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# **Parent/ Caregiver Information Sheet: ENGAGE**

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

## **Main investigators**: Dr Alison Leversha, Ms Anne Denham, Dr Dione Healey, Mr Russell Burt.

Your child is invited to take part in a study looking at how effective the games played in the ENGAGE program are at improving your child’s behaviour, memory, ability to manage emotions and co-operative game play. The ENGAGE games were used in the Manaiakalani schools in 2020 with overall improvements in behaviour. This year we want to adapt the games to help language, motor skills, and have Te Ao Māori and Pacific adaptations. We will then compare how good this adaption is (LEAP), with that of the original games in ENGAGE. Whether or not your child takes part is your choice. If you do not want them to take part, you do not have to give a reason. If you are happy for them to take part now, but change your mind later, you can pull out of the study at any time.

This Information Sheet will help you decide if you are happy for your child to take part. It sets out why we are doing the study, what your child’s participation would involve, what the benefits and risks might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether your child will participate in this study. You may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers before you decide. Feel free to do this.

If you agree for your child to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Information Sheet and the Consent Form to keep. This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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| **What is the purpose of the study?** |

Self-regulation is a set of skills that control our thoughts, emotions, and behaviours. Lack of self-regulation is related to behavioural, emotional, and learning difficulties in childhood, which can lead to difficulty getting and keeping jobs, and health difficulties in adulthood. Children learn new skills through games, and play-based games have been shown to improve self-regulation.

All schools in Manaiakalani will be using the games as part of usual classroom teaching: approximately half will use LEAP and half ENGAGE. The aim of this study is to see which one is better at helping children improve their thoughts, emotions, and behaviour. The best program will be used in all schools at the end of the study.

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| **How is the study designed?** |

All schools in the Manaiakalani Communities of Learning in Tamaki are participating. All children in year 1 and 2 in these schools will play the games for 30 minutes each school day. These children are eligible to take part in this study. We will collect information on children’s behaviour using two measures: Strengths and Difficulties Questionnaire (SDQ) and Behavioural Assessment System for children (BASC-3). They will be completed by teachers and you, before and after using the games for a term and then again one term later to make sure things are still going well. These are the same forms used in 2020 when the schools started using ENGAGE. The school will record information about your child’s participation, attendance, and school progress just like they normally do. This will be used in combination with the questionnaires to decide whether the games in LEAP have a better effect on behaviour and school progress than the games used in ENGAGE.

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| **what will my participation in the study involve?** |

This consent is for permission for your child’s teacher to complete the questionnaires, and for this information to be passed on to the research team so we know whether the games are working or not. You will be asked to complete the questionnaires too. These normally take about 5 minutes and can be either done by paper or on a computer. If you need some help with the questions, please ask the classroom teacher. The questionnaires will be completed at the beginning of the year, at the end of term 2 and again at the end of term 3. We will be holding school/whānau hui where you can learn about self-regulation and how the games work. We encourage you to play the games at home with your child too, but you do not have to.

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| **what are the possible risks of this study?** |

We do not think there are any risks to your child as they are normal games that children play.

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| **What are the possible benefits of this study?** |

We expect that taking part in this study will improve in your child’s self-regulation and behaviour. The information we gather will help create games that can be used by a wider range of children. If you have concerns about your child’s behaviour, then talk to your child’s teacher and they will be able to link you with someone who can talk with you about possible reasons for the behaviour concern and suggest some solutions.

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| **will any costs be reimbursed?** |

Taking part will not cost you anything.

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| **what if something goes wrong?** |

If your child were injured in this study, you would be eligible **to apply** for compensation from ACC just as they would be if they were injured in an accident at school or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your child’s claim is accepted, you will receive funding to assist in your recovery.

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| **what will happen to my CHILD’S information?** |

Identifiable Information

Identifiable information is any data that could identify your child (e.g., name, date of birth, or address). Only researchers will have access to your child’s identifiable information.

De-identified (Coded) Information

To make sure your child’s personal information is kept confidential, information that identifies them individually will not be included in any report. Instead, they will be identified by a code. The main investigator will keep a list linking the code with your child’s name, so that your child can be identified by coded data if needed. The results of the study may be published or presented, but no children’s names will be used.

Security and Storage of Your Information.

Your child’s information is held at Starship Hospital during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years after your child turns 16, then destroyed. Your child’s coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your child’s privacy, absolute confidentiality of your information cannot be guaranteed.

