Dartmouth College • Dartmouth-Hitchcock Medical Center

**COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS**

APPLICATION FOR REVIEW

FOR RESEARCH OR DATABASE DEVELOPMENT

 INVOLVING ONLY CLINICAL HEALTH INFORMATION OR SPECIMEN USE

OR USE OF SECONDARY RESEARCH INFORMATION OR SPECIMENS

v. 02.11.2013

**\*\*\*\*\*\*\* TO CONTACT CPHS: cphs.tasks@Dartmouth.edu or 603-646-6482 \*\*\*\*\*\*\***

***Instructions:***

*This form is primarily intended for the review of studies collecting retrospective data or specimens that exist from clinical services. If you are proposing to collect data or specimens prospectively, please consider using the application for expedited review if the questions asked by this form will not result in an accurate and complete description of your proposed study.*

*Conceptually, specimens are considered a medium for data and a database is the equivalent of a tissue or blood bank.*

*Please note: Applications are reviewed in the order that all needed materials are received by the CPHS Office.* ***Let us know if you have an upcoming deadline.***

***Please send a copy of your completed application for review by e-mail to CPHS.Tasks@dartmouth.edu.***

**CPHS #: 24438**

**LOCAL PRINCIPAL INVESTIGATOR:** Dr. Jay Buckey Jr. **DEPT:** Center for Hyperbaric Medicine

**LOCAL CO - INVESTIGATOR(S):** Judy Ptak RN MSN CHT **DEPT:** Center for Hyperbaric Medicine

**CONTACT PERSON:** Judy Ptak **EMAIL:** Judy.A.Ptak@Hitchcock.org

**STUDY TITLE:** Multicenter Registry for Hyperbaric Oxygen Therapy

**FUNDING SOURCE (SPONSOR):** none

**SPONSOR PROTOCOL # AND VERSION DATE, OR FEDERAL AWARD #:** n/a

**SIGNATURES**:

 *Principal Investigator* DATE

 *\*Department Chairperson* DATE

\* Department Chairperson signature indicates : a) the scientific questions addressed in this study have adequate merit to justify experimentation involving human subjects b) the potential risks of this study have been accurately and fully described and c) the study design is adequate to answer the questions being asked.

XX Check here to confirm all investigators and key personnel have completed IRB education. See “Education Requirements” on our website for more information: www.dartmouth.edu/~cphs

**CPHS FEE:** Externally funded, non-federal studies will receive an invoice of $750 for Expedited CPHS review.

**Instructions:**

**Respond to each of the following sections** **that request information, even if to indicate “not applicable”,** leaving the template language of this form intact. Some guidance is provided under each category of requested information. For questions please call the CPHS office.

**1. This application is for (check one or more):**

[ ]  Research project using health information from clinical records

[ ]  Research project using specimens obtained for clinical use

X Establishment of a database for future research

[ ]  Research using information from a CPHS approved database

[ ]  Research using information from a source other than clinical records. (DESCRIBE SOURCE for example a previous study or from public records)

**2. Describe the research purpose or the purpose of the database:**

The purpose of this database is to provide data for quality improvement work through a mechanism for collecting selected information about patients receiving hyperbaric oxygen treatments (HBOT) from many hyperbaric centers. This information will be used to understand the characteristics of patients receiving HBOT, the indication that it is being used for, the outcomes of the treatments, the variations in treatment protocols, adverse events associated with HBOTs, and safety issues. At present, this type of data is limited and mainly comes from small case series. Most hyperbaric centers see only a small number of patients with a particular indication each year. For one center to gather enough cases to be meaningful would take many years. By combining data from many centers it should be possible to get enough cases to provide meaningful data about outcomes and safety in a reasonable period of time. The information about outcomes can be used to;

Provide information so patients will be able to make better informed choices about HBOT Provide feedback to physicians and centers to determine how well they are performing
Provide information to payers and others about the appropriateness and effectiveness of HBOTs

**3. Describe the data fields necessary for research or to be retained in the database:**

The database has been setup to collect information on the following areas;
Demographic – Basic demographic information is included to allow linking to other registries in the future to help answer questions about some of the theoretical adverse effects of HBOTs. Fields included in this section are; Last name, First name, last four of Social Security Number, Date of Birth, Sex, and Zip code. These fields are included to allow patients in this database to be linked with other registries (e.g. cancer registries) to help answer some of the questions about potential adverse or beneficial effects of HBOTs. The other fields in this section; Distance from HBOT center, Type of Insurance, Patient type (inpatient vs. outpatient), Urgency (treatment needed within 24 hours vs treatment can wait) are included to help understand some of the characteristics of patients receiving HBOTs.

