiality and security concerns. PaTH has deployed two mechanisms for storing, protecting, and sharing data (as described previously under PaTH Governance and Regulatory Issues): (1) data with PHI are stored and protected behind each institution's firewall in the distributed data network and (2) de-identified data are sent to the PaTH data center at

the University of Pittsburgh (CERC-DC). Once data integration is accomplished at each site, sites will remove all PHI and send the de-identified version of the integrated data to the CERC-DC through PaTH's virtual private network/secure file transfer protocol (VPN) which has been operational for data transmission since November 2014. Data analysis can then be performed via secure remote computing using standard statistical software packages (e.g., SAS). This model ensures that the highest level of privacy and confidentiality for the data that are maintained at each site, the CERC-DC, and at Penn State.



8.0 Statistical Plan

Descriptive statistics will be generated to describe the characteristics of different cohorts of interest. The diabetes related outcomes will be summarized at the individual level on a yearly basis. There will be binary outcomes (Yes/No) such as controlled diabetes, controlled blood pressures, receiving annual eye exam, receiving obesity and/or nutritional counseling, and count outcomes such as numbers of clinic visits, emergency department visits and hospitalization, and continuous outcomes such as cost of healthcare utilizations. The distributions of outcome measures will be examined by using minima, maxima, ranges, medians, quartiles, means, and standard deviations for continuous variables, and frequency and contingency tables for categorical variables.

To evaluate the impact of policy changes on these outcomes, we will examine how these outcomes change over time, in response to the policy changes. As descriptive analyses, we will plot the mean trajectory of each yearly outcome at clinic level, health system level and state level. The statistical modeling of patterns of changes in individual level outcomes will be carried out through multi-level mixed-effects models.[12-15] The mixed-effects model is a common and popular modeling technique for longitudinal data. A mixed-effects model can accommodate within- and between-subjects variability, as well as serial correlations. In addition, it has the flexibility to incorporate time-dependent covariates, incomplete data, and heteroscedasticity of the variances and correlations. The mixed-effects model will be specified in a multi-level fashion so that different levels of variability (e.g., individual characteristics, social environment, built environment) can be taken into account. The pattern of changes in the outcome will be assessed for pre- and post-periods, respectively, based on the piecewise/segmented regression models. The slope of each segment indicates the trend of change in diabetes outcome in that period. Therefore, the change in the trend/slope post-policy implementation may reveal the actual impact of the new policy controlling for baseline level and trend. Such modeling strategies share the same spirit of interrupted time series analysis. While the classical interrupted time series design often generates a single long series of data, we have a large number of short series from each individual subject, namely, longitudinal data. Depending on the types of the outcomes, we will specify mixed-effects models based on logistic

regression for a binary outcome, Poisson regression for a count outcome and linear regression for a continuous outcome as detailed below.

In the multi-level modeling, the first-level unit is the yearly measurement for the individual subject (pre- and post-policy), the second–level unit is the individual subject, the third-level unit is the health system or clinic within the health system (cluster), and the fourth-level unit is the state. We set year 2014 as time origin for Utah when considering the policy impact of the ACA. Let Y_{ijkt} denote the binary response of having controlled diabetes at year t since policy changes for the k^{th} subject within the j^{th} cluster of the i^{th} state, t=-5, -4, …, 0, 1, …, 5, i = 1, 2, 3; j = 1, 2, …, c_i, and k = 1, 2, …, n_{ij}, where c_i is the number of clusters within the i^{th} state and n_{ij} is the sample size within the j^{th} cluster of the i^{th} state. An individual subject may not be in the system for all 11 timepoints of measurement, so t will have a smaller range of values for that individual subject. Also due to the different timeline of policy changes, the number of years before and after policy changes may vary. The probability of having controlled diabetes, $\mu_{ijkt} = E(Y_{ijkt}) = Pr[Y_{ijk} = 1]$, can be described by the following segmented logistic regression model

$$\begin{aligned} \text{logit } \mu_{ijkt} &= \log\{Pr[Y_{ijk} = 1]/ Pr[Y_{ijk} = 0]\} \\ &= \beta_{0ijk} + (t+5)\,\beta_{1ijk} && \text{if } -5 \le t \le 0, \text{ pre-period before policy changes} \\ &= \beta_{0ijk} + 5\,\beta_{1ijk} + t\,\beta_{2ijk} && \text{if } 0 \le t \le 5, \text{ post-period after policy changes} \end{aligned}$$

where β_{mijk} (m= 0, 1, 2) are subject-specific regression parameters, with β_{0ijk} being the log odds of having controlled diabetes at t = -5, and β_{1ijk} and β_{2ijk} being the slopes (annual change in log odds) for the pre- and post-periods, respectively. In the framework of a mixed-effects model, each β_{mijk} is modeled by

