Version 1.0
August 18, 2022

Explanatory Document on Life Sciences and Medical Research Involving Human Subjects

This is an instructional document to help you decide for yourself whether or not to participate in this study.

Development of an echocardiography-guided AI to assist in echocardiography acquisition

Request for cooperation

The researcher assigned to you in this study

(Name) _____

[Contact].
Name of Institution:
Hamamatsu University School of Medicine Center for Next Generation Creative Medicine and Engineering Information Education 053-435-2431

If you have any questions or concerns about this study,

please do not hesitate to ask the researchers (principal investigators and research assistants).

Introduction

1.1 About this Explanatory Document

This information document describes the life science/medical research in which you are being asked to participate. It is provided to supplement the researcher's explanation and to assist you in understanding the study when you (or your family member) decide whether or not to participate in this study.

If you are willing to participate, please sign the attached "Consent Form" and hand it to the researcher.

1.2 For life science and medical research involving human subjects

Life science and medical research involving human subjects is conducted to improve people's health or recovery from illness or quality of life by investigating the causes and characteristics of diseases and establishing new methods of disease prevention, diagnosis, and treatment. There, diseases that develop over a long period of time or are seen only rarely may be targeted, and the effectiveness of treatments already in place and their subsequent course may be observed.

In addition, research may incorporate genetic analysis techniques with the aim of more accurately identifying the causes of disease, in order to establish effective treatment and prevention methods.

Research in the life sciences and medical sciences involving human subjects is conducted with your cooperation in order to obtain reliable information that can be used to improve people's health and provide medical care(Hereafter referred to as "research").

All researchers involved in this study are subject to the "Declaration of Helsinki" and the "Human Subjects

This research is being conducted in compliance with the "Ethical

Guidelines for Life Science and Medical Research〃 and other relevant regulations.

1.3 About the Ethics Review Committee

In conducting research, the Ethics Review Committee examines the scientific and ethical appropriateness of the purposes and methods of this research.

This study has also already undergone its review by the following Ethics Review Committee and the head of the research institution has approved the conduct of the study. The committee will also periodically review this research to ensure that it is conducted in accordance with the research protocol during the continuation of this research.

Committee name: Hamamatsu University School of
Medicine Life Sciences and Medical Sciences
Research Ethics Committee Establisher: President,
Hamamatsu University School of Medicine
Location: 1-20-1 Handayama, Higashi-ku,
Hamamatsu-shi, Shizuoka 431-3192 Contact
Phone: +81-53-435-2680

2. Research Implementation Structure

Please refer to the ″Appendix: List of Research Implementation Structure″ at the end of this explanatory document.

3. Purpose and Significance of this Study

Ultrasound systems are used as clinically important diagnostic imaging equipment because they can be used at the bedside and disaster sites without radiation exposure. In addition, because the equipment is relatively inexpensive, it is also expected to be used in remote medical care. Unlike CT and MRI, however, the cross-sectional imaging is performed by manipulating the probe, and it is reported that it takes up to six hours to acquire the basic skills. This is the amount of time required for one-on-one practice between

instructor and practitioner, and it is impossible to provide this amount of time to an entire group of medical students.

Ultrasound systems are capable of dynamic observation and are particularly powerful in the observation of the cardiovascular system. In echocardiography, the heart is observed from various directions, and it is necessary to judge whether the acquired cross-sectional images are appropriate for diagnosis (appropriate cross-section). When practicing with an instructor, the instructor can evaluate the appropriateness of the cross-sectional image on the spot, and if it is not appropiate (inappropriate cross-section), the instructor can provide feedback on how to operate the probe, etc. However, feedback cannot be obtained in independent study.

In this study, we used a diagnostic ultrasound system to investigate the effects of ultrasound on the health of healthy volunteers.

We will build an artificial intelligence that takes and stores echocardiograms and determines whether the cross-sectional images are appropriate.

4. Research Methods

4.1 Research Methods

Your echocardiogram is taken using a diagnostic ultrasound machine. While lying on your back or side on the bed, the ultrasound probe is pressed against your chest to take a cross-sectional moving image. The imaging takes about 10 minutes.

The collected videos are used to build or evaluate artificial intelligence.

4.2 The duration of this study and the number of expected participants

[Research period for this study.