Referrals – Information about who made the referral and for what reason. Fields included in this section are; Date referral received, name of referring physician, specialty of referring physician, reason for referral, region referral is from.

HBOT Evaluation – information about the evaluation. Fields included in this section are; Date of evaluation, which provider did the evaluation, has the patient had HBOTs in the past, is HBOT indicated, Indication for HBOT, anatomic location of problem being treated with HBOT, or the reason HBOT was not indicated.

HBO Treatments – This section includes basic information about the HBOTs to allow comparison of outcomes. There is variation in the treatment parameters (ATA, time at pressure, number of treatments per day, number of treatments) from center to center; we hope to be able to determine if these variations have an impact on outcomes. Fields included in this section are; Number of treatments prescribed, treatment pressure, daily frequency of HBOTs, length of HBOT, start and stop date of HBOT, number of HBOTs completed, and were the prescribed number of HBOTs completed, if not the reason HBOT not completed.

Adverse effects/safety issues – This section includes information about the occurrence of adverse effects or safety related problems. The fields included in this section are; ENT referral needed, pressure equalization tubes needed, changes in vision, complications (seizure, pneumothorax), part of research protocol, diabetes, smoking history.

Outcomes – Provide information about outcomes of the HBOT. We are trying to determine if the condition they were being treated for improved. The lack of reliable data from large numbers of patients has been a hindrance to moving the field of hyperbaric medicine forward. Fields in this section are scores from simple questionnaires patients complete for some indications and percent of change in wound measurements and status of wound at the end of HBOTs if a wound was being treated.

Long-term follow up – For long-term follow up patients at Dartmouth Hithcock Medical Center (DHMC) only for the pilot program will be provided with questionnaires that assess their symptoms, the durability of treatment, and any long-term complications they may be experiencing as a consequence of treatment.

**4. Describe the source of the data to be used in this research or to be retained in the database:**

The information entered into this database will come from the patients’ medical record and the simple questionnaires the patient will complete for some of the hyperbaric indications (osteoradionecrosis of the jaw, radiation cystitis, radiation proctitis).

Each site will collect their own information and only de-identified long-term data will be sent to the registry at Dartmouth College.

For long term follow up data at DHMC only during the pilot phase which will be obtained through a separate consenting process, we will recruit current patients, future patients, patients who do not choose HBO treatment, patients who choose HBO but stop treatment early, and patients who are treated elsewhere for similar indications (as control subjects). Patients will be provided the consent form at the initial evaluation for HBO treatment and later during treatment. Patients who have similar indications not being treated with HBO will be recruited through clinics that refer patients to HBOT. We will recruit any age person for this study.

Once a year, at DHMC only for the pilot phase we will collect information on symptoms through a questionnaire that we will send each year by email, telephone, or mail. If patients are willing, they will complete the surgery through a local registry REDCap link. Otherwise they will be contacted to complete it by telephone or mail.

**5. Describe the methods of data abstraction:**

Staff members at participating centers will gather the required information from their medical records and enter it in the database from a computer at their center via secure link. The registry contains many drop down menus and checkboxes to facilitate consistent data entry.

**6. For database creation:**

a. List individual(s) with direct access to database and confirm individuals are aware of confidentiality procedures. If access is provided via 'database managers' please describe process:

The following will have access to all the information entered in the database, Dr. Jay Buckey Jr, Judy Ptak RN MSN, Judy A. Kertis RN, Pamela M. Hannigan RN, Kati J. Miller RN, Jennifer C. Curtin RN, Jean Proehl RN, Abigale Pelletier RN, and Devin R. Cowan. They are all aware of confidentiality procedures and have completed CITI training.

Each participating center will assign staff to enter their data. These staff will only have access to the data from their center. According to the agreement the participating staff must be trained and aware of confidentiality procedures. Each center is responsible for ensuring their staff have successfully completed appropriate training.

b. Please explain the plan for internal review of future use of the database. For example, will the Principal Investigator be contacted for their approval prior to IRB review? Can IRB submissions come from any of the individuals listed in response to question #6a without separate approval from the P.I.?

An Executive Committee, consisting of one member from each participating center, will be responsible for approving use of the data (see enclosed draft agreement). The Executive Committee will set up policies and procedures for requesting use of the data. They will only be given the data they need for the project they are doing, they will not be granted unlimited access to the database. According to the agreement people requesting use of the data must have completed the appropriate training.

