Application for Protocol Review

Front Page

Wait...does this research involve the VA?

Yes ☐ No ☑ *Is this study funded, in whole or in part, by the VA?

Yes ☐ No ☑ *Are any research procedures performed on VA property, with VA patients, or using VA equipment/resources?

Yes ☐ No ☑ *Will any study personnel be working on VA time for this study?

A. Review Dates

*Date of Initial Submission: 29-Oct-2012

*Version Date: 29-Oct-2012

B. Project Information

Protocol Number: 12-1149

Project Title:

Evaluation of the incidence of hyperkalemia in patients prescribed spironolactone for the treatment of resistant hypertension

Disease/Condition/Topic studied: Hyperkalemia in resistant hypertension

If you are completing this form to request the use of an HUD or Treatment IND throughout this form answer the questions as if the word "research" is replaced by "Use of Device or Drug".

C. Personnel / Contact Information

Personnel - Review (Add Personnel - Review)

Chomicki, Jacqueline Rose

1) List Personnel

Name
Chomicki, Jacqueline Rose

Primary Investigator	Start Date	End Date	Role
☐	05-Sep-2012		PI

Certifications

Certification	Begin	End
HIPAA Research Course	06-Sep-2012	31-Dec-2030
CITI Human Subjects Protection	01-Aug-2012	01-Aug-2015

Leave End Date Blank

Instructions for Completing this page

Klem, Patrick

1) List Personnel

Name
Klem, Patrick

Primary Investigator	Start Date	End Date	Role
☐	05-Sep-2012		Faculty Advisor

Certifications

Certification	Begin	End
CITI Human Subjects Protection	11-Nov-2009	11-Nov-2012
CITI Human Subjects Protection	18-Oct-2006	
HIPAA Research Course	15-Oct-2004	

Leave End Date Blank

Instructions for Completing this page

Marrs, Joel C

1) List Personnel

Name
Marrs, Joel C

Primary Investigator	Start Date	End Date	Role
☐	05-Sep-2012		Co-Inv

Certifications

Certification	Begin	End
HIPAA Research Course	28-Oct-2009	
HIPAA Research Course	11-Aug-2005	
CITI Human Subjects Protection	02-Nov-2009	
CITI Human Subjects Protection	10-Aug-2005	

Leave End Date Blank

Instructions for Completing this page

Faculty Mentor

*2) Are you a student or trainee, or are you doing this research to complete an educational requirement? ☑ Yes ☐ No

*a. Who is your faculty mentor (required)? Patrick Klem

*b. Mentor's Department/Division: UCH Department of Pharmacy

Faculty mentor must appear under personnel section above

Contact Information

Providing accessible contact numbers can help expedite your review in case of questions.

*3) PI Office Phone: 720-848-6879

4) PI Cell Phone/Pager 303-266-0122

*5) Primary Contact Phone: 913-205-6712 *Name: Jacqueline Chomicki

6) Best contact for scientific questions:

a. Phone:

b. Name:

*7) Faculty Advisor/Mentor Phone: 720-848-2278

D. Type of Review being Requested

*Type of review being requested: Expedited

*Complete (F) -- Attachment F: Expedited Research Complete

E. Funding

*1) Do you have any funding for this study? ☐ Yes ☑ No

F. Perfomance Sites

*1) Is this a multi-site study? ☐ Yes ☑ No

*2) Is the PI responsible for any data, samples or research procedures collected or conducted outside of the USA? ☐ Yes ☑ No

Section F(a): Affiliate Performance Sites

3) Will any of the following Affiliates be utilized as sites for this research?

Yes ☑ No ☐ *a. University of Colorado Hospital

Yes ☐ No ☑ b. Veteran's Administration Hospital (ECHCS)

Yes ☐ No ☑ *c. Is any Investigator employed by the VA?

Yes ☐ No ☑ *d. Denver Health and Hospitals

Yes ☐ No ☑ *e. Is any Investigator employed by Denver Health and Hospitals?

Yes ☐ No ☑ *f. Children's Hospital Colorado

Yes ☑ No ☐ *g. Anschutz Medical Campus

Yes ☐ No ☑ *h. Downtown Denver Campus

Yes ☐ No ☑ *i. Colorado Prevention Center

Definition of Affiliate

Section F(b): Non-Affiliated Performance Sites

*Does this study involve other Non-Affiliated sites? ☐ Yes ☑ No

Definition of Non-Affiliate

Section F(c): COMIRB Requested Attachments

For the billing forms below, click on the Form Link to download the form and click SAVE to save the document to your local computer. Complete the form and then attach the completed form to this application. Both of these forms may also be found on the COMIRB Website

Billing Information Form

Fee Waiver Request

Include a copy of the Protocol with this Submission by clicking the link:
'Add Institution Forms/Supporting Documents' on the
Components for Initial Application page.

