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Exploring Consent

Perspectives from a Principal Investigator

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28th April 2021

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IDS-TILDA

Joins the Global Family of Longitudinal Studies

The Intellectual Disability Supplement to
The Irish Longitudinal Study on Ageing
(IDS-TILDA)

IDS-TILDA

Objectives

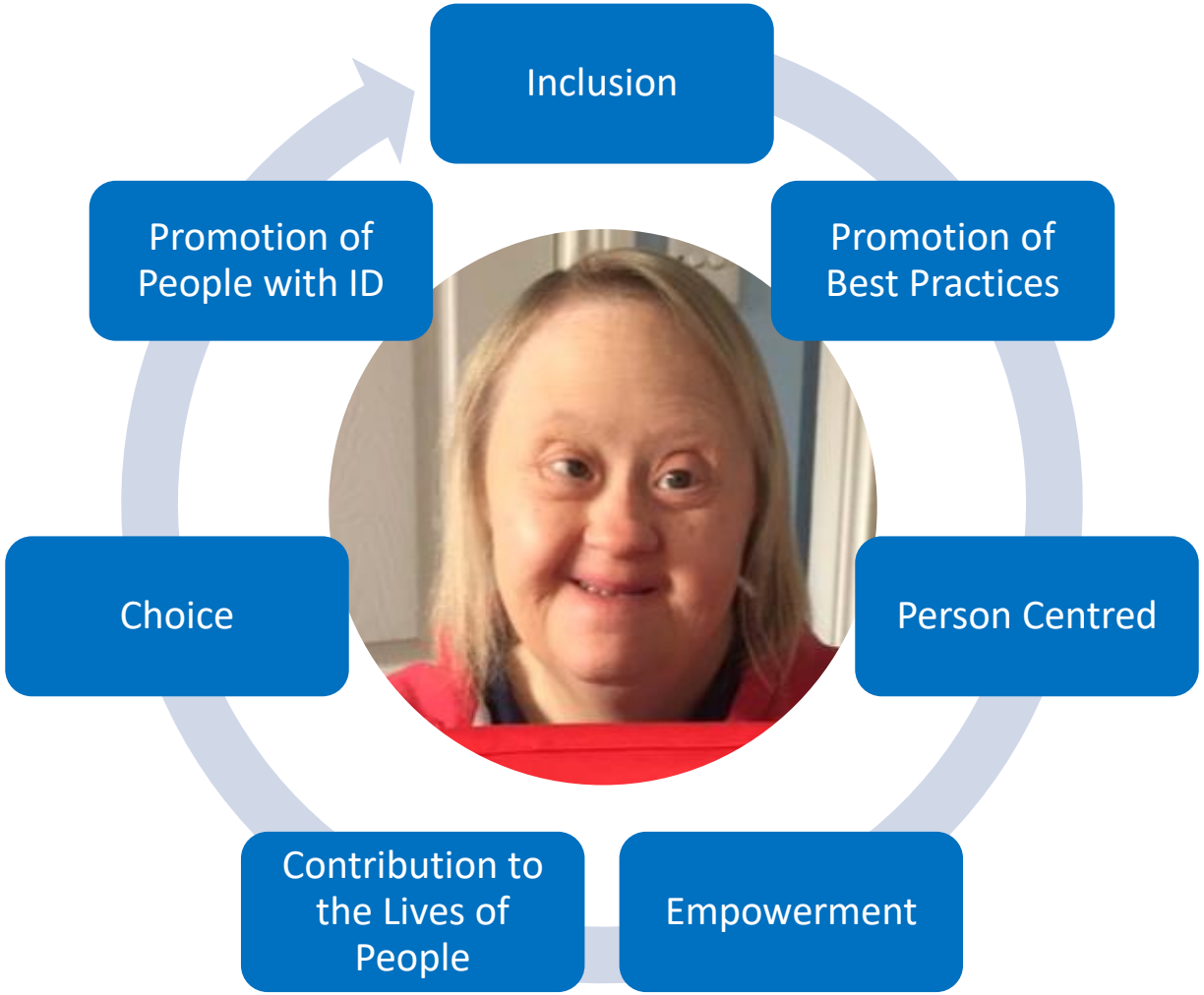
The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

