Date: 9/11/2014 1:55:44 PM

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View: 01. Project Information

1. Project Identification

1.0 * **Does this project involve any minor subjects, or use of records or biospecimens related to minors?** Minor status is defined by the legal age of consent for the state or country where the research activity takes place; e.g., under 18 years of age in Wisconsin.

(select one)

- ○ All minors
- ◉ **Some adults and some minors**
- ○ All adults of legal age

☑ **If you selected "All minors" or "Some adults and some minors" above, you must consult with the MCW/FH IRB Office (414-955-8422). Check the box to confirm that you have done so and have been advised to submit this project to the MCW/FH IRB.**

1.1 * **Short Title:**

Ketamine and Excited Delirium

1.2 * **Full Title of Project:**

EMS Use of Ketamine in Excited Delirium: A Case Series

1.3 * **Principal Investigator (PI):** Charles Cady

1.3.1 * **Does the Principal Investigator, their immediate family members (spouse and dependent children) or their significant other have a "Significant Financial Interest" with the sponsors of this research or that might affect the result of this research?**

○ Yes ◉ **No**

If Yes:

☐ **1.3.1.1 Has this interest already been fully reported to MCW Grants and Contracts Office or MCW Corporate Compliance?**

If not, immediately update this financial interest information using the MCW Corporate Compliance form for this purpose.

1.4 * **Provide phone/pager number in case of an emergency and/or if the IRB Committee has questions during the Committee meeting:**
414-828-7244

1.5 * **Will there be other project team members in addition to the Principal Investigator (PI)?**

◉ **Yes** ○ No

Responses Provided Prior to December 14, 2008

Previous 1.3 Complete title as shown on grants and contracts: Only answer if you have a grant or funded study requiring a submission to the Grants & Contracts Office.

Grant Number:

Previous
1.4

View: 02. Project Team

2. Project Team

2.1 Project Team Members Other Than PI:

	Last Name	First Name	Department	Is Primary Contact	Can Edit	Receives Emails	Role on Project	Consenting Subjects	SFI
View	Curtis	Michael	Non-MCW	☐	☑	☐	Key Personnel	☐	☐

View: 03. Project Type

3. Project Category

3.1 * Which category best describes the type of project you are submitting for review?

(select one)

- ◉ **a) Research study - including clinical trials, retrospective record reviews, specimen reviews, surveys, etc.**
- ○ b) Research study plus distant bank. No banking at a local study site
- ○ c) Research study plus creating a new local bank; at least one at a local study site *Note: see 3.1.1 below
- ○ d) Creating a new Local Bank - no research study being proposed in this submission
- ○ e) Treatment Use: Use of investigational drugs, medical devices, biologics or Humanitarian Use Devices (HUDs) solely for clinical purposes with no elements of research or research data collection
- ○ f) Emergency Use: use of an investigational drug, medical device, biologic or Humanitarian Use Device (HUD) – after-the-fact report to the IRB
- ○ g) Deferral to NCI CIRB - for Cancer Cooperative Group (RTOG, ECOG, SWOG, etc.) studies in which the NCI CIRB will be the IRB of record

3.1.2 * Is this research study designed to evaluate the safety or effectiveness of some form of research TREATMENT/intervention?

(select one)

- ○ YES
- ◉ **NO**

3.1.3 Does the research involve:

(select all that apply)

- ☐ Drug: FDA-approved, investigational, or other
- ☐ Device: FDA-approved, 510(k), investigational, HUD, or other
- ☐ Biologic: FDA-approved, investigational, or other
- ☐ Botanical, medical food, or dietary supplement
- ☐ None of the above

View: 03. Project Type - Part II

3. Elements and Review Category

3.3 * Does this project involve any of the following elements?

(select all that apply)

(select all that apply)

- ☐ 100% of subjects are known to be deceased, e.g., work with cadavers or biospecimens of deceased persons; record reviews where all subjects are demonstrably deceased
- ☐ In-vitro or laboratory diagnostic tests in the absence of FDA approval and/or CLIA certification: chemistry, drug monitoring, immunological/hematologic, tumor marker, genetic disorder, infectious disease, microorganism, bio-threat tests
- ☑ **More than one site. Study activity will take place at other institutions or locations that are not under the supervision of the PI listed on this IRB application.**
- ☐ Subjects are recruited by home location or neighborhood; key project procedures take place in the subjects' homes or neighborhoods e.g., churches, bars, public places
- ☐ Any part of the project takes place in another country. Check here if the PI is the lead PI for a multi-site study where one or more sites are in another country or if any project related work or oversight work is being done in another country.
- ☐ Application to waive informed consent requirements for certain types of planned emergency medicine research [(21 CFR 50.24 or 45 CFR 46 Waiver of Informed Consent Requirements in Certain Emergency Research) or (FR doc. 96.24968)]
- ☐ Research using the internet as a source of information or a survey tool
- ☐ None of the above

3.4 * **What type of review is being requested?**

(select one)

- ○ Full Committee
- ◉ **Expedited**
- ○ Exempt

If Expedited or Exempt Review:

3.4.1 If all the proposed activities fall within one or more of the categories described below, it is possible that your proposal will meet criteria for "exemption" or "expedited review" by the IRB.