From the date of approval for implementation by the head of the research institution (A.D.) Until October 2025

Number of research subjects who will participate in the study] 100

Duration of your participation in the study] 1 day

4.3 Provision of Samples and Information to Other Research Institutions and Contractors

Samples, information, and research results obtained from this research will not be provided to other research institutions or contractors.

5. Participation in this study

5.1 Reasons for requesting participation in this study

This study will be conducted on healthy adult volunteers. Your health status and medical history will determine whether you are willing to participate. Please note that even if you agree to participate in this study, during the course of the experiment, the researcher may need to determine whether your participation in the study is medically necessary.

We may decide that it is not academically appropriate for you to participate in the study. If this is the case, you may not participate in the study.

Please note that the following is not possible.

5.2 Conditions of Participation

If you are interested in joining us, please contact us.

The conditions for participation in this study are as follows

Healthy people between the ages of 18 and 40

For those who are not able to attend

If any of the following apply to you, you are not eligible to participate

Those who have ever had a medical checkup that indicated a heart abnormality.

Pregnant or possibly pregnant

5.3 Discontinuation of Research

After you have participated in the study, the principal investigator will discontinue the study if any of the following apply to you

1) If you wish to withdraw from participation in the study
2) If the results of the tests or other results do not meet the criteria for participation in the study
3) If the principal investigator determines that it is difficult to continue the research due to the occurrence of adverse events, etc.
4) Other cases in which the principal investigator determines that the research should be discontinued

6. Burden and anticipated benefits and risks associated with this study

6.1 Burden to be incurred

If you participate in this study, you will undergo an echocardiographic examination for the study. The echocardiographic examination will take about 10 minutes. The entire procedure, including its preparation, will

take about 30 minutes.

6.2 Anticipated Risks

Any undesirable symptoms, signs of illness, or changes in laboratory values that occur when using an ultrasound device are referred to as ″adverse events″ and are related to the device or the procedure

is not required. Therefore, ″not related to the equipment″ is included. Among adverse events, those judged to be ″caused by the device″ or ″suspected to be caused by the device″ and those in which the device did not perform as expected or did not show efficacy due to malfunction of the device are called ″malfunctions. The diagnostic ultrasound equipment used in this study is already in use in Japan, and there have been no reported cases of definite adverse effects at the level of diagnostic ultrasound for the past several decades.

If you experience any physical changes during your participation, please do not hesitate to contact the researcher. We will provide the best possible treatment or therapy. Even after the completion of the study, we will take the same responsibility.

6.3 Projected Profits

This study is open to healthy individuals and there will be no benefit from their participation in the study. It is hoped that the study will contribute to the education of future medical students, initial residents, and clinical laboratory technicians.

7. Consent to Participate in Research

Please listen to the researcher's explanation of the study, fully understand the study, and decide of your own free will whether or not you wish to participate in this study. If you do not participate, you will not be disadvantaged in any way.

Even after you have agreed to participate in the research, we will promptly provide you with any new information that may affect your willingness to continue the research. In such cases, we will confirm your willingness to continue the research in writing. If you would like to

know any other information related to the research, please do not hesitate to ask the researcher.

8. Withdrawal of Consent to Participate in Research

If you wish to withdraw from participation in the research (withdraw your consent), please fill out the consent withdrawal form and hand it to the consultation desk. In this case, there will be no prejudice.

No profit will be received.

At that point, you can rest assured that we will consult with our staff and provide the treatment that we believe is best for you.

Please note that it is possible to withdraw consent without a written withdrawal of consent, so please contact the consultation desk if you are unable to do so.

9. Disclosure of Information Regarding Research

The results of this study will be published in medical journals and conferences, but your privacy will be protected.

An outline of this study will also be registered in jRCT, a public database, before the study begins.

10. Access to materials related to this research

You may request or inspect materials about the design and methods of this study upon your request. If you wish to do so, please inform the researcher. The information will be presented to the extent that it does not interfere with the protection of the personal information of other research subjects or the intellectual property rights of the researcher or others.

11. Protection of your personal information

11.1 Protection of Personal Information

Information obtained from you, such as the results of a study, may be published in medical journals or conferences without identifying who it is from.

If you withdraw from participation in the study, your information and the study results will be immediately discarded. Please note, however, that if the results have already been reported in a paper or other media,

we will not be able to discard them.

