# PARTICIPANT INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

**TITLE:** **Prospective Observational Study of Decompression Sickness in Scuba Divers with Patent Foramen Ovale (PFO)**

**SPONSOR:** **Divers Alert Network (DAN)**

**PRINCIPAL INVESTIGATOR:**
**Douglas G. Ebersole, MD**
**Watson Clinic LLP**
**1600 Lakeland Hills Boulevard**
**Lakeland, FL 33805**
**Telephone: (863) 680-7973**

**CO-INVESTIGATORS:**
**Petar Denoble, MD, D.Sc.**
**Divers Alert Network**
**6 West Colony Place**
**Durham, NC 27705**
**Telephone: (800) 446-2671**

**John Lippmann, OAM, MAppSc**
**Divers Alert Network Asia-Pacific**
**49A Karnak Road**
**Ashburton, VIC, Australia.**
**Telephone: +61-3-9886 9166**

## INTRODUCTION

You are asked to volunteer for an observational study to describe risk and benefits of trans-catheter PFO closure in scuba divers. You qualify for this study because you have a known PFO diagnosis or have had a previous closure of PFO within five years and are a certified scuba diver with medical clearance for diving, you are being considered for this trial. This document tells you about the study. This study is being sponsored by the Divers Alert Network (DAN). One hundred fifty (150) individuals will be asked to participate.

## PURPOSE OF THE STUDY

The purpose of the study is to understand the risks and benefits in divers who undergo PFO closure and continue diving. The risk/benefit estimation will be based on occurrence of adverse events due to the closure procedure and post-closure reduction in number of decompression sickness (DCS) episodes compared to pre-closure incidence.

BACKGROUND

Decompression sickness in divers occurs due to the free gas (bubbles) forming in the body during or after decompression from dive. Bubbles may cause injury in the site of origin or in other body tissues if they enter the arterial circulation. Most bubbles are washed out from the site of creation into venous circulation and filtered out by lungs. In divers with patent foramen ovale (PFO) some bubbles may pass to the arterial system and cause symptoms of DCS. The DCS risk in divers with PFO may be three to four times greater risk than in divers without PFO. The relative risk for DCS in divers with PFO increases with size of the patency and with the severity of exposure. Some divers with PFO who suffer several episodes of DCS elect to undergo trans-catheter PFO closure in order to reduce the risk of DCS while continuing diving. Some divers with diagnosed PFO continue diving regardless. Data on the risk/benefit of PFO closure in divers are not available. The purpose of this study is to establish the risk/benefit of PFO closure in divers.

HOW THE STUDY WORKS

The trial will enroll 150 qualified participants with annual follow-up over 5 years. You must be 18 years of age or older, a certified diver with medical clearance for diving, undergone trans-catheter PFO closure in past five years or diagnosed PFO.

Prior to participation you will be fully oriented to the study and if you decide to participate, you will sign Informed Consent. We will ask you to complete a diving history questionnaire and provide medical documentation for the diagnosis of PFO and PFO closure. If you qualify for the study, you will record all your future dives and provide your logs periodically for the study. If your usual physician feels that follow-up imaging of your PFO or closure device is indicated, you will provide the results of those studies to the Principal Investigator and Co-Investigators of this study. There is no inherent risk associated with participation in the study.

You will dive according to your own schedule, but during your participation in the study you will maintain a log of all your dives, make available all electronic records from your dive computer and or closed-circuit apparatus for research, and report how you feel after each dive. You are responsible for maintenance of your dive equipment and for its proper function. It is your responsibility to follow safety procedures deemed necessary for a specific dive circumstances.

PERMISSION TO OBTAIN A PHOTOGRAPH FOR REPORTING RESULTS AT PRESENTATIONS

Photographs are taken to demonstrate protocols used in research studies. You will be asked if you agree to be photographed before any are taken. If taken, such photographs might be presented at meetings describing the research, in which case a bar will be placed in the photograph over the area of your eyes to make the photograph less identifiable. You will not be identified nor will your individual results be discussed in such cases.

Please read the sentence below and "initial" next to your choice. You may participate in the study, without allowing your photograph to be taken.