(select all that apply)

- ☐ Surveys, questionnaires, interviews, focus groups, or observation of behavior
- ☐ Evaluations or comparisons of effectiveness among instructional techniques or curricula within an accredited educational setting
- ☑ **Analysis of records (e.g., medical records, other databases) not created for the purpose of this study**
- ☐ Use or analysis of biospecimens not created for the purpose of this study
- ☐ Minimal risk, minimally-invasive or non-invasive procedures routinely employed in clinical practice, e.g., blood draws, urine samples, buccal swabs, EKGs, ultrasound procedures
- ☐ Analysis of existing data if the sources are publicly available.
- ☐ None of the above-listed categories apply

3.5 * **Use of Identifiers - indicate the level of "subject identification" you require to BEGIN this work.**

- If any element of your records, data files, or administrative records contains an identifier, you should select Identified Data.
- If you plan to de-identifiy data at any time other than the first day you access the information, you should select Identified Data.
- If different levels apply, choose the "most identified" one, e.g., if level A and level B apply, choose level A.

(select one)

- ◉ **A - IDENTIFIED DATA: Utilizes one or more identifiers, including those defined by HIPAA Privacy Rule but not using a "limited data set." See help text for complete listing.**
- ○

(select one)

B - CODED DATA, KEY held by study team: Data is coded; **and** key code held by any person at MCW, Froedtert Hospital, Children's Hospital of Wisconsin, or BCW whether or not they are part of the project team.

○ **C - CODED DATA, KEY not held by study team**: Data is coded; key code not held by any MCW/Froedtert faculty member, employee, fellow, resident, or student; key code not held by any member of the project team; **and** the key code will never be accessible to any member of the project team.

○ **D - LIMITED DATA SET**: The only HIPAA identifiers utilized are dates or certain allowable geographic subdivisions; an IRB "limited data set" data use agreement has been executed by the PI; and is uploaded into this IRB application.

○ **E - DE-IDENTIFICATION PROCESS**: The IRB application describes how the project team will de-identify data in one of two approvable methods: 1) reliance on an MCW/FH IRB-sanctioned "honest broker" or 2) receiving coded data/specimens without identifiers and without a key code. For details see *"Two ways to de-identify data or biospecimens for IRB purposes."* To use these options, no code keys may be created or saved and the resulting dataset can never be re-identified. In addition, a complete list of project variables must be uploaded in Section 52.

○ **F - ANONYMIZED**: The investigator receives data in anonymized form and no other party has the potential to re-identify data (i.e. no code key exists anywhere in the world). In this case, the IRB application must include a detailed description of how the data was collected, e.g., anonymous surveys, or who provided the anonymized data or biospecimens, so the IRB can verify the source and the irreversibility of anonymization. In addition, a complete list of variables, e.g., data recording sheet, Case Report Form, anything that summarizes all the information that will be recorded, must be included in Section52 Attached Documents.

View: 03F. Records Research - Part I

3F. Records Research - Part I

You received this section because in Section 3 Elements and Review Category, Question 3.4.1, you checked "Analysis of records…"

3F.1 * **For what purpose were the records originally created?**

(select all that apply)

- ☑ **Clinical care**
- ☐ Quality assurance
- ☐ School or teaching records
- ☐ Billing or insurance
- ☐ Program administration
- ☐ Hospital or community surveillance
- ☐ Different research project
- ☐ Other

3F.1.1 Specify other:

3F.2 * **Are some or all of the records publicly available?**

○ Yes ◉ **No**

If Yes,
Instruction: Upload published description of the public-access database and its access criteria for IRB documentation to Section 52.

View: 03F. Records Research - Part II

3F. Records Research - Part II

3F.3

*** Do you plan to use/analyze records created before the date of IRB submission (retrospective records)?** (i.e., NO additional cases created after that date, and NO opportunity to include follow-up information created after that date)

◉ **Yes** ○ No

If Yes,
3F.3.1 What is the date for the earliest records you will access?

3F.4 *** Do you plan to access records created after the date of IRB submission (prospective records)?**

○ Yes ◉ **No**

If Yes,
3F.4.1 How will these records be obtained?

- ☐ Using informed consent
- ☐ From an IRB approved bank
- ☐ Other

3F.4.1.1 Specify other:

3F.5 ***Estimate the total number of SUBJECTS in this record-review project that you intend to:**

Screen, whether you use the record for this study or not.

100

Use for this study.

100

3F.6 *** Explain how you determined the number of records to include in the project at this site.**

Through professional discussions, this is the estimate of the number of subjects in Wisconsin that have been treated with ketamine for excited delirium. This is only an estimate as a formal request for subject data has not occurred yet. We want to capture as many instances of the use of ketamine as possible to simply describe the current experience.

Responses Provided Prior to April 12, 2014

3F.3.1 What is the date for the earliest records you will access?

1/1/2000

View: 04. Additional Features

4. Additional Features

4.1 *** Does the proposed project involve any of the following features?**

(select all that apply)

- ☐ Deception studies
- ☐ Direct contact with subjects
- ☐ Genetic Research/ Gene Therapy
- ☑ **None of the above**

4.2 If drug or biologic clinical trial, what is the phase of this clinical trial? For combined phase studies - e.g., Phase II/III - select only the smaller number

-
☐ Phase I
☐ Phase II
☐ Phase III
☐ Phase IV
☐ N/A

View: 06. Project Locations

6. Project Locations

6.1 ***Under the direction/supervision of this Principal Investigator, project activities will take place at the following locations:**

☑ Froedtert & the Medical College of Wisconsin Hospitals and Health Partners

Froedtert Hospital Campus (including all specialty clinics, the Cancer Center and the Eye Institute)

☐ Medical College of Wisconsin
☐ Center for AIDS Intervention Research (CAIR)
☐ Adult Translational Research Unit (TRU - formerly GCRC)
☐ BloodCenter of Wisconsin and Blood Research Institute
☐ Children's Hospital of Wisconsin†
☐ Clement J. Zablocki Veteran's Affairs Medical Center†
☐ UW-Milwaukee†
☐ Marquette University†
☐ Milwaukee School of Engineering†
☑ **Other**

6.1.1 For all locations other than MCW, Froedtert Hospital, or BloodCenter of Wisconsin list the lead collaborator at each institution, their role at each institution, and the name of the institution.

