Data Protection Impact Assessment

Dementia Research Database
The Alzheimer Society of Ireland

Submitting controller details

Name of controller	The Alzheimer Society of Ireland (ASI)
Subject	Dementia Research Database (DRD)
Name of controller DPO	Clare Murphy

The need for a DPIA

Processing under consideration

In Ireland, there is no national database or registry of people with dementia and carers who are interested in taking part in research.

The ASI wishes to develop a database/registry of people living with dementia and carers who are interested in taking part in research for the primary purpose of 'matching' them with dementia-related research opportunities in Ireland. This would be the first database of its kind in the Republic of Ireland, and will provide the following benefits:

- People living with dementia and carers are presented with opportunities to take part in dementia-related research that they may not have otherwise been aware of.
- People living with dementia and carers may benefit from the research they take part in as a result of being on this database (e.g. therapies, activities, having their voice heard).
- People living with dementia and carers will be kept up to date with research news from the ASI and will receive 4-6 newsletters per year.
- The ASI will be able to maintain a gatekeeping role by holding third party researchers to high ethical and data protection standards when they request research participants through the DRD.

Type of Processing

This project involves collecting, storing, screening and sharing personal data and special category personal data for the purposes of linking people with opportunities to take part in dementia-related research studies and keeping database members informed about research news through a newsletter 4-6 times per year. In some cases, it will involve sharing data subjects' contact information and diagnosis with research teams carrying out ethically approved research studies for the purposes of inviting the database member to take part in relevant research studies.

Need for Consultation with DPC

The envisaged processing necessary to create and maintain the DRD will involve potentially the large scale processing of the special category data of vulnerable individuals. Although ASI does not believe that mitigating actions cannot address any high risk that could be posed to these individuals (meaning no residual high risk is indicated by this DPIA) nevertheless the charity wants to ensure it is not mistaken in this regard. It therefore wishes to refer this DPIA to the Supervisory Authority in accordance with Recital 84 GDPR. The as yet outstanding Regulations set out in s.84 (9) DPA 2018 means ASI also wishes to refer for clarity.

The nature and methods of processing

Method of collecting data

Should a person wish to sign up to the DRD, ASI will collect data on the legal basis of explicit consent and by using a specially developed and extensively piloted form. Information obtained using this form will be inputted to the ASI CRM system (Salesforce).

1. Over the phone with the ASI staff member dedicated to the Dementia Research Database.

   The prospective data subject can either contact the DRD Research Officer directly or they can fill out a basic contact form on the ASI website (First name, contact number, e-mail address, and suitable time to contact). The DRD Research Officer will then phone the person at the time they indicated suits them best.

   The Research Officer will explain the project and using a specific script, request their explicit consent. If explicit consent is given, the research officer asks the person each question on the form and enters directly into the CRM system. Some data subjects will have a diagnosis of dementia making this more challenging, but the ASI holds expertise in communicating with this group. The person's responses to each statement of explicit consent will be transcribed verbatim into the CRM system.

   In future, we hope to collect data using a digital form on the ASI website once we have appropriate resources and security controls in place.

Consent

For this DPIA, ICO guidelines have be followed in relation to explicit consent. The ICO guidelines state that explicit consent must be affirmed in a clear statement (whether oral or written).This is particularly relevant for Point 1 above, whereby the person will be asked to affirm their consent to specific statements over the phone.

The guidelines also state that 'explicit' consent can be affirmed by individuals clearly indicating that they agree to a written statement – for example by signing their name or ticking a box next to it. This is potentially relevant for future, where we hope to include a digital sign-up option for DRD Members.

The ICO also advises caution with wording. The ASI will pilot consent statements with people living with dementia and carers, and with input from the ASI Advocacy Team who carry expertise in developing easy-read information for people living with dementia.

Consent Options

The individual is offered five explicit consent options for the processing of their data as outlined below. Four relate to the collection, storage, screening, and processing of data by ASI and three to the subsequent transfer of that data to research studies. A fifth invites individuals to receive a newsletter from the relevant ASI research team, receipt of which is regarded as important to maintain the informed consent of the individual although the person can refuse to accept it.

Consent will be re-verified upon each point of contact and at a minimum of once per year.

When a data subject signs up to the DRD they are asked to give their explicit consent to the following

A) ASI to process their personal data for as long as they consent to this

B) Personal data undergoing a basic screening by ASI to identify if the person should be told about the research opportunity.

- This screening is to assess if the person is likely to be eligible to participate in a particular study. This is important to ensure that:

    i. Data subjects' time is not wasted being informed about a project they can't take part in (e.g. informing people with Vascular Dementia about an opportunity to take part in a study that is only open to people with Alzheimers Disease).
    ii. Data is not unnecessarily transferred to a research team for a particular study unless the person is likely to be eligible to take part (e.g. avoiding sending contact information of women to a researcher recruiting men).

- No person's personal data will be subject to this basic screening by ASI unless there is valid explicit consent in place. This screening process will never result in a person automatically being enrolled in a study. The individual must provide separate explicit consent to the subsequent third party team conducting the research project. This is included in the ASI DRD Terms and Conditions which research teams are required to sign.

C) One of the consent options below

<u>Data Transfer Consent</u>

1. Data transfer consent (All approved research):
    - Consent to share contact details with any approved researchers conducting dementia-related studies that the data subject is eligible to participate in.

2. Data transfer consent (Academic research only):
    - This consent option is almost identical to the above, but in this case the individual has only consented to their data being shared with academic research projects. This means that data is only passed to researchers working in academic institutions. No data is shared with any projects considered commercial in nature.

