**Summary of informed Consent Form**

*Guidance: For studies funded or supported by a US federal funding agency (e.g., NIH, DHHS, etc.) include this summary of information as required by the US federal regulations. This summary should contain only the information that is most likely to assist a prospective participant in understanding the reason for or against participating in the research, as outlined below. Some items included in the summary section may be repeated in the subsequent consent sections if necessary to ensure the subsequent sections make sense or if the information is core to informed consent (e.g., risk of death), otherwise duplication should be avoided.*

**Title** {Enter the full title of study, exactly as it appears on the Protocol. Add protocol number if applicable.}

You are being asked to take part in a research study. Below is a summary of information about the study. Full information about the study is provided in the {other sections of this consent form/main consent form}. The research team will also talk to you about the study and you can ask any questions you may have.

**Participation in research is voluntary**. It is your choice whether you take part in this research study.

**Study Purpose**

The purpose of this study is {provide a brief description of the primary reason why the research is being conducted, no more than 2-3 sentences}.

**Duration**

It is expected that study participation will last {provide expected duration}*.* Participants will be followed for {define period of time}.

**Study Procedures**

*Guidance: Briefly describe the intervention(s), highlight key study procedures and, if applicable, outline procedures that may be lengthy/burdensome to participants.*

This study is looking at {describe interventional group(s)}. Participants will also {briefly describe key procedures e.g., study visits every X weeks during which the researchers will do some tests}.

[If applicable:]

You will be asked to do {describe lengthy or burdensome procedures} which may take {specify time} extra time.

**Risks**

*Guidance: Describe the most important risks. Consider those most probable and/or with the highest magnitude of harm. Key information should not include the full list of risks.*

Participation in this study may involve risks to you. These risks are described in detail in the informed consent form.

*Guidance: Include the risks participants are most likely to experience. This should not include the entire ‘very likely’ or ‘likely’ category from the main consent. Researchers must review the risks and identify those that are most likely.*

The risks you are most likely to experience are:

* {Specify risk in lay language with expected frequency}

*Guidance: If applicable, include any serious risks. For the purposes of this summary, serious risks are considered those that may result in death, hospitalization, or are permanent.*

The most serious risks are:

* {Specify risk in lay language with expected frequency}

**Benefits**

*Guidance: Insert direct benefit, or state if there is no direct benefit. If direct benefit to participant is unknown but there is a greater benefit to society, include:*

We do not know if you will receive medical benefit from participation but researchers hope that this study will fulfil its purpose and benefit others in future.

**Alternatives**

You do not have to participate in this study to receive medical care.

[If applicable:]

You may have other medical options – you should discuss this with your health care provider.