REQUEST FOR BROAD CONSENT FOR FURTHER USE OF COLLECTED DATA

DO YOU WANT TO PARTICIPATE IN OTHER RESEARCH PROJECTS RELATED TO CARDIAC ARREST?

This is an additional request for patients that have consented to participate in the research project referred to as the RescueDoppler study.

Throughout the RescueDoppler study, information will be collected that may be of great utility for several future studies involving cardiac arrest and the applications of RescueDoppler. The main purpose of these studies is to enhance knowledge about cardiac arrest to provide better treatment for patients experiencing it. Therefore, consent is requested for the further use of data without direct identifying information about you for future research projects related to cardiac arrest.

The responsible parties for these future studies will be one or more of the institutions that participated in the RescueDoppler study.

We encourage you to read this information carefully. You may take the time you need to consider it. The study physician can answer any questions you may have.

WHAT DOES PARTICIPATION IN THIS STUDY ENTAIL FOR YOU?

The information we have collected and recorded about you in connection with the RescueDoppler study, which we wish to share with other research projects, includes the data we gathered about pulse and blood circulation from the ultrasound examination with RescueDoppler. Additionally, we wish to share information from the defibrillator used by healthcare personnel, recorded data from treatments performed in connection with resuscitation, as well as the following data from your medical records: age, gender, past illnesses, medications, likely cause of your cardiac arrest, cardiopulmonary resuscitation outcome, and a report from healthcare personnel about the cardiac arrest you experienced.

If you consent to us sharing information about you with other research projects, data (without direct identifying information) may be shared with and used by other research projects related to cardiac arrest in the future without contacting you.

Your participation ends when you have decided whether to consent to the inclusion of your de-identified data in further research or not.

If the research project shows that the RescueDoppler device may be useful, the results of the study may contribute to supporting the safety and efficacy of future CE marking for similar devices. Beyond this, there will be no commercial exploitation of you or your health information.

POTENTIAL BENEFITS AND DRAWBACKS

Further use of collected data about you will not subject you to any risks, disadvantages, or discomfort and will not affect your treatment now or in the future.

PARTICIPATION AND THE OPPORTUNITY TO WITHDRAW YOUR CONSENT

Participation is voluntary. If you wish to share your information with other research projects, please sign the consent form on the last page. You may withdraw your consent for further use of data at any time and without providing any reason. There will not be any negative consequences for you or your treatment if you do not wish to share your data with other research projects. This is only a voluntary addition to participation in the RescueDoppler study.

If you agree to share information with other research projects, according to the European Union's General Data Protection Regulation (GDPR), you have the right to access the information recorded about you. This information will be provided within 30 days. You also have the right to object to and correct any inaccuracies in the information we have obtained. Additionally, you have the right to access information about the security measures in place for handling your information. If you withdraw from the study, no further information will be collected. Information already collected will not be deleted and may be used in further research within this study. You can file a complaint about the handling of your information with the Data Protection Authority and the institution's Data Protection Officer.

If you later wish to withdraw or have questions about the study, you can contact the project leader Charlotte Ingul, by phone: +47 95 80 58 86 or email: charlotte.b.ingul@ntnu.no.

WHAT HAPPENS TO YOUR INFORMATION?

The information recorded about you shall only be used as described under the purpose of the study and as described in this information sheet.

All information will be processed without names and social security numbers or any other directly identifying details. A code links you to your information through a name list. This means that the information is de-identified. The list that can connect your name to the code will only be kept at the hospital you are admitted to, and only study personnel for the RescueDoppler study at the hospital will have access to this list. Other institutions for which your data might be shared with will not have access to this list.

Representatives from the sponsor, the Norwegian Medicines Agency, and regulatory authorities both domestically and internationally may be provided with study information and granted access to relevant parts of your medical record. The purpose is to verify that the study information aligns with corresponding details in your medical record. Anyone granted access to information about you is bound by confidentiality.

The information collected about you may be utilized for up to 10 years, until the end of 2035. For documentation purposes, data will be retained for a minimum of 10 years after the completion of the various studies and then anonymized. Your information will be stored in NTNU's NICE database. Only studies related to cardiac arrest at the following institutions may use data without direct identifiers in their studies: Cimon Medical AS, which developed RescueDoppler, NTNU, responsible for the RescueDoppler research project, or one of the following hospitals participating in the RescueDoppler study: St. Olav's Hospital, Akershus University Hospital, Oslo University Hospital Ullevål, Oslo University Hospital Rikshospitalet, Stavanger University Hospital, Nordland Hospital, or Aarhus University Hospital (Denmark). It is noted that the laws of the country where the information and/or material is

stored will apply, and the Regional Committee for Medical and Health Research Ethics does not have the authority to assess the subsequent use of information and/or material stored abroad.

Publication of results is an essential part of the research process and is done on aggregated data, making it highly unlikely for you to be identifiable. We are obliged to inform you that we cannot exclude the possibility. Any extensions in use and storage time can only occur with approval from the Regional Committee for Medical and Health Research Ethics and other relevant authorities.

Publishing of results is a necessary part of the research process and is done on aggregated data, making it highly unlikely that you will be identifiable. We must inform you that we cannot rule out the possibility of it occurring.

Any extensions in the use and storage period can only occur after approval from the Regional Committee for Medical and Health Research Ethics and other relevant authorities.

CONTACT INFORMATON

NTNU will be responsible for privacy in the studies. We process information about you for purposes related to scientific research and because the research projects have been assessed to be in the public interest.

The processing of personal data is based on the General Data Protection Regulation (GDPR) Article 6(1)(e), cf. Art. 6(3)(b), cf. Art. 9(2)(j), cf. Sections 8 and 9 of the Personal Data Act. Consent is obtained in accordance with the Health Research Act § 13.

If you have any questions, experience unwanted events, or wish to withdraw from participation, you can contact Charlotte Ingul at mobile number +47 95 80 58 86 or email charlotte.b.ingul@ntnu.no.

If you have questions about privacy in the study, you can contact the institution's data protection officer at …….

FINANCE

You will not have any expenses associated with the further use of the collected data in future research projects, and you will not receive any financial compensation for participation.

INSURANCE

You are insured according to the Patient Injury Compensation Act.

INFORMATION ABOUT THE STUDY OUTCOME

A description of the study will be accessible on www.clinicaltrials.gov. Upon completion of the study, you can contact the project leader to obtain information about the outcome. Approximately one year after the trial has concluded, a summary of the results will be available on www.clinicaltrials.gov. A summary of the study findings may also be presented at a conference or published in a journal.

I GIVE BROAD CONSENT TO FURTHER USE OF MY PERSONAL INFORMATION AS DESCRIBED

With this, I also confirm that I have received information about the further use of de-identified data in future studies related to cardiac arrest, that any questions have been answered, and that I have received a copy of the information sheet.

Place and date	Participant's signature
	Participant's name in capital letters

CONFIRMATION THAT THE PARTICIPANT IN THE STUDY HAS BEEN INFORMED

I hereby confirm that information about the study has been provided.

Place and date	Signature
Role in study	