Basic Study Information

1.1 Indicate the appropriate IRB. NOTE:

- If you are unsure which IRB to select, please refer to the guidance or contact an IRB office for assistance.
- For studies that may qualify for review by the commercial (e.g., Western) IRB or NCI Central IRB, select the Health Sciences IRB below.

* MR IRB

1.2 Provide a short, lay-terms study title.

* Provider and Clinic-level Determinants of Blood Pressure Control Among Patients with Early Stage Chronic Kidney Disease

1.3 Provide the full, formal study title. NOTE: This is the title that will appear in correspondence.

* Provider and Clinic-level Determinants of Blood Pressure Control Among Patients with Early Stage Chronic Kidney Disease

1.4 Is this study being transferred from another institution?

* ☐ Yes ☐ No

1.5 Identify the Principal Investigator.

* PEGGY MUNSON

1.6 Identify the points of contact for this study (limit of four).

NOTE:

- Points of contact can edit the application and will receive email notifications about this submission. For the HS and MR IRBs only, points of contact can also submit materials on behalf of the PI.
- If the PI is serving as a study point of contact, indicate that here.

* PEGGY MUNSON

PI Status

Principal Investigator: PEGGY MUNSON

2.1 Select which of the following criteria describe(s) how the person identified as the PI meets UW-Madison requirements to serve as PI:

* PI has a UW-Madison faculty appointment (generally 50% or more). This includes faculty with a full-time UW-Madison position but who hold a $0 UW-Madison appointment only because their position is funded by the federal government...
2.1.1 If the PI does not meet any of the above criteria and an exception to allow the individual to serve as PI is being requested, indicate below why an exception is being sought and the person's qualifications to serve as PI. NOTE: Campus policy does not allow student researchers to serve as PI.

2.1.2 If required, upload "Request for Approval to Serve as Principal Investigator on a Human Subjects Protocol."

File
There are no items to display

ID: IRB00003319

Study Team

NOTE: All members of the study team (key personnel) must be listed on this page. Study team members can be listed as having either edit/email access or read-only access, but all study team members (apart from the PI and POC) must be listed in one category or the other.

If the study team includes anyone (including students) who is not affiliated with (e.g., employed by, holds an appointment at) the UW-Madison, UWHC, or Madison VA (Wm. S. Middleton VA Hospital) AND for whom you are requesting that UW-Madison serve as IRB of record, these individuals must be listed in either 3.1 or 3.2. If the study team includes anyone who is not affiliated with the UW-Madison, UWHC, or Madison VA (Wm. S. Middleton VA Hospital) for whom you are NOT requesting that UW-Madison serve as IRB of record, DO NOT list these individuals in either 3.1 or 3.2. The study protocol must include all external collaborators and their roles in this study.

3.1 Identify study team members with edit/email access.
NOTE: Study team members listed here will be able to edit the application and receive email notifications regarding this study. Only the PI and Point of Contact can formally submit materials to the IRB.

3.2 Identify study team members with read-only access.
NOTE: Study team members listed here will be able to read the application but will not be able to edit the application or receive email notifications.

ID: IRB00003319

Study Team: Roles

NOTE: Depending on the nature of the study or project, it is possible that some or all study team members will not fit into the categories below. If this is the case, select Not Applicable.

4.1 Identify the study team members who will be involved in identification and recruitment of subjects for this study, if applicable.

Person
There are no items to display

✓ Not applicable

4.2 Identify the study team members who will be responsible for obtaining informed consent, if applicable.

Person
There are no items to display

✓ Not applicable
4.3 Identify the study team members who will be intervening or interacting with subjects (e.g., administering surveys, conducting physical interventions), if applicable.

Person
There are no items to display

✓ Not applicable

4.4 Identify the primary point of contact for this study. NOTE: If the PI is serving as the primary point of contact, indicate that here.