3. Case by case basis
    - Each time a relevant research opportunity arises, the ASI will contact the data subject via their preferred contact method and tell them about the study. If the person is interested in learning more they can ask for ASI to pass their contact details to the research team. This consent option exists to ensure that data subjects are not excluded from research they would otherwise like to take part in due to a lack of confidence/ability to contact researchers independently.

<u>Information Only Consent</u>

4. Information only consent:
    - Each time a relevant research opportunity arises, the ASI will contact the data subject via their preferred contact method, tell them about the study, and share the contact information of the researcher carrying out the study. If the person is

interested in learning more they can then choose to get in touch with the research team themselves.

5. Consent to receive communications from ASI (research dept.)

    - In the form of a newsletter 4-6 times per year. We will be recommending to individuals that if they are on the DRD they should receive this as it helps them to stay informed but people do not have to receive it and they can decline. No data will be transferred to researchers unless this consent is given in addition to a further consent (options 1, 2 or 4 above). This consent will be reviewed with the data subject at least once per year.

Withdrawing consent: To withdraw consent, the data subject can contact the DRD Research Officer by phone, post or e-mail. The details of the Research Officer will be included in all correspondence, the newsletter and available online. In addition, information on withdrawing consent will be at the bottom of e-mail correspondence regarding the DRD. This is discussed further in Point 8 on Page 6.

How data will be used:

1. To match people to dementia-related research opportunities.

   Typically, potential research participants need to meet different criteria to be included in studies. This varies depending on the research study (e.g. one study might require males with vascular dementia over 70 years of age). Data will be used to identify which DRD members are likely to be eligible to participate in different research studies (only after explicit consent is in place). This will not involve enrolling the person in the study, just to make them aware of the opportunity to participate. The person's contact details will be securely transferred to the research team using a password protected Microsoft Excel spreadsheet over e-mail in line with their selected consent option. The unique password will be shared over the phone. E-mails will only be sent to official organization e-mail accounts (e.g. @alzheimer.ie, @ucd.ie) rather than non-official accounts (e.g. hotmail.com, @yahoo.com). Research teams then contact the person to give them further information about the study and invite them to take part.

2. Distribute a general research newsletter from the ASI (approx. 4-6 times per year) via post or e-mail (depending on person's preferred contact method). The newsletter will not directly or indirectly disclose a diagnosis of dementia as the news and information will be of a general nature and relevant to the general public as well as DRD members. The envelope will have an ASI logo.

3. Anonymised data from the DRD may also be used by the ASI for planning research priorities and communications through statistical analysis. E.g. looking at numbers of people with diagnosis of Vascular Dementia in last 5 years. The personal data would be converted into purely statistical data that makes it impossible to re-identify the individual concerned. This anonymised data would be stored separately to the DRD. This type of data will not be shared with third party researchers/organisations for the above purposes as this would be better served by a dementia registry from which the DRD is distinct.

Data storage

All data will be stored electronically on a password-protected purpose-built ASI CRM system Salesforce that is only accessed using ASI secure IT devices.

Sharing data

The purpose of the project is to match and link people with dementia-related research opportunities. Data will be shared with ethically approved researchers (discussed below) carrying out dementia-related research studies. This will typically include researchers from academic institutions and may also include commercial organisations. Proof of ethical approval will always be essential.

For data to be shared with researchers carrying out studies the following must apply:

1. The Research Team must be ASI approved (see below)
2. The data subject must explicitly consent to their data being transferred to research teams.
3. The data subject must be likely to be eligible to participate in a study (e.g. contact details of males under 65 years of age will not be passed to researchers who require participant to be males over 65 years of age). This avoids excessive sharing of data.

ASI Approved Researchers

To be an 'ASI approved' researcher/research team, the following must apply

1. The researcher must fill out an ASI DRD access request form detailing relevant study information.
2. The research team must have proof of ethical approval for their study from a Research Ethics Committee[1].
3. The research team or their employer must accept, sign, and return the ASI DRD Terms & Conditions of Use
4. Use of the DRD must have potential to benefit the research study i.e. ASI reserves the right to be confident that use of the DRD would provide significant benefit to the study being conducted.

DRD Process

1. With their explicit consent, the person's details are recorded by an ASI staff member over the phone with the DRD research officer dedicated to the DRD.

   *In future, we also hope to allow people to sign up using a digital form. However, this will only be implemented if the ASI website can be securely resourced with high levels of protection.

2. The person is offered several consent options for storing and transferring their data (contact details) to approved research teams carrying out dementia-related research.

   a) Data-transfer consent (one year, all approved research)
   b) Data-transfer consent (one year, academic research only)
   c) Case by case consent
   d) Information only consent
   e) Consent to receive newsletter communications from ASI

   These consent options are outlined on pages 3 and 4 of this document.

[1] There are 12 Research Ethics Committees (https://health.gov.ie/wp-content/uploads/2016/07/European-Communities-Clinical-Trials-on-Medicinal-Products-for-Human-Use-Regulations-2004.pdf) in addition to several academic Research Ethics Committees (based in third level institutions). This year, the cabinet has approved proposals for a Bill to support the establishment of a national ethics committee infrastructure that will work alongside and support existing local or institutional RECs.

No specific linking of a Person with Dementia and their carer (that also has their data entered on the DRD) is planned. The only linking of individuals that may occur on the DRD is coincidental (e.g. a Person with Dementia may list their carer as their next of kin).