Rights to Access Your Information.

You have the right to request access to your child’s information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information, ask Dr Alison Leversha.

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| **what happens if i change my mind?** |

You may withdraw your consent for the collection and use of your child’s information at any time, by informing your researcher.

If you withdraw your consent, your child will continue as participate in the games as part of usual classroom teaching, but you and teacher will not need to fill in any further questionnaires. Information collected up until your child’s withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

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| **Can i find out the results of the study?** |

The results from the completed study will be published in a scientific journal. The information will be presented in such a way that neither you nor your child can be identified in any way.

A summary of the results will be shared at school/whānau hui.

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| **Who has approved the study?** |

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study.

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| **Who do i contact for more information or if i have concerns?** |

If you have any questions, concerns or complaints about the study, you can contact:

 Dr Alison Leversha, primary investigator

 Telephone number: 021629047

 Email: alisonl@adhb.govt.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Dr Helen Wihongi, Director of Māori Health Research, Auckland and Waitemata DHBs

021 0203 1167

helen.wihongi@waitematadhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study:

 Phone: 0800 4 ETHIC

 Email: hdecs@health.govt.nz

# **Parent/Caregiver Consent form: ENGAGE**

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

**Please tick to indicate you consent to the following**

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| I have read and understand the Participant Information Sheet.  | Yes o |
| I have been given sufficient time to consider whether my child will participate in this study. | Yes o |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes o |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes o |
| I understand that my child will be participating in the games as part of usual classroom teaching.  | Yes o |
| I consent to the teacher completing the behaviour questionnaires and for school progress data to be passed on to the researchers. This is voluntary (my choice). I can withdraw permission for this information being collected and passed on at any time without affecting my child’s schooling. | Yes o |
| I agree to completing the questionnaires about my child’s behaviour. | Yes o |
| I consent to the research staff collecting and processing my child’s information. | Yes o |
| If I decide to withdraw my child from the study, I agree that the information collected a up to the point when I withdrew them may continue to be processed. | Yes o |
| I understand that my child’s participation in this study is confidential and that no material, which could identify them personally, will be used in any reports on this study. | Yes o |
| I understand the compensation provisions in case of injury during the study. | Yes o |
| I know who to contact if I have any questions about the study in general. | Yes o |
| I understand my responsibilities as a parent/caregiver of a study participant. | Yes o |
| I wish to receive a summary of the results from the study. | Yes o |

**Declaration by participant:**

I hereby consent to my child taking part in this study.

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| Child’s name: |
| Parent’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the parent/caregiver and have answered questions about it.

I believe that the parent/caregiver understands the study and has given informed consent for their child to participate.

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| Researcher’s name: |
| Signature: | Date: |

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# **Parent/ Caregiver Information Sheet: LEAP**

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

## **Main investigators**: Dr Alison Leversha, Ms Anne Denham, Dr Dione Healey, Mr Russell Burt.

Your child is invited to take part in a study looking at how effective the games played in the **ENGAGE** program are at improving your child’s behaviour, memory, ability to manage emotions and co-operative game play. The **ENGAGE** games were used in the Manaiakalani schools in 2020 with overall improvements in behaviour. This year we want to adapt the games to help language, motor skills, and have Te Ao Māori and Pacific adaptations. We will then compare how good this adaption is (**LEAP**), with that of the original games in **ENGAGE**. Whether or not your child takes part is your choice. If you do not want them to take part, you do not have to give a reason. If you are happy for them to take part now, but change your mind later, you can pull out of the study at any time.

This Information Sheet will help you decide if you are happy for your child to take part. It sets out why we are doing the study, what your child’s participation would involve, what the benefits and risks might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether your child will participate in this study. You may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers before you decide. Feel free to do this.

If you agree for your child to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Information Sheet and the Consent Form to keep. This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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| **What is the purpose of the study?** |

Self-regulation is a set of skills that control our thoughts, emotions, and behaviours. Lack of self-regulation is related to behavioural, emotional, and learning difficulties in childhood, which can lead to difficulty getting and keeping jobs, and health difficulties in adulthood. Children learn new skills through games, and play-based games have been shown to improve self-regulation.

All schools in Manaiakalani will be using the games as part of usual classroom teaching: approximately half will use **LEAP** and half **ENGAGE**. The aim of this study is to see which one is better at helping children improve their thoughts, emotions, and behaviour. The best program will be used in all schools at the end of the study.