* PEGGY MUNSON

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**Project Sponsorship and Billing Information**

6.1 Does this submission primarily represent a trainee project?

* Yes  No

6.1.1 If yes, identify the student(s)/trainee(s).

<table>
<thead>
<tr>
<th>Student/Trainee</th>
<th>Category</th>
<th>Course</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are no items to display</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

6.2 Is this an investigator-initiated project? NOTE: The UW-Madison Health Sciences IRBs define investigator-initiated research as research that is originated and designed by individuals, independently of any sponsor or funding agency. Such research is not conducted under the auspices of a formal sponsor, such as a pharmaceutical company, and the protocol is not developed or generated by a funding agency (e.g., National Cancer Institute, Cystic Fibrosis Foundation).

To be considered investigator-initiated research, the following must apply:

- The project receives no or very limited industry funding or support (e.g., support is limited to the provision of the drug or device)
- If an IND or IDE exists, it is held by an individual investigator and not a study sponsor

* Yes  No

---

**Funding: General**

7.1 Identify the organization through which the PI will conduct the study. NOTE: If you are requesting the UW-Madison defer to another IRB, select the organization with which the PI is affiliated.

*  
- Madison VA (Wm. S. Middleton VA Hospital)
- University of Wisconsin Hospital and Clinics (UWHC)
- University of Wisconsin-Madison

7.1.1 If the University of Wisconsin-Madison, identify the specific department or organization unit under which the research study will be conducted:
7.2 Are you or do you plan on receiving funding to support this project (includes internal UW-Madison/UWHC/UWMF funds)?

* Yes  No

7.2.1 If the answer to 7.2 is Yes, will any of the funding be administered by the University of Wisconsin-Madison AND be at least one of the following types of accounts: 133 (not federally sponsored), 144 (federally sponsored), 233 (gift account), or 135 (WARF gift account). NOTE: For a 136 revenue account, please answer No to this question.

* Yes  No

7.2.2 If the answer to 7.2 is Yes, will any of the funding be administered by the Madison VA (Wm. S. Middleton VA Hospital) or the UWHC?

* Yes  No

ID: IRB00003319

Conflict of Interest (COI)

13.1 Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a financial interest in an entity that (a) sponsors the study or (b) owns or licenses technology tested or evaluated in the study (including any agent, device, or software) that meets or exceeds one of the thresholds below:

(a) Compensation of $20,000 or more in a calendar year from a publicly traded or privately held business entity;

(b) An ownership interest in a publicly traded business entity valued at $20,000 or more or a 5% or greater equity interest;

(c) Any ownership interest in a privately held business entity whatever the value;

(d) A combination of compensation and ownership interest in a publicly traded business entity valued at $20,000 or more;

(e) A leadership position in a business entity (Leadership positions are positions with fiduciary responsibility, including senior managers (e.g., presidents, vice presidents, etc.) and members of boards of directors). Scientific advisory board membership is not a leadership position.

* Yes  No

13.1.1 If yes, identify the personnel who have this interest.

Person
There are no items to display

13.1.2 Upload the COI management plan(s).

File
There are no items to display

13.2 Do ANY of the study team involved in the design or conduct of the research study, or their immediate family (spouse or dependent children), have a proprietary interest in the research, such as royalties, patents, trademarks, copyright, or licensing agreement, that is relevant to this research study (including any agent, device,
or software being evaluated as part of the research study)?

* [ ] Yes  [ ] No

13.2.1 If yes, identify the personnel who have this interest.

Person
There are no items to display

13.2.2 Upload the COI management plan(s).

File
There are no items to display

13.3 Do ANY of the study team involved in the design or conduct of the research study have a financial interest that requires disclosure to the sponsor or funding source?

* [ ] Yes  [ ] No

13.3.1 If yes, identify the personnel who have this interest.

Person
There are no items to display

ID: IRB00003319

Conflict of Interest (COI): Continued

14.1 In addition to the sponsor(s) of this study or project, are other companies or business entities involved or potentially affected in a significant way by this study or project?