3. The DRD research officer is responsible for inputting the data into a purpose-built ASI CRM account on Salesforce. In future, if data is collected through the online form, it will be sent to the DRD e-mail account, the research officer is responsible for ensuring this is entered into the Salesforce account and destroying the e-mail copy within 10 working days.

4. Data will be stored on Salesforce in a password protected account, the security of which is monitored by the ASI IT department. Only the ASI Research Team and the ASI IT department will have access to this account (i.e. a strictly need to access basis). This is less than 5 people in total.

5. Academic and commercial research teams will apply to the ASI DRD for support with recruitment to dementia-related studies using a specific application form. They will be required to supply

    a. Study information (e.g. lay summary meeting INVOLVE[2] Guidelines, objectives, methodology, data collection, data storage, dissemination plans etc.)
    b. The inclusion/exclusion criteria for potential participants
    c. Signed acceptance of the ASI Research Database Terms & Conditions
    d. Proof of ethical approval from the relevant Research Ethics Committees.
    e. Copies of study information leaflet and Data Protection Fair Processing Notice that will be provided to participants

6. The DRD Research Officer runs a basic screen of the DRD using basic parameters provided by the third-party research team. Those identified as being likely to be eligible to participate are then made aware of the opportunity to take part in the specific research study in line with their consent option identified below. This basic screen is not part of any research study and does not automatically enroll data subjects in a research study, rather it is to avoid wasting their time or causing disappointment (by avoiding making individuals aware of studies they aren't eligible to take part in). If data subjects are likely to be eligible to participate the following applies:

    f. **If data transfer consent** (i.e. Consent options 1 or 2): ASI DRD transfers the data subjects' contact details (relating to their preferred method of contact) to researcher. Data will be transferred via e-mail on a password protected excel spreadsheet. Data will only be transferred to official e-mail accounts (e.g. @ucc.ie), and not a personal account (e.g. @hotmail.com). The unique password will be given to the project contact over the phone.

    g. **If information only consent:** ASI contacts data subject via preferred method of contact and informs them about study. If data subject is interested in participating, the ASI gives them the researchers contact details so the data subject can contact them.

    h. **If case by case consent:** ASI contacts data subject via preferred method of contact and informs them about study. If data subject is interested in participating ASI obtains permission to send the person's contact information to the researchers. This will only be done with the person's specific permission and at their request.

[2] INVOLVE supports active public involvement in NHS, public health and social care research. INVOLVE guidelines instruct researchers on writing for a public audience, rather than specialists

7. Once data is passed from ASI to the research team, they are responsible for processing that data responsibly as per the Terms and Conditions of Use, prevailing data protection laws, and ethical regulations. ASI does not believe that a data processor agreement (Art 28 GDPR) or a Joint controller agreement (Art 26 GDPR) are relevant or necessary in this regard, as ASI has no further involvement in the processing of the shared data after it has been transmitted to the third party.

8. ASI will continue to process the relevant data for as long as a valid consent is in place. If the data subject no longer wants to be on the DRD, their data will be removed within 48 hours of their request to have it removed. It will be ensured that their data is not transferred to any third party and that they do not receive an ASI Research Newsletter between the withdrawal of consent and removal of their data. The ASI will contact data subjects to ask if they continue to consent to their data being held on the DRD at least every 12 months. This will be carried out via the person's preferred method of contact. To withdraw consent, the data subject can contact the DRD Research Officer by phone, e-mail or post. The details of the Research Officer and information on withdrawing consent will be included in all correspondence and available online. If an individual withdraws their explicit consent and ASI has recently transmitted their data to a research team (meaning there is a reasonable chance that individual may not already have been enrolled by the research project) then ASI must contact that research team and inform them that the individual's data must not be further processed and should be securely destroyed as they have withdrawn their explicit consent for this data sharing.

Nature of Data

The data processed are personal data and special category personal data. Although only names and contact numbers will be transferred to research teams, special category personal data may also be indirectly revealed. For example, when that data subjects' information is transferred to research teams who are recruiting people living with dementia, the research team will be aware that certain persons have a diagnosis of dementia.

Type and amount of data:

The following data will be processed:

- Name
- E-mail address
- Home address
- Contact Number
- Presence of dementia diagnosis (if applicable)
- Dementia Type (if applicable)
- Date of birth
- Presence of disabilities (if applicable)
- Caregiving situation (i.e. former/current) (if applicable)
- Year diagnosed with dementia (if applicable)
- Next of kin (name, contact number**)**
- Ethnic Group
- Race
- Occupation/former occupation
- Is there a history of dementia within your family (yes/no)

Frequency of data collection

Data will be collected once, when the person signs up to be part of the DRD. The data subject will be contacted at least every 12 months to ensure continued consent and this opportunity will also be used to check the accuracy of the data.

Frequency of data use

Data will be used each time we search for potential participants to take part in a research study and approximately 4-6 times per year for the purposes of sending research newsletters.

We estimate that there will be approximately 10-15 research studies that request the use of the DRD in Year 1. This estimation is based on the first year of Join Dementia Research in the UK, in which 30 studies used the database. Given the smaller population of Ireland, and the lower amount of dementia-related research studies that take place here, we estimate that 10-15 research studies will request the use of the DRD.

Length of data storage

Data will be processed for as long as the person continues to consent to it which could range from days to years. If the person no longer wants to be on the DRD, their data will be removed within 48 hours. It will be ensured that data is not 'used' between the withdrawal of consent and deletion of data. At least every 12 months, the ASI will contact the person to ask if they continue to consent to their data being held on the DRD.

Number of individuals impacted

We aim to sign up as many people with dementia and carers as possible to the database. We will only process data of those who wish to be part of the database and explicitly consent to this.