Michael D. Curtis, MD
Emergency Physician
Ministry Saint Michael's Hospital
900 Illinois Avenue
Stevens Point, WI 54481
715-498-2240

6.2 * **Will any subject recruitment activities or research procedures under the responsibility of this Principal Investigator take place outside of Wisconsin but within the US?**

○ Yes ◉ **No**

If Yes,
6.2.1 Identify those states (within the US) where project activities will take place; and describe the activities that will take place in those jurisdictions.

Responses Provided Prior to November 19, 2011

Previous 6.1.1 **Specify any other location(s) not appearing in the lists at 6.1 (above) or 6.2 (below) and note whether or not each location has its own IRB. Upload IRB approvals for**

other locations supervised by the MCW PI, with this application in Section 52 or as soon as they become available.

View: 07. Multi-Center

7. Multi-Center Study/Project

7.1 * Is the project being implemented as identical protocols at multiple sites (US or international) under the direction of multiple Principal Investigators (not counting coordinating sites, data coordinating sites, or statistical coordination centers)?

- (●) **Yes**
- ( ) No
- ( ) N/A

7.2 * Are different activities being performed from one site to the next under the direction/supervision of different Principal Investigators?

- ( ) Yes
- (●) **No**
- ( ) N/A

7.3 * Approximately how many total sites are participating in this study?

2

7.4 * Is this Principal Investigator managing the Coordinating Center of this multi-site study?

( ) Yes (●) **No**

If Yes,
7.4.1 Describe the Coordinating Center leadership structure:

n/a

7.4.2 Describe the Coordinating Center's responsibilities:

n/a

7.4.3 If the project is supported by any federal grants, contracts or subcontracts, list here the FWA # for each institutional site:

n/a

Instruction: When this Principal Investigator is managing the Coordinating Center, upload the following documents in Section 52:

a. Local IRB approval with approved consent form or documentation of consent waiver for each performance site
b. Protocol or procedure manuals to be used by any of the performance sites
c. Central data collection and management plan
d. Comprehensive multi-site safety monitoring plan
e. If federally funded, all grants, contracts and subcontracts to non-MCW/FH performance sites related to this project

7.5 If this Principal Investigator is not managing the central/coordinating site, provide the name and address of the central/coordinating site:

Michael D. Curtis, MD
Emergency Physician
Ministry Saint Michael's Hospital
900 Illinois Avenue
Stevens Point, WI 54481
715-498-2240

View: 08. Cooperative Groups

8. Cancer Cooperative Groups

8.1 * **Is this project part of a cancer cooperative group?** (University of Chicago and Northwestern Consortium projects are not considered "Cancer Cooperative Group" projects)

○ Yes ◉ **No**

If Yes:
8.1.1 Which group?

(select all that apply)
☐ ACOSOG
☐ ACRIN
☐ CALGB
☐ ECOG
☐ GOG
☐ NCCTG
☐ NSABP
☐ RTOG
☐ SWOG
☐ Other (SPECIFY)

If Other:
8.1.2 Specify below:

Note: If your project is sponsored by a cooperative group listed above, the Medical College of Wisconsin and Froedtert Hospital IRBs will accept the **cooperative group consent template with the modifications permitted by the IRB policy on Cancer Cooperative Group consent templates.**

- IRB checklist for modifications to the NCI Cooperative Group Informed Consent on Cooperative Group consent templates

Upload completed cooperative group consents in Section 52.

View: 11. Funding Source

11. Funding Source

11.1 * **Do you have funding to support any of the activities for this project:**

○ Yes ◉ **No**

If Yes,
11.1.1 List all current MCW department funding for this study:

Title	Cost Center	Fund	Project Number
There are no items to display			

11.1.2 List all current and pending funding sources for this study (excluding department funds listed in 11.1.1):

Validated	Type	Short Title	Funding Source	Prime Grantor	Grant Award Number	FP ID	FP Current State	Budget ID	FP Parent State
There are no items to display									

11.1.3 Do you have funding that is not managed through MCW:

○ Yes ○ No

If Yes:
11.1.3.1 Provide the name of the funding source(s):

Responses Provided Prior to December 14, 2008

Previous 11.1 **What is the source of financial support for this study? Check all that apply and enter the name.**

a. Industry / Sponsor funded	**a.** Name:
b. Federally Funded**	**b.** Name:
c. Foundation	**c.** Name:
d. Department Funded	**d.** Name:
e. Other (Specify)	**e.** Name:
f. No Funding	

Previous 11.2 **If applicable, enter the Sponsor's tracking number:**

Previous 11.3 **Previous Pending Funding Sources**

Type	Short Title	Funding Source	Prime Grantor	FP ID	FP Status	Budget ID	FP Parent State