- **To understand the health characteristics** of people ageing with an intellectual disability;
- **To examine the service needs and health service utilization** of people ageing with an intellectual disability;
- **To identify disparities in the health status** of adults with an intellectual disability as compared to TILDA findings for the general population; and
- **To support evidence-informed policies, practices and evaluation.**

IDS-TILDA: Values Framework

"Nothing about us, without us"

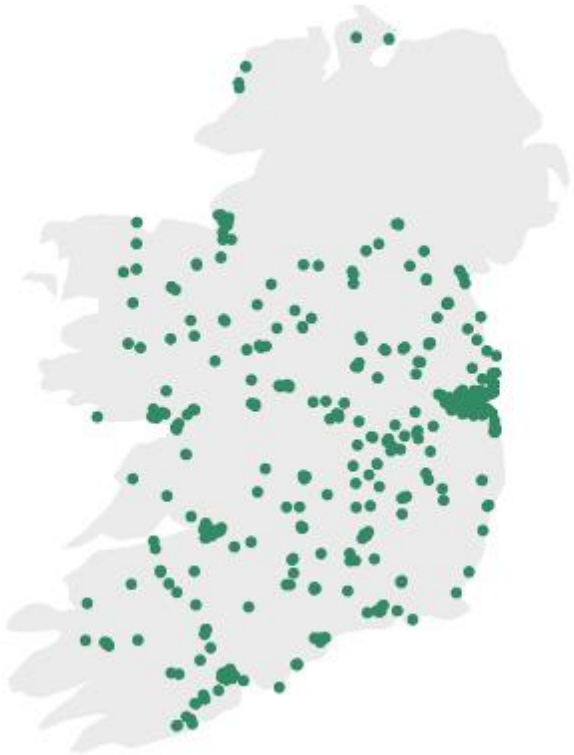
The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

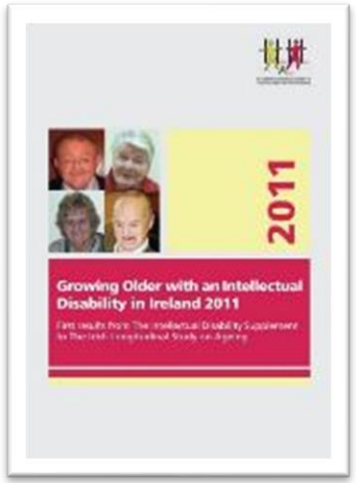


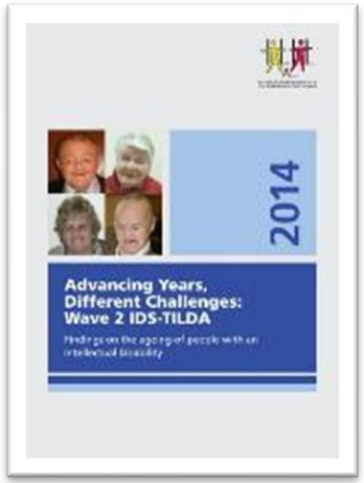
The IDS-TILDA Story: 2007 – Present

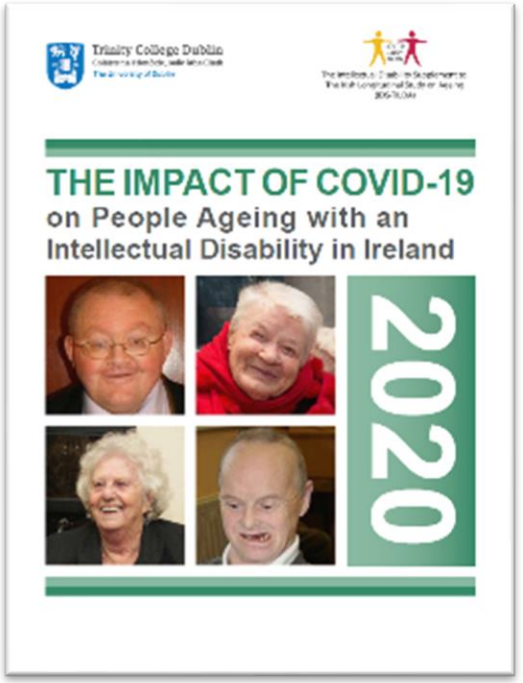
The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