We estimate that approximately 100-150 individuals will sign up in Year 1. This estimate is based on the number of sign ups that the Join DRD in the UK achieved in Year 1.

Geographical scope

Data subjects must reside in the Republic of Ireland, and ASI will only engage with researchers in the Republic of Ireland. This is the decided initial stance of the DRD in the face of Brexit and data protection inconsistencies that could arise between the jurisdictions of even the Republic and Northern Ireland. This stance may be reviewed in the future if a more favourable and stable geo-political backdrop was to emerge.

Context of Processing

Nature of relationship with individuals

The ASI is the leading dementia specific service provider in Ireland. The ASI works across the country in the heart of local communities providing dementia specific services and supports and advocates for the rights and needs of all people living with dementia and their carers.

Regardless of whether they engage with services or not, most individuals will have heard of, and likely trust the organisation. Therefore it is imperative that this trust is respected and considered when we work with and process data of individuals on the DRD. When engaging with any person in relation to the DRD, it will be stressed that signing up for the DRD will never have any bearing (positive or negative) on their entitlement or

access to any ASI or HSE supports and services.

Data subjects' control over their data

Data subjects will have a large amount of control over their data. They can choose whether or not they wish to be part of their database (via explicit consent) and can have this data amended or removed at any time by contacting the ASI Research Officer. Data subjects will have five explicit consent options to ensure that they have their desired level of control over the processing and sharing of their data. These can be altered or withdrawn entirely by the data subject at any time.

To withdraw consent, the data subject can contact the Research Officer via phone, e-mail (checked several times per day) or post, if they prefer. Their data will then be removed within 48hours of receipt of their request. Data is removed by deleting that data subject's record in the DRD which is easily completed. Should the person wish to rejoin the database at any stage, they will have to go through the same consent process again.

Circumstances may arise whereby a family member may wish for a person with dementia to be removed from the DRD. A person's explicit consent to be on the database will only be overturned if the family member has Power of Attorney (or other legally established right to represent the individual) or if the family member's request for the individual to be removed from the DRD is reiterated, in writing, by a supporting health practitioner. In this section, "health practitioner" has the same meaning as it has in the Health Identifiers Act 2014. If the issue of overturning the explicit consent of a Person with Dementia due to lack of capacity is ever raised by the carer or family member of a DRD participant then ASI must attempt to verify a withdrawal of explicit consent directly with the individual concerned before that individual is removed from the DRD.

Data subjects' expectations of data usage

Data is being processed for a specific purpose which data subjects will be asked to explicitly consent to. To manage expectations and provide further clarity on how data will be used, easy-to-read information will be provided to data subjects and the project will be verbally explained if necessary. This information will be available online too. This information will be piloted by people with dementia and carers before data collection commences. At this stage of the development, the ASI Advocacy Team, who are highly experienced in formulating lay materials tailored for people living with dementia, will be also be involved.

Vulnerable Groups

Data subjects will include people living with dementia who will have some degree of cognitive impairment. Only those who have capacity to explicitly consent to being part of the project will be included on the database, and consent will be re-verified at least every 12 months. In addition, the ASI can communicate with trusted relatives or friends if the data subject wishes (this will be outlined in the Information Leaflet). These relatives/friends may be able to support the person to make decisions in their best interests. The person can also talk their decision through with the Research Officer. As an employee of the ASI, the research officer follows relevant ASI policies and abides by the values of the ASI – respect, integrity, striving for excellence, empathy and inclusiveness. Therefore, the Research Officer will first and foremost work in the best interests of the person rather than in the best interests of the DRD.

Are there prior concerns over this type of processing or security flaws?

There is always concern around consenting vulnerable adults, particularly those who have dementia as capacity to consent may decline over time as levels of cognitive impairment progress. For this reason, consent will be reaffirmed each time we are in touch with the person, and at a minimum of once per year. This is keeping in line with the Assisted Decision Making (Capacity) Act 2015, which advises that it cannot be assumed that a person lacks capacity to consent in the first instance.

We are aware of data security risks associated with postal forms (e.g. getting lost in the post, ending up the wrong hands). Therefore, we provide a telephone sign up. Data subjects can either phone the DRD Staff Member directly or they can fill in a simple contact form and request the DRD Research Officer to phone them back. In addition, people can sign up to the database in person with a DRD staff member. In future, we hope to add a digital sign-up option to increase efficiency and enable individuals to sign up quickly and easily.

Is it novel in any way? What is the current state of technology in this area?

In Ireland, this kind of database is novel (i.e. matching participants to research studies) though it does not represent the use of any new technology.

In the UK, a similar and very successful project exists called Join Dementia Research (JDR) which is a standalone platform. JDR is a collaborative project funded by the UK Department of Health and Social Care and coordinated by the National Institute for Health and Research (NIHR) and the three national UK Alzheimer's charities: Alzheimer Scotland, Alzheimer's Society UK and Alzheimer's Research UK. JDR was launched in February 2015, and has over 40,000 volunteers registered to it. It has been established to support all ethically approved dementia research studies taking place in the UK. JDR recruits both people with a diagnosis of dementia and people without a diagnosis of dementia.

There are key differences between the proposed ASI DRD and JDR. The most marked difference is that on JDR, research teams become Joint Data Controllers when they use the platform as data is not actually transferred. Instead, on JDR, researchers are given a unique profile on the database that they can use to access information of those who are matched with their study. In addition, JDR is hosted on a standalone platform, while the ASI DRD will be internal and managed using the ASI CRM system Salesforce.