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| **How is the study designed?** |

All schools in the Manaiakalani Communities of Learning in Tamaki are participating. All children in year 1 and 2 in these schools will play the games for 30 minutes each school day. These children are eligible to take part in this study. We will collect information on children’s behaviour using two measures: Strengths and Difficulties Questionnaire (SDQ) and Behavioural Assessment System for children (BASC-3). They will be completed by teachers and you, before and after using the games for a term and then again one term later to make sure things are still going well. These are the same forms used in 2020 when the schools started using **ENGAGE**. The school will record information about your child’s participation, attendance, and school progress just like they normally do. This will be used in combination with the questionnaires to decide whether the games in **LEAP** have a better effect on behaviour and school progress than the games used in **ENGAGE**. The children in the **LEAP** schools will have some additional assessments about their speech and communication, memory, and motor skills. This will occur twice: The first time will help us understand how well the children are doing with their language, memory, and motor skills. We will then know which skills are relative strengths for the children and which skills they need more help with. This will help us decide how best to modify the games and which games to use. The second time will be in term 3 to see how much effect the games had on those areas of their development. The assessments will take about an hour and will be done by speech therapists and occupational therapists: experts in child development.

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| **what will my participation in the study involve?** |

This consent is for permission for your child’s teacher to complete the questionnaires, and for this information to be passed on to the research team so we know whether the games are working or not. You will be asked to complete the questionnaires too. These normally take about 5 minutes and can be either done by paper or on a computer. If you need some help with the questions, please ask the classroom teacher. The questionnaires will be completed at the beginning of the year, at the end of term 2 and again at the end of term 3.

We are also asking permission for your child to have the additional speech and language, memory, and motor skill tests. We will discuss the findings with you and will talk with you about options if there are any areas where your child needs a bit of extra help.

We will be holding school/whānau hui where you can learn about self-regulation and how the games work. We encourage you to play the games at home with your child too, but you do not have to.

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| **what are the possible risks of this study?** |

We do not think there are any risks to your child as they are normal games that children play.

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| **What are the possible benefits of this study?** |

We expect that taking part in this study will improve in your child’s self-regulation and behaviour. The information we gather will help create games that can be used by a wider range of children. If you have concerns about your child’s behaviour, then talk to your child’s teacher and they will be able to link you with someone who can talk with you about possible reasons for the behaviour concern and suggest some solutions. We will talk with you about options if we find any areas where your child needs a bit of extra help.

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| **will any costs be reimbursed?** |

Taking part will not cost you anything.

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| **what if something goes wrong?** |

If your child were injured in this study, you would be eligible **to apply** for compensation from ACC just as they would be if they were injured in an accident at school or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your child’s claim is accepted, you will receive funding to assist in your recovery.

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| **what will happen to my CHILD’S information?** |

Identifiable Information: Identifiable information is any data that could identify your child (e.g., name, date of birth, or address). Only researchers will have access to your child’s identifiable information.

De-identified (Coded) Information: To make sure your child’s personal information is kept confidential, information that identifies them individually will not be included in any report. Instead, they will be identified by a code. The main investigator will keep a list linking the code with your child’s name, so that your child can be identified by coded data if needed. The results of the study may be published or presented, but no children’s names will be used.

Security and Storage of Your Information.; Your child’s information is held at Starship Hospital during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years after your child turns 16, then destroyed. Your child’s coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks. Although efforts will be made to protect your child’s privacy, absolute confidentiality of your information cannot be guaranteed.

Rights to Access Your Information. You have the right to request access to your child’s information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information, ask Dr Alison Leversha.

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| **what happens if i change my mind?** |

You may withdraw your consent for the collection and use of your child’s information at any time, by informing your researcher. If you withdraw your consent, your child will continue as participate in the games as part of usual classroom teaching, but you and teacher will not need to fill in any further questionnaires and they will not have any assessments. Information collected up until your child’s withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

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| **Can i find out the results of the study?** |

The results from the completed study will be published in a scientific journal. The information will be presented in such a way that neither you nor your child can be identified in any way.

A summary of the results will be shared at school/whānau hui.

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| **Who has approved the study?** |

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study.