$$\beta_{mijk} = x_{mijk}^T \beta_m + z_{ij}^T \gamma_{1ij} + \gamma_{2mijk}$$

where x_{mijk} is the vector of regressors for the fixed effects, β_m is the corresponding vector of fixed-effects parameter coefficients, z_{ij} is a vector of cluster-level regressors for the random effects for the j^{th} cluster of the i^{th} state, γ_{1ij} is the cluster-level random-effect coefficients and is common to all m, and γ_{2mijk} is the subject-level random-effect coefficients associated with the parameter β_m for the k^{th} subject within the j^{th} cluster. The random effects are assumed to follow a multivariate normal distribution with mean zero. Because the vector x_{mijk} may include subject-level, cluster-level and state-level exposure variables, the fixed effects parameter vectors β_1 and β_2 represent the effects of different exposure variables on the annual changes in the pre- and post-periods. Thus, we may perform statistical tests to examine whether there are differences in trends between the pre- and post-periods overall and for each state, and whether the patterns of changes differ between the states.

Similarly for a count outcome Y_{ijkt} (e.g., number of clinical visits), we define the expected value $\mu_{ijkt} = E(Y_{ijkt})$ and apply a Poisson regression model based on the natural log link function. The log expected number of clinical visits, $\log(\mu_{ijkt})$, can be modeled with the aforementioned segmented mixed-effects model. The use of an offset term in the models yields the estimates of the rate of clinical visits rather than the mean number of visits. The fixed-effect parameters, β_1 and β_2, represent the effects of exposure variables on the annual changes in log of incidence rates for the pre- and post-periods, respectively. For a continuous outcome Y_{ijkt}, we will model the mean, $\mu_{ijkt} = E(Y_{ijkt})$, with the mixed-effects model and the parameters β_1 and β_2 indicate the effects of exposure variables on the annual changes in the outcomes for the pre- and post-periods, respectively. All final statistical models will be assessed with respect to the goodness-of-fit and the appropriateness of model assumptions. Statistical software SAS 9.4 and R environment will be used to implement the proposed analyses.

Furthermore, we will use the similar models as described above to evaluate post-policy impact of obesity screening and counseling (number of visits) on the outcomes such as weight loss, diabetes incidence, and diabetes outcomes (including hemoglobin A1c, controlled blood pressure, use of a statin medication). The outcome data collected after the universal coverage change (i.e., t=0, 1, ... 6) will be used to estimate the trend of change. The number of screening and counseling will be used as a predictor in the mixed effects models. The effects of patient and practice characteristics will also be examined in the models. Statistical software SAS 9.4 and R environment will be used to implement the proposed analyses.

Subgroup analyses

Due to the heterogeneity of the population and a dynamic cohort in our study, we will investigate subgroup analyses to assess how the policy impact varies across different subgroups. Following the general modeling approaches as described above, we will examine the benefits of policy changes for different subgroups including (1) patients with insurance throughout the study period, (2) patients who obtained insurance after the policy changes, (3) patients without insurance throughout the study period, (4) patients newly enrolled in the system after policy changes, and (5) other subgroups of interest according to gender, age (e.g., age 65 and older), race-ethnicity. Meta-analysis has been a powerful approach to combining the effects of interest across different studies, different populations, and different subgroups.[16,17] We will adopt this method to evaluate the average impact of policy changes across subgroups. A forest plot will be generated to reveal how the addition of a subgroup to the meta-analysis may affect the average policy impact.

Propensity scores matching

In the proposed modeling framework above, we adjust for the subject-level and cluster-level differences by including the exposure variables at different levels as covariates in the models. We also will consider a secondary analysis with a propensity scores matching approach to adjusting for these differences.[18,19] A wide array of patient measures in the EHR, including demographics, insurance coverage, medical co-morbidities, health behaviors, and information on use of health care services, will be used to calculate the propensity scores. Propensity score-based stratification analysis will be performed to evaluate the overall impact of health policy using the modeling framework similar to that described above.

Analyses of diabetes outcomes at population level

The primary analysis of our study focuses on the individual-level outcomes. The statistical models yield the estimate of average change at individual level post policy implementation. Given the information in the EHR data, we can also aggregate the diabetes outcomes at community level, clinic level, etc. For example, the proportion of patients with controlled diabetes can be obtained for each clinic and used as the outcome variable in the statistical modeling. The proposed mixed-effects modeling framework are still applicable in this case. The statistical analyses can be performed in a similar fashion to that for the individual-level outcomes.

