DATA MANAGEMENT PLAN

Version: 1

Date: 14th July 2022

A Research Evaluation of the Let's Play Programme

Co-sponsors: Laura Fergusson Trust and Joyce Fisher Endowment Fund Trust

Site: University of Canterbury

Co-ordinating Investigator: A/Prof Laurie McLay

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1 INTRODUCTION

This Data Management Guide outlines how data will be handled during the study titled "An evaluation of the Let's Play Programme" and after its completion.

2 STUDY STRUCTURE

TABLE 1. STUDY STRUCTURE

Sponsor	Laura Fergusson Trust Ascot Office Park Building B, Level 1 93 Ascot Ave Remuera Auckland 1051
Lead Site (New Zealand)	Faculty of Health University of Canterbury Private bag 4800 Christchurch 8041
Co-ordinating Investigator	A/Prof Laurie McLay Faculty of Health University of Canterbury Private bag 4800 Christchurch 8041

3 ORGANISATIONAL DATA GOVERNANCE OVERSIGHT

The following institutional data policies apply for the Study:

The University of Canterbury Human Ethics Committee guidelines note:

It is the responsibility of the researcher to securely store their research data for the appropriate length of time as stated in their ethics application. The researcher must then ensure that any data is securely destroyed after this period of time has elapsed.

Should it become necessary to transfer hard-copy or video data to electronic format, this should be done in a secure manner and any hard-copy or video data should then be securely destroyed. The electronic format data should then be held for the appropriate length of time as stated in the ethics application and then securely destroyed.

4 CONSENT FOR DATA COLLECTION AND USE

All participants will be informed of, and provide consent for, the collection and use of their data for the purposes of this research and for any mandatory secondary uses. Additional written consent will be sought for future use of the data in studies related to autism or the specific treatments investigated in this research.

5 DATA COLLECTION

Data will be collected from the following sources:

- Direct communication with the participant.
- Study assessments, including standardised measures, questionnaires, interviews (in-person, via phone or Zoom), and video observations (of children interacting with their parents).

Data will be collected primarily by the Investigator or designated study staff (e.g., Dr Ashley Hinten). All study personnel involved in data collection will be trained in the study protocol and collection requirements.

Data generating assessments/procedures (e.g., statistical analyses, observation coding) will be performed by those who are suitably qualified by education, training, and experience.

Collection of data will be limited to that necessary for the specified purposes of the study, or for additional purposes that the participant has explicitly consented to.

6 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.

6.1 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 of the disclosed material.
- The participant will be informed of the breach as soon as possible and provided with support as required (unless the participant is under the age of 16 and notification would be contrary to his/her interests, in which case their caregiver will be notified and provided with support).

- A site quality review will be conducted to ascertain factors contributing to the breach, and any corrective action required to prevent future breaches.
- 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.

7 FORMS OF DATA

7.1 IDENTIFIABLE DATA

Some study data will be collected in an identifiable form and held at the site in an identifiable form.

Identifiable data in this study includes video observations of participant (parent-child) interactions

7.2 DE-IDENTIFIED DATA

De-identified data in this study includes but is not limited to:

- Screening and post-participation interview notes
- Questionnaires/standardised assessments
- Parental logs of intervention practices & additional professional intervention received
- Video coding data

De-identified data will carry the participant's unique study code. The Investigator will retain a log linking the participant code with identifiers. This log will not be made available to anybody who is not a member of the research team. All data sent to the Sponsors will be de-identified.

7.3 ANONYMOUS / ANONYMISED DATA

Not applicable. Future research will utilise de-identified data.

8 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. Sponsor reports may also include analysed data as evidence of study outcomes. Data may also be used for related future research if participants consented to such use. De-identified individual participant data that underlie published results may be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for individual participant data meta-analysis immediately following publication and ending 10 years after publication.

8.1 Identifiable Data

Identifiable data may be accessed by the following groups:

- The Investigator and designated study staff, to fulfil protocol requirements.
- The Health and Disability Ethics Committee, for legal and regulatory purposes.
- Health, regulatory, or government agencies, for legal and regulatory purposes.
- The participant's GP or appropriate specialist, to inform them of study participation, and in the event of an incidental finding of potential clinical significance.

Rarely, it may be necessary for the Investigator to share identifiable data with people or groups not listed above – for example, in the event of a serious threat to public health or safety, or to the life or health of the participant or another person; or if the data is required for certain legal situations.

8.2 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.
- The study co-sponsors may access aggregated and analysed data.
- The Health and Disability Ethics Committee, to comply with legal and regulatory duties.
- Health, regulatory, or government authorities, to comply with legal and regulatory duties.

De-identified data may be included in published study results including, but not limited to, peer-reviewed publications, clinical trial registry websites, scientific meetings, and regulatory / marketing submissions.

De-identified data may be included in clinical trial registries and data banks.

8.3 [Anonymous/Anonymised] Data

Not applicable.

8.4 Sending of Data Overseas

De-identified data may be sent overseas to investigators for individual participant data meta-analysis.

Participants will be informed of the potential risks and cultural issues associated with sending [and storing] data overseas, and that there may be no New Zealand representation on overseas governance committees.

8.5 Future Use of Data

De-identified data will be used for future medical or scientific research as specified below:

- unspecified purposes which are directly related to the study question(s).
- unspecified purposes which are related to the item and/or condition under study.
- unspecified medical or scientific purposes which are not related to the study questions.