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| **Who do i contact for more information or if i have concerns?** |

If you have any questions, concerns or complaints about the study, you can contact:

 Dr Alison Leversha, primary investigator

 Telephone number: 021629047

 Email: alisonl@adhb.govt.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Dr Helen Wihongi, Director of Māori Health Research, Auckland and Waitemata DHBs

021 0203 1167

helen.wihongi@waitematadhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study:

 Phone: 0800 4 ETHIC

 Email: hdecs@health.govt.nz

# **Parent/Caregiver Consent form: LEAP**

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

**Please tick to indicate you consent to the following**

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| I have read and understand the Participant Information Sheet.  | Yes o |
| I have been given sufficient time to consider whether my child will participate in this study. | Yes o |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes o |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes o |
| I understand that my child will be participating in the games as part of usual classroom teaching.  | Yes o |
| I consent to the teacher completing the behaviour questionnaires and for school progress data to be passed on to the researchers. This is voluntary (my choice). I can withdraw permission for this information being collected and passed on at any time without affecting my child’s schooling. | Yes o |
| I agree to completing the questionnaires about my child’s behaviour. | Yes o |
| I consent to my child having the additional speech and language, memory, and motor skills assessments. | Yes o |
| I consent to the research staff collecting and processing my child’s information. | Yes o |
| If I decide to withdraw my child from the study, I agree that the information collected a up to the point when I withdrew them may continue to be processed. | Yes o |
| I understand that my child’s participation in this study is confidential and that no material, which could identify them personally, will be used in any reports on this study. | Yes o |
| I understand the compensation provisions in case of injury during the study. | Yes o |
| I know who to contact if I have any questions about the study in general. | Yes o |
| I understand my responsibilities as a parent/caregiver of a study participant. | Yes o |
| I wish to receive a summary of the results from the study. | Yes o |

**Declaration by participant:**

I hereby consent to my child taking part in this study.

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| Child’s name: |
| Parent’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the parent/caregiver and have answered questions about it.

I believe that the parent/caregiver understands the study and has given informed consent for their child to participate.

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| Researcher’s name: |
| Signature: | Date: |

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# Teacher information sheet

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

## **Main investigators**: Dr Alison Leversha, Ms Anne Denham, Dr Dione Healey, Mr Russell Burt.

Thank you for participating in **ENGAGE**: the play-based program to improve children’s self-regulation. With your help, we are hoping to make it even better in 2021. You are invited to take part in a study to compare **ENGAGE** with an adapted program **LEAP** on self-regulation in year 1 and 2 children in the Manaiakalani Kāhui ako. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason. If you do want to take part, but change your mind later, you can pull out of the study at any time.

This Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether you will participate in this study. Before you decide you may want to talk about the study with other people, such as the school principal, family, friends, or the Welcome to School team. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Information Sheet and the Consent Form to keep. This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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| **What is the purpose of the study?** |

Self-regulation is a set of skills that control our thoughts, emotions, and behaviours. Lack of self-regulation is related to behavioural, emotional, and learning difficulties in childhood, which can lead to poverty, poor job performance, and health difficulties in adulthood. Self-regulation can be improved by training: You were involved with delivering play-based games with **ENGAGE** this year. Early findings show it does appear to improve children’s self-regulation and behaviour.

The aim of this study is to compare the effect of **ENGAGE** on self-regulation with a modified program, **LEAP**, adapted by a group of teachers, kaitiaki, a speech therapist, an occupational therapist and a neuropsychologist who is an expert in self-regulation and child development. We will collect information on changes in children’s behaviour using two measures: Strengths and Difficulties Questionnaire (SDQ) and Behavioural Assessment System for children (BASC-3). They will be completed by you and other participating teachers for each consented child at the beginning and at the end of the program (term 1, end term 2 and end term 3).

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| **How is the study designed?** |

This study is being conducted in all schools in Manaiakalani Communities of Learning in Tamaki. All year 1 and 2 children are eligible to take part in this study. You have been asked to take part in the study as you are teaching children in years one or two in one of these schools. Schools will include the play program into their current curriculum for a total of 30 minutes each day. Half the schools in the COL will implement **ENGAGE** and half will trial the modified program **LEAP**. Which school uses which program has already been decided by the principals.

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| **what will my participation in the study involve?** |

Teachers are being asked to complete 2 questionnaires for each participating child using the same questionnaires you used last year. The questionnaires will be completed immediately before the program commences and twice again later in the year. Teacher training will be provided for all schools with an approved trainer. At the end of term 2 or 3, we will also ask you what worked well for whom and your suggestions about modifications to the program.