* [ ] Yes  [ ] No

14.1.1 If yes, list those companies/business entities.

14.1.2 If yes, describe the nature of each company/business entity’s involvement.

14.2 Do ANY of the study team involved in the design or conduct of the study or project have any other financial interest that the investigator believes may interfere with his or her ability to protect subjects?

* [ ] Yes  [ ] No

14.2.1 If yes, identify the personnel who have this interest.

Person
There are no items to display

14.3 Do any of the study team receive any incentives for recruiting human subjects or any other purpose directly related to the study or project?

* [ ] Yes  [ ] No
14.3.1 If yes, describe the nature of the incentive.

**ID: IRB00003319**

**Determination of VA Status**

15.1 Indicate if any of the following apply to this study or project:

* None of the above

**ID: IRB00003319**

**Scientific Review: UW Carbone Cancer Center (UWCCC) Protocol Review Monitoring Committee (PRMC) and Clinical and Translational Research Core (CTRC)**

17.1 Is the scientific question of the protocol cancer related?

* Yes  No

17.2 Are you specifically targeting cancer patients for enrollment in this study?

* Yes  No

17.3 Does this study involve the review and/or use of biological specimens/data/images/records from cancer patients?

* Yes  No

17.4 Will this study use the Clinical and Translational Research Core (CTRC)?

NOTE: If the answer to this question is Yes, you must upload a copy of the CTRC application to the Submit activity form. You will see the Submit activity form when you click on the Submit link to submit the completed IRB application.

* Yes  No

**ID: IRB00003319**

**Scientific Review: Other**
18.1 Does this study require scientific review by ICTR Scientific Review Committees? NOTE: If none of the options in 18.1.1 apply, scientific review is required.

*  Yes  No

18.1.1 If no, select why scientific review is not required.

- Application for exemption from IRB
- Retrospective medical records research study

ID: IRB00003319

ICTR Support Services

19.1 Select all of the research support services available through the Institute for Clinical and Translational Research (ICTR) that you consulted while preparing this study or project for submission. If none of these services were used, select Not Applicable.

* Community Academic Partnership Core (CAP)

19.1.1 If other, specify.

19.2 Is this study coordinated by the Office of Clinical Trials?

* Yes  No

ID: IRB00003319

Clinicaltrials.gov Registration

NOTE: Registration at Clinicaltrials.gov may be required in the following situations:

- Per FDA regulations, most studies involving the testing of a drug, biologic, or device must be registered.
- If publications resulting from this study will be published in a member journal of the International Committee of Medical Journal Editors (ICMJE) or in a publication that adheres to the standards of the ICMJE, the study must be registered.

Click on the help link above for additional information on these requirements.

20.1 Does this study need to be registered at Clinicaltrials.gov?

* Yes  No

20.1.1 If yes, who has or will register the study prior to the enrollment of the first subject?

20.1.1.1 If other, specify.
Type of Application

1.1 Indicate the type of application:

* Initial review application: Exemption (includes projects that may not qualify as research, such as quality assurance or quality improvement)

ID: IRB00003319

Initial Review Application: Exemption

2.1 Select the relevant category or categories for which you are requesting an exemption determination:

* Section - AT.Exemption.Exemption Category:
  Not Human Subjects.
  IRB oversight of the project is not required because it does not involve human subjects as recognized by 45 CFR 46.102(f) which defines a ‘human subject’ as “a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

ID: IRB00003319

Study Location: General

1.1 Is this a multi-site study? NOTE: A multi-site study involves at least one site or individual NOT affiliated with the UW-Madison/UW Health/Madison VA (Wm. S. Middleton VA Hospital). Select Yes if this study:
  ○ Will be conducted at sites outside the UW
  ○ Includes study team members NOT affiliated with the UW
  ○ Involves sending or receiving samples/data/images to/from collaborators outside the UW

*  Yes  No

1.1.1 If yes, does the study have a coordinating center? NOTE: A lead site or coordinating center is typically responsible for coordinating activities at all other sites, receiving and analyzing data, and developing and updating the study protocol as needed.

