DMD Registry

Data Protection Policy

May 2018 v2

Introduction

Action Duchenne established a UK Duchenne Muscular Dystrophy Registry (The Registry). In order to secure compliance with the Data Protection Act (the Act) and GDPR 2018 and with the eight data protection principles, it is necessary for Action Duchenne to issue and maintain this Data Protection Policy. The Policy will act as a guidance for the Trustees and the employees of Action Duchenne to ensure compliance with Action Duchenne's legal obligations in so far as it holds and processes personal data within the Registry.

Scope

This document covers the Data Protection policies for the Registry, with respect to the following Acts of Parliament:-

- **The Data Protection Act 1998 and GDPR 2018)**

The Data Protection Act 1998 and GDPR 2018 covers all "personal data" (including patient information) relating to living individuals that are held on a computer system. It is a criminal offence to hold or disclose information in breach of the registration requirements of the Act and GDPR.

- **The Computer Misuse Act 1990**

The Computer Misuse Act 1990 provides criminal sanctions against unauthorised access or damage to computerised information. Authorised users have permission to use certain programmes and data. If those users go beyond what is permitted, it is a criminal offence. The Act makes provision for accidentally exceeding permitted activities and also covers fraud, extortion and blackmail.

Subjects

The Registry holds personal data on the following data subjects:

- Participant – Person with a variant in their Dystrophin Gene.
- Parent / Guardian - Person with Parental Responsibility (where required) for Participant.
- Health Professionals - Clinicians or other Health Professionals bound to confidentiality of the Participant.
- Researchers
- Administrators

In so far as the Registry holds data on Participants then this will be considered as "sensitive personal data" within the meaning of Section 2 and Schedule 3 of the Act as it relates to the physical health or condition of the data subject.

References

This is a list of policies and consent forms used by the Registry: -

a) Policies and Data

- Governance Policy
- Security Policy
- Terms of Use
- Database Design (review July 2018)
- Participant

b) Participants

- Participant Consent (includes Participant contact and medical data)
- Participant Medical Release Form

• First Principle

The first principle states that data is "Fairly and Lawfully Processed" and in particular shall not be processed unless certain preconditions are met. These conditions will vary depending upon whether the personal data concerned is sensitive personal data.

a) Categories of Personal Data

The following categories of Personal Data are kept in the Registry:

- Contact Information (name, address, telephone, and email).
- Basic Medical Information (date of birth, gender, NHS number)
- Genetic Variation Information (DNA mutation)
- Interventions (e.g. medicines)
- Symptoms (for research projects)
- Clinical Assessments (for research projects)

** The Database design document describes the data in complete detail

b) Grounds for Legitimate Processing of Personal Data

The Personal data held is Contact Information for the family members of the participant, for those involved professionally in the care of the Participants and for those who are carrying out clinical research. All these categories of individuals have consented to the processing of their personal data. Personal Data is held and processed for the following reasons.

- Contact Participants, Parents and Guardians about research
- Contact Doctors about Participants treatments
- Contact Researchers about their Research
- Contact Health Professionals about data validation issues.

c) Grounds for Legitimate Processing of Sensitive Personal Data

Sensitive Personal Data is only kept for Participants. Sensitive personal data includes (all Personal Data except contact data) the following:

- Basic Medical Data (date of birth, gender, NHS number)
- Genetic Variation Data (DNA mutation)
- Medical Interventions (e.g. medicines)
- Clinical Assessments (for research projects)
- Adverse reactions (for research projects)

All the individuals have either given explicit consent for this data to be held or consent has been provided by the appropriate person with parental responsibility. This information is being held in order to help research and the development of treatments of the individuals concerned and of all individuals who are diagnosed as suffering from Muscular Dystrophy as follows:

- Identify Participants for research or treatments
- Cross relate data with research
- Watch for reactions to treatments
- No data in the Registry is held for profit.

d) Obtaining Personal Data

All personal data has been obtained after being given explicit consent either from the data subject or the person with parental responsibility. Consent is agreed during the online registration process which states 'I agree to the DMD Registry Terms and Conditions'. The registration process can only continue and be completed if the appropriate 'tick box' is 'ticked'. Medical Release Forms are required to be printed, signed and returned by post to the DMD Registry Curator, giving consent to contact health professionals to release medical information.

The following consent documents are available online for Participants or persons with parental responsibility: -

- Consent obtained at point of online registration process (agreement to Terms and Conditions)
- Participant Medical Data Form

Personal data is currently acquired using the following forms: -

- Consent obtained at point of online registration process (agreement to Terms and Conditions)
- Participant Medical Data Form

Administrators' and Researchers' necessary contact information is held as part of their role as data controllers or data processors of the database, rather than "personal" data, even though the contact information is part of the Participation personal data.

Health Professionals' necessary contact information is held as part of their role and as such forms *part* of the Participant personal data.

e) Lawful Processing

The Registry complies with the common law duty of confidentiality and Article 8 of the Human Rights Convention (Human Rights Act 1998). All staff have been informed of their obligations of confidentiality under common law, Human Rights law, the Data Protection Act (1988), GDPR 2018 and the Computer Misuse Act (1990). Trustees of Action Duchenne will not have access to any of the data which is held save where it has been anonymised.

f) Fair Processing

Every member of staff has been informed of their obligations to process the data fairly. In processing information Action Duchenne and its staff will pay regard to the interpretation of what is "fair" processing set out at Part 11 of Schedule 1 of the Act. In particular the data subject will be informed of:

- The identity of the data controller
- The identity of any nominated representative of the data controller
- The purpose or purposes for which the data are intended to be processed
- Any further information which is necessary, having regard to the specific circumstances in which the data is to be processed, to enable processing in respect of the data subject to be fair.

g) Exemptions from the First Data Protection Principle

When a Participant references a Health Professional (e.g. Doctor) their contact details will be added to the system. This has been done to allow users of the Registry to contact that Health Professional to improve the treatment of the Participant. The data held about the Health Professional will be restricted to professional contact details.

Researcher contact details will be added to the system because they are using the Registry as part of their work, and the Registry Administrators may need to contact them. The data held about the Researcher will be restricted to professional contact details.

Geneticist contact details will be added to the system because they are using the Registry as part of their work and to validate a Participant's gene mutation as part of the registration process. The data held about the geneticist will be restricted to professional contact details.

Second Principle

The Second Principle states that data is processed for one or more specified and lawful purposes and shall not be further processed in any manner incompatible with that purpose or those purposes. The data subject will be notified of the purposes for which the data is to be used and notification will also be sent to the Information Commissioner.

a) Uses of Personal Data