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| **what are the possible risks of this study?** |

We do not think there are any risks related to the study.

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| **What are the possible benefits of this study?** |

We expect that taking part in this study will improve self-regulation and behaviour in school age children. The information we gather is likely to be of benefit in creating games that can be used by a wider range of children with different developmental skill sets and from different communities. We will let you know about the results. All schools will then use whichever games make the most difference.

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| **will any costs be reimbursed?** |

You will not incur any monetary costs through participation in this study, nor will you be compensated directly.

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| **what if something goes wrong?** |

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

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| **what will happen to my information?** |

As mentioned above, teacher ratings of child behaviour will be collected as will your feedback and suggested modifications. This information will be used to examine any changes in behaviour with the 2 games-based programs.

All information gathered regarding the children will be kept confidential. Should the parents/caregivers request feedback about the results of the completed questionnaires, they will receive feedback but will not have access to any confidential comments provided by you.

We are only collecting teachers’ names and classrooms with no other identifiable information. You will be allocated a unique identifier. The main investigator will keep a list linking your code with your name, so that you can be identified by your coded data if needed. You name will not be listed in any formal report the research team produces.

Security and Storage of Your Information.

Your identifiable information is held at Starship Community during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years after the youngest participating child turns 16, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask Dr Alison Leversha.

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| **what happens if i change my mind?** |

You may withdraw your consent for the collection and use of your information at any time, by informing your researcher.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

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| **Can I find out the results of the study?** |

The results from the completed study will be published in a scientific journal as well as presented at education and health conferences. The information will be presented in such a way that neither you nor any children can be identified in any way.

We will feedback preliminary results at the end of this year.

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| **Who has approved the study?** |

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study.

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| **Who do i contact for more information or if i have concerns?** |

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 Dr Alison Leversha, Primary investigator

 Phone: 021 629 047

 Email: alisonl@adhb.govt.nz

Or Anne Denham, **ENGAGE** coordinator

 Phone: 022 326 2919

 Email: anne@engageplay.co.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Dr Helen Wihongi, Director of Māori Health Research, Auckland and Waitemata DHBs

Phone: 021 0203 1167

Email: helen.wihongi@waitematadhb.govt.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

 Phone: 0800 4 ETHIC

 Email: hdecs@health.govt.nz

# Consent form: Teachers

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

**Please tick to indicate you consent to the following**

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| I have read and understand the Participant Information Sheet.  | Yes 🞏 |
| I have been given sufficient time to consider whether to participate in this study. | Yes 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 |
| I understand that I will be using either **ENGAGE** or **LEAP** as part of usual classroom pedagogy | Yes 🞏 |
| I understand that taking part in this study is voluntary. | Yes 🞏 |
| I consent to the research staff collecting and processing my information. | Yes 🞏 |
| As part of this project, I will be asked to complete questionnaires regarding children’s behaviour at 3 points in time, and to provide some preliminary feedback and suggestions re modifications to the games. | Yes 🞏 |
| If I decide to withdraw from the study, I agree that the information collected by me up to the point when I withdraw may continue to be processed. | Yes 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 |

 **Declaration by participant:**

I hereby consent to take part in this study.

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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: |
| Signature: | Date: |

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# **Workshop Participant Information Sheet**

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

## **Main investigators**: Dr Alison Leversha, Ms Anne Denham, Dr Dione Healey, Mr Russell Burt.

With your help, we are hoping to make **ENGAGE**: the play-based game program to improve children’s self-regulation, even better in 2021. You are invited to take part in 2 workshops with teachers, **ENGAGE** trainers, Kaitiaki, a speech therapist, an occupational therapist and neuropsychologist (expert on child development and self-regulation) to adapt **ENGAGE** so it has intentional language, intentional motor planning and is developmentally and culturally appropriate for the tamariki in Tamaki. This adaptation will be called **LEAP**: Language ENGAGE and Play. Whether or not you take part is your choice. If you do not want to take part, you do not have to give a reason. If you do want to take part, but change your mind later, you can pull out at any time.

This Information Sheet will help you decide if you would like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether you will participate in this study. Before you decide you may want to talk about the study with other people, such as the school principal, family, friends, or the Welcome to School team. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Information Sheet and the Consent Form to keep. This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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| **What is the purpose of the study?** |

Self-regulation is a set of skills that control our thoughts, emotions, and behaviours. Lack of self-regulation is related to behavioural, emotional, and learning difficulties in childhood, which can lead to poverty, poor job performance, and health difficulties in adulthood. Self-regulation can be improved by training: You were involved with delivering play-based games with **ENGAGE** this year. Early findings show it does appear to improve children’s self-regulation, and we want to see if we can make it more appropriate for the tamariki in Tamaki.