Issues of Public Concern

Dementia represents a significant global public health issue that is projected to steadily worsen over time. In Ireland alone, it is estimated that over 55,000 people are currently living with dementia, of whom approximately 35,000 are living in the community. The number of people living with dementia in Ireland is set to double by 2036 with profound implications for the health and social care system (O' Shea, Cahill & Pierce, 2017). Therefore, enhanced and diverse research to develop services and supports for people living with dementia and those who care for them is crucial. Furthermore, in the UK, the National Institute for Health and Care Excellence (NICE) guidelines[3] (2018) recommend that people diagnosed with dementia (at all stages) should be informed about opportunities to take part in research. In Ireland, it is important to follow suit, and ensure that the growing population of people living with dementia and those who care for them are informed about research opportunities and empowered with the choice to partake or decline to partake.

[3] National Institute for Health and Care Excellence (June, 2018). Dementia: assessment, management and support for people living with dementia and their carers (NG97).

Purposes of the processing

There are two main purposes of the processing

1. To match and link people with dementia-related research opportunities
2. To communicate news and updates about dementia-related research to members of the DRD through 4-6 newsletters per year

Benefits of processing and intended effects

For individuals

Interested individuals can be informed about opportunities to take part in research that they may not have otherwise known about or had the opportunity to participate in. In addition, they can keep up to date with dementia-related research news and information if this is something they are interested in. This benefit is also reinforced by the fact that the National Institute for Health and Care Excellence (NICE) guidelines[4] (2018) recommend that people diagnosed with dementia (at all stages) should be informed about opportunities to take part in research.

For the ASI

Dementia research is making great strides around the world. The ASI want to work on behalf of those with dementia and their carers in Ireland and views this area as one in which it can make a highly practical contribution to helping science and medical research find cures, potentially, or more prevalently, ways of easing the symptoms and progression of dementia and thereby easing the burden on those with dementia and their families. ASI is passionately committed to work in this area and currently channels 5% of all revenue received by the charity into supporting research. The significant majority of research that the ASI supports is academic, and very rarely commercial. The existence of the DRD will also enable the ASI to raise its research profile in Ireland and become a significant stakeholder in Irish dementia research while still maintaining the organisation's gatekeeping qualities by holding research teams to high standards before they can engage with people signed up to the database

More broadly

This project will make research samples more diverse and facilitate input and views from people who may not have otherwise had their voices heard or input recognised. Recruiting for dementia research studies is extremely challenging as people with dementia and their carers are a 'hard-to-reach' group, particularly when recruiting through non-medical channels. This project has the potential to greatly alleviate this difficulty by having a centralised list of people with dementia and carers who wish to be a part of dementia research. This will contribute to improving the evidence used to develop policy, services, medical research, and supports.

Consultation process

Seeking individuals views and consultation

[4] National Institute for Health and Care Excellence (June, 2018). Dementia: assessment, management and support for people living with dementia and their carers (NG97).

ASI has prioritised the data protection aspect of this project first to enable it to be build on a firm foundation that can proceed with confidence and in compliance with new data protection laws. People living with dementia and carers will be extensively consulted with before any final launch of this project. We will consult with them on their thoughts on the project itself, in addition to the process of signing up, learning about research opportunities, and having their data transferred to approved researchers. The project will be continuously reviewed and feedback will be sought through surveys.

Other groups to be involved within the ASI

We will also consult with colleagues within the ASI who have different areas of expertise relevant to the project. This will include:

- Staff members working in ASI services
- The Data Protection Officer
- The IT Department
- The Research Department
- The Communications Department
- The Advocacy Department
- The Fundraising Department
- The Finance Department

Consultation with other experts

We have consulted with those working on Join Dementia Research in the UK about the viability, and recruitment strategies in relation to the DRD including the Join Dementia Research Delivery Manager. We have gained valuable insights from their expertise, and JDR provides an excellent service and platform from which we can model our own. The Join Dementia Research Team say they will continue to provide their expertise and guidance throughout the project.

Necessity and proportionality

Lawful basis for processing

All data will be processed on the legal basis of explicit consent. The data subject will be asked to give their explicit consent to being part of the project and having their data transferred to research teams or being contacted and informed about research opportunities (the three consent options have been discussed earlier). This consent will be re-verified at least every 12 months.

Does the processing actually achieve our purpose? Is there another way to achieve the same outcome?

Yes, by processing this level of data we will be able to 'match' and link data subjects with research projects they are likely to be eligible to take part in. In addition, we will be able to keep data subjects informed about research. We are not aware of any other way to achieve this outcome on this scale.

This type of project runs successfully in the UK (Join Dementia Research) and has achieved worldwide recognition. To date, it has 40,000 people signed up to the database with almost 12,000 enrolled in research studies. This includes people with and without a diagnosis of dementia.

Preventing Function Creep

Access to the data will be limited to a very small number of ASI employees on a 'need to know' basis (< 5 employees). These employees will be well informed about the DRD and its dedicated purpose and secondary processing for any other purpose will not be entertained. In this regard the database will be entirely ring-fenced with technical and organisational controls.

Data minimisation

The data collected is essential for 'matching' participants with research studies. Research studies have varying eligibility criteria and it is necessary to understand if a person is likely to be eligible to take part before informing them about the research opportunity. To not store this level of data would make the system inefficient and waste both data subjects' and researchers' time.

When data is transferred to research teams, only the person's name and contact details will be transferred. In some cases, it may also be necessary to include the county (but not the home address) the person lives in, but this will only be transferred if absolutely necessary.