Section F(d): UCH Requested Attachments

*Preliminary Budget or Budget Template 

Contact Phone Number

Instructions for Completing this page

PI Office Phone: _____

PI Cell Phone: _____

Primarcy Contact Phone: _____

Faculty Advisor/Mentor (if applicable) Phone: _____

G. Description of Study

*1) Summary in lay terms: Provide a brief statement describing the research project in 8th Grade Language. This section should include the study aims and rationale, and a brief overview of how you will answer the research questions. (Approx. 1 paragraph)

This study aims to:
1. Determine the incidence of high potassium in patients prescribed spironolactone for the treatment of high blood pressure that cannot be controlled with three or more medications.
2. Identify patient specific factors associated with an increased risk of developing high potassiumm levels.
Successful completion of this study will offer insight into the development of appropriate use guidelines for spironolactone in the management of high blood pressure resistant to treatment at the University of Colorado Hospital (UCH).
This is a retrospective, observational study of patients at UCH from January 2011 to June 2012. Data previously documented in the medical record as a part of clinical care at UCH in the ambulatory setting will be recorded from baseline (pre initiation of spironolactone) and post initiation. Data collection will be completed using electronic medical records (EMR).

Please note: A separate protocol document must be submitted in addition to this Application form. See the COMIRB protocol template on the COMIRB website for the suggested format. Please upload your protocol separately.

2) Are there special review considerations?

Yes ☐ No ☑ *a. Will this project need CTRC Review (Clinical Translational Research Center)?

Yes ☐ No ☑ *b. Is this an Oncology or Cancer Center Project? (Protocol Review & Monitoring Committee)

Yes ☐ No ☑ *c. Would you like this study reviewed by the Social/Behavioral panel?

Yes ☐ No ☑ *d. Does the composition of the drug involve human gene transfer or recombinant DNA?

Yes ☐ No ☑ *e. Does the protocol involve the use of radioactive drugs or materials not under an IND (including PET scans, VQ scans, etc.) for research purposes only?

Yes ☐ No ☑ *f. Does the protocol invovle the administration of therapeutic radiation doses, using sealed sources, for research purposes only?

H. Human Subjects

Instructions for Completing this page

1) Age Range of subjects to be enrolled:

*(lower limit) 18 89 *(upper limit) Both upper & lower age limits are required

*2) Total Number of Subjects For All Sites: Up to 500

*3) Total Number of Local Subjects: Up to 500

Local enrollment number reflects the maximum number of subjects to be consented by the local investigators. If a chart review, local enrollment number should reflect the maximum number of charts to be reviewed by local investigators, regardless of where they originate. For single-site studies, total and local enrollment numbers should be the same.

*4) Is the enrollment limited on the basis of gender, race or ethnicity? ☐ Yes ☑ No

*5) Inclusion Criteria:

Define the characterists of the population to be included in the study (must match protocol)

Patients at the University of Colorado Hospital from January 1, 2011 through June 30, 2012 who were exposed to spironolactone and prescribed ≥ 3 antihypertensives who have not achieved individual blood pressure goal

*6) Exclusion Criteria:

Define the characterists of the Population(s) to be excluded. Include age < 18, prisoners, pregnant women, and decisionally challenged subjects, unless you check "yes" for the appropriate population in the Vulnerable Populations section below.

Patients less than 18 years of age or greater than 89 years of age, pregnant women, prisoners, patients with active diagnosis of heart failure or liver disease

Vulnerable Populations

Instructions for Completing this page

7) Inclusion of Vulnerable Populations: (check all that apply)

These vunerable populations cannot be enrolled into a study without prior IRB approval. Will any of these populations be enrolled into the study?

Yes ☐ No ☑ *a. Children (under age 18)?

Yes ☐ No ☑ *b. Wards of the state?

Yes ☐ No ☑ *c. Neonates (Birth to 30 days)?

Yes ☐ No ☑ *d. Prisoners or those on probation/alternative sentencing?

Yes ☐ No ☑ *e. Pregant Women / Fetuses?

Yes ☐ No ☑ *f. Decisionally challenged?
(Cognitively impaired, incompetent to consent, proxy, consenting in life threatening situations)

Attachment J must also be completed if the study intends to follow women who become pregnant during the study.

TARGETED Recruitment

8) Are any of the following populations being TARGETED for recruitment?