First nationally-representative longitudinal study on ageing with an intellectual disability comparable to the general population









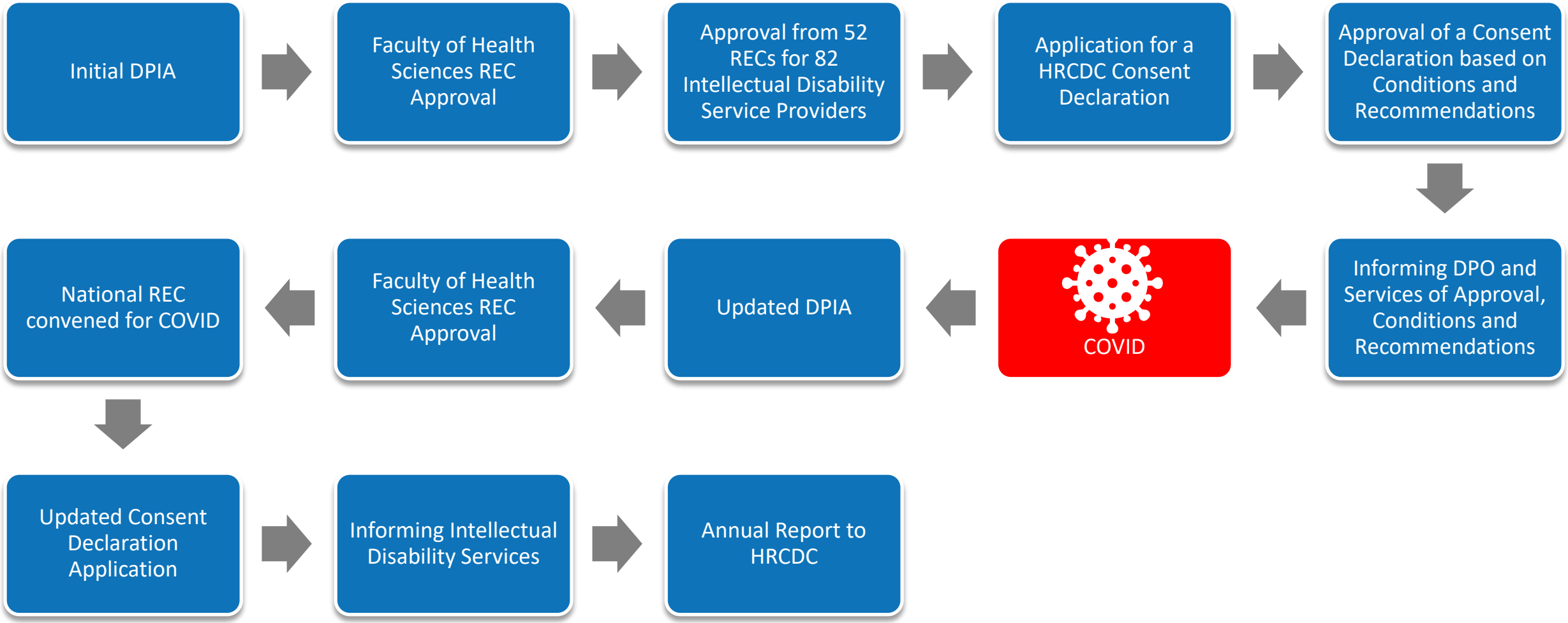
IDS-TILDA Wave 4 Health Fair

- **Health Fair reintroduced for Wave 4**
  - More extensive – suite of 24 measures
  - Additional measures driven from findings
- **Objective measures add strength to self-reported data collected**

Stages of ethical approval

IDS-TILDA Wave 4

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)



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Ethical considerations working with people with an intellectual disability