**7. For use of CPHS approved database:**

a. CPHS # of approved database:

b. Has the appropriate permission been obtained from the manager of this QI/Research Database, as specified in the original CPHS approval? [ ]  YES or [ ]  NO

Please describe:

**8. Provide the inclusive dates of the information collected for the research or to be retained in the database:**

The Center for Hyperbaric Medicine at DH began collecting data on October 1, 2011. Other Centers will begin collecting information in the future. There is no predetermined end for this database, we hope that it will be an ongoing project.

**Is the information or specimens all existing as of today’s date?** [ ]  YES or X NO – We are planning on collecting information in real time as it is generated.

**9. Will identifiable protected health information (PHI) be disclosed (released) outside of the DHPG ?** (Note: This release does not refer to publication (which should be released with no patient identifiable information), rather, is the PHI being collected for release to an entity outside of DHPG (e.g. data analysis, archiving). X – Maybe YES [ ]  NO [ ]  No PHI Involved

If yes, explain to whom: It is possible that in the future the Executive Committee will decide to link this registry with other registries to help answer questions about beneficial or adverse effects of HBOT (e.g. effect on cancer), In this case PHI would be used to link to other registries. At this point in time this is the only anticipated use of the PHI. The Executive Committee would make the decision to link to another specific registry. If they decide to pursue this they will ensure that all necessary precautions are taken to protect the data. It would be extremely difficult for all the participating centers to go back and obtain the required information to do this linking.

**10. Please indicate which type of data you will collect, A, B, or C. These terms are defined at the end of this form:**

[ ]  **A. “De-identified Health Information"**

(Note: If using Statistical Waiver fill out justification section at end of this form)

**Check one:**

[ ]  There is or will be a link established with de-identified data in order to trace back to PHI.

[ ]  There is no and will be **no** link established with de-identified data. No data can be possibly traced to PHI.

[ ]   **B. "Limited Data Set"** Review the list of excluded data elements on the last page. The project involves only the collection of data elements listed in the Limited Data Set.

**Check one:**

[ ]  There is or will be a link established with the Limited Data Set in order to trace back to PHI.

[ ]  There is no and will be **no** link established with the Limited Data Set. No traceability to PHI is possible.

X **C. "Individually Identifiable Health Information"**

To inform patients at the time of consent for their hyperbaric treatments, additional language will be added to the Hyperbaric oxygen procedure consent form stating: "You should be aware that your identifiable information (name, last 4 digits of social security number and date of birth) will be used for quality improvement activities in the Hyperbaric Registry located at Dartmouth-Hitchcock Medical Center. Your identifiable information is not disclosed in publication for scientific, educational or professional purposes." This is the same language used in the Northern New England Cardiovascular Electrophysiology Registry (NNEEP) here at Dartmouth.

For the Dartmouth Hitcocock Medical Center (DHMC) Site only we are piloting a long term follow up data collection program. At some point in the future, we will reapply for approval to open this part of the research study up to other centers.

Patients will be offered the opportunity to participate in long-term data collection with a separate consent form. This long-term collection is optional and involves us contacting them annually with a survey about their symptoms.

***[ ]*  D. Other**

**11. Informed consent:**  Explain how informed consent will be obtained. In general, a copy of a signed consent form from each research participant is necessary except in specific circumstances. Only when certain criteria are satisfied can the CPHS grant a waiver for consent to research participation by each potential participant or for a signed, written consent form. When a waiver for a signed consent form is granted, potential research subjects should be informed about the research procedures and given an opportunity to decline participation. In addition, most often they should be provided with an information sheet. With this application include a copy of a consent form or an information sheet, whichever is applicable. Please check the CPHS website to obtain a template for a consent form or information sheet, which should be used to create the form specific to the study. [www.dartmouth.edu/~cphs](http://www.dartmouth.edu/~cphs)

*Check one:*

X A consent form based on the CPHS template is included with this application. If you are obtaining a signed consent form please describe your proposed recruitment and consent process below. This is for the long term followup up pilot at DHMC only. Approval for later sites will be requested at a later date. This includes the consent form and assent form.

[ ]  I intend to obtain consent for research participation but I am requesting a waiver for the use of a *signed and dated* consent form. Please respond to the criteria listed in **CPHS Study Plan Attachment I** and include an information sheet based on the CPHS template. Please also describe your recruitment and consent process below.

