Consent Form

Please see attached Human Participant Research Determination Tool from Wayne State University for further reference. As the treatment provided the patient in our case report was not originally intended to be conducted as research (Section B: A, Page 2), and as all 18 protected health information elements per HIPAA regulations have been de-identified (Section B: A, Page 2 and Section B: I, Page 4), our case report does NOT require a signed authorization to disclose information per institutional policy as outlined in the attached Human Participant Research Determination Tool.

This form is therefore attached in lieu of formal patient consent.

Corresponding Author Signature: _____ Date: 6/30/17

Printed Name: CHOICHI SUAAWA

WAYNE STATE UNIVERSITY

IRB Administration Office
87 E. Canfield, Second Floor
Office (313) 577-1628
Detroit, MI 48201
http://irb.wayne.edu/index.php

Human Participant Research Determination Tool

The regulatory requirement for IRB review, under the Common Rule applies to research that is "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Only research meeting this definition, (definition of Human Participant Research or HPR) or research, for which the FDA regulations apply, requires IRB review and IRB oversight.

This tool is for determining when a project requires IRB review and approval. Use this tool to determine if a project is limited to the common research activities described in Section B or if it meets the regulatory definition of research requiring IRB review in Sections C and D. If assistance is needed of if written documentation from the IRB office is required, complete the entire form and submit the form and any relevant supporting documents (i.e. grant, protocol, data collection tools) to the IRB administration office, or email it to the IRB Education Coordinator. Please do not submit handwritten documents to the IRB office.

HPR Determination Number_____
IRB Use ONLY

Section A: Project Information

Project Title:	Hydrogen Peroxide Ingestion at an Urban Medical Center			
Name of person conducting the project:	Jonathan Martin	Title:	Resident	Date: 3/14/17
Status: **Select all that apply**	☐ Wayne State Faculty ☐ WSU Graduate Student ☐ WSU Undergraduate Student ☐ DMC Staff ☐ Karmanos Staff ☐ J. D. Dingell VAMC Staff ☒ Resident/Fellow/Trainee ☐ Other: ____			
Division or College:	School of Medicine	Campus Address:	4201 St. Antoine St, 6C-UHC	
Department:	Michael and Marian Ilitch Dept of Surgery	Email Address:	jvmartin@med.wayne.edu	
Alternate or Home Address:	☒ N/A	Phone:	530-401-4248	
Faculty Sponsor/ Supervisor for this project:	Name: Dr. Choichi Sugawa Email: csugawa@med.wayne.edu ☐ I do not have a Faculty Sponsor/Supervisor	Phone: Title:	(313) 577-5001 Professor	
Form completed by:	Jonathan Martin	E-mail:	jvmartin@med.wayne.edu	

Section B: Activities Determined by the WSU IRB Office to not be Human Participant Research

Select any of the following activities that apply to this project.
NOTE: The intent to publish is an insufficient criterion for determining whether a project involves activity that requires IRB review.

A. ☒ **Case Report**: The project consists of a case report or series (up to three cases) which describe an interesting treatment, presentation or outcome. A critical component is that nothing was done to the patient(s) with prior "research" intent.

NOTE: For case reports, HIPAA requires that the disclosure of an individual's protected health information must be authorized by that individual. If a case report contains any of the 18 Protected Health Information Elements, per the HIPAA regulations, a signed authorization (using the authorization form from the entity that holds the record) to disclose this information must be obtained from the individual(s) whose information is being disclosed.

B. ☐ **Course-Related Activities**: The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom.

NOTE: IRB approval is required if a student is involved in an activity designed to teach research methodologies and the instructor or student wishes to conduct further investigation and analyses in order to contribute to scholarly knowledge.

C. ☐ **Decedents:** The project involves research that is limited to death records, autopsy materials, or cadaver specimens. If the project involves the use and/or collection of Protected Health Information (PHI), HIPAA regulations apply to decedent research. As the Privacy Board, the IRB Office requires that you confirm the following conditions as set forth in the Privacy Rule at 45 CFR 164.512(i)(ii)(iii), have been met.