If participants provide optional additional consent, de-identified data will be made available to other researchers on request for future research as specified above and / or will be added to data from other sources to form larger datasets.

In all cases, the co-ordinating investigator must be satisfied that appropriate Data Management Plans are in place and that ethical approval for use has been obtained in accordance with local laws and regulations.

8.6 Commercial Use of Data

Study data analysis may lead to discoveries and inventions or development of a commercial product or producers. The rights to these will belong to the coordinating investigator. 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.

8.7 Data Linking

Not applicable.

8.8 Databank / Registry

Not applicable.

9 Storage and Destruction of Data

9.1 Identifiable Data and Source Documents

During the study, study-specific source documents will be maintained in password-protected, cloud-based storage on a secure University server. Paper documents will be stored in locked filing cabinets at the Autism NZ offices and the University of Canterbury. These notes will be scanned, uploaded into the secure, password-protected, cloud-storage, and then destroyed. Participants' coded information will be in a secure electronic database which is also password-protected.

Collection and storage of each study-specific document:

1. *Social Attention and Communication Surveillance, Revised or Preschool versions (SACS-R or PR)*. If completed on paper, the administrator will store it in a locked filing cabinet until they are able to scan and upload it into the cloud storage. The paper copy will be destroyed. If completed electronically, the administrator will upload it into the cloud storage as soon as possible.

2. *Paper questionnaires*. The paper questionnaires (listed below) will be mailed to participants. If participants choose to complete them by themselves, they will post the completed questionnaires back to the research team. If they request a researcher helps them complete the questionnaires in-person, the researcher will take the questionnaires away with them. In either case, these will be stored in a locked filing cabinet until the research team is able to scan and upload them into cloud storage. The paper copies will be destroyed.

a. Parenting Stress Index – Fourth Edition, Short Form (PSI-4-SF).
b. Depression, Anxiety, and Stress Scale-21 (DASS-21).
c. Parenting Sense of Competence Scale (PSOC).
d. Social Responsiveness Scale, Second Edition Preschool Form (SRS-2).
e. Pediatric Quality of Life Inventory Generic Core Scales (PedsQL 4.0).
f. Strengths and Difficulties Questionnaire (SDQ).
g. Treatment Acceptability Rating Form-Revised (TARF-R).
h. Let's Play technique use and support service access weekly logs.

3. *Parent-child interaction videos*. If participants choose to film the play video themselves, the research team will email them a file request through Dropbox. After they upload their video to the private and secure Dropbox folder, an automatic notification is sent to the research team by Dropbox. A member of the research team will log on, transfer the video to the cloud storage, and permanently delete the video off of Dropbox as soon as possible. If participants request a researcher helps them film their video in-person, the video will be either a) filmed on the participant's phone/camera and stored using the steps above, or b) filmed on the researcher's phone/camera, uploaded into the storage cloud as soon as possible, and permanently deleted off of the researcher's phone/camera.

4. *Researcher notes*. Any notes taken by the researchers (examples listed below) will either a) be written electronically and directly stored in the storage cloud, or b) be written manually on paper and stored in a locked filing cabinet until the researcher can scan and upload it into the cloud storage. Any paper copies will be destroyed.
    a. Parent-child interaction video notes/coding.
    b. Systematic Analysis of Language Transcripts, Version 20, New Zealand/Australia (SALT-NZAU) notes/output.
    c. Parent interview transcripts and notes.
    d. Interobserver agreement observation notes.

Post-study, study-specific source documents will be archived on a password-protected computer. The maintenance and archiving of source documents are described in University of Canterbury's Research Conduct Policy.

In line with *the National Ethical Standards for Health and Disability Research and Quality Improvement,* source documents will be retained for 10 years after the youngest participant has turned 16, and then they will be destroyed by secure deletion as per University of Canterbury processes.

9.2 De-identified Data

Identifiable data will be converted to a de-identified form at the study site, at which point it is entered into a password-protected study database kept on a secure University server. Data entry will be limited to designated study staff trained and experienced in transcribing data for this purpose.

De-identified data will carry a participant code. The Investigator will retain a log linking participant code with identifiers. This log will not be made available to anybody who is not a member of the research team.

The de-identified database will remain on the University of Canterbury's servers for 10 years after the youngest participant has turned 16.

De-identified data will be retained for 10 years after the youngest participant has turned 16.

10 CONSULTATION

Consultation regarding data management will be undertaken with the following relevant communities/stakeholders:

Māori - ongoing consultations with our Kaiārahi Rangahau at UC (see Section 10.1) will be undertaken in regard to data sovereignty.

For all other participants, data management best practices will be employed and this will be described to participants/stakeholders in the project information sheet.

10.1 MĀORI DATA SOVEREIGNTY

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

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 for New Zealand study site(s). Any recommendations for additional measures to improve Māori rights and interests in relation to data will be acted upon.

The principles of whakapāpā, whanaungatanga, tino rangatiratanga, kotahitanga, manaakitanga, and kaitiakitanga are applied in the following ways: consultation was undertaken and will continue to do so with our Kaiārahi Rangahau at UC.

11 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.

11.1 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 may be notified, and follow-up will be arranged, as specified in the project safety plan.

11.2 RESULTS ARISING FROM FUTURE RESEARCH

11.2.1 Data

Results will not be made available to participants of any future research conducted using data collected in this study. Participants are informed of this in the PISCF.

11.2.2 Databank / Registry

Not applicable.

12 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, unless participants withdraw after data analysis has commenced.

APPENDIX

Not applicable.