There are no items to display

View: 12. Project Subject Types

12. Project Subject Types

12.1 * **What type of subjects will be included?**
(check all that apply)

☐ **a.** Healthy subjects, i.e. subjects NOT selected because they have a particular medical condition or history

☐ **b.** Inpatients

☐ **c.** Outpatients

☑ **e.** Other

12.2 * **Will subjects in any of the following groups be a focus of the project?** Do not check a box only because it is possible you might enroll one or a few subjects.

check all that apply	
☑	**Persons with alcohol or drug use disorders**
☐	Traumatized, sedated, or comatose patients
☑	**Issues of cognitive or decisional impairment**
☐	Persons with developmental disabilities - neurologic or psychiatric
☑	**Persons with mental illness**
☐	Elderly - age 70 and over
☐	Employees including faculty, staff, residents or fellows
☐	Fetuses or fetal tissue
☐	Neonates
☐	Pregnant women

check all that apply

- ☐ Limited or non-reader
- ☐ Non-English speaking
- ☐ Nursing home residents
- ☐ Poor and/or uninsured
- ☐ Prisoners - see help text
- ☐ MCW students
- ☐ Terminally ill patients
- ☐ Visually / hearing impaired
- ☐ Other (SPECIFY)
- ☐ None of the above

If Other,12.2.1 Specify:

12.3 * **Are the exclusion criteria for this project likely to exclude groups or categories of subjects based on race, socioeconomic status, or insurance coverage?**

○ Yes ◉ **No**

If Yes,
12.3.1 Please specify and provide the rationale for excluding these subjects. Selection of subjects must be fair and equitable. Explain how the subject selection process in this research is fair and equitable, taking into account eligibility criteria, vulnerability and recruitment process.

Instruction: Please upload any project materials in other languages in section 52.

Responses Provided Prior to November 20, 2010

Previous 12.3

Number of Normal Healthy Volunteers:

Number of Inpatients:

Number of Outpatients:

Number of Vulnerable Populations:

Number of Other:

View: 12A. Minors – Part I

12A. Minors – Part I

You received this section because in Section 1 Project Information, Question 1.1, you checked "all minors" or "some adults and some minors …"

12A.1 * **What is the age range of the children in this research?**

12-17

12A.2 * **Where will the children participate?**

- ☐ Home
- ☐ School (K-12th grade)
- ☐ Hospital/clinic/doctor's office
- ☐ Non-medical College or University setting
- ☑ **Other**

If Other,
12A.2.1 Specify:

Retrospective chart review. Children as patients of emergency medical services.

If School,
12A.2.2 Have you obtained the necessary permission from the school district?
○ Yes ○ No

If Yes,
Instruction: Attach documentation of permission to Section 52.

12A.3 * **Are any of the children wards of the state or any other agency, institution, or entity?**
○ Yes ◉ **No**

If Yes,
12A.3.1 Provide details:

Allowable Categories

12A.4 * **Check the category below that best represents the degree of risk and benefit to which the children in this study will be exposed and explain your choice in 12A.4.1. Note: more than one category may be indicated.**

- ☑ **Category 1: The proposed research poses risks no greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (i.e., minimal risk).**
- ☐ Category 2: The proposed research poses a greater than minimal risk with the potential for direct benefit to subjects, i.e., the benefit to the subject is at least as favorable as alternative approaches.
- ☐ Category 3: The proposed research poses a greater than minimal risk with no potential for direct benefit to individuals, but likely to yield vital generalizable knowledge about the subjects' conditions.
- ☐ Category 4: The proposed research does not meet the criteria in the above categories but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.

* **12A.4.1 Explain your choice of category:**

This is a retrospective chart review with no subject contact or intervention. It poses no more than minimal risk which will be managed with secure data storage.

View: 12A. Minors – Part II

12A. Minors – Part II

Parental Permission

12A.5 * **What permission will be obtained from the parents?**

- ○ Permission will be obtained from both parents where possible
- ○ Permission from only one parent is being requested
- ◉ **A waiver of parental permission is being requested (see SmartForm Section 38)**

12A.6 * **If the research is being conducted in a group setting (e.g. day camp, day care, classrooms, boy/girl scouts), explain what provisions have been made for children whose parents have not given permission for them to participate. If you are not conducting research in a group setting, please enter N/A.**

n/a

Instruction: Upload the parental consent form in Section 52.

Assent from Children

12A.7 * **Please indicate whether the children you will study are generally capable of providing assent; evaluate age, maturity and psychological state of the children involved. Please be specific:**

- ○ All are capable
- ◉ **None are capable**
- ○ Some are capable

12A.7.1 Explain if none or some are capable:

No contact will be made with subjects.

12A.8 * **Describe the assent process, including what information will be provided to the subjects:**

n/a

12A.9 * **Describe how assent will be documented:**

n/a

Instruction: Attach copies of all assent forms, if any, in Section 52.

View: 14. Biospecimen Collection

14. Biospecimen Collection

14.1 * **In this project, will the study team (or their agents – lab technicians or cooperative surgeons) collect biospecimens from human subjects for RESEARCH purposes?**

○ Yes ◉ **No**

If Yes,
14.1.1 Provide the following information regarding the biospecimens collected for research:

Type of Biospecimen	Volume/Size per sample	Estimated total # samples per subject	Estimated total # samples for this project
There are no items to display			

View: 15. Inclusion/Exclusion Criteria

15. Inclusion/Exclusion Criteria

15.1 * **List inclusion criteria (e.g., age, gender, ethnicity):**
Patients treated by emergency medical services in Wisconsin.