  ○ Yes  No

1.1.1.1 If yes to question 1.1.1, is the UW-Madison/Madison VA (Wm. S. Middleton VA Hospital) serving as the coordinating center?

  ○ Yes  No

1.1.1.2 If no to question 1.1.1, how is it being ensured that all sites have IRB approval prior to initiating study activities?

1.2 Will UW-Madison , Madison VA (Wm. S. Middleton VA Hospital), or UWHC personnel or personnel under UW-Madison IRB purview conduct research activities at sites outside of the US?

*  Yes  No

1.2.1 If yes, specify.

Site Name  Country
ID: IRB00003319

Study Location(s): UW-Madison Sites

3.1 Select the UW-Madison/UW Health/Madison VA (Wm. S. Middleton VA Hospital) location(s) at which this study will occur. Check all that apply:

Other UW-Madison/UW Health location(s)

3.1.1 If other, specify.

PI's Department/location

ID: IRB00003319

Study Summary

1.1 Upload the stand-alone scientific protocol associated with this application. NOTE: A protocol is required for the types of studies listed below. This list is NOT exhaustive and the IRB may request a protocol in other cases as appropriate.

- All multi-site studies (regardless of risk level)
- All studies requiring scientific review
- All studies involving drugs or devices
- All studies posing more than minimal risk to subjects

File

There are no items to display

1.1.1 If no protocol was uploaded, select the reason(s) below.

Study may qualify for exempt status

1.1.1.1 If other, provide a justification.

1.2 Will study activities involve interaction and/or communication with human subjects, even if only to obtain informed consent?

* Yes  ❌ No

1.3 Provide the expected duration of the study (i.e., the time from IRB approval to completion of all study activities).

* 12 Months

ID: IRB00003319

Special Considerations and Procedures

2.1 If your study involves any of the following special procedures or considerations, additional information
may be needed. Select all that apply. If none apply, check Not Applicable.

* Review of records/data/images, includes:
  * Chart reviews
  * Medical records reviews
  * Databases
  * Registries

ID: IRB00003319

**Research Design and Procedures**

1.1 What is the overall purpose of this project or study?

* The primary purpose is to evaluate blood pressure control of patients with early stage chronic kidney disease and the characteristics of the patients, provides and clinics that may effect control.

1.2 What are the specific aims of this project or study?

* The aim of the study is to assess patient, provider, and clinic-level determinants of blood pressure control among patients with early stage (stage I-III) chronic kidney disease.

1.3 Background: What prior information or knowledge exists to support the conduct of this project or study?

* Chronic kidney disease (CKD) is an increasingly common chronic condition (20 million people in the U.S.) with significant long-term health consequences, including cardiovascular disease morbidity and mortality. Uncontrolled blood pressure is an important cardiovascular risk factor for future adverse health outcomes (myocardial infarction, stroke, worsening CKD). The development and targeting of strategies to optimize outcomes for patients with early stage CKD requires an understanding of patient, provider, and clinic-level determinants of cardiovascular risk factors.

1.4 Briefly describe the procedures and interventions that will be performed for this project or study and all study arms involved.

* The current investigation will include electronic health record information for patients with Stage I-III CKD in 2011 (baseline) and 2012 (reporting year) (n=1,270). The primary outcome variable of interest is blood pressure control (<140/90 mmHg, yes/no). Explanatory variables include the following as measured in the baseline year: sociodemographics (age, gender, marital status, race/ethnicity, language), insurance, health behavior (body mass index, tobacco use), comorbidities (as measured by 29 chronic condition indicators), and UW outpatient visits in the baseline year (primary care provider and specialist). Additional socioeconomic and environmental contextual factors from ESRI database (e.g., describe types of elements from PHINEX to be used).

