Exploring Consent
Perspectives from a Principal Investigator

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IDS-TILDA
Joins the Global Family of Longitudinal Studies
IDS-TILDA
Objectives

• 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 IDS-TILDA Story: 2007 – Present

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

Initial DPIA → Faculty of Health Sciences REC Approval → Approval from 52 RECs for 82 Intellectual Disability Service Providers → Application for a HRCDC Consent Declaration → Approval of a Consent Declaration based on Conditions and Recommendations

National REC convened for COVID → Faculty of Health Sciences REC Approval → Updated DPIA → COVID → Informing DPO and Services of Approval, Conditions and Recommendations

Updated Consent Declaration Application → Informing Intellectual Disability Services → Annual Report to HRCDC

Trinity College Dublin, The University of Dublin
@ageingwithID #ageingwithID
Ethical considerations working with people with an intellectual disability
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 especially important when working with groups who are vulnerable.

(Flaskerud and Winslow 1998: 69)
Guiding ethical principles

- 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)*
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
Discussing and agreeing consent
IDS-TILDA and informed consent

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

Consent as an Event

Avoiding acquiescence

Consent as an Ongoing Process
Stages of Consenting
IDS-TILDA Wave 4

Individual participant level
➢ Consent to take part in the study
➢ Written consent reaffirmed each wave
➢ Process consent throughout interview
IDS-TILDA Health Fair Process Consent

**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
Information Booklets and Consent Forms
3. What does taking part in the study mean?

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>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.</td>
</tr>
<tr>
<td>2.</td>
<td>Next, you will do an interview. A researcher will call out to do this with you. You can ask someone to support you for this.</td>
</tr>
<tr>
<td>3.</td>
<td>Then, you will have a health assessment. A nurse will call out to you for this.</td>
</tr>
</tbody>
</table>

6. Who will visit you?

<table>
<thead>
<tr>
<th>Visit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trinity College Dublin</td>
<td>A researcher from Trinity College will call out to speak to you.</td>
</tr>
<tr>
<td>Trinity College</td>
<td>A nurse from Trinity College will also call out to do the health fair with you.</td>
</tr>
</tbody>
</table>

7. How will they collect the information?

<table>
<thead>
<tr>
<th>Method</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Computer</td>
<td>The researcher will put your answers into a computer.</td>
</tr>
<tr>
<td>Phone</td>
<td>The nurse will write down your health assessment results. Your results will be put into a computer later.</td>
</tr>
</tbody>
</table>
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.
### 6. If you are selected, who will call you?

<table>
<thead>
<tr>
<th>Trinity College Dublin</th>
<th>A researcher from Trinity College will call you on the telephone to speak to you.</th>
</tr>
</thead>
</table>

### 7. How will they collect the information?

<table>
<thead>
<tr>
<th></th>
<th>The researcher will put your answers into a computer.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All of your information will be kept safe and private.</td>
</tr>
</tbody>
</table>

### 8. If you are selected, how long will it take?

<table>
<thead>
<tr>
<th></th>
<th>The interview will last for around an hour and a half.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If the interview is too long, you can take a break.</td>
</tr>
<tr>
<td></td>
<td>The researcher can also ring you back a second time to finish the interview.</td>
</tr>
</tbody>
</table>

### 9. Do you have to take part?

Yes

No

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.
### 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:

<table>
<thead>
<tr>
<th>Action</th>
<th>Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Take your blood pressure.</td>
<td><img src="image" alt="Blood Pressure" /></td>
</tr>
<tr>
<td>Measure your grip. This helps us find out how strong you are.</td>
<td><img src="image" alt="Grip Test" /></td>
</tr>
<tr>
<td>Find out how tall you are. If you cannot stand up, we will measure your arm instead.</td>
<td><img src="image" alt="Standing Measure" /></td>
</tr>
<tr>
<td>Measure your weight</td>
<td><img src="image" alt="Weight Scale" /></td>
</tr>
<tr>
<td>Measure your waist and hips.</td>
<td><img src="image" alt="Waist Measurement" /></td>
</tr>
<tr>
<td>Measure around your calf.</td>
<td><img src="image" alt="Calf Measurement" /></td>
</tr>
<tr>
<td>Take a sample of your breath. This will tell us how healthy your stomach is.</td>
<td><img src="image" alt="Breath Sample" /></td>
</tr>
<tr>
<td>Ask you about your feet</td>
<td><img src="image" alt="Feet Measurement" /></td>
</tr>
<tr>
<td>Measure how strong your bones are.</td>
<td><img src="image" alt="Bone Measurement" /></td>
</tr>
<tr>
<td>Ask you questions about what you eat and drink.</td>
<td><img src="image" alt="Food Image" /></td>
</tr>
<tr>
<td>Count your teeth and check your mouth</td>
<td><img src="image" alt="Teeth Image" /></td>
</tr>
<tr>
<td>Prick your little finger to take small drops of blood.</td>
<td><img src="image" alt="Blood Drop" /></td>
</tr>
<tr>
<td>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.</td>
<td><img src="image" alt="Steady Image" /></td>
</tr>
</tbody>
</table>
IDS-TILDA participant information booklet

- 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:

✓

I have read, or had read to me, the information booklet about this study.

Yes No

The researcher has explained to me what the study is about.

Yes No

Any questions that I had were answered.

Yes No

I know who to contact if I have any more questions.

Yes No

I understand that I will be asked questions about my:

• life
• health
• work
• friends, and
• things I like to do

Yes No

I know that I will be asked questions about Coronavirus.

Yes No

I know that it is my choice to take part in this study.

Yes No

I know that I do not have to answer questions I do not feel happy with.

Yes No

The researcher can ask the HSE what medicine I take.

Yes No

I know that I can stop taking part in this study when I want to.

Yes No

I do not have to give a reason.

Yes No

I understand that all information I give during this study will be kept safe and private.

Yes No

I know that I will not be named in any reports.

Yes No

I know that there are no known risks with this study. And that there are no direct benefits to me from this study.

Yes No

I know this study will continue and I will be contacted again in three years about consenting to take part in the next Wave.

Yes No

I am happy to take part in this study.

Yes No
Assessing capability to give informed consent

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

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

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.
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.
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.
People with an intellectual disability did practice interviews with field researchers and then provided them with feedback.
The next issue for consent and people with an intellectual disability
The next stage for Consent Processes

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.
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