XX I am requesting a waiver of the entire consent process and use of a consent form. Please respond to **CPHS Study Plan Attachment H. This is for all research sites.**

All information from hyperbaric oxygen therapy patient’s treatment will go into the registry under the hyperbaric oxygen procedure consent. In addition to this, at DHMC only during the pilot program, patients will be given the option to participate in long-term data collection to learn more about the ongoing benefits of HBO. This option will be offered thorough a consent and, when appropriate, assent form. The consent form will be presented by the hyperbaric staff and physicians at the time of consultation and during HBO treatment.

**12. Authorization:** Explain how authorizations will be obtained for the recruitment procedure and other use or disclosure of protected health information (PHI) in the study. Protected health information is individually identifiable health information obtained from a health care provider or insurance plan. In general, the HIPAA Privacy Rule permits the use or disclosure of PHI for research purposes only with a valid authorization from each patient whose PHI will be involved. Only when certain criteria are satisfied can the CPHS grant a waiver of authorization or for a signed authorization form. A waiver of authorization is necessary for recruitment procedures when patient information is used to identify and contact potentially eligible research subjects. A single form may combine the requirements for both consent and an authorization. The CPHS template for a consent form contains this combination and is available on the CPHS website at [www.dartmouth.edu/~cphs](http://www.dartmouth.edu/~cphs).

*Check all that apply:*

[ ]  This study does not involve PHI.

[ ]  A single form combining an authorization with the consent form and based on the CPHS template is included with this application.

[ ]  A separate authorization form is included with this application.

[ ]  I am requesting a waiver of authorization for only the recruitment procedure. Please respond to CPHS Study Plan **Attachment H.**

[ ]  I am requesting a waiver of *signed* *and dated* authorization. Please respond to **CPHS Study Plan Attachment I.**

X I am requesting a waiver of authorization for the use or disclosure of PHI in this entire study. Please respond to **CPHS Study Plan Attachment H.**

**13. Conflict of Interest Review**

*Dartmouth College, Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital, and the Hitchcock Foundation have adopted a policy on Conflict of Interest that applies to each study reviewed by the CPHS. Copies of the policy are available on the CPHS web site at <http://www.dartmouth.edu/~cphs/policies/>.*

***Instructions:*** *To assist institutional review of the proposed research for conflicts of interest, please respond to the questions below as applicable to this study. Definitions of terms are available at the end of this section.*

**Regarding only this proposed research study,** does any investigator or other individual among the research staff, including certain family members, hold a financial or other outside interest that would reasonably appear to affect or be affected by the proposed study that:

**a.** Consists only of compensation for services or equity in a publicly held entity worth less than $5000 when combined in the prior 12 months or anticipated during the next 12 months?

X No or not applicable. *Please answer the next question.*

[ ]  Yes. *Please add an appropriate disclosure to the "Funding" section of the consent form for this study.*

**b.** Consists of i) compensation for services or equity in publicly held company worth $5000 or more when combined in the prior 12 months or anticipated during the next 12 months, ***or*** ii) any equity in a privately held entity, iii) intellectual property rights, iv) another outside interest, which may present a conflict? The latter interests listed here are limited to those held or received over the prior 12 months and those anticipated in the next 12 months.

X No or not applicable. *Please answer the next question.*

[ ]  Yes. *Please follow the instructions below.*

**c.** Consists of reimbursed or sponsored travel from a single entity worth $5000 or more that was received over the prior 12 months and is anticipated in the next 12 months?

XX No or not applicable.

[ ]  Yes. *Please follow the instructions below.*

*If you have answered "****No****" to the three questions above, no further information or action is needed.*

*If you have answered "****Yes****" to question #13b or #13c, then* *please identify each individual holding the outside interest*

***Each individual listed above*** *should complete a CPHS Conflict of Interest Disclosure Form. The* ***CPHS Conflict of Interest Disclosure Form*** *is available on the CPHS website at the following url: <http://www.dartmouth.edu/~cphs/tosubmit/forms/>*

*Please send an electronic copy of the completed disclosure form to CPHS.Tasks@dartmouth.edu or a paper copy to the CPHS office at Hinman box #6254. These copies should be clearly identified as containing confidential information.*

**COI Definitions:**

“**Conflict of interest**” occurs when an individual's outside interests, financial or otherwise, might reasonably lead an independent observer to question whether the individual's actions or decisions in connection with a study are influenced by the outside interests.