1.5 Will subjects be randomized?

* [ ] Yes  [ ] No

ID: IRB00003319

**Research Design and Procedures: Continued**

NOTE: Depending on the nature of your study or project, these questions may not apply. If this is the case, select Not Applicable.

2.1 Describe the current alternatives to participation in this research study, including treatments subjects could undergo outside of the research study. If there is no accepted treatment or no effective treatment, state this.
2.2 Describe how this patient population is treated clinically.

Not Applicable

2.3 List the procedures that will be performed solely for research purposes (i.e., those that are not performed as part of standard of care).

Not Applicable

**Risks and Benefits: General**

1.1 Describe any potential direct benefits to subjects. If there are no direct benefits, state this.

* No direct benefits are expected for the subjects.

1.2 Describe the potential benefits of this research to society.

* A better understanding of patient, provider and clinic-level determinants of cardiovascular risk factors will contribute to more effective development and targeting of strategies to optimize outcomes for patients with early stage CKD.

1.3 Does this study involve direct physical intervention with subjects? NOTE: A physical intervention refers to study procedures that may pose a risk (however minimal) to a subject’s body (e.g., blood draws, MRI scans, drug or device trials, exercise, dietary restrictions/supplements). Examples of activities that are NOT physical intervention include obtaining informed consent and administering surveys.

* Yes  
No

1.4 Will subjects incur any costs as a result of study participation (e.g., pharmacy preparation fees, payment for a device, billing of study procedures to subject’s insurance)?

* Yes  
No

1.4.1 If yes, describe any costs. NOTE: Costs to subjects must be included in the consent form.

**Risk/Benefit Analysis**

4.1 Describe any potential psychosocial risks to subjects, such as psychological stress or confidentiality risks (including risk to reputation, economic risks, and legal risks).

* The only risk to subjects is a potential for loss of confidentiality.

4.2 Describe how ALL the risks of the study will be minimized.
* We minimize the risk of loss of confidentiality by protecting the data as well as using data with no direct identifiers. We store data on secure servers and limit access to that data to persons who need to use it. The data used for this research cannot be linked by the research team to patients, providers or clinics.

4.3 Explain why the risks to the subjects are reasonable in relation to the anticipated benefits.

* We believe the minimized risk of loss of confidentiality is outweighed by the potential benefits of this research to society. We believe that the results of this research will add to a broader understanding of the factors related to cardiovascular risk factors in patients with CKD.

4.4 Describe the provisions in place to identify and address unanticipated problems or complications.

* Access to the data is restricted to project personnel. Any unanticipated problems will be reported to the IRB in accordance with campus policy.

4.5 Does this study constitute minimal risk research? NOTE: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

* Yes No

4.5.1 If no, describe the data and safety monitoring plan for this study. NOTE: If a formal Data Safety Monitoring Board or Data Monitoring Committee exists, provide a general description of the committee or board’s membership (e.g., number of members, expertise, and whether members are independent of the sponsors/researchers) and the expected frequency of their meetings.

ID: IRB00003319

Privacy and Confidentiality

1.1 Describe the precautions that will be used to ensure subject privacy is protected (e.g., research intervention is conducted in a private room; collection of sensitive information about subjects is limited to the amount necessary to achieve the aims of the research).

* Access to research data is restricted to key personnel. We do not directly interact with the subjects. These data do not include direct identifiers. We do not use sensitive data and we are collecting only that data necessary to address our study aims.

1.2 Select how subjects are identified in the research records. Check all that apply:

* Indirectly: Information identifying subjects is linked to data record but stored separately

1.3 Describe the measures that will be implemented by your research team to safeguard the identifiable subject information from unauthorized use or disclosure for both paper and electronic forms of information. Include how and where data will be stored.

* This research will not use identifiable data.