For example, our proposed statistical analysis plan can be easily modified to compare the differences in weight loss and diabetes outcomes (including diabetes control, controlled blood pressure, use of a statin medication, receipt of an annual eye exam and annual urinary microalbumin test, and lower extremity amputations) between rural and urban areas. As stated in the proposal, although our main analysis is on individual-level outcomes, aggregated outcomes at the community- or county-level can also be extracted from the electronic health record (EHR) data. For example, the proportions of patients with controlled diabetes in each county at each year can be obtained and used as the outcome variable after arcsine-square root transformation in the statistical modeling. We can evaluate the rural/urban effects on the pattern of changes in diabetes outcomes over years by including county-level characteristics such as rural vs. urban in the mixed-effects models as fixed effects. The time origin in the analysis will be the beginning of the study period, rather than the time when insurance policy changes occurred. The counties sharing similar characteristics (e.g., access to the same health system) will be considered as a cluster and the clustering effect will be accounted for in the mixed-effects model analysis by including cluster-level random effects. Instead of using segmented regression models to evaluate the trend in diabetes outcomes before and after the policy change, we will consider linear or non-linear trends in the diabetes outcomes and allow rural and urban counties to have different patterns of changes in the models.

Statistical Power. Given the very large sample sizes that are anticipated for the research studies (more than 320,000 patients with diabetes and 2,000,000 patients at-risk for diabetes), there is tremendous statistical power to detect very small effect sizes for individual-level exposure variables. Therefore, the clinical investigators on this project will need to

examine each statistically significant result and determine whether it is clinically significant. Furthermore, such large sample sizes ensure the robust estimation results from the proposed multi-level statistical modeling which involves large number of regression coefficient and covariance parameters. The major benefit of the large sample size for each research study is that it provides sufficient statistical power for investigating effects of interest within subgroups that might be constructed according to age, race-ethnicity, cohort decompositions, etc.

9.0 Confidentiality, Privacy and Data Management

See Data Plan Review Form HRP-598

9.1 Confidentiality

9.1.1 Identifiers associated with data and/or specimens

- ☐ Names;
- ☐ All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes;
- ☐ Birth date, admission date, discharge date, date of death;
- ☐ Phone numbers;
- ☐ Fax numbers;
- ☐ Electronic mail addresses;
- ☐ Social Security numbers;
- ☐ Medical record numbers;
- ☐ Health plan beneficiary numbers;
- ☐ Account numbers;
- ☐ Certificate/license numbers;
- ☐ Vehicle identifiers and serial numbers, including license plate numbers;
- ☐ Device identifiers and serial numbers;
- ☐ Web Universal Resource Locators (URLs);
- ☐ Internet Protocol (IP) address numbers;
- ☐ Biometric identifiers, including finger and voice prints;
- ☐ Full face photographic images and any comparable images (including videos);
- ☐ Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code the data);
- ☐ Other (please specify):

9.1.1.1 Use of Codes, Master List

N/A

9.1.2 Storage of Data for This Study

N/A

9.1.3 Access to Data for This Study
N/A

9.1.4 Transferring Data for This Study
N/A

9.2 Subject Privacy
N/A

10.0 Risks

Only de-identified patient level data will be collected, so while loss of confidentiality is a risk, it's unlikely. To minimize the likelihood of a breach in confidentiality, we will follow standard PaTH procedures with regards to data management. Individual health data will be de-identified at each institution and loaded into the PaTH i2b2 instance, transferred, and stored at the University of Pittsburgh CERC-DC.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects
None

11.2 Potential Benefits to Others
Potential benefits to others include understanding the effectiveness of obesity counseling benefits for patients with type 2 diabetes an at-risk for diabetes.

12.0 Other Approvals

12.1 Other Approvals from External Entities
N/A

12.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – Hershey only – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of the Use of Human Tissue For Research Form on the Supporting Documents page in CATS IRB. This form is available on the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/forms

☐ Animal Care and Use – All campuses – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – All campuses – Research involves bio-hazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy.

☐ Conflict of Interest Review – All campuses – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – Hershey only – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload the Radiation Review Form on the Supporting Documents page in CATS IRB. This form is available on the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/forms

☐ IND/IDE Audit – All campuses – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – Hershey only – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review

requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. Note: Review by the Penn State Hershey Cancer Institute Scientific Review Committee is required if the study involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website at: http://www.pennstatehershey.org/web/irb/home/resources/investigator

13.0 Multi-Site Research

13.1 Communication Plans

The lead investigative team (Core PI, co-PIs, core project manager) meet on a bi-weekly basis to create and modify the protocol and well as address any issues that arise from any of the sites. The core project manager and core Principal Investigator will work together to create a standard protocol and disseminate it among the sites to submit to each institution's IRB. The core project manager will also coordinate and review any modifications to the protocol with both the lead team and with all the site project managers (there is a project manager for each site) to submit the appropriate changes to their IRB.