Data quality

Data will be collected directly from the data subject, meaning that inaccuracies are unlikely. The data subject will be contacted at least every 12 months to ensure continued consent and this opportunity will also be used to check the accuracy of the data. Data can easily be amended in Salesforce and the data subject will have the Research Officers contact details should they wish to make any changes to their data.

Information given to individuals

Individuals will be given an ASI data protection Fair Processing Notice (dedicated to the processing carried out by the DRD), Information Leaflet, and a consent form outlining what the person is consenting to. The consent form will have the same wording as the script used to record consent over the phone. All documents will be easy-to-read and piloted with people with dementia and carers to ensure that they are easily understood. In addition, these documents can be augmented by verbal explanations from the Research Officer if needed.

Supporting data subjects' rights

Data subjects will be given an easy-to-read (and previously piloted) data protection FPN document that has all details of data subject rights under GDPR, the purpose and processing that will be carried out including retention and security. The contact details for the ASI Research Officer and DPO will both be on this document, and it will be stressed that data subjects are welcome to contact them should they have any queries. In addition, data subjects will be given contact details for the Data Protection Commission should they wish to contact them to make a complaint or observation.

International Transfers

ASI will not transfer the relevant data outside of the Republic of Ireland. Furthermore, the DRD will only be available to researchers operating within the Republic of Ireland. This is the decided initial stance of the DRD in the face of Brexit and data protection inconsistencies that could arise between the jurisdictions of even the Republic and Northern Ireland. This stance may be reviewed in the future if a more favourable and stable geo-political backdrop was to emerge.

Measures to reduce risk

Planned or existing measures that contribute to data security	Description
Logistical Security Controls	
Equipment Encryption	ASI staff laptops are encrypted. ASI uses three types of encryption within the organization (BitLocker, TrueCrypt, VeraCrypt). BitLocker is the primary encryption software used.
Logical Access Controls	<u>Authentication</u> All AS ICT equipment is password protected. The DRD account on Salesforce will also be password protected (with a different password). Passwords shall be composed of a minimum of eight characters and will be changed regularly. If there are any concerns that a password may be compromised a new password will be set. <u>Permissions</u> When a staff member leaves the ASI, IT closes their accounts. If a role changes and an employee no longer needs access, the employee must inform IT who will then revoke permissions. As the research team involved with the project is small, it can be easily ensured that permissions are swiftly revoked if required.
Traceability (logging)	Salesforce software logs user actions meaning that access to the DRD and actions are traceable to specific users within the organization.
Minimising the amount of personal data	The minimum amount of data required to make the database efficient and effective is stored. When data is transferred to a research team, only the data subjects name and contact details are transferred. In addition, the data subject's county may also be transferred (but not their specific address).
Physical Security Controls	
Physical Access Control	The ASI requires visitors to sign in, and is only accessible using staff member key fobs. Offices are locked when not in use. ASI National Office has a small number of staff, and unknown visitors to the department would be questioned about their presence and who they are meeting.
Organisational Security Controls	

Organisation	The ASI has a Legal Officer/Data Protection Officer who is responsible for providing guidance and advice related to data protection within the organisation. The DPO also works to safeguard the fundamental rights and freedoms of individuals, particularly vulnerable individuals such as Persons with Dementia. The research team involved in the project will have clear and defined roles and responsibilities regarding the protection of privacy.
Relations with third parties	The purpose of the DRD is to 'match' potential participants with dementia-related studies. Third parties (i.e. researchers) must meet the below minimum criteria if they wish to engage with the DRD. • The researcher must fill out the application form detailing relevant study information. • The research team must have proof of appropriate ethical approval for their study. • The research team must sign the ASI DRD Terms & Conditions of Use
Personnel Management	It is mandatory for new ASI staff to attend a comprehensive GDPR training session which is facilitated by the Data Protection Officer. Data protection Training materials, instructional videos and advice memos are also available on the ASI internal “Staff Hub”. In addition, staff involved in this specific project will receive peer-training and information that will include protocols, data protection and privacy guidance specific to the project.
Project Management	Access to the DRD will be limited according to the 'need to access’ principle. Only those working directly on the project (i.e. the ASI Research Department) and the IT department will have access to the DRD. This equates to less than five people. This DPIA is a significant measure to prioritise, plan, and integrate the protection of personal data into this new project. Data protection at all stages of the processing has been given in-depth consideration. Any new staff member who will work with the DRD will receive a presentation on the protocols and processes that are involved to ensure that these are followed. These will also be available on the staff shared drive to refer back to and will essentially amount to a manual on the procedures that must be adopted. This manual will be reviewed at reasonable intervals. Therefore, all those interacting with the DRD will be familiar with the manual, this DPIA, any DPC guidance relating to this DPIA, and the measures required to mitigate against any risks posed to individuals and potential data risks.

Managing personal data violations	Prevailing data laws will be adhered to, and ASI will ensure that any breaches are addressed appropriately and efficiently. If a breach, or suspected breach occurs the ASI manager or staff member concerned will report it to their line manager immediately or as soon as they become aware of the breach. This line manager will in turn swiftly involve the DPO. If any significant delay could result in waiting to communicate with a line manager the incident will be reported directly to the DPO who will assess the risk to individuals. The ASI reaction plan to a breach could include any or all of the following steps: - Gather an immediate detailed description of the nature of the personal data likely to have been contained in the breached documents or digital files. - Ascertain the categories and approximate number of individuals affected. - Describe the likely consequences or risks that may flow from the personal data breach. Risk Assessment conducted (Recital 75 GDPR). - Ascertain the recipient or likely recipient of the personal data. - Consider the engagement of outside data protection advisors to perform an analysis and possible technical forensic assessment of the breach. - Identify the measures that can be employed to mitigate any risks caused by the breach, such as isolating the cause and/or replicating any affected data. - Consider whether external notification action is required. If deemed necessary the DPC will be contacted within 72 hours of becoming aware of the breach. Where the notification to the DPC is not made within 72 hours, it shall be accompanied by reasons for the delay. If the situation is deemed to be “high risk” then the individuals affected will be contacted without undue delay to enable them to take appropriate protective measures. - Consider whether an internal communications plan should be executed across ASI to better educate and inform staff.