Datasets created for analysis will be stored on a secure data server under control the principal investigator. The datasets created for this research will be protected by storing data on a secure computer server located in a secure environment with restricted access. In addition, all access to the computer server is password protected and a second password is required to access the computer server where the data is stored. The secure server is housed in a state-of-the-art data center managed by the UW SMPH. The levels of security for the Server are fourfold and include: 1) Physical Security: server is located in a secure server room of the UW Centennial Office building which is a dedicated computer machine room (passkey access only) containing emergency backup power, an uninterruptible power supply (UPS), and an automated fire suppression system; server rack has locks on cabinet doors; 2) Firewall: located behind UW-Madison campus firewall; 3) data directory access controlled by HIP Administration and granted only to approved personnel; 4) virtual...
server security including a) configuration of permissions at the folder level can be done only by the "administrator," and b) password protection is used at the network levels for all transactions that allow entry and editing of data, provide access to subject data, or administrative privileges.

The ESRI data will be added to the patient level dataset by HIP. To do so, HIP provides a list of ZIP codes included in the patient sample to the PHINEX team. The PHINEX team will return a dataset to HIP consisting of the ESRI variables attached to the patient ZIP codes. The HIP data programmers will merge the ESRI data with the patient level data, and ZIP codes will be removed from the data prior to its transfer to the study team. The final dataset given to the study team will include none of the 18 HIPAA identifiers.

No sensitive information will be included in the analysis dataset. No individual PHI will be released in presentation or publication. Only aggregate statistical output representing groups of subjects will be released.

Note that the Health Innovation Program is creating datasets for this research as a Business Associate of UW Health (UWMF and UWHC). While HIP maintains a coded link to the original, identifiable data, it is not accessible to the study team and will not be released outside of HIP under any circumstances.

1.4 Are you planning to retain data collected for this study for purposes not described in this application (e.g., future unrelated research project)?

*   Yes  No

1.4.1 If yes, do you confirm that any future uses not described in this application will be submitted separately for IRB review?

*   Yes  No

ID: IRB00003319

Privacy and Confidentiality: Continued

2.1 Will data be stored on laptops or portable devices?

*   Yes  No

2.1.1 If yes, what additional safeguards have been put in place (e.g., link for coded data will be stored separately, data will be deidentified) to protect these data from risk of breach of confidentiality (e.g., theft of laptop, loss of portable device)? NOTE: Consult with your IT department about security of data storage on laptops or portable devices.

2.2 Will subject data, specimens, or images be shared outside the UW-Madison, the Madison VA (Wm. S. Middleton VA Hospital), or UWHC (including UWMF clinics)? NOTE: This is not referring to industry-sponsored clinical trials or cooperative group studies. For such studies, select Not Applicable.

*   Yes  No

☐ Not Applicable

ID: IRB00003319

HIPAA: General

NOTE: For guidance on the HIPAA privacy rule, including what constitutes individually identifiable information and Protected Health Information (PHI), refer to the HIPAA website. If the purpose of this study or project is to create a database or registry, contact the HIPAA Privacy Officer to determine whether it needs to be registered.

1.1 Will the research involve the access, collection, use, or disclosure of individually identifiable information?
1.1 If yes, are you or any member of the study team conducting the study under a Madison VA (Wm. S. Middleton VA Hospital), UWHC, or UW Medical Foundation appointment or an appointment that is within the UW-Madison Health Care Component (HCC)? NOTE: The HCC of the UW-Madison currently includes SMPH clinical departments; School of Pharmacy (clinical units only); School of Nursing; University Health Services (non-student records only); State Laboratory of Hygiene; Waisman Center (clinical units only); and L&S Psychology Clinic.