Behavioral emergency.

Use of ketamine.

Any age considered, but most will be adults, youngest likely adolescents. (age 12 and up)

Any gender, any ethnicity.

15.2 * **List exclusion criteria (e.g., age, gender, ethnicity):**

Not cared for by paramedics.

Ketamine given for any reason other than behavior control.

View: 17. Recruitment Strategies

17. Recruitment Strategies

17.1 * **To recruit potential subjects, will you use any of the following:**

☐ **Print advertisements (e.g. newspapers, magazines, flyers, posters, brochures)**

Specify where the print advertisements will be posted:

☐ **Letters/emails**

Identify who will sign the letters/send the emails and indicate the relationship between the sender and recipient(s):

☐ **Radio or television advertisements**

Specify the radio or television station(s):

☐ **Web solicitations**

Specify the website address(es):

☐ **Telephone**

Identify who will telephone the subjects and indicate the relationship between the caller and the recipient(s):

☐ **Recruiting company**

Specify the organization and the services they will be providing:

☐ **Physician referrals (includes in-house and/or outside referrals)**

Describe the process:

☐ **Approach subjects in-person** (Example: a public place or knocking door-to-door)

Briefly describe the process and specify if any MCW or Froedtert patients will be approached in-person:

☐ **Other strategies (not already covered) to identify, screen, or recruit subjects**

Specify those strategies in detail:

☑ **No recruitment activities**

Instruction: Upload all recruitment materials in Section 52.

View: 18. Subject Compensation Reimbursement

18. Subject Compensation/Reimbursement

18.1 * **Will you offer subjects stipends, gifts or compensation for their participation, or reimbursement for project-related expenses, e.g., transportation, baby-sitting, parking?**

○ Yes

◉ **No**

If Yes,
18.1.1 Describe what will be offered and why this was determined to be appropriate:

n/a

View: 26. Connecting with a Bank

26. Connecting with a Bank

26.1 * **Will this project contribute data to a local bank or access data from a local bank? (Data includes records and biospecimens)**

○ Yes ◉ **No**

26.1.1 Cite the PRO for the local bank to which this project will contribute data (records or biospecimens):

Bank ID	Bank Title	Principal Investigator	Bank State	Contributing Records	Contributing Biospecimens

There are no items to display

26.1.2 Cite the PRO for the local bank from which you will access data (records or biospecimens) for this project:

Bank ID	Bank Title	Principal Investigator	Bank State	Accessing Records	Accessing Biospecimens

There are no items to display

View: 27. Safety and Research Review Committees

27. Safety and Research Review Committees

27.1 * **What other MCW safety or research review committee should review this project, per MCW Office of Research policies?** The IRB review process will begin as soon as all these other reviews have been completed.

(select all that apply)

- ☐ Project proposing to use Adult Translational Research Unit (TRU) facility or resources
- ☐ Safety Committees (Institutional BioSafety Committee, HazChem Committee, MRI Committee) or Office of Radiation Safety
- ☐ Human Stem Cell Committee
- ☑ **None of the above**

If Safety Committee:
27.1.1 Check the relevant committees or safety offices that address the issues raised in your project. The IRB review process will begin as soon as all these other reviews have been completed.

(select all that apply)

- ☐ Office of Radiation Safety (Irradiators, CT, X-ray, Fluoroscopy and Unsealed Radioactive Materials)
- ☐ HazChem Committee (Carcinogens, Acutely Toxic, Reproductive Hazard, Highly Reactive, Homeland Security Chemical of Interest, Untested Substance, Other) View a detailed list of Particularly Hazardous Substances: PHS List (MCW network access is required to view this link.)
- ☐ MRI Safety Committee
- ☐ Institutional BioSafety Committee

- ☐ Human Source Material (human blood, tissues, cell lines)
- ☐ Toxins
- ☐ Pathogens
- ☐ rDNA

☐ Synthetic nucleic acids

Note: If you have checked one of the Committees listed above, use the link(s) below to access and complete the application for that Committee. The IRB has no mechanism for tracking the review progress of these Committees. If you have questions, please contact that Committee directly.
Additional Information:

- **Adult Translational Research Unit** (TRU):
  - Click **here** to complete the online request form. Before you can submit your request, please complete a one-time registration to join CTSI.
- **HazChem Committee** :
  - **Website** (MCW network access is required to view this link.)
- **Institutional BioSafety Committee** :
  - **Website** (MCW network access is required to view this link.)
- **Office of Radiation Safety:**
  - **Website**
- **MRI Safety Committee:**
  - **Website**
  - Complete form and attach in Section 52.
- **Human Stem Cell Committee:**
  - **Website**

View: 28. Purpose and Justification

28. Purpose

28.1 * **Why is it significant or important to conduct this project?**
Excited Delirium Syndrome (ExDS) is a serious medical emergency that has been associated with death sometimes in the setting of restraint and custodial arrest by law enforcement officials, which accounts for its notoriety. Although a small proportion of subjects with ExDS progress to cardiopulmonary arrest and death, it is not universally fatal and is very amenable to therapy. Many gaps exist in our knowledge of this syndrome.