1) ☐ the use will be solely for research on the information of a decedent; and

2) ☐ the Principal Investigator has documentation of the death of the individual about whom information is being sought, and

3) ☐ the information sought is for the purposes of the research

NOTE: This exception may not be available for decedent Information that contains Psychotherapy Notes or Information relating to HIV, mental health, genetic testing, or drug or alcohol abuse

D. ☐ **Journalism/Documentary Activities:** The activities are limited to investigations and interviews that focus on specific events, views, etc., and that lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

NOTE: IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models).

E. ☐ **Oral History**: The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

NOTE: IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories).

F. ☐ **Program evaluation /Quality Improvement/Quality Assurance Activities**: The project is limited to program evaluation, quality improvement or quality assurance activities designed specifically to assess or improve performance within the department, hospital or classroom setting. The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

NOTE: Investigators, who plan to conduct a QI/QA project, should ensure that they have received approval from any applicable committees within their department or the site in which the activity will occur.

G. ☐ **Public Use Datasets:** The project is limited to analyzing de-identified data contained within a publicly available dataset. The research will NOT involve merging any of the data sets in such a way that individuals might be identified, and the researcher will NOT enhance the public data set with identifiable or potentially identifiable data.

NOTE: IRB approval is required for the use of restricted use data, if a proposal is required to obtain the dataset, or if a data use agreement is involved.

List Source(s) of Public Use Dataset(s):

H. ☐ **Coded* Private Information and/or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as "specimens"). IRB Approval is not required if all of the following conditions apply to the project:

1) ☐ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; **and**

2) ☐ The investigator(s)** cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:

a) ☐ the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased (note that the HHS regulations do not require the IRB to review and approve this agreement);

b) ☐ there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or

c) ☐ there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased, **and**

3) ☐ Specimens are <u>not</u> being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, **and**

4) ☐ The records/images/charts that are being collected for this study are <u>not</u> from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

From the Office for Human Research Protections (OHRP) guidance document dated October 16, 2008:

Coded* means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens. **The code cannot be derived from or related to the information about the individual.

***Investigator* includes anyone involved in conducting the research. The act of solely providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in the conduct of the research. If the individuals who provide coded information or specimens collaborate on other activities related to the conduct of this research with the investigators who receive such information or specimens, then the IRB would consider such additional activities to constitute involvement in the conduct of the research. Examples of such additional activities include, but are not limited to: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.

I. ☒ **De-Identified Private Information or Human Biological Specimens:** The project is limited to the use of existing and/or prospectively collected de-identified private information and/or human biological specimens (hereafter referred to as "specimens"). IRB Approval is not required if you can confirm the following:

1. ☒ The private information or specimens were/are not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and

2. ☒ The investigator can confirm that the use of the private information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected; and

3. ☐ The investigator will only receive information or specimens that are fully de-identified. De-identified means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. Note: To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers. and

4. ☒ Specimens are <u>not</u> being used to test the effectiveness of a medical device or as a control in an investigation of an investigational device and the results of the activity are to be submitted to the FDA or held for inspection by the FDA, and

5. ☒ The records/images/charts that are being collected for this study are <u>not</u> from individuals who are or will become recipients of an FDA regulated product (approved or experimental) or act as a control as directed by a research protocol and not by medical practice, and the results are to be submitted to the FDA or held for inspection by the FDA.

Next:

- ✓ If the activities for this project are limited to one of the categories described in Section B above, such that it is clear that the project does not require IRB review – **STOP.** The project involves activities that the WSU IRB has determined to not be human participant research. Retain this tool in your files to document this determination. You do not need to submit this form to the IRB.

- ✓ If the activities for this project are outside of the activities described in Section B above, continue to Sections C and D to determine if the project is human participant research requiring IRB review.

Section C: Does the Project Require IRB Review under the Common Rule (45 CFR 46.102)?

1. Does the project involve a systematic investigation designed to contribute to generalizable knowledge?

NOTE: If the investigation is characterized by order, planning, and methodology and the intention of the investigation is to generate conclusions that can be applied universally, outside of the immediate environment where the investigation occurred (i.e., the classroom, hospital, department), then the activity meets the definition of research.