Yes ☐ No ☑ *a. Poor/uninsured

Yes ☐ No ☑ *b. Nursing home residents

Yes ☐ No ☑ *c. Students of PI or study staff

Yes ☐ No ☑ *d. Students to be recruited in their educational setting

Yes ☐ No ☑ *e. Employees directly under the supervision of PI or co-investigator

Yes ☐ No ☑ *f. People engaged in illegal activites and/or illegal immigrants

Yes ☐ No ☑ *g. People with Post Traumatic Stress Disorder (PTSD)

Yes ☐ No ☑ *h. People with Traumatic Brain Injury (TBI)

Yes ☐ No ☑ *i. Terminally Ill Patients

Yes ☐ No ☑ *j. People with mental illness or learning disabilities

Yes ☐ No ☑ *k. Others vulnerable to coercion

I. Procedures

Instructions for Completing this page

*1) Duration of study procedures for each subject: N/A

*2) Are all study procedures for local site(s) accurately described in the protocol?
☑ Yes ☐ No

*3) Does this research involve the delivery of health care? ☐ Yes ☑ No

*6) Are any additional materials used with subjects (questionnaires, interview guides, informational, diaries)?
Not Applicable

Special Procedures

7) Indicate if any of these procedures are relevant to the study:

Yes ☐ No ☑ *a. Are any Drugs, Biologics or Supplements being prescribed to subjects as part of the research study? (i.e. will the risks of these items be listed in the Consent?)

Yes ☐ No ☑ *b. Are any Devices being used for research only procedures? (i.e. will the risks of the device be listed in the Consent?)

Yes ☐ No ☑ *c. Will the internet be used to collect research data? (e.g. Tests, Surveys, Chat Room, etc.)

Yes ☐ No ☑ *d. Will you create a database for future recruitment?

Yes ☐ No ☑ *e. Will Genetic Testing be involved with this study?

Yes ☐ No ☑ *f. Will Biological samples such as urine, sputum, or blood be collected for use in this study?

Yes ☐ No ☑ *g. Will data and/or biological specimens be stored (banked) for future unspecified research questions?

Yes ☐ No ☑ *h. Are daycares to grade 12 schools being used as a setting for the research?

J. Potential Risks to subjects

*1) Do you view the risk of this study as minimal? ☑ Yes ☐ No

Note: the committee may disagree

*a. Justify this determination:

Because this study involves a retrospective review of patients prescribed spironolactone for the treatment of resistant hypertension, it meets the criteria for minimal risk and will not adversely affect the rights of subjects. This qualifies it for HIPAA and consent waivers. There will be no intervention performed on patients and no patient-specific identifiers will be present in any publication or presentation of the data.

*2) Describe the anticipated risks of the research:

[list risks in order of likelihood and magnitude (very common, common, uncommon, rare but serious)]

The only potential risk is the violation of patients' HIPAA rights by unanticipated disclosure of confidential patient information. The risk of this is rare and would be of small magnitude. In the unlikely circumstance where the primary investigator indentifies a concerning laboratory value, such as hyperkalemia that did not have appropriate follow-up, the primary investigator will refer to prescribing physician.

*3) Describe the plan to minimize risk:

(use procedures that are standard of care where possible)

Study pateints will be assigned unique study identification number. Only the investigators will have access to the data. The electronic database will be stored on the University of Colorado Hospital (UCH) server which has restricted access. The IT department of UCH periodically backs up the UCH server. Only the primary investigator's computer will be used to store data. The computer is password protected. Analyses will be performed only by members of the research team. Responsibility and accountability for the security and confidentiality of the data will lie with the primary investigator during the collection, analysis, and storage phases of the project.

*4) Is it possible that the research team may be made aware of certain incidents/diseases that are reportable to state authorities?

Yes ☐ No ☑

5) Describe the Potential Benefits

*Describe the potential benefits of the study:

The investigators believe the results of the study will help identify patient specific factors associated with an increased risk of developing hyperkalemia. This information will be useful in the development of appropriate use guidelines for spironolactone for the treatment of resistant hypertension at UCH. The investigators believe the guidelines could be generalized to other academic institutions.

Risk/Benefit Analysis:

Instructions for Completing this page

6) Describe why the risk to subjects are reasonable in relation to the anticipated benefits to participants and/or society, and in relation to the importance of the knowledge that may reasonably be expected to result, thereby falling in favor of performing the study:

*a. To Participant:

The risks to those patients whose medical information are reviewed will be minimal. Due to this study being a retrospective review, no patients will be recruited and no interventions will be performed outside of the clinical care provided at UCH during January 1, 2011 through June 30, 2012. The only potential risk to patients is compromising their HIPAA rights if the data should become compromised (of which the risk is minimal). There are no monetary or direct clinical benefits to the participants involved in this study.

*b. To Society:

The purpose of this study is to evaluate the incidence of hyperkalemia **(defined as serum potassium ≥ 5.5 mmol/L) associated with** spironolactone for the treatment of resistant hypertension. Successful completion of this study will offer insight into the development of appropriate use guidelines for spironolactone in the management of resisant hypertension at UCH, and potentially, other academic institutions.