ExDS may be identified by the presence of a distinctive constellation of clinical and behavioral characteristics that can be recognized in the pre-mortem state. Fundamentally, ExDS manifests as a state of delirium with alterations in consciousness and cognition that begin rapidly (over hours or days) and sometimes fluctuate widely over a brief course. If the outcome is not fatal, the syndrome usually terminates with complete resolution of symptoms, though there can be residual sequelae, including amnesia for the event. These types of "kindling" events when the subject experiences ExDS but recovers are thought to be "near-miss" events that may herald an increased risk of subsequent events and possible death. The term "excited delirium" characterizes delirium at one end of a wide spectrum of psychomotor activity that typically accompanies delirium and spans the gamut from lethargy to extreme agitation.

That a cause of delirium can usually be identified is no less true in ExDS than it is in delirium more commonly seen in clinical practice. Stimulant drugs of abuse appear to be associated with ExDS in the largest cohort of fatal cases. Cocaine, most commonly, methamphetamine and phencyclidine comprise the cast of culprit drugs most often cited in the forensic medical literature although there have been reports of ExDS behavior with LSD, Ecstasy, GHB and marijuana. Chronic use as well as abrupt cessation of psychotherapeutic medications, including atypical antipsychotics and certain antidepressants, appears to also be closely related to development of ExDS. Other putative causes include untreated new-onset psychiatric disease, abuse of hallucinogens, alcohol intoxication or withdrawal, and a variety of general medical conditions, such as thyrotoxicosis. Less is known about the causal factors that differentiate survivors from non-survivors.

While gaps exist in our knowledge of why these factors lead to ExDS, recently published evidence suggests that in some cases down regulation of dopamine transporters in the striatum may drive the central physiologic derangements that underlie the clinical and behavioral manifestations of the syndrome. Other recent evidence suggests that profound metabolic acidosis and marked hyperthermia manifest in the peri-arrest period and may be causally related to death. Additionally, there is likely to be a genetic predisposition that has not yet been identified. This would be consistent with the typical

ExDS demographic that overwhelmingly favors male gender for developing this syndrome.

Patients in a state of excited delirium often display extreme agitation and erratic, bizarre behavior that necessitates a call to law enforcement for assistance. On arrival, the police typically encounter a male subject, inappropriately clothed or displaying some amount of nudity, sweating profusely, speaking incoherently and loudly, sometimes violent, with a rapidly shifting focus of attention, and unable to follow simple commands to desist or comply with their orders. This usually prompts the police to apply various physical means to control the subject, whereupon they discover his unusual strength and stamina, insensitivity to painful stimuli, and relentless struggle against physical restraints. In fatal cases, a brief period of calm often precedes cardiopulmonary arrest, leading witnesses to assume falsely that the disturbance has resolved. When immediate terminal heart rhythms have been documented, bradyasystole and PEA have most often been found, not shockable rhythms like ventricular fibrillation or ventricular tachycardia. Standard BLS and ALS interventions have generally proven futile.

Not infrequently forensic pathologists are perplexed to explain the death, because there is often minimal evidence of trauma, and body fluid analyses frequently fail to reveal lethal levels of toxins. History has demonstrated that numerous law enforcement tools and tactics have received blame (such as use of handcuff and hobble restraints, prone positioning, chemical irritant sprays, TASER® electronic control devices) and result in authorities changing practices. However, when mandates have prohibited use of these tools and tactics, these types of deaths still occur and evidence of causality is lacking. Newer data appears to implicate a worsening acidosis state coupled with a hyperadrenergic state as the likely final common pathways that lead to fatality.

In the last few years, anecdotal reports that certain goal directed therapies may prevent death have emerged. These usually involve therapeutic strategies to rapidly tranquilize or sedate, and to rapidly correct the putative culprits, acidosis, hyperadrenergia and hyperthermia. Efforts to train EMS personnel to support law enforcement personnel by "chemically restraining" these subjects, aggressively treating them and delivering them quickly to definitive care are growing. Likewise there is an emerging trend to train law enforcement personnel, including dispatchers, to recognize ExDS and shift their response paradigm from interdiction in a criminal matter to intervention in a medical emergency. Little evidence exists to guide or support the therapeutic interventions and strategies that have been proposed. The goal of this case series is to collect information on the use of ketamine administered for the purpose of rapidly gaining control of the severely agitated patient.

In some cases, paramedics arrive on scene and discover a patient that fits these criteria before law enforcement officers are involved. Because of the threat of physical harm to the paramedics, the public, and the patient, ketamine may be given.

28.2 * **Briefly summarize findings from previously published data or pilot studies that substantiate the soundness of protocol being proposed; or describe formulation of research questions:**

This is a simple case series looking to describe a current therapy in this patient population.

View: 29. Hypothesis and Objectives

29. Hypotheses and Objectives

Some projects are designed around explicit scientific hypotheses. Others (chart reviews, pilot studies) may be better described in terms of Aims or Objectives. Answer the question (29.1 or 29.2) that suits your project best.

29.1 **State the hypotheses:**
See 29.2

29.2 Describe the Aims and Objectives of this project:

The purpose of this case series is to report on the collective experience of several EMS systems in Wisconsin that have implemented protocols for administering ketamine to rapidly gain control of patients with severe psychomotor agitation.

Responses Provided Prior to November 20, 2010

Previous 29.3 Bibliography:

View: 30. Procedures and Analysis

30. Procedures and Analysis

30.1 * Narrate project procedures listing in sequential order the steps that will be followed to conduct the protocol:

1. EMS system directors and/or medical directors will be queried simply through professional collegial conversations making them aware of this study.