Sign off

Item	Name/position/date	Notes
Measures approved by:	Dr Bernadette Rock Research & Policy Manager 01/07/2019	Integrate actions back into project plan, with date and responsibility for completion
Residual risks approved by:	Dr Bernadette Rock	If accepting any residual high risk, consult the DPC before going ahead

	Research & Policy Manager 01/07/2019	

Summary of DPO advice on 02/07/2019: (Clare Murphy, ASI Legal Officer / DPO)

Dr Laura O'Philbin has sought advice from me as DPO over the last number of months as she begins the task of attempting to devise and launch a new Dementia Research Database (DRD). She has consistently taken on board all observations I have made, or problems I have pointed out that required a solution. A pre-DPIA query was submitted to the DPC in relation to explicit consent but unfortunately ASI did not receive a reply. Laura O' Philbin redesigned her proposals to a more streamlined approach to try to by-pass the issues raised in the submitted query. (Therefore this query is no longer relevant).

As DPO, I would have some continuing concerns about the project but this largely centers on the core difficulty of maintaining an informed and valid consent from a Person with Dementia. However, if any organisation can rise to this challenge it is the Alzheimer Society of Ireland. The Assisted Decision Making (capacity) Act 2015 (yet to be commenced) will mean many data controllers will have to grapple with the types of issues outlined in this DPIA due to the presuming of capacity that will become the law.
As this project advances, I would propose that I continue to consult closely with Laura O' Philbin as she takes on board any advice from the DPC and works towards the launch of the DRD. Once in operation I would then propose that the DPO is involved in a structured way in the continued administration of the DRD. This would require a documented audit process, satisfying all training & awareness needs and being on hand to deal with incidents or queries as they arise. Any future concerns that I may have as DPO about how the DRD is functioning I can raise in the following way: discuss it with the ASI Research department and the relevant line management; bring the concern directly to the ASI CEO; report the concern to the ASI Senior Management team; report the concern with the ASI Audit & Risk Committee; report the concern to the Data Protection Commission.

Although the DRD data shared by ASI with third parties is then processed by that third party as a data controller in its own right, I would view it as important for ASI to know if subsequent problems arise to enable ASI effectively manage risk in relation to the data of (vulnerable) individuals. It would not seem appropriate to require third parties to report any breaches of the shared data back to ASI (as this is the remit of the regulator). However, ASI will make it an obligation on third parties to report to ASI any action taken against it by the DPC under s.127, s.137, s.141, s.144 or s.145 of the DPA 2018.
Please note that I am available to discuss any issues that arise as a result of this DPIA and can be contacted directly on clare.murphy@alzheimer.ie

This DPIA has been compiled by:	Dr Laura O' Philbin Research Officer	
This DPIA will be kept under review by:	Dr Laura O' Philbin Research Officer	The DPO should also review ongoing compliance with DPIA

Table of Potential Risks and Mitigations

Issue	Title	Description	Risk Priority	Criticality	Recommended Mitigation	Residual Risk Priority	Residual Criticality
Technical Risks					**Mitigations**		
ASI DRD 001	Data deletion	Data may be destroyed due to technical issue/error on the platform in which it is hosted	3	3	Data will stored on Salesforce and therefore is backed up once a week.	2	2
Governence/Compliance related risks					**Mitigations**		
ASI DRD 002	Service User Data Subject Rights	Service users may not be fully informed of the processing of their data on the Dementia Research Database due to it being explained poorly. As data subjects, they have a right to be informed clearly and transparently on what is happening to their data, in an appropriate manner of communication.	42	14	ASI will ensure that all data subjects are aware their data is being processed and how. ASI has extensive expertise in communicating with people with dementia and their families. Study information materials will be developed and piloted with people with dementia (including input from the ASI Advocacy team). Materials will be in clear, plain English and supplemented with pictures if neccessary. In the case of data subjects with dementia, ASI will communicate with family (if desired) to enhance understanding who will be able to support the person to understand and make decisions in their best interests.	5	5
ASI DRD 003	Cross-border data transfer	Data may be transferred outside the EU by Salesforce or Google.	30	10	The data processors store data within the EU. The DRD will only be available to researchers from the Republic of Ireland who are conducting research within the jurisdiction.	7	3
External Risks					**Mitigations**		
ASI DRD 004	Inappropriate use of data by research teams after handover	When ASI transfers personal data to a research team, this data may not be processed responsibly by the researchers leading to breaches or inappropriate use of the personal data.	50	17	Researchers using the DRD will be required to read and sign the DRD Terms & Conditions, which includes provisions relating to the use and storage of DRD data transferred to them. The T&Cs stipulate that data must be managed according to prevailing data protection legislation and GDPR requirements. Researchers must also have ethical approval to be eligible to utilise the DRD. Research Ethics Committees assess data privacy and security provisions of research teams, in addition to research ethics.	5	5
ASI DRD 005	Hacking	There may be a breach of data held electronically by “hackers”.	81	27	Data will only be stored within Salesforce which is a reputable organisation for data protection. Unique passwords will be used and changed regularly. In addition, it will be policy that the DRD can only be accessed via ASI encrypted equipment.	6	6

