Example of Informed Consent Form

Sub-study title:

Principal study title: *[if applicable insert study in which cough monitoring is embedded]*

Principal investigator: *[insert Principal investigator name & title]*

Funding: *[insert study funding source]*

Ethical review ID: *[insert information regarding the IRB approval body and reference]*

This informed consent form has two parts;

- PART 1 - Information sheet to share information of the project with the participants
- PART 2 -Certificate of consent to collected signatures of participants agreeing to participate

A full copy of this informed consent is to be given to the participant after signature

PART 1 – Information sheet

Introduction

You are invited to participate in the study titled XXX.

The design of the study including the risks and benefits are explained below. Please ask the staff member who provided this consent form to explain any words or information that you do not clearly understand. Before you agree to take part, it is important for you to understand why the research is being done and what it will involve if you agree to take part. We are requesting you to read this information sheet and ask any questions you may have before agreeing to participate in the study. Participation in this research study is completely voluntary, if you do not participate, you will still be offered medical care as required by your medical condition.

This is a collaborative study involving *[insert information regarding the investigators]*

Study objectives / Purpose of the study

[insert study objectives]

In this study, the Hyfe CoughMonitor Suite will be used to monitor your cough in a way that does not compromise your privacy. Then the pattern of your cough will be analyzed using artificial intelligence computer techniques. This is called digital cough monitoring. It is a new field of research that seeks to improve clinical diagnosis and management of respiratory diseases.

Study procedures

[insert study procedures]

The Hyfe CoughMonitor Suite is designed to detect and record cough frequency using a dedicated smartwatch. The app does not "listen", it merely uses the smartwatch microphone to monitor sound levels. The app detects and processes 0.5 second explosive sounds and uses an on-device algorithm to extract mathematical features of the sound for determining if the sound is or is not a cough. This app does not compromise your privacy because it does not record, store or sync any audio. In addition, only the timestamps of the cough sounds are sent to Hyfe's Cloud and shared with the research study team via a web-based password-protected portal. The use of the app will not lead to additional medical interventions or different medical care. In order to use the App, you will be asked to agree to the app Terms of Use and Privacy Policy.

Risks & benefits

Risks: The risks associated with participation in the study are minimal. The Hyfe CoughMonitor watch is a consumer-grade device and may cause skin irritation or allergic reactions. There is also a possibility the watch may overheat, becoming warm to touch and causing discomfort or injury. If you experience discomfort, irritation, or any adverse effects, remove the devices and contact the research team immediately.

Benefits: There are no anticipated benefits associated with participation in this study. If you decide to participate in this study, you will have access to the best available medical services. Your participation in this study will contribute to science and the development of tools for better medical care and disease surveillance in the future.

Confidentiality

All your data will be securely stored at Hyfe, Inc and only delegated members of the Research Team will have access to maintain confidentiality.

We are committed to protecting the privacy of your personal information and guarantee total confidentiality. Within this study, you will be provided with a unique study ID and unique Hyfe CoughMonitor user identifier if you provide consent to participate in this study. Only the investigator will have access to both identification systems and be able to link cough data with your patient identification collected within the study. Your personal information may be viewed by research staff involved in this study during data collection, however, this will not be shared outside the limits of this study. In any publications or presentations, your identity will not be revealed, and it will remain strictly confidential. Your medical records may be viewed by members of the ethical committee who have authorized this study.

Data storage

The timestamps of the cough data, de-linked from your personal and clinical data will be stored in Hyfe's Cloud. You may request removal of your data by sending a request to privacy@hyfe.ai . Your data will never be made public or shared with third parties.

Secondary usage

Your pseudo-anonymized cough data may be used by Hyfe for studies aimed at improving the performance and expanding the boundaries of the cough-detection algorithm. Given that your personal information and your cough count data will not be linked, it will not be possible to inform you of the results of said studies.

Costs and compensation

[insert information regarding costs and compensation if applicable]

Voluntary participation and possibility to withdraw

You do not have to take part in this study if you do not wish to. Refusing to participate in this study will in no way affect your access to the medical services.

You have the right not to sign this form. If you do not sign this form, you cannot take part in this study. This is because we need your written permission to use your information.

You have the right to leave the study at any time. If you leave, we will not use your information. If you would like to leave the study, please tell a member of the study staff. You do not need to explain why you want to leave.

You must also know that you could be excluded from the study if the promoter and/or researchers consider it to be adequate, either for your own safety, to prevent any adverse consequence deriving from your participation, or because they consider you are not complying with the established procedures. In any case, you will always receive a proper explanation of what caused your withdrawal from the study.

Sharing the results

[insert information regarding sharing results]

To be certain of their accuracy, digital cough monitoring and artificial intelligence tools need to be tested using data from different patients in different places in the world. This is why the cough data and medical data collected in this study will be shared with other researchers in the world. If this happens, [research institution] will establish a data sharing agreement with external researchers to ensure that your personal and medical information will be protected. We will never share your personal identification and no one except the investigator will know that you participated in this study.

Ethical approval

Before it begins, this research was approved by *[insert details on IRB which approved the study]*. This committee agreed that the research is important and made sure that all participants' safety and rights are protected.

Who to Contact if I have questions or concerns?

If you have any questions about this study or procedures, any questions about your rights as a research participant, any complaints, now or in the future, you can call *[insert local patient safety protection office or contact name and phone number].*

Part 2 - Certificate of Consent

I have read the foregoing information, or it has been read to me. I was able to ask questions about it and any questions that I have asked has been answered to my satisfaction. I consent voluntarily to take part as a participant in this study.

☐ I agree to take part in the research
☐ I do not agree to my anonymized data being used in optimization studies led by Hyfe
☐ I do not wish to take part in the research, and I have not signed the assent below

_____ _____ _____
Participant Name Participant Signature Date

_____
(initialed by child/minor if applicable)

If illiterate
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumbprint as well.

I have witnessed the accurate reading of the consent form to the participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

_____ _____ _____
Witness Name Witness Signature Date

AND

Thumb print of participant

Statement by the researcher/person taking consent
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:
[enter here key points of what was explained to the patient]

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

_____	_____	_____
Researcher Name	Researcher Signature	Date