* Yes  No

**ID:** IRB00003319

**Review of Records/Data/Images**

1.1 Will the study involve contacting subjects to obtain additional information for this study?

* Yes  No

1.2 Select all of the sources of the records/data/images and, if applicable, protected health information that will be used for this study:

* HealthLink (i.e., UW Hospital & Clinics and UWMF electronics medical records system)
Other database or source (including external sources)

1.2.1 Specify clinic, department, or other database or paper records system or sources.

ESRI database maintained by PHINEX (ESRI database, a publicly-available database, includes: ESRI Updated Demographics, Census Demographics, Tapestry Segmentation, Consumer Spending, Market Potential, and Business Summary. Data is provided at the following levels of geography: State, Core-based Statistical Area (CBSA), Designated Market Area (DMA), County, ZIP Code, Tract, and Block group.)

1.2.2 If a database will be the source of data for this study, is the database primarily used for clinical purposes?

* Yes  No

Not Applicable

1.2.2.1 If no, provide the IRB protocol number of the research database.

1.3 Describe the means by which potentially eligible subject records/data/images will be identified (e.g., ICD9 codes).

* The eligible subjects are those that UW Health has previously identified and reported on to WCHQ. To identify subjects for the WCHQ public reporting, a complex algorithm is used employing ICD-9 diagnosis codes, dates and CPT procedure codes in this algorithm.

1.4 If medical records are being used to identify potential subjects, do you confirm that all key personnel reviewing the records have valid clinical access? NOTE: Valid clinical access means that all key personnel reviewing records have a clinical role, independent of this research study, for which access to patient records/data/images is already present.
1.4.1 If 1.4 is answered no, do you confirm that all key personnel accessing medical records have authorized access to identify subjects via these records. NOTE: Authorized access to identify subjects means research personnel have obtained access to patient lists or other records for the purpose of subject identification through the formal authorization process of the record holder. If access cannot be confirmed for UW Health medical records, contact UW Health-UWHC Information Technology Services to obtain access. For other health systems, contact that organization’s medical records department.

ID: IRB00003319

Review of Records/Data/Images: Continued

2.1 Identify any vulnerable groups whose records/data/images will be targeted for collection, if applicable.

* None of the above

2.2 Describe the population whose records/data/images will be accessed for this study or project.

* Patients with Stage I-III CKD in 2011 (baseline) and 2012 (reporting year) (n=1,270). Patients who have died during the measurement year will be excluded.

2.3 Provide the date range of the data to be collected (e.g., 1/1/1990 - 12/31/2000). NOTE: If you are applying for an exemption, the data must be in existence at the time of IRB submission AND the end date must be no later than the date of IRB submission.

* 01/01/2011-12/31/2013

2.4 Upload a data collection sheet or a list of all data elements that will be collected.

* File

There are no items to display

2.5 Provide the estimated number of records/data/images that will be accessed for this project.

* 1270

2.6 Provide a brief rationale for the number of records/data/images to be used in this study.

* 1270 is the number of patients included in the WCHQ reporting by UW Health on Stage I-III CKD.

2.7 Will the data collected as part of this project be used for purposes other than those that are described in this application?

*  Yes  No

2.7.1 If yes, do you confirm that all future uses will be submitted as separate applications to the IRB?
1.1 Does this submission represent a replacement of a protocol previously approved by a UW-Madison IRB (e.g., one closed under the campus Five Year Renewal Policy)?

* Yes  No

Not applicable

1.1.1 If yes, please provide the reason for the replacement (e.g., IRB required closure due to Five Year Renewal Policy):

1.1.2 If yes, provide the previous number assigned to this protocol by the UW-Madison IRB that approved the study:

2.1 Provide any additional relevant documents (e.g., supplemental statistical justification information), if applicable.

File
There are no items to display

2.2 Describe what additional documents were added in 2.1.

Final Page

1.1 Do you certify that (1) the information presented in this application is accurate; and (2) if the application is being submitted on behalf of the Principal Investigator (PI) rather than by the PI, the information presented was done so with the PI's agreement?

* Yes  No

Click the "Finish" button to exit this page. Click on the "Submit" activity in the project workspace to send this application to the IRB Office.