Conflicting interests do **not** include:

* Salary from Dartmouth College, Dartmouth-Hitchcock Clinic, Mary Hitchcock Memorial Hospital, and the Hitchcock Foundation or income from consulting done on behalf of one of these entities;
* Income from seminars, lectures, teaching engagements, or service on advisory committees or review panels sponsored by:
* A federal, state, or local governmental agency,
* A U.S. institution of higher education,
* An academic teaching hospital,
* A medical center, or
* A research institute that is affiliated with a U.S. institution of higher education;
* Income from mutual funds or other retirement accounts where the holder does not directly control the investment decisions;
* Copyrights in books, primary literature, or presentations. This exclusion does not apply to income resulting from such copyrights.

“**Investigator or research staff**” means the project director or principal investigator and any other person, including a student, research support staff member, consultant, or collaborator who is responsible for the design, conduct, or reporting of research involving human subjects. For the purposes of conflict of interest review, this term includes spouses, domestic partners, and dependent children of investigators and research staff.

"**Publicly held entity**" means a company that has stock publicly traded on a stock exchange.

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**For CPHS USE ONLY:**

[ ] Approved [ ] Specific Minor Revisions Required for Approval

COMMENTS:

COMMENTS FOR LETTER:

[ ] Study participation involves no more than minimal risk.

[ ] Consent waived per 45 CFR 46.116(d)

[ ] Signed consent waived per 45 CFR 46.117(c)

[ ] Authorization waived per 45 CFR 164.512(1)(2)(ii)

[ ] Authorization altered per 45 CFR 164.512(1)(2)(ii)

[ ] Note: Future research projects utilizing this database must be submitted to CPHS for review referencing the CPHS approval number of the database.

Expedited category(s):

ADDITIONAL COMMENTS FOR LETTER:

REVIEWER'S SIGNATURE: DATE:

**DEFINITIONS OF SOME TERMS USED IN THIS FORM**

**Dartmouth Hitchcock Privacy Group (DHPG)**

Dartmouth Hitchcock Clinics

Mary Hitchcock Memorial Hospital

Geisel School of Medicine at Dartmouth

Dartmouth-Hitchcock Psychiatric Associates

**De-Identification** 45 CFR 164.514(b)(2)(i)

In order to be considered "de-identified" the health information collected does not contain the following information.

* Names
* Geographic subdivisions smaller than a state, except the initial three digits of a zip code as noted below
* All elements of dates (except year) for dates directly related to an individual
* Age, if over 89
* Telephone numbers
* Fax numbers
* E-mail addresses
* Social security numbers
* Medical record numbers
* Health plan beneficiary numbers
* Account numbers
* Certificate and license numbers
* Vehicle identification and serial numbers, including license plate numbers
* Device identifiers and serial numbers
* URLs
* Internet Protocol addresses
* Biometric identifiers, including finger and voice prints
* Full face and comparable images
* Any other unique identifier, characteristic, or code

\*The first 3 digits of a zip code can be retained if publicly available data from the Bureau of the Census indicates that the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and the initial 3 digits of a zip code of all such geographic units containing 20,000 or fewer people is changed to 000.

**Statistical de-identification** 45 CRF 164.514(b)(1)

* A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable;
* Determines that the risk of re-identification of the data, alone or in combination with other reasonably available data, is very small; and
* Documents the methods and results of the analysis to justify the determination

Signature of Statistical Reviewer: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name:

Justification of analysis:

## Re-identification 45 CFR 164.514(c)

## A covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re-identified by the covered entity, provided that:

1. Derivation. The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
2. Security. The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

**Limited Data Set** 45 CFR 164.514(e)

A limited data set permits the retention of some identifying information not found in the "de-identified" data.

**Not Allowed** **Allowed**

* Names Dates
* Addresses, except for city, town, State, and zip code Age (including 90 or over)
* Telephone and Fax Numbers Zip codes
* e-Mail addresses
* Certificate or license numbers
* Vehicle ID and serial numbers, including license plate numbers
* URLs and IP Addresses
* Full Face Photos and Comparable Images
* Social security numbers
* Medical record numbers
* Health plan beneficiary numbers
* Account numbers
* Device identifiers and serial numbers
* Urls
* IP addresses
* Biometric identifiers, including finger and voice prints
* Full face and comparable images

**Protected Health Information (PHI)**

Individually identifiable health information, which is created or received by the DHPG and is related to the past, present, or future

* Physical or mental health or condition of an individual,
* Provision of health care to an individual, or
* Payment for the provision of health care to an individual.