13.2 Data Submission and Security Plan

To minimize the likelihood of a breach in confidentiality, we will follow standard PaTH procedures with regards to data management. Individual health data will be de-identified and loaded into the PaTH i2b2 instance, transferred, and stored at the University of Pittsburgh CERC-DC. No identifiable patient information will leave institutional firewalls. Data analysis by Penn State investigators will occur through secure remote computing. No patients will be contacted for this study.

13.3 Subject Enrollment

The lead investigative team will meet regularly and communicate with the PaTH project manager to coordinator data extraction.

13.4 Reporting of Adverse Events and New Information

N/A

13.5 Audit and Monitoring Plans

There are several processes in place to ensure all site investigators conduct the study appropriately. First, PaTH has multiple internal procedures to ensure data is accurate. Given the study is reliant on the PaTH Network, a regular meeting schedule will be determined to ensure the data is being extracted and reported to meet study requirements in accordance with protocol. Local procedure will include the Penn State study team (PI, core project manager) jointly overseeing the auditing and monitoring plans. Specifically, the PCORI milestones have been back-dated to allow one month for review by the PI and core project manager. Data will be checked for completeness and accuracy, based on expected values and ranges. Biweekly meetings between the PI and core project manager will be used to review protocol and site progress and ensure proper conduction of the study.

14.0 Adverse Event Reporting

14.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be

(1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

15.0 Study Monitoring, Auditing and Inspecting

15.1 Auditing and Inspecting

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.)

16.0 Future Undetermined Research: Data Banking

N/A. This study is not collecting or retaining identifiable data.

16.1 Data being stored
N/A

16.2 Location of storage
N/A

16.3 Duration of storage
N/A

16.4 Access to data
N/A

16.5 Procedures to release data
N/A

16.6 Process for returning results
N/A

17.0 References

1. Ogden CL, Carroll MD, Fryar CD, Flegal KM. Prevalence of Obesity Among Adults and Youth: United States, 2011-2014, 2015.
2. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Statistics NCfH. Healthy People 2010. Washington, D.C., 2000.
3. Flegal KM, Carroll MD, Ogden CL, Curtin LR. Prevalence and trends in obesity among US adults, 1999-2008. *Jama* 2010; **303**(3): 235-41.
4. Mokdad AH, Ford ES, Bowman BA, et al. Prevalence of obesity, diabetes, and obesity-related health risk factors. *JAMA* 2001; **289**(1): 76-9.
5. Thompson D, Edelsberg J, Colditz GA, Bird AP, Oster G. Lifetime health and economic consequences of obesity. *Archives of internal medicine* 1999; **159**(18): 2177-83.
6. Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2014. Atlanta, GA: U.S. Department of Health and Human Services, 2014.
7. Healthy People.gov. HealthyPeople 2020 Diabetes. 2015. http://www.healthypeople.gov/2020/topics-objectives/topic/diabetes (accessed February 1 2015).
8. Patient Protection and Affordable Care Act (''PPACA''). 2010.
9. Schoen C, Osborn R, Huynh PT, et al. Primary care and health system performance: adults' experiences in five countries. *Health Aff (Millwood)* 2004; **Suppl Web Exclusives**: W4-487-503.
10. Services CfMM. Decision Memo for Intensive Behavioral Therapy for Obesity. 2015. http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo (accessed February 14 2015).

11. Krishna S, Gillespie KN, McBride TM. Diabetes burden and access to preventive care in the rural United States. *J Rural Health* 2010; **26**(1): 3-11.
12. Keppel KG, Pearcy JN, Klein RJ. Measuring progress in Healthy People 2010. *Healthy People 2010 Stat Notes* 2004; (25): 1-16.
13. Rural Healthy People 2020 Texas A&M Health Science Center School of Public Health, Southwest Rural Health Research Center; 2015.
14. Massey CN, Appel SJ, Buchanan KL, Cherrington A. Improving diabetes care in rural communities: An overview of current initiatives and a call for renewed efforts. *Clinical Diabetes* 2010; **28**(1): 20-7.
15. Nawal Lutfiyya M, Patel YR, Steele JB, et al. Are there disparities in diabetes care? A comparison of care received by US rural and non-rural adults with diabetes. *Primary Health Care Research & Development* 2009; **10**: 320-31.