*c. Justify the importance of the knowledge gained:

The study will add to the literature to help support the importance of monitoring serum potassium and identifying patient specific factors associated with increased risk of hyperkalemia to prevent hyperkalemia-associated adverse events.

K. Recruitment Methods---

*1) Will subjects be recruited for this study? No (secondary data or sample use only)

L. Informed Consent

*1) Will subjects be screened prior to consent (e.g., phone screening)? No

*2) Will subjects provide information about other identifiable persons such as relatives or friends (secondary subjects)? Not Applicable

*3) Are you using any level of Deception? No

*4) Will a signed and dated copy of the consent form be provided to the subject?

☐ Yes ☑ No

*a. If NO, please explain:

We will request the Colorado Multi-Institutional Review Board (COMIRB) waive the requirement to obtain or to include all elements of informed consent.

*5) Will consent be obtained prior to any research procedures being done? ☐ Yes ☑ No

*a. If NO, please explain:

We will request the Colorado Multi-Institutional Review Board (COMIRB) waive the requirement to obtain or to include all elements of informed consent. The study involves minimal risk to the subjects. Additionally, the reserach involves material (laboratory data, electronic medical records) that have already been collected and documented for non-research purposes. The waiver of consent will not adversely affect the rights and welfares of the subjects. The research will be difficult to perform without the waiver of consent.

Based on your answers above, Waiver of Consent, or Waiver of Documentation of Consent, MUST be requested for these activities (see next section).

Waiver of Consent / Waiver of Documentation of Consent

Instructions for Completing this page

*6) Is a Waiver of Consent or a Waiver of Documentation of Consent being requested?

☑ Yes ☐ No

*If YES, describe which group or portion of study:

A waiver of consent is requested for all patients and all portions of this study.

*Complete (M) -- Attachment M: Waiver of Consent Request Complete

Consent Process

All studies must either have a consent process or waive consent completely. Note that studies using deception or a waiver of documentation of consent still have a consent process of some kind. For the next question, answer no only if you are requesting a full waiver of consent. Otherwise, answer yes and provide details of the consent process used in this study in the subsequent questions.

*7) Does this study have a consent process? ☐ Yes ☑ No

M. Privacy and Confidentiality during Study Procedures

Instructions for Completing this page

Privacy - refers to persons and their interest in controlling the access of others to themselves.

*1) Will the PI/research team interact with subjects to collect information?

☐ Yes ☑ No

*2) Could association with the research be considered stigmatizing or damaging to the subjects financial standing, employability, or reputation?
(e.g. STD/HIV clinic, Substance abuse rehabilitation center)

☐ Yes ☑ No

Confidentiality

*3) Is any of the following personal information is collected as research data? ☑ Yes ☐ No

- Name/Initials
- Address
- Telephone/Fax Number
- E-Mail Address
- Social Security #
- Medical Record/Health Plan/Ascension Number

*a. Indicate which information and explain why this information is necessary to conduct the research:

Patient medical record numbers will be recorded and assigned to unique study indentification numbers in order to protect personal information throughout the course of the study. It is necessary to collect this information to identify patients who were prescribed spironolactone for the management of resistant hypertension from January 1, 2011 through June 30, 2012.

*4) Will personal information elements be stored separately from other research data? ☑ Yes ☐ No

*5) Will personal information be available to anyone other than research personnel?

☐ Yes ☑ No

*6) Will any study data about an individual, group, or institution be considered sensitive?

☐ Yes ☑ No

N. HIPAA

*1) Do HIPAA regulations apply to this research?
(i.e. covered entity accessing, using or disclosing PHI) ☑ Yes ☐ No

Access/Disclosure

Instructions for Completing this page

2) How are you accessing PHI under HIPAA regulations (i.e. what authorizations are in place)?

Yes ☐ No ☑ *a. Treatment relationship (i.e. for clinical purposes)
Yes ☐ No ☑ *b. HIPAA authorization
Yes ☑ No ☐ *c. HIPAA Waiver *Complete (O): Attachment O: HIPAA Waiver Complete
Yes ☐ No ☑ *d. Data Use Agreement
Yes ☐ No ☑ *e. Business Associate Agreement
Yes ☐ No ☑ *f. Other

*3) Will PHI be disclosed outside the covered entity? ☐ Yes ☑ No

4) What authorization(s) is (are) in place for the use and disclosure of the PHI collected?

Yes ☐ No ☑ *HIPAA B Authorization
Yes ☑ No ☐ *N/A - HIPAA waiver requested
Yes ☐ No ☑ *Data Use Agreement
Yes ☐ No ☑ *Business Associate Agreement

5) Will a signed and dated copy of the HIPAA B form be provided to the subject?