_____ Yes, I agree to be photographed.

_____ No, I do not agree to be photographed.

WHAT ARE THE RISKS OF THE STUDY?
In order to decide whether you wish to be in this study, you will need to be aware of the risks that could happen to you if you decide to join.

There are no physical risks associated with this study. There is, however, the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this can not be guaranteed. If your usual physician conducts a follow-up imaging test as part of the standard of care for follow-up for PFO closure, there is no risk of physical harm from the ultrasound methods used to evaluate the state of your PFO closure.

WHAT ABOUT RESEARCH RELATED INJURIES?
This is an observational study and the research team is not present to provide any medical coverage during your dive. It is your responsibility to plan for any emergency and provide for first aid and medical services, as you would do when not participating in the study. Twenty-four hour emergency telephone line operated by Divers Alert Network is available for assistance in organization of medical evacuation to an appropriate medical facility if needed. Divers Alert Network will notify the Principal Investigator in the event of an emergency. However, there is no commitment by Lakeland Regional Medical Center, Divers Alert Network, or the participating physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

BENEFITS TO YOU
There are no benefits to you for participating in the study.

However, your participation will help us to develop a risk/benefit estimation of adverse events encountered in divers with PFO closure, which may help other divers in the future to make informed decisions.

WILL MY INFORMATION BE KEPT CONFIDENTIAL/AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION
All study records/photographs, if applicable, that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records/photographs, if applicable, disclosed outside of this study. For records/photographs, if applicable, disclosed outside of this study, you will be assigned a unique code number. The key to the code will be kept in a locked file in the Watson Clinic Center for Research, Inc.

Your records/photographs, if applicable, may be reviewed in order to meet federal or state regulations. Reviewers may include:

- Representatives from the Divers Alert Network.

- Watson Clinic Center for Research, Inc. staff.
- The Institutional Review Board of Lakeland Regional Medical Center.

If any of these groups review your research records, they may also be required to review your medical records/photographs, if applicable. Watson Clinic Center for Research, Inc. will not disclose your study records/photographs, if applicable, to other parties unless disclosure is required by law. Once Watson Clinic Center for Research, Inc. discloses information to an outside reviewer for audit purposes, this information will no longer be protected by federal law.

The study results will be retained in your research record for at least six years after the study is completed. At that time all identifying PHI research data will be destroyed. Your name will not be used in journal articles or at meetings when the results of this study are reported.

WHAT ABOUT COMPENSATION?
You will receive no compensation for participation in the study. You are responsible for all your expenses during participation in the study and in case of an injury.

The sponsor, Divers Alert Network, will fund the Watson Clinic Center for Research staff to obtain consent, collect and compile the data.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal. All data that have already been collected for study purposes will be sent to the study sponsor.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Lakeland Regional Medical Center. If you do decide to withdraw, we ask that you contact Douglas Ebersole, MD in writing and let him know in writing that you are withdrawing from the study. His mailing address is: Watson Clinic LLP, 1600 Lakeland Hills Blvd., Lakeland, Florida 33805 USA.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have complaints, concerns or suggestions about the research, contact Douglas Ebersole, MD at 863-680-7973 during regular business hours and at 863-687-1322 after hours and on weekends and holidays. You may also contact Petar Denoble, MD, D.Sc. at (800) 446-2671 during regular business hours, after hours, and on weekends and holidays.

For questions about your rights as a research participant, please contact the Institutional Review Board of Lakeland Regional Medical Center at 863-687-1053.

STATEMENT OF CONSENT

The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have voluntarily agreed to participate in this study. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions related to the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a copy of this consent form.

By signing this form, I am not giving up any of my legal rights or releasing the sponsor, the Principal Investigator and Co-Investigators, the institution, or the research site or its agents from liability for negligence.

_____

Name of Subject *(printed)*

_____ _____

Signature of Subject Date

(mst:PFO.icf-2.doc)

**APPROVED**
LRMC - Institutional Review Board
DATE APPROVED: 6-15-17
DATE EXPIRED: 6-14-18