Ethical considerations with vulnerable populations

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*Research with **vulnerable populations** challenges us to consider once again **ethical principles** basic to research. Issues of providing **informed consent, maintaining confidentiality** and privacy, weighing the **risks and benefits** of a study and paying attention to issues of **fairness** are all <u>especially important when working with groups who are vulnerable</u>*

(Flaskerud and Winslow 1998: 69)

Guiding ethical principles

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

- Attaining ethical approval
- Respect for persons/autonomy
- Justice/fairness and veracity
- Anonymity and confidentiality
- Beneficence & Non-maleficence
- Honesty and Integrity
- **Informed Consent**

(*Beauchamp and Childress 2001*)

Elements of Informed Consent

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Informed consent is a process that ensures all participants **understand** the potential risks and benefits of taking part in the study.

Four Elements

- Disclosure of **all crucial information** relating to the study
- Presenting the information in such a way that the participant will gain **full understanding**
- The **capability** of the participant to give consent to take part
- The consent is given **without coercion or pressure** to do so and is fully voluntary

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Discussing and agreeing consent

IDS-TILDA and informed consent

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Before each interview, field researchers:

1. Step through the **Information Booklet** sent earlier
2. Provide opportunity for participant to **Ask Questions**
3. Confirm understanding on **Consent Form Checklist**
4. Ask participant/proxy to **Sign the Consent Form**

IDS-TILDA and informed consent

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Consent as an Event

Consent as an Ongoing Process

Avoiding acquiescence

Stages of Consenting

IDS-TILDA Wave 4

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Individual participant level

- Consent to take part in the study
- Written consent reaffirmed each wave
- Process consent throughout interview

On recruitment

Before interview

During interview

IDS-TILDA Health Fair Process Consent

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

BAY 1

Meet and greet
Introductions and explanations
Gain consent
Conduct Nutritional assessment

BAY 2

Meet and greet
Reaffirm consent, provide explanations
Conduct physical health assessment

BAY 3

Meet and greet
Reaffirm consent, provide explanations
Conduct cognitive assessments

Exit with results and certificate of achievement

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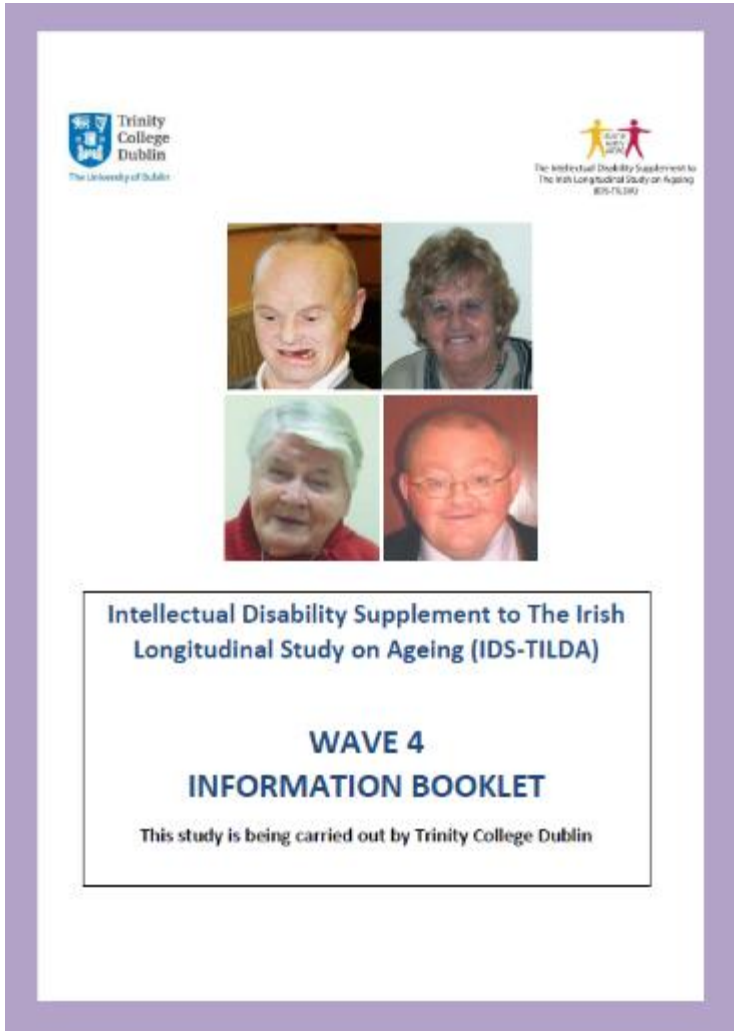
Information Booklets and Consent Forms