Yes ☐ No ☑ *a. Yes
Yes ☐ No ☑ *b. N/A - combined consent/HIPAA document used
Yes ☐ No ☑ *c. No - waiver of consent (or waiver of documentation of consent) precludes HIPAA authorization
Yes ☑ No ☐ *d. No - requesting HIPAA waiver

O. Data Management and Security Plan

Electronic Data

*1) Will data be stored in ELECTRONIC format? ☑ Yes ☐ No

*a. Describe the system/application(s) used for the collection, storage, and management of data:
(e.g. Access, electronic CRF, Red Cap)

Collection: EPIC 2010 IU 6 at University of Colorado Hospital
Storage: Microsoft Excel database (Microsoft, Seattle, WA)
Management: Data will be stored on a protected shared drive.

2) Describe where the primary data set will be located:

Yes ☑ No ☐ *a. Secure server:

i. Describe Server:

The primary data set will be stored on the UCH server which has restricted access. Only the primary investigator's computer will be used to store data. The computer is password protected. The IT department of UCH periodically backs up the UCH server.

Yes ☐ No ☑ *b. Local Hard Drive:
Yes ☐ No ☑ *c. Data are transmitted directly to sponsor/funder site:
Yes ☐ No ☑ *d. REDCap data storage

3) How will this data be protected?

Yes ☐ No ☑ *a. Encrypted
Yes ☐ No ☑ *b. Part 11 (FDA) compliant Note: No UCD servers are Part 11 compliant
Yes ☑ No ☐ *c. Restricted Access

*i. If restricted access, who will have access to the data?

Only the primary investigator will have access to the data. The data will be stored on the primary investigator's computer, which is password protected.

*4) Is removal of identifiable data from the department restricted? ☑ Yes ☐ No

*5) Will identifiable data be stored on a mobile device? ☐ Yes ☑ No

*6) Will additional copies of identifiable data be created? ☐ Yes ☑ No

*7) Will data be backed up? ☑ Yes ☐ No

*a. If YES, describe location and security

The primary data will be stored on the University of Colorado Hospital (UCH) server which has restricted access. Only the primary investigator's computer will be used to store data. The computer is password protected. The IT department of UCH periodically backs up the UCH server.

*8) Will media used for backup be stored off-site? ☐ Yes ☑ No

*9) Will the system/application be accessible via the internet? (other than e-CRF transmission to Sponsor) ☐ Yes ☑ No

Audio Recordings, Video Tapes, Digital Videos, and Photographs

Audio Recordings

Instructions for Completing this page

*10) Will data be collected as Audio Recordings or Digital Audio? ☐ Yes ☑ No

Video Recordings

*11) Will data be collected as Video Tape or Digital Video? ☐ Yes ☑ No

Photograghs

*12) Will data be collected as Photographs or Digital Photo? ☐ Yes ☑ No

Paper Data

Instructions for Completing this page

*13) Will data be stored in paper format?

[Remember this includes consent and HIPAA documents] ☐ Yes ☑ No

Data Destruction Plan

*14) Is there a plan to destroy study data? ☑ Yes ☐ No

Yes ☑ No ☐ *a. HIPAA regulations: 7 years after IRB acknowledgement of study closure.

Yes ☐ No ☑ *b. NIH regulations: >3 years from the date the Final Financial Status Report is submitted.

Yes ☐ No ☑ *c. FDA regulations involving drugs: 2 years following the date a marketing application is approved (or per sponsor requirements which may be longer)

Yes ☐ No ☑ *d. FDA regulations involving devices: 2 years following the approval for marketing (or per sponsor requirements which may be longer)

Yes ☐ No ☑ *e. VA regulations: Cannot destroy records following closure of the study

Yes ☐ No ☑ *f. Other Agency Criteria

P. Data and Safety Monitoring Plan

Unanticipated Problems (UAPs), required monitoring and reporting

All studies have potential unanticipated problems (at minimum, breach of confidentiality is a reportable UAP). This includes any "unanticipated event" or any "unexpected adverse event that is at least probably related to the research." All UAPs must be reported in accordance with current COMIRB policy using the electronic forms available on protocol manager.

*1) Describe who will monitor for unanticipated problems of local subjects:

Breach of confidentiality will be monitored by the PI.

*2) Confirm that all unanticipated problems will be reported to COMIRB within 5 days: ☑

Safety Monitoring

Instructions for Completing this page

3) Will the PI be responsible for ongoing review of local adverse events and serious adverse events (physical or psychological harms to subjects)?
N/A (study does not involve physical/psychological harms)

4) To what external entities will local adverse events be reported?