11.2 Disclosure of Personal Information

Personal information that can identify you, such as the results of an echocardiogram, will be used by the Center for Information Technology and Education for the Next Generation of Creative Medicine and Engineering at Hamamatsu University School of Medicine to provide you with information that can be used to identify specific individuals.

If you wish to have your personal information processed into a state in which it is no longer necessary to provide your original name, etc., you may do so. If you wish to have your personally identifiable information disclosed, please inform the researcher and we will disclose your personally identifiable information to you in accordance with the disclosure procedures at the research institution. If someone other than yourself wishes to have your personally identifiable information disclosed, we will not, in principle, do so. No fee will be charged for disclosure.

12. Handling of Samples and Information

Samples and information obtained from you will be kept under non-personally identifiable symbols and will be stored appropriately for a period of time determined by the University. The computer on which the personal information is stored will be kept separate from other computers and will be kept under strict control. When we dispose of information obtained from you, the information will be shredded or destroyed electronically.

13. Funding, conflicts of interest, and intellectual property rights related to this research

About the fund]

This research will be conducted using the Hamamatsu University School of Medicine Intramural Research Project (HUSM Grant-in-Aid) (Graduate Student Research Support Program).

Conflicts of Interest

In planning, conducting, and reporting this study, we have no interest in any company or other entity that would affect the results of the study or the interpretation of the results. The conduct of the study will not

prejudice your rights or interests.

Intellectual Property Rights

The results of this research may generate intellectual property such as patent rights. In that case, the intellectual property rights will belong to Hamamatsu University School of Medicine.

14. Explanation of results obtained from the study, etc.

If you wish, we would be happy to share your results from this study with you.

Please let us know if you wish to do so in the following section. Please note that if, in the course of conducting this study, we incidentally find any abnormal findings that we believe require treatment, we will inform you of the results and suggest that you visit the appropriate department.

15. Consultation Service

If you have any questions or concerns about this study, please contact the researcher or person listed on the cover page at any time.

16. Secondary Use of Samples and Information

In the future, as medical science develops, new research may be conducted on diseases related to the research topic. If there is a possibility that the samples and information obtained from you may be used for other research, we will prepare a new research plan, which will be reviewed by the Ethical Review Committee and approved by the head of the research institution, and will be conducted properly according to the rules.

17. Fees and honoraria for participation in this study

About the cost]

There is no cost to you for participating in this study.

About gratuities.

No honorarium for participation will be paid in this study.

18. Other Treatment Options

Healthy individuals are invited to participate in this study and will not receive any other treatment.

19. What to do after the study is completed

Healthy individuals are invited to participate in this study, and there are no other treatment options available.

20. Access to Samples and Information

In order to ensure the proper implementation of this research, your research records may be viewed by the physicians who are collaborating with you, the Ethics Review Committee and other related parties, and those who confirm that the research is being conducted properly (e.g., Ministry of Health, Labor and Welfare officials, Ethics Review Committee personnel for this research, etc.). In such cases, your personal information will be protected as these parties are obliged to maintain confidentiality.

Appendix: List of research implementation systems

Name of Research Institution
[Principal] Investigator Takeji Saito

Hamamatsu University

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letter of intent

Dear Principal Investigator

research task Name:. Development of an echocardiography guide AI to assist in learning echocardiography

I have received a full explanation of my participation in this study in writing. I understand the content of the research and agree to participate in this research of my own volition. I also receive a copy of the written explanation and this consent form.

(Date of Agreement) (A.D.) Year Month Date

Name of research subject
(self-signed)_____

(Date of agreement confirmation) (Western calendar year) Year Date Date

Name of person confirming
(Principal Investigator and Co-Principal Investigator) (Self-signed)_____

*The researcher should keep the original consent form.

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withdrawal of consent

Dear Principal Investigator

research task Name:. Development of an echocardiography guide AI to assist in echocardiography acquisition

I have given my consent to participate in the above-mentioned research, but I hereby withdraw my consent of my own volition. I also receive a copy of this withdrawal of consent form.

(Western calendar year) Year Month Date

Name of research subject
(self-signed)_____

We confirm that the above research subject has withdrawn from participation in the study.

(Western calendar year) Year Month Date

Name of confirming party

(Principal Investigator and Assignments)

(Person)

(Self-signed)_____

The researcher should keep the original consent withdrawal form.

*The researcher should give this to the research subject at the time consent is obtained.