IDS-TILDA participant information booklet

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)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Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

WAVE 4
INFORMATION BOOKLET

This study is being carried out by Trinity College Dublin

3. What does taking part in the study mean?

There are three main parts to the study:

1. First you will fill in a **survey** that we will send out to you.

   This is a booklet with questions about your health.

   You can ask someone to help you fill in the survey.

2. Next you will do an **interview.**

   A researcher will call out to do this with you to.

   You can ask someone to support you for this.

3. Then you will have a **health assessment.**

   A nurse will call out to you for this.

6. Who will visit you?

Trinity College Dublin
The University of Dublin

A researcher from Trinity College will call out to speak to you.

A nurse from Trinity College will also call out to do the health fair with you.

7. How will they collect the information?

The researcher will put your answers into a computer.

The nurse will write down your health assessment results.

Your results will be put into a computer later.

IDS-TILDA participant information booklet

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

1. What is this study about?	
	This study is about growing older with an intellectual disability in Ireland. Trinity College Dublin is doing this study.
	This study will help us to understand what is important to people with an intellectual disability.
	It will help us to learn about the • health • well-being • and lifestyles of people as they get older.

IDS-TILDA participant information booklet

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

6. If you are selected, who will call you?	
Trinity College Dublin, The University of Dublin	A researcher from Trinity College will call you on the telephone to speak to you.
7. How will they collect the information?	
	The researcher will put your answers into a computer.
	All of your information will be kept safe and private.

8. If you are selected, how long will it take?	
	The interview will last for around an hour and a half.
	If the interview is too long, you can take a break.
	The researcher can also ring you back a second time to finish the interview.
9. Do you have to take part?	
	No. It is your choice to take part in the study. You can also change your mind and stop taking part at any time. Your decision will not affect the support you receive.

IDS-TILDA participant health fair information booklet

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

5. What else will happen?	
We also assess your health as part of the study. A nurse will visit you to do the assessments. We will:	
	Take your blood pressure.
	Measure your grip. This helps us find out how strong you are.
	Find out how tall you are. If you cannot stand up, we will measure your arm instead.
	Measure your weight

	Measure your waist and hips.
	Measure around your calf.
	Take a sample of your breath. This will tell us how healthy your stomach is.
	Ask you about your feet
	Measure how strong your bones are.

	Ask you questions about what you eat and drink.
	Count your teeth and check your mouth
	Prick your little finger to take small drops of blood.
	We will see how steady you are on your feet. We will ask you to stand up and sit down 5 times. We will see how long it takes you to do this.

IDS-TILDA participant information booklet

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

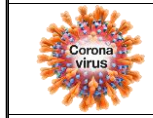
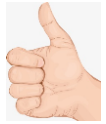
- What the study is about
- Who is taking part in the study
- What is involved in taking part in the study (i.e. PIQ, main interview, Health Fair)
- What types of questions will be asked and what participants will be asked to do
- Who will visit participants
- How information is collected and kept safe
- How long each part of the study will take
- Rights (e.g. of refusal or to end participation) and data protection
- Risks and benefits
- Contact details if participants have any further questions about taking part