Yes ☐ No ☑ *a. Sponsor
Yes ☐ No ☑ *b. Coordinating Center/Lead Site
Yes ☐ No ☑ *c. FDA
Yes ☐ No ☑ *d. None
Yes ☐ No ☑ *e. Other

*5) Will periodic review of safety and adverse events (SAE's and AE's) across all sites occur?
Yes ☐ No ☑

Additional Protections

*6) Will an Interim Analysis be performed? ☐ Yes ☑ No

*7) Are there any protocol/study stopping rules? ☐ Yes ☑ No

*8) Are there defined participant discontinuation criteria? ☐ Yes ☑ No

Q. Resources for Conducting the Research

COMIRB wants to ensure that the PI has the resources to conduct a safe and compliant study.

Instructions for Completing this page

*1) Are there any factors that limit the feasibility of this study? (e.g. limited populations, competing resources, other studies, etc.)

☐ Yes ☑ No

*2) Describe the facilities available for the research:

Electronic data will be gathered from the University of Colorado Hospital. Data analysis will be performed at the PI's office, located in the Leprino Building of the University of Colorado Hospital.

*3) Describe resources available to conduct the research (e.g. support staff, time, funding, etc.):

The PI has adequate time during her residency to complete this project.

4) What resources are available at performance sites to treat emergencies resulting from study-related procedures? (Check All that Apply)

Yes ☑ No ☐ *a. Not Applicable

Yes ☐ No ☑ *b. Basic Life Support (BLS) trained personnel

Yes ☐ No ☑ *c. Advanced Cardiac Life Support (ACLS) trained personnel and crash cart

Yes ☐ No ☑ *d. Emergency drugs/supplies to stabilize subject until emergency personnel arrive

Yes ☐ No ☑ *e. Emergency response team within facility

Yes ☐ No ☑ *f. Call 911

Yes ☐ No ☑ *g. Other:

*5) Describe process to ensure that all persons assisting with the research are adequately informed about the protocol and their related duties and functions:

The PI and co-investigators have reviewed the study protocol prior to submission for COMIRB approval. Once approved, all investigators will review the protocol and additional changes to study protocol as needed prior to data collection. The PI is responsible for data collection. All investigators will review the data analysis and contribute to reporting the outcomes of the study.

*6) Will other medical or psychological resources be required as a consequence of the research? (include referral plans for newly identified diagnoses, suicidal ideation, or problem behaviors [e.g., EtOH abuse])

☐ Yes ☑ No

R. Conflict of Interest

The following is based on the UCD Definition of Conflict of Interest:

*1) Have all investigators and coordinators listed on this application completed and submitted a UCD COI disclosure form to the UCD COI office?
This applies to affiliate investigators even if they have submitted a COI declaration in accordance with their institutional policy.
[The requisite form for UCD can be found at:
http://www.ucdenver.edu/academics/research/AboutUs/regcomp/Pages/Regulatory-Compliance.aspx] ☑ Yes ☐ No

*2) Are there any Conflicts of Interest issues to be disclosed for the investigators? ☐ Yes ☑ No

UCD Definition of Conflict of Interest
Conflict of Interest Management

Attachment F: Request Expedited Review

Protocol

Protocol

Protocol #: 12-1149

Chomicki, Jacqueline Rose

PI: Full Name Chomicki, Jacqueline Rose

Project Title:

Evaluation of the incidence of hyperkalemia in patients prescribed spironolactone for the treatment of resistant hypertension

*Version Date: 05-Sep-2012

Minimal Risk:

Definition of Minimal Risk

To Qualify for expedited review, the research Must Be No More Than Minimal Risk.

Does the study involve any of the following:

*1. Research Involving Prisoners as subjects..... ☐ Yes ☑ No

*2. Research that includes genetic testing with direct or indirect identifiers..... ☐ Yes ☑ No

*3. Research involving major deception (see Attachment N: Deception)..... ☐ Yes ☑ No

Major Deception: Mislead subjects about their health status, the researchers, or the research purpose.

Minor Deception: Incomplete disclosure of some purpose of the study to avoid biasing the results.

*4. Research involving consent via proxy..... ☐ Yes ☑ No

*5. Research involving emergency waiver of consent..... ☐ Yes ☑ No

*6. Classified research involving research subjects..... ☐ Yes ☑ No

*7. Requests for non-significant risk determination for devices..... ☐ Yes ☑ No

*8, Prospectively validating greater than minimal risk medical care..... ☐ Yes ☑ No

*9. Do any of the investigators have any Conflict of Interests to be disclosed? ☐ Yes ☑ No

*10. Identification of subjects or their reponses will reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing..... ☐ Yes ☑ No

Expedited Research Categories

Instructions:

If the research does not fit any of the categories below, it must be reviewed at full board review even if it is minimal risk.

Ckeck all of the following categories that apply to this research. More than one category may be checked.