2. EMS system directors and/or medical directors in the State of Wisconsin will identify patients that meet inclusion criteria in their respective systems and provide us a copy of the patient care report. The copies will be provided in the format chosen by the sharing system based on their HIPAA requirements which may include hard copies, fax, or secure email.

3. Patient care reports provided will be verified for inclusion criteria.

4. Data will be extracted from reports and collated for descriptive analysis. This data will be stored on a password protected computer in Dr. Curtis' office. Aggregate data will be shared with the PI either in person or via secure email and then stored on the PI's password protected MCW server.

Note: If desired, upload an activity table into Section 52 listing tests that will be conducted (e.g., lab draws, EKG, chest x-ray, genetics, proteomics, H&P, survey) as well as the frequency of these tests.

30.1.1 Explain the details of all research treatments.

- Where will the research treatments take place (inpatient, outpatient, residential or home setting)?
- What degree, professional license, or training do those administering the research treatment possess?

N/A

30.2 * Explain how you intend to analyze the data:

Simple descriptive statistics will be used to describe current experiences.

View: 31. Procedures and Expenses

31. Procedures and Expenses for Subjects

31.1 * Explain which procedures are research-related:

This case series report is all research related.

31.2 * Explain what expenses are NOT covered in the project, i.e., the expenses the subject is expected to pay:

There are no expenses expected and subjects will not be responsible for any expense.

31.3

*** Explain what expenses ARE covered in the project, i.e., the expenses the subject is not expected to pay:**

There are no expenses expected and subjects will not be responsible for any expense.

View: 32. Risks and Safeguarding Against Risks

32. Risks and Safeguarding Against Risks

32.1 *** List all reasonably foreseeable risks or discomforts. Consider physical, psychosocial, confidentiality, and privacy risks. List in order of frequency (likelihood), but be sure to include uncommon risks that might influence a person's decision to participate.**
Loss of confidentiality and privacy.

32.2 *** Identify features of the project, e.g., recruitment practices, project design, procedural plans, intended to minimize safety risks to subjects**:

Subjects will be identified by local directors so the study team will only have access to patient care records that pertain to this study.

Paper records will be secured in Dr. Curtis' locked office and all electronic data will be secure in password protected files on Dr. Curtis' computer and the MCW Department of Emergency Medicine server a password protected file belonging to the PI.

View: 35. Benefits

35. Benefits

35.1 ***Identify and list separately the potential benefits:**

- **to subjects participating in this project or state "none", if appropriate**
- **to science or society from this project**

There will be no benefits to subjects.

It is hopeful that society and future patients with this condition may benefit from the knowledge gathered from this case series report.

View: 38. Informed Consent

38. Informed Consent

38.1 *** Indicate your approach to the informed consent process requirement for this project:**
(select all that apply)

- ☐ Subjects or parents of minor subjects participate in an informed consent process and sign an informed consent document
- ☑ **Waiver of the Informed Consent Process is granted by the IRB. This option is not permitted for most FDA regulated research.**
- ☐ Subjects participate in an informed consent process, but a Waiver of Documentation of Informed Consent is granted by the IRB
- ☐ None of the above

View: 40. Waiver of Informed Consent

40. Waiver of Informed Consent

40.1 *** Does the project meet the IRB's definition of "minimal risk"?** (see help text)
◉ **Yes** ○ No

40.1.1
*** Explain:**

This is a retrospective chart review with no change in medical care or any active intervention being applied to subjects as a result of this research project.

40.2 *** Will the waiver of informed consent adversely affect the rights and welfare of the subjects?**

○ Yes ◉ **No**

40.2.1
*** Explain:**

This is no greater than minimal risk and all precautions will be taken to protect and respect subject confidentiality and privacy.

40.3 *** Would it be practicable to conduct the research without this waiver?**

○ Yes ◉ **No**

40.3.1
*** Explain:**

Many times the exact identity of these patients is uncertain and contact information is either unavailable or unreliable. Attempting to confirm identities and obtain contact information would actually increase exposure to the risk of loss of privacy and often times would be impossible regardless.

40.4 *** Would it be appropriate to provide subjects with additional pertinent information before or after their participation?**

○ Yes ◉ **No**

40.4.1
*** Explain:**

In this retrospective review, there is not information that would be pertinent to the subject.

View: 42. HIPAA: Protected Health Information

42. HIPAA: Protected Health Information

42.1 *** Indicate the HIPAA authorization pathway applicable to this project.** Generally, the Health Insurance Portability and Accountability Act (HIPAA) prohibits collecting, accessing, using or disclosing a person's protected health information (PHI) for research without valid authorization. Under some circumstances, a waiver of authorization may be granted by the IRB:

(select all that apply)

- ☐ **No Private Medical Information Will Be Accessed or Used For This Project**
- ☐ **An IRB-Approved Consent Process and Document will be Used** that incorporates the required HIPAA authorization
- ☑ **Waiver of HIPAA Authorization Is Requested. Generally, this request should accompany the "Waiver of the Informed Consent Process" at 38.1.**
- ☐ **Research using only information on deceased persons**
- ☐ **Limited Data Set**, as defined by HIPAA regulations (download "Data Use Agreement" form located on InfoScope HIPAA website, complete it or an equivalent, and upload in Section 52)
- ☐ **De-identification of data** subject to the IRB's definition and verification of de-identification
- ☐ **None of the above**

View: 48. Request for PHI w/o Patient Authorization: Justification

48. Waiver of HIPAA Authorization: Justification

48.1 * **Is it practicable for the investigator to conduct this project without a waiver of HIPAA authorization?**

○ Yes ◉ **No**

If No:
48.1.1 Explain:

Many times the exact identity of these patients is uncertain and contact information is either unavailable or unreliable. Attempting to confirm identities and obtain contact information would actually increase exposure to the risk of loss of privacy and often times would be impossible regardless.

