



CONSENT TO PARTICIPATE IN RESEARCH STUDY

DRACO - Diver Return After COVID-19 - A longitudinal assessment

IRB #026-20-20 (expiry: 2021-08-05)

CONCISE SUMMARY

This study aims to provide answers to divers, dive businesses, and medical professionals regarding returning to diving following COVID-19 diagnosis and the possible long-term effects COVID-19 can have on divers.

Participation in this study will include periodical online surveys regarding your COVID-19 infection, recovery, and experience after returning to diving following recovery from the disease.

There are no direct benefits or physical risks associated with participation in this study and you can withdraw at any time.

If you are interested in learning more about the study, please continue to read below.

INTRODUCTION

You have the opportunity to participate in a long-term research study about COVID-19 infection and return to diving. The study is being entirely sponsored by DAN.

PURPOSE OF THE STUDY

DAN aims to collect information from up to 1,000 adult divers with confirmed or suspected COVID-19 infection, document recovery time and severity of the acute phase of their infection, and document diving practices and medical issues/health problems possibly encountered while diving after recovery from the disease.

BACKGROUND

COVID-19 is an infection caused by the novel coronavirus SARS-CoV-2 which has evolved to become a worldwide pandemic affecting all aspects of life. Travel and non-essential activities have been curtailed or stopped in an effort to contain the spread of the virus. The absence of a vaccine or effective medications at the time this study was initiated, has made the entire population vulnerable to infection. Significant affects have been seen in multiple organ systems and questions have arisen that imply that COVID-19 infection is unique and requires special consideration, possibly even disqualification from diving.

Case reports of significant medical long-term effects that include permanent lung injury, heart or neurological issues have been identified for further investigation. These problems are of great importance in any determination for future fitness to dive considerations. Current guidance for returning to dive is based on prior experience with viral pneumonias which often include similar features. This guidance is based on full recovery, a rehabilitation period to achieve previous baseline exercise tolerance and a formal evaluation by a physician with the assistance of diving medical expertise if required.

HOW THE STUDY WORKS

You qualify for this study, if you have/had a confirmed or suspected COVID-19 infection. If you decide to participate, you will receive a series of up to nine online surveys over the course of the next 5 years at various time points with regards to dates, symptoms, and practices during your infection, recovery, and

return to diving. This initial survey should not take longer than 15-20 minutes, and each follow-up survey no longer than 5-10 minutes to complete.

BENEFITS TO YOU

There are no direct benefits to you participating in the study. However, the results of this study will assist physicians in creating reliable guidelines for divers who have contracted COVID-19 infection and plan to return to diving.

WITHDRAWALS

You may withdraw from this study at any time for any reason without penalty. The investigators also have the right to stop your participation at any time without explanation. After the study has been closed and your identifying information has been removed from the data for final analysis, it will not be possible to identify and remove your data from the study anymore.

CONFIDENTIALITY

Federal privacy regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, address, telephone number, or any other direct personal identifier in study records disclosed outside of DAN. Please note, that communication via e-mail is not considered completely secure and confidential, so complete confidentiality cannot be guaranteed if you share medical information with DAN via e-mail.

Study records that identify you will be kept confidential as required by law. For records disclosed outside of DAN, you will be assigned a unique code number. The key to the code will be kept on a secure server at DAN until the study is completed and final analyses have been conducted.

The study results will be retained for 5 years or until the study is completed, whichever is longer. Once all data is collected, information identifying you will be removed from the study results. Your name or other identifying information will not be used in journal articles or at meetings when the results of this study are reported. All data will be destroyed upon final analyses.

YOUR RIGHTS, RISK, AND COMPENSATION

It is necessary that you read and understand several general principles that apply to everyone who takes part in this study:

1. Taking part in this study is entirely voluntary. 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. Your decision not to participate or to withdraw from the study will not involve any penalty. If you do decide to withdraw, we ask that you contact us in writing and declare that you are withdrawing from the study. At that time, we will ask your permission to continue using all of your information that have already been collected as part of the study prior to your withdrawal. You may withdraw your authorization for us to use your data that have already been collected (other than data needed to keep track of your withdrawal).

2. Although there is a minimal risk of loss of confidentiality, DAN will abide by all Federal privacy regulations that provide safeguards for privacy and secured and authorized access to data. Research records

are maintained according to confidentiality requirements, but authorized reviewers such as representatives from the OHRP (Office of Human Research Protection) and/or DAN IRB may examine your records. Thus, complete confidentiality cannot be guaranteed.

3. There will be no charge to you for taking part in this study. You will not receive any monetary compensation for study participation.

QUESTIONS

Should you have any specific questions regarding this research, you are urged to contact Dr. James Chimiak in writing covidstudy@DAN.org.

Information concerning the rights of subjects in research can be obtained from the DAN Institutional Review Board at irb@DAN.org.

You can always contact the DAN medical helpline (+1-919-684-2948) to speak with a medic or physician about any aspect of your COVID infection with respect to return to diving.

(Please keep this study information in your files. An online consent process including this information is part of the initial survey.)