People related risks					Mitigations		
ASI DRD 006	Inappropriate disclosures of personal information outside the organisation	Staff members may deliberately or accidentally inappropriately disclose information about members of the DRD to others outside the organisation.	56	14	Access to DRD data will be limited on a 'need to know' basis. All ASI employees undergo mandatory GDPR training. Any ASI employee involved in this project will receive training and information in which data protection, data management and processing will be an integral part. Less than five staff members will have access to the DRD.	6	3
ASI DRD 007	Inappropriate disclosures of personal information within the organisation	Staff members may deliberately or accidentally inappropriately disclose information about members of the DRD to others within the organisation. .	27	9	Access to DRD data will be limited on a 'need to know' basis. All ASI employees undergo mandatory GDPR training. Any ASI employee involved in this project will receive training and information in which data protection, data management and processing will be an integral part. Less than five staff members will have access to the DRD.	5	3
ASI DRD 008	Incorrect recording or modification of data	Data may be recorded or modified incorrectly by an ASI staff member and not rectified in a timely manner.	63	21	Information in the DRD can be easily amended to rectify any incorrect data. Data will be collected dircetly from the data subject which will reduce the risk of incorrect data. Recorded information will be read back to subjects at time of collection to reduce this risk. Consent will be re-verified at least yearly, and this opportunity will be used to check that data are correct. This will be considered a random sampling method for assessing data accuracy. If significant anomolies are arise, a review of processes will be carried out. Only skilled staff will work on data input and management of the DRD.	6	3
ASI DRD 009	Loss of equipment containing data	Accidental loss of electronic equipment by organisation's personnel may lead to risk of disclosure of personal information to third parties.	16	16	ASI equipment is encrypted and password protected. The research Officer is typically based within the Department at ASI National Offices, and laptops are powered down at the end of the day. Data will be stored on the ASI Salesforce account and not stored locally on equipment. This account will be password protected, and a very small number of individuals will have access to this account. Therefore, if equipment is lost it is highly unlikely that data can be accessed by unauthorised persons.	3	3

Process Related Risks					Mitigations		
ASI DRD 010	Legitimate expectations of the individual	Personal data being used for purposes not expected by data subjects due to failure to explain effectively how their data would be used.	36	12	All communications in relation to processing personal data for this project will be reviewed by people living with dementia and caregivers to ensure that explanations are clear. As people with dementia can experience memory loss, it is possible that some data subjects may not recall signing up. Where possible (and where desired) the data subjects next of kin will be involved. Data subjects will be given a hardcopy of all material related to data processing and the project that they can consult. They will also be given easy-to-read information on how to contact the project research officer.	6	3
ASI DRD 011	Securely destroying data	Electronic data (i.e. received via e-mail) data may not be deleted in a timely fashion after being uploaded to Salesforce.	12	12	The importance of deleting/destroying data will be emphasised to any ASI staff involved in signing members up. Data that is received via online sign-up form will be removed from the dedicated e-mail account within 10 working days.	4	4
ASI DRD 012	Data retention	Data may be processed for longer than required leading to unncessary risks	30	15	Data will only be stored for as long as the data subject continues to consent to it. Consent can be withdrawn at any time and data will no longer be processed by ASI. Continued consent will be verified at least once per year. If the data subject passes away, the data will be removed within one week of our knowledge of this.	5	5
ASI DRD 013	Unneccessary or excessive Data processing	Data unnecessary for the project may be collected and processed, leading to unnecessary risks. Design of forms and storage may create this risk.	15	15	A specific form for the puposes of collecting data willl be used so only data that is necessary will be collected. The minimum amount of data neccessary to make the system work will be processed. The current criteria as listed in this DPIA can be amended if neccessary following advice from DPC.	2	2
ASI DRD 014	Inappropriate Staff access to data	Risk of inappropriate accesses given to staff	42	14	The Dementia Research Database will be hosted through the ASI Salesforce account, with only those working directly on the project being granted access (< 5 people). In addition, Salesforce logs user access so illegitimate access can be traced. Access to the Dementia Research Database will be limited according to the 'need to know principle' and access will be password protected. Only those working in the ASI research department and the IT department will have access.	4	4

ASI DRD 015	Untrained staff	Staff who are not aware or knowledgeable of data protection regulations may unknowingly cause a data breach	30	15	It is mandatory for new ASI staff to attend a GDPR training session which is given by the Data Protection Officer. It will be required that staff undertake this training before being given access to the DRD. In addition, staff who are involved in this specific project will receive bespoke training and information that will include data protection. The Research Officer role is a specific post that requires research experience and knowledge of data protection. Typically this person will hold an advanced academic degree and have managed data previously.	6	6
ASI DRD 016	Subject Access Request	Failure to properly fulfil requests to exercise data subject rights due to lack of procedure and defined responsbility.	96	24	A procedure for responding to access requests will be written with the guidance of the DPO. There will be clear responsibility assigned for this task, including who has responsibility should the responsible person be unavailable for an extended period of time.	6	6
ASI DRD 017	Staff resignation	DRD Research Officer leaves their post at ASI meaning that good data protection practices associated with the DRD are not upheld due to lack of knowledge of new post holder.	24	24	Should the project manager leave the ASI, a detailed manual will have been written. This will be handed over to the incoming project manager who will be supported by the remaining members of the research team to uphold data protection policies and procedures on the project.	6	6