**DATA MANAGEMENT PLAN**

**Version: 2.0**

**Date: 3.5.22**

Does Artificial Intelligence Improve Polyp Detection at Colonoscopy?

**Site:** Waitakere Hospital, 55-75 Lincoln Road, Henderson, Auckland 0610

Dr Cameron Schauer

# Organisational Data Governance Oversight

This study has gained locality assessment approval at Waitemata District Health Board (WDHB).

# Consent for Data Collection and Use

*Consenting:* All participants will be informed of, and provide consent for, the collection and use of their data for the purposes of this study.

# Data Collection

No additional data is collected for the purposes of this study than would ordinarily be collected and recorded during the standard procedure.

Data will be collected primarily by the Investigator or designated study staff. All study personnel involved in data collection will be trained in GCP, study protocol.

# Privacy and confidentiality

Participants’ privacy and confidentiality will be respected through the protection of their data as outlined in this plan. The Investigator will comply with legal and regulatory requirements regarding the privacy and confidentiality of participants’ data.

Participants have the right to access and correct personal data held by the site.

## Breach of Privacy / Confidentiality

A breach of privacy means unauthorised or accidental access to, or disclosure, alteration, loss, or destruction of a participant’s information.

In the event participant privacy and confidentiality is breached during the study, the following steps will be taken:

* Action will be taken to reduce the risk of harm following the breach. Where possible, the recipient will be contacted and asked to destroy or return any electronic the disclosed material.
* The participant will be informed of the breach as soon as practicable (unless the participant is under the age of 16 and notification would be contrary to his/her interests; or notification would be likely to prejudice the health of the participant (after consultation with the participant’s health practitioner, where practicable), and provided with support as required.
* The approving HDEC will be informed.
* For notifiable privacy breaches of privacy under the Privacy Act 2020, the New Zealand Privacy Commissioner will be notified in accordance with that Act.

# Forms of Data

## Identifiable Data

Initially, study data will be collected in identifiable form (with NHI).

Source documents refer to identifiable data collected for the purposes of this study. For the purposes of this data management plan, identifiable data includes the participant’s existing medical / clinical records.

Source documents will be held at the site in identifiable form.

## De-identified Data

De-identified data will be formed when sent off-site for statistical analysis. All data generated by these parties will be in de-identified form. No attempt will be made to re-identify participants.

## Anonymous / Anonymised Data

De-identified data may be anonymised prior to being made available for future research. Anonymised data will be irreversibly stripped of the unique participant code and any other identifiers.

Participants will be informed that anonymous / anonymised data is unable to be accessed, corrected, or withdrawn; and that return of individual results will not be possible.

# Access to and Use of Data

Collected data will be used to answer the research questions and fulfil the study requirements described in the study protocol.

## Identifiable Data

For study purposes, identifiable data may be accessed by the following groups:

The Investigator and designated study staff, to fulfil protocol requirements only.

## De-identified Data

De-identified data may be accessed and used by the following groups:

The Investigator and suitably trained and experienced study staff, to conduct the study.

## [Anonymous/Anonymised] Data

Anonymised data may be accessed and used by the groups described in Section 8.2.

Anonymised data may also be made available to other researchers, as described in Section 8.5.

## Sending of Data Overseas

*N/A*

## Future Use of Data

De-identified [and/or anonymised] data will be used by the Sponsor for future medical or scientific research as specified below:

* unspecified purposes which are directly related to the study question(s)
* other unspecified research

## Commercial Use of Data

Study data analysis may lead to discoveries and inventions or development of a commercial product or producers. Study investigators AND Participants will not receive any financial benefits or compensation from, nor have any rights to, any developments, inventions, or other discoveries arising from this analysis.

## Data Linking

The study will link data obtained from the procedures performed (as recorded at the time of colonoscopy). It will be entered into a spreadsheet.

## Databank / Registry

Collected data will be stored on a centralised spreadsheet on the WDHB Hospital Intranet on the “G-Drive.” This is password protected within the hospital firewall system. Computers can also only be accessed by hospital staff. Once all data has been reviewed and finalised, it will be de-identified (i.e. NHI removed) when stored.

1. **storage and Destruction of Data**
   1. **Identifiable Data and Source Documents**

During the study, study-specific source documents will be maintained as above.

Post-study, study-specific source documents will be archived on the Hospital G drive (as above).

Data will be stored for 10 years. This is so if data is required to be reviewed (i.e. for a meta-analysis or otherwise), it can be accessed. All data for this purpose will be de-identified.

**De-identified Data**

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into electronic proformas. The data platform complies with international and national regulatory requirements for electronic data capture systems.

Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

# Consultation

Consultation regarding data management will be undertaken with the following relevant communities/stakeholders [describe].

## Māori Data Sovereignty

During the study, data may be collected from participants identifying as Maori.

Personal and health information is a tāonga (treasure) and will be treated accordingly.

Formal Māori consultation for this study has been completed as part of the Locality Approval Process

Return of Results

Screening and safety results will be provided to participants on request.

Participants have the right to request a lay summary of study results if/when results are published.

## Incidental Findings

In the event that a study assessment returns a result of potential clinical significance, the participant will be informed. The participant’s usual doctor and / or an appropriate specialist will be notified, and follow-up will be arranged.

## Results Arising from Future Research

### Data

No future unspecified research is planned for data collected in this study.

# Withdrawal of Data

Participants may withdraw consent for the collection of data at any time, without providing a reason.

Should a participant withdraw consent, no further data will be collected by study staff.

Data collected prior to the participant’s withdrawal will not continue to be used and analysed.