IDS-TILDA consent form

CONSENT FORM

IDS-TILDA Wave 4 - CAPI

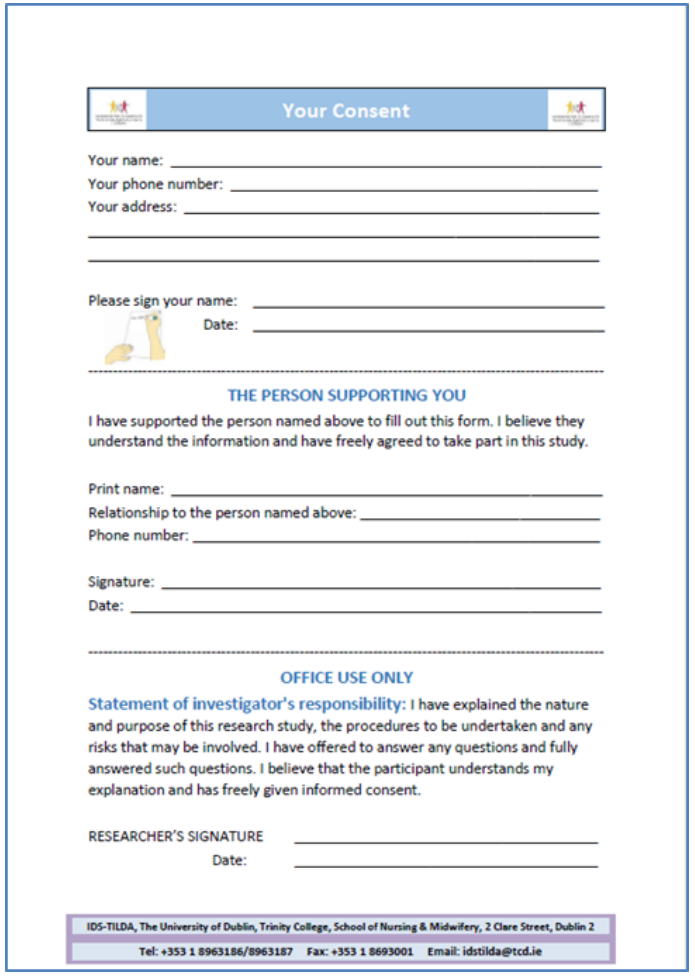
Please read the information below. Then tick the boxes and sign this consent form if you wish to take part in this fourth wave of the study.

	I agree with the following statements: ✓	Yes	No
	I have read, or had read to me, the information booklet about this study.	☐	☐
	The researcher has explained to me what the study is about.	☐	☐
	Any questions that I had were answered.	☐	☐
	I know who to contact if I have any more questions.	☐	☐
	I understand that I will be asked questions about my: • life • health • work • friends, and • things I like to do	☐	☐
	I know that I will be asked questions about Coronavirus.	☐	☐
	I know that it is my choice to take part in this study.	☐	☐
	I know that I do not have to answer questions I do not feel happy with.	☐	☐
	The researcher can ask the HSE what medicine I take.	☐	☐
	I know that I can stop taking part in this study when I want to. I do not have to give a reason.	☐	☐
	I understand that all information I give during this study will be kept safe and private.	☐	☐
	I know that I will not be named in any reports.	☐	☐
	I know that there are no known risks with this study. And that there are no direct benefits to me from this study.	☐	☐
Trinity College Dublin The University of Dublin	I know this study will continue and I will be contacted again in three years about consenting to take part in the next Wave.	☐	☐
	I am happy to take part in this study.	☐	☐

IDS-TILDA consent form

Participant signs/marks here

Proxy/Support Person signs here



Your Consent

Your name: _____

Your phone number: _____

Your address: _____

_____

_____

Please sign your name: _____

Date: _____

THE PERSON SUPPORTING YOU

I have supported the person named above to fill out this form. I believe they understand the information and have freely agreed to take part in this study.

Print name: _____

Relationship to the person named above: _____

Phone number: _____

Signature: _____

Date: _____

OFFICE USE ONLY

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHER'S SIGNATURE _____

Date: _____

IDS-TILDA, The University of Dublin, Trinity College, School of Nursing & Midwifery, 2 Clare Street, Dublin 2

Tel: +353 1 8963186/8963187 Fax: +353 1 8693001 Email: idstilda@tcd.ie

Assessing capability to give informed consent

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Interviewer assesses the participant's ability to understand the study information and to give informed consent.