48.2 * **Is it practicable for the investigator to conduct this project without access to and use of the identified health information?**

○ Yes ◉ **No**

If No:
48.2.1 Specify:

The health information is essential to the purposes of this case series report and the identifiers, while their use will be limited, would be difficult to remove without risking duplicating enrollment of subjects.

Responses Provided Prior to November 20, 2010

Previous 48.2.1 If "No", why?
There are no items to display

View: 49. Request for PHI w/o Patient Authorization: Safeguards

49. Waiver of HIPAA Authorization: Safeguards

49.1 * **Use or disclosure of identified health information without authorization from subjects may adversely affect their rights and welfare. How will subjects' rights and welfare be protected to assure that use or disclosure poses no more than minimal risk?**

The information will be treated with the utmost respect and remain secured. Attempting to get authorization would actually force us to unnecessarily find more identifiers which would further put the subject at risk.

49.2 * **Under this (Waiver) request, the identified health information can NOT be removed from the institution that owns the information (i.e., Froedtert Hospital, Children's Hospital of Wisconsin, and/or MCW). What is the plan to ensure that the identified health information will NOT ever be removed from the institution?**

No PHI will be removed from MCW/Froedtert or CHW.

View: 50. Request for PHI w/o Patient Authorization: Procedures

50. Waiver of HIPAA Authorization: Procedures

50.2 * **Who will have access to the identifiers?**

Study team members

50.3 * **How will the identifiers be protected from improper use and disclosure?**

No identifier will be published and any identifier in collected data will remain secured.

Responses Provided Prior to November 20, 2010

Previous 50.1 Who will obtain the identifiers?

Previous 50.4 When will the identifiers be destroyed?

Previous 50.5 **How will the identifiers be destroyed?**

View: 52. Attached Documents

52. Attached Documents

52.1 * **Select all items that will be included for IRB review:**

(select all that apply and upload documents in Section 52.1.2, using the prefix in the title of the document. For example, ICF-PRO1234 (document name), IB-PRO1234(document name))

- [x] **PRO - Sponsor's protocol, protocol summary or narrative**
- [ ] IB - Investigator Brochure
- [ ] ADV - Advertisement
- [ ] ICF - Informed Consent form
- [ ] SMP - Safety Monitoring Plan
- [ ] DM - Device Manual
- [ ] SUR - Surveys / Questionnaires
- [x] **DCF - Data Collection forms/tools**
- [ ] INF - Informational material for subjects
- [ ] TBL – Activity table, schedule of assessments
- [ ] BNK – Bank documents and forms
- [ ] SAF – Ancillary Safety Committee or Human Stem Cell Committee approvals, Adult Treatment Research Unit (TRU) approvals
- [ ] LET - IND/IDE/HDE or 510(k) documentation, communication from/with the sponsor, IRB approvals or administrative letters from other institutions
- [ ] DA - Data agreements or contracts
- [x] **Other(s) (SPECIFY)**

52.1.1
Give a brief description of "Other" items:

Response letter

52.1.2
Upload each item specified from 52.1 and 52.1.1 in the section below:

Name	Last Modified Date	Version
Response to modification letter.docx | History	9/22/2013 8:23 PM	0.01
Ketamine for Excited Delirium Data Collection September 2013.doc | History	9/22/2013 8:22 PM	0.01
Ketamine and Excited Delirium Protocol.doc | History	9/11/2013 7:50 PM	0.01

52.2 **Previously attached documents related to specific sections of the PRO SmartForm:**

Note: In this section you can revise or remove previously attached documents. All new documents should be uploaded in question 52.1.2.

Section 8 Cancer Cooperative Groups (previous question 8.1.3)

Below are completed cooperative group consents:

Name	Last Modified Date	Version

There are no items to display

Section 27 Other Safety and Research Review Committees (previous question 27.2)

Below are application documents for Adult TRU, Safety Committees, and/or Human Stem Cell Committee:

Name	Last Modified Date	Version

There are no items to display

Section 30 Procedures and Analysis (previous question 30.1.1)

Below are activity table listing tests that will be conducted (e.g., lab draws, EKG, chest x-ray, genetics, proteomics, H&P, survey) as well as the frequency of these tests may accompany the narrative:

Name	Last Modified Date	Version

There are no items to display

Section 32 Risks and Safeguarding Against Risks (previous option for 32.1)

Name	Last Modified Date	Version

There are no items to display

View: Final Check

Final Check

(a) Please do the following:

- **Clicking "Finish" does NOT submit this Project to the IRB. It saves your work and exits the SmartForm, taking you back to the Workspace.**
- **From the Workspace, the Principal Investigator must click "Submit Application" to submit this Project to the IRB for review.**

(b) Spelling and Grammar:

The Human Research Protection Office will not accept any application that has not been checked by the submitter for spelling and grammatical errors. Spellchecking capability is not available within the eBridge system at this time.

(c) Attached Documents:

Make sure all documents have been uploaded before submission.

(d) Copy and Pasting from Word or PDF:

If the format of your text is altered when it is pasted into eBridge, please refer to the "*How to Cut & Paste from a Word Document*" directions.