Category 1

☐ Clinical studies of drugs and medical devices only when conditions (a) OR (b) is met:

a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risk associated with the use of the product is not eligible for expedited review.)
b. Research of medical devices for which
   i. an investigational device exemption application (21 CFR Part 812) is not required; OR
   ii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

Category 2

☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipucture as follows:

a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; OR
b. from other adults and children considering the age, weight and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount may not exceed the LESSER of 50 ml or 3ml per kilogram in an 8 week period and collection may not occur more frequently than 2 times per week.

Category 3

☐ Prospective collection of biological specimens for research purposes by noninvasive means.

Examples:

a. hair and nail clippings in a nondisfiguring manner.
b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction.
c. permanent teeth if routine patient care indicates a need for extraction.
d. excreta and external secretions (including sweat).
e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or applying a dilute citric solution to the tongue.
f. placenta removed at delivery.
g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor.
h. supra- and subgingival dental plaque and calculus provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings.
j. sputum collected after saline mist nebulization.

Category 4

☐ Collection of data through noninvasive procedures (not involving general anestesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects' privacy
b. weighing or testing sensory acuity.
c. magnetic resonance imaging.
d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography
e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Category 5

☑ Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected, solely for non-research purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from HHS Regulations for the protections of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

Category 6

☐ Collection of data from voice, video, digital, or image recordings made for research purposes.

Category 7

☐ Research on individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Attachment M: Waiver of Consent Request

Protocol

COMIRB #: 12-1149

Principal Investigator:

Protocol Title:

Evaluation of the incidence of hyperkalemia in patients prescribed spironolactone for the treatment of resistant hypertension

*Version Date: 05-Sep-2012

Except as provided below, written documentation of informed consent that embodies all the required elements of informed consent, as described in 45 CFR 46.116 is required for all research subjects.

A Full Waiver is not an option if the study is subject to FDA Regulations unless the study meets the exemption criteria as defined by the FDA.

With sufficient justification, the IRB may approve a consent process that does not include or alters some or all of the elements of informed consent, provided that it finds and documents specific requirements. If requesting a waver of consent, justify such in accordance with the following four criteria established under 45 CFR 46.116(d) (1-4) or 45 CFR 46.117(c) (1 or 2).

The research must involve no more than minimal risk to the subjects.

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.

If Subject to HIPAA regulations and requesting a full or partial waiver, you will need to complete Attachment O - Waiver or HIPAA Authorization

Type of Waiver being Requested

Select the type of waiver being requested (more than 1 may be chosen):

Yes ☑ No ☐ *Full Waiver

Yes ☐ No ☑ *Partial Waiver (screening/recruitment purposes or for deception)

Yes ☐ No ☑ *Waiver of Written Documentation (i.e., verbal consent)

A. Full or Partial Waiver:

If requesting a waiver or alteration from the requirements for obtaining informed consent, justify such in accordance with all of the criteria established under 45 CFR 46.116(d) (1-4). This is not an option if the study is subject to FDA regulation.

1. Explain why the proposed waiver poses minimal risk to the subjects:

Because this study involves a retrospective chart review it meets the criteria for minimal risk and will not adversely affect the rights of the subjects. There will be no intervention performed on patients or on their behalf and no patient-specific identifiers will be present in any publication or presentation of the data.

2. Explain why the waiver or alteration will not adversely affect the rights and welfare of the subjects:

The waiver will not adversely affect the rights and welfare of the subjects as this will be a retrospective chart review. No interventions will be performed on patients or on their behalf. The analysis of data does not change patient care. No patient-specific identifiers will be present in any publication or presentation of the data.

3. Explain why the research could not practicably be carried out without the waiver or alteration *(note: a survey can still provide subjects with elements of consent in writing; see postcard consent template on the COMIRB website)*:

This research is a retrospective chart review. In many cases, the patient may no longer be contactable (i.e. no current address, no current phone number), making it extremely difficult and even impossible to get their consent for participation in this chart review.

4. Once subjects have completed the study, will an information sheet be given to, or other debriefing be done with, the subject?

Explain:

No. There will be no active subject participation in this study as it is a retrospective review. It is an observational study that will make no interventions or alterations to a patient's treatment course. Therefore it will be unnecessary to provide subjects with additional information.

Attachment O: HIPAA Waiver

Protocol

COMIRB #: 12-1149

Pricipal Investigator: Chomicki, Jacqueline Rose

Protocol Title:

Evaluation of the incidence of hyperkalemia in patients prescribed spironolactone for the treatment of resistant hypertension

*Version Date: 05-Sep-2012

*This request is for: Full Waiver

1) Check the protected health information (PHI) that will be collected or accessed* for this project:

*If the research includes looking at medical records or some other form of PHI, this is considered to be accessing PHI, regardless of whether this information is being recorded.