This assessment is on a number of sources:

1. Information from the IDS-TILDA office (caseload)
2. First interactions with the participant at time of appointment/interview
3. The participant's response/reaction to study information
4. Information from the participant's family or support service

Assessing capability to give informed consent

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Capability to provide consent is assumed unless found otherwise

If the person is considered not to have this capability, interviewer seeks proxy agreement

This requires a Consent Declaration from the HRCDC

Proxy respondents

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

A proxy respondent must -

- be a knowledgeable informant,
- have known the person with ID for at least six months,
- be prepared to assist the participant in answering the questions

The participant may require assistance for **some or all** of the questions in the interview, depending on the topic being discussed.

A proxy may also assist to **communicate** all of the answers to the interviewer on behalf of the person with ID. This may occur where a person has a severe or profound ID.

Recruiting and Training Fieldworkers

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

Fieldworkers all had a background in research with people with an intellectual disability or had worked with people with an intellectual disability

Fieldworkers had a number of days of training in areas such as process consent and had ongoing support and follow-up contact while out in the field

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Public and Patient Involvement (PPI) in IDS-TILDA

IDS-TILDA Participant Involvement

Developing the Study with Advisory Groups

People with ID **reviewed questions, gave opinions and provided their thoughts** on the research questions, using **pictures, music, words and video.**

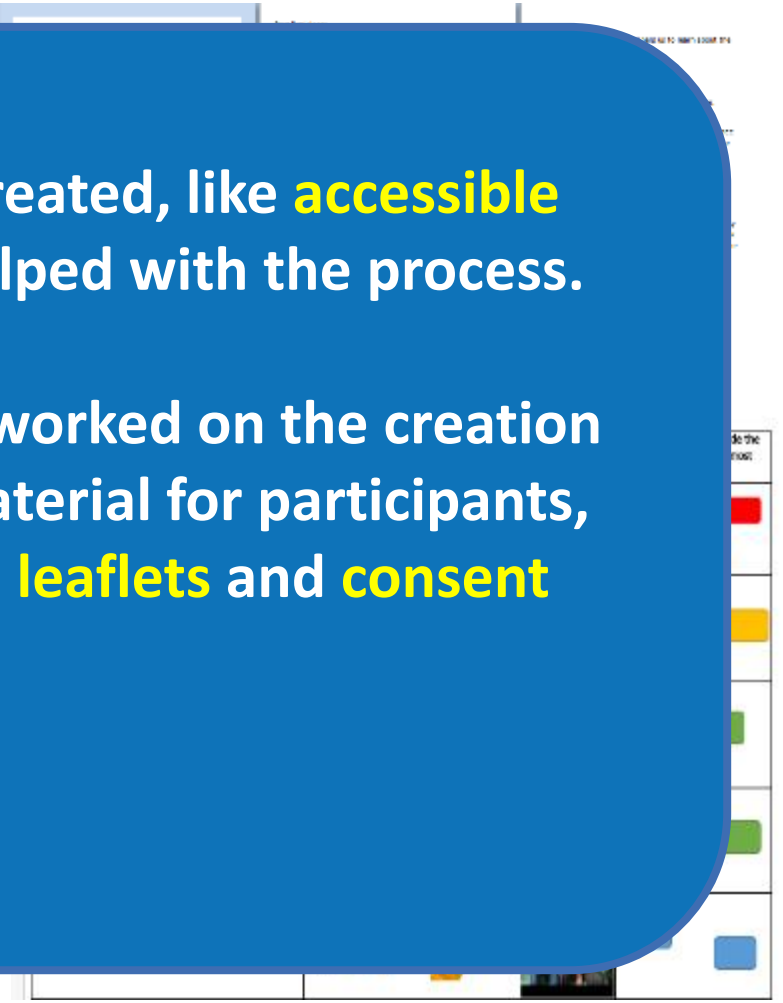
Each person could **choose to be involved** in some, all, or none of the activities.