☐ Yes - go to Q #2

☒ No - go directly to Section D

2. Does the research involve obtaining information about LIVING individuals?

☐ Yes - go to Q #3

☐ No - go directly to Section D

3. Does the research involve collecting data through intervention (i.e., physical procedures or manipulation of the environment) or interaction (i.e., communication or interpersonal contact between investigator and person) with the individuals?

☐ Yes - IRB Review is required, skip section D and see **Next Steps** below.

☐ No, go to Q #4

4. Does the research involve using identifiable information (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information)?

☐ Yes - go to Q #5

☐ No - go directly to Section D

5. Is the information private?

NOTE: *Private* information refers to data or behavior that an individual would reasonably expect no observation or recording is taking place. This is data provided, or behavior that occurs, for specific purposes by an individual and which the individual can reasonably expect will not be made public.

☐ Yes - IRB Review is required, skip section D and see **Next Steps** below.

☐ No - go to Section D to see if FDA regulations apply.

Section D: Does the Project Require IRB Review under the FDA Regulations?

1. **Is this is an experiment that involves a test article and one or more human participants, and the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit? A participant is an individual (either healthy or a patient) who is a recipient of the test article or a control.**

   NOTE: Test article means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Food, Drug, and Cosmetic Act.

   ☐ Yes, IRB Review is Required ☒ No, continue to question #2

2. **Is this is a clinical investigation or research involving one or more human research participants to determine the safety or effectiveness of a device? A research participant is an individual (healthy or has a medical condition or disease) on whom or on whose specimen an investigational device is used, or who participates as a control.**

   ☐ Yes, IRB Review is Required ☒ No, continue to question #3

3. **Is this an experiment in which a drug is administered or dispensed to, or used involving, one or more human research participants? This excludes the use of a marketed drug in the course of medical practice. A research participant is an individual (healthy or patient with a disease) that participates either as a recipient of the investigational new drug or as a control.**

   ☐ Yes, IRB Review is required.

   ☒ No, the project involves activities that the WSU IRB has determined to not be human participant research. Retain this tool in your files to document this determination.

Next Steps:

- ✓ If by the use of this tool, you have determined that the project does not require IRB review, you do not need to submit this form to the IRB office. Retain this tool in your files to document this determination.
- ✓ If you have determined that IRB review is required, IRB approval must be gained **before** conducting human participant research. See the WSU IRB website for additional information and the forms required for a new submission: http://irb.wayne.edu/
- ✓ If you are unsure as to whether or not this project is human participant research requiring IRB review, then complete Section E and submit this form and any relevant supporting documents to the IRB office.

Section E: Request for a Determination by the IRB Administration Office

Check ALL that apply:	☐ Behavioral, social, education, non-medical research ☐ Medical research

Provide a description of the project with enough detail for the determination. Enter "N/A" where appropriate.

Describe the purpose, study question, study objectives or aims for this project:
State the location(s) where research activities will take place:
Describe the participants (if applicable) for the project:
Describe the data/information that would be collected for the study:
Describe how data will be obtained (e.g. survey, interview, observation, testing, review of existing records, etc.):
Describe whether or not the data will include individually identifying information (e.g. names, DOBs, MRNs, email address, other codes or etc.):

Instructions:

In addition to providing a complete description above, please submit any relevant supporting documents (i.e. grant, proposal, data collection tools) with this tool to the IRB administration office, or as an email to the IRB Education Coordinator for assistance in making the determination.

IRB Administration Office Staff Contact Information: **http://irb.wayne.edu/ContactUs.php**

This form is modified and based on a form and guidance used by the Institutional Review Board Office of Northwestern University. Permission granted for use on 03/26/2015 by Northwestern University.

WSU IRB Determination:

(To be completed by IRB Administration)

- ☐ Not Human Participant Research - IRB review is not required
- ☐ Exempt IRB review is required
- ☐ Expedited IRB review is required
- ☐ Full Board IRB review is required

Comments:

Signature: _____ Date _____

Printed name: _____