- ☐ Names/Initials
- ☐ Telephone numbers
- ☐ Fax numbers
- ☐ Electronic mail addresses
- ☐ All dates (except year) that are directly related to an individual (Date of birth, discharge date)*
- ☐ Social security numbers
- ☑ Medical record numbers
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ URLs (http://...)
- ☐ Vehicle identifiers and serial numbers
- ☐ Certificate/license numbers
- ☐ Device identifiers and serial numbers
- ☐ Biometric identifiers (including finger and voice prints)
- ☐ Full face photographic images and any comparable images
- ☐ IP address numbers
- ☐ Geographic subdivisions smaller than a state
- ☐ Any other unique identifying number, characteristic or code

*For all subjects over 89 years, all elements of dates including year that are indicative of their age cannot be used

*2) Describe what health information will be recorded under this waiver:

Medical record numbers (MRNs) will be recorded to identify patients prescribed spironolactone for the management of resistant hypertension. MRNs will be destroyed after the chart is reviewed.

3) Criteria to justify HIPAA waiver:

*a. Is it possible or likely that the PHI collected under this waiver will contain information that puts the subject at risk for civil or criminal liability, or that could be damaging to a subjects financial standing, employability, or reputation?

☐ Yes ☑ No

*b. Is there a plan to destroy the identifiers as soon as possible? ☑ Yes ☐ No

*i. If YES, describe:

A list of MRNs will be generated for patients included in this study. Once the MRNs have been used to identify patient charts and data has been gathered in the protocol application, the list of MRNs will be destroyed per hospital policy by placing the list in a shred bin.

*c. Will the PHI be disclosed to parties outside of the research institution? ☐ Yes ☑ No

*4. Is there more than minimal risk to privacy? ☐ Yes ☑ No

*5. Will a signed informed consent document be obtained? ☐ Yes ☑ No

*6. Could this research be done without the HIPAA waiver? ☐ Yes ☑ No

Please explain:

Care has already been provided to the patients. Also, some of these patients could be lost to follow-up.

Appendix 1

EForm Name:	Application for Protocol Review (FB/Exped)
Page:	Page 3
Section:	Section F(c): COMIRB Requested Attachments
Question:	Billing Information Form
File Name:	COMIRB-Billing-Form.docx

IRB Review Fee Billing Form

Protocol Number: 12-1149

NOTE: Payment of the IRB Review Fee is due at time of Protocol Submission. You must complete the information below and submit one (1) IRB Review Fee Billing Form with each initial Expedited and Full Board protocol submission.

An IRB Review fee is charged for initial and annual continuing full board review and initial expedited review of non-federally sponsored research and for research awards administered by affiliated institutions. FOR THE FULL FEE POLICY AND FEE WAIVER APPLICATION, PLEASE SEE THE COMIRB WEBSITE AT http://www.ucdenver.edu/academics/research/AboutUs/comirb/Pages/COMIRBFees.aspx

1. Type of IRB Review I am Requesting (check only one):

   _____Full Board Initial Review __X___Expedited Initial Review

   _____Full Board Continuing Review _____Expedited continuing Review, no fee.

2. Method of payment selected is based upon the Grantee Institution. YOU MUST DESIGNATE AND COMPLETE ONE OF THE FOLLOWING OPTIONS (check only one):
   - _____UCD, AMC/UCH: Provide Speed Type_____
   - _____CHC
   - _____DHHA
   - _____DVAMC
   - _____CPC and Others: Submit check payable to COMIRB with submission packet

OR, PAYMENT IS NOT INCLUDED BECAUSE:

- _____ This is a federally funded study granted to University of Colorado Denver, Anschutz Medical Center - (No Fee & No Fee Waiver Required)
- _____ Downtown Denver Campus (DDC) is the performance site – (No Fee & No Fee Waiver Required)
- __X__ I am requesting waiver of the IRB review fee and have attached a completed COMIRB Fee Waiver/Reduction Application containing two (2) signatures for consideration for the following reason(s):
  - __X__This is a Student Project Without Funding
  - _____This is an investigator-initiated Study Without Funding
  - _____This is a Pilot Study Without Funding
  - _____This is a Foundation-funded study with limited funding of only $_____
  - Other_____

Note: If Billing Information is Incomplete, the Protocol Review Cannot Be Processed!

Appendix 2

EForm Name: Application for Protocol Review (FB/Exped)
Page: Page 3
Section: Section F(d): UCH Requested Attachments
Question: Preliminary Budget or Budget Template
File Name: Preliminary-Budget-Form.doc

Preliminary Budget

Protocol Number: 12-1149

This is a retrospective chart review.

The budget for this study is **$0.00**