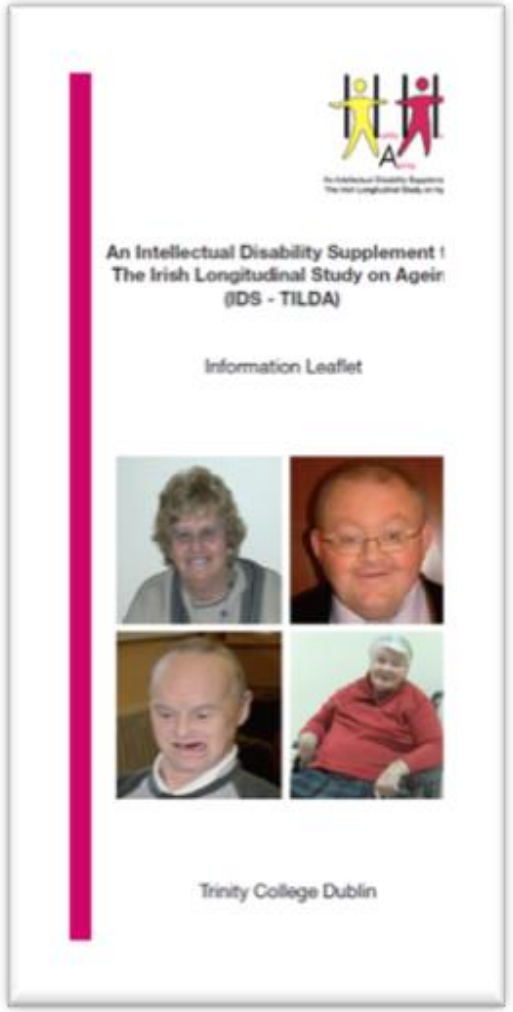
IDS-TILDA Participant Involvement

Developing Accessible Materials

The materials created, like **accessible voting cards**, helped with the process.

The group also worked on the creation of accessible material for participants, like **information leaflets** and **consent forms**.





IDS TILDA Steering Committee Membership

IDS-TILDA Steering Committee

Paddy Monaghan and Mei Lin Yap are an integral part of the IDS TILDA Steering Committee

Training Field Researchers for Wave 4 of IDS-TILDA

August 2019

People with an intellectual disability did practice interviews with field researchers and then provided them with feedback

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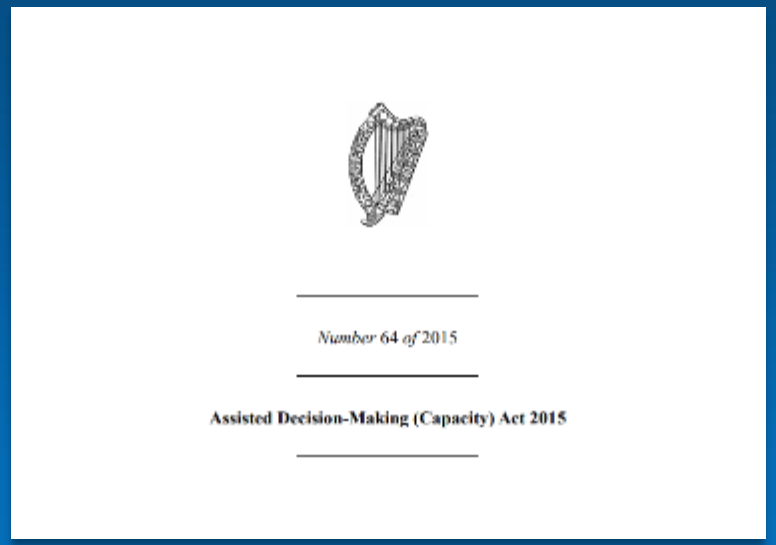
The next issue for consent and people with an intellectual disability

The next stage for Consent Processes



Number 64 of 2015

Assisted Decision-Making (Capacity) Act 2015

Enacting the Assisted Decision Making (Capacity) Act, 2015
Final sections due to be enacted in mid-2022.
The legislation does not refer to health research specifically.

- Assisted Decision Making
- Co-Decision Making
- Decision Making Representatives

IDS-TILDA

Acknowledgements

The Intellectual Disability Supplement to The Irish Longitudinal Study on Ageing (IDS-TILDA)

The IDS-TILDA Team extends grateful appreciation to:

- Participants, Families and Carers
- The IDS-TILDA Steering Committee and International Scientific Advisory Board
- Advisors and Advisory Groups
- Our Funders

An Roinn Sláinte
DEPARTMENT OF HEALTH

HRB Health Research Board

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