You are invited to adapt the ENGAGE games in 2 workshops across term 1 using your and others expertise. This adaptation, **LEAP**, will then be introduced across half the schools in the COL and the effect on self-regulation compared with that of **ENGAGE**.

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| **How is the study designed?** |

This study is being conducted in all schools in Manaiakalani Communities of Learning in Tamaki. All year 1 and 2 children are eligible to take part in this study. You have been asked to take part in the workshops as you have valuable skills to adapt the games.

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| **what will my participation in the study involve?** |

You will be required to attend two 4-hour workshops during term 1. These will be collaborative approaches to adapting the games to ensure they are set at the right initial level for Tamaki children and scaffold appropriately to facilitate language, motor planning, memory, emotional regulation, and self-regulation. We are particularly keen to ensure there are cultural adaptations and Māori and Pacific games are included so all children are engaged in these games. These adaptations will be collated into game cards for use in the participating schools. If you are a teacher, you will then likely implement these games in your class timetable and will participate in the assessments to compare outcomes for the children. There is a separate consent form for this.

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| **what are the possible risks of this study?** |

We do not think there are any risks related to the study.

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| **What are the possible benefits of this study?** |

We anticipate the workshops will be beneficial for all bringing together expertise on child development and learning from many different perspectives. The adaptations will ensure **ENGAGE** is modified for maximal effect creating games that can be used by a wider range of children with different developmental skill sets and from different communities.

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| **will any costs be reimbursed?** |

You will not incur any monetary costs through participation in this study. We have budgeted a modest koha as recognition of your time and expertise.

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| **what if something goes wrong?** |

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study will not affect your cover.

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| **what will happen to my information?** |

We are collecting participants names and roles with no other identifiable information. You will be allocated a unique identifier. The main investigator will keep a list linking your code with your name, so that you can be identified by your coded data if needed. You name will not be listed in any formal report the research team produces.

Security and Storage of Your Information.

Your identifiable information is held at Starship Community during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years after the youngest participating child turn 16, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

If you have any questions about the collection and use of information about you, you should ask Dr Alison Leversha.

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| **what happens if i change my mind?** |

You may withdraw your consent for participation in the workshops at any time, by informing your researcher. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

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| **Can I find out the results of the study?** |

The results from the completed study will be published in a scientific journal as well as presented at education and health conferences. The information will be presented in such a way that neither you nor any children can be identified in any way.

We will feedback preliminary results at the end of this year.

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| **Who has approved the study?** |

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study.

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| **Who do i contact for more information or if i have concerns?** |

If you have any questions, concerns or complaints about the study at any stage, you can contact:

 Dr Alison Leversha, Primary investigator

 Phone: 021 629 047

 Email: alisonl@adhb.govt.nz

Or Anne Denham, ENGAGE coordinator

 Phone: 022 326 2919

 Email: anne@engageplay.co.nz

If you want to talk to someone who is not involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz

Website: https://www.advocacy.org.nz/

For Maori health support please contact:

Dr Helen Wihongi, Director of Māori Health Research, Auckland and Waitemata DHBs

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# **Workshop Participant Consent form**

# **LEAP: Language, ENGAGE and Play: Building self-regulation through Play**

**Please tick to indicate you consent to the following**

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| I have been given sufficient time to consider whether to participate in this study. | Yes 🞏 |
| I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study. | Yes 🞏 |
| I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet. | Yes 🞏 |
| I understand that taking part in this study is voluntary. | Yes 🞏 |
| I consent to the research staff collecting and processing my information. | Yes 🞏 |
| As part of this project, I will attend 2 four-hour workshops to adapt the games, participate in discussion re any modifications and agree the games to be trialled.  | Yes 🞏 |
| If I decide to withdraw from the study, I agree that the information collected up to the point when I withdraw may continue to be processed. | Yes 🞏 |
| I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study. | Yes 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 |
| I wish to receive a summary of the results from the study. | Yes 🞏 |

**Declaration by participant:**

I hereby consent to take part in this study.

|  |
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| Participant’s name: |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

|  |
| --- |
| Researcher’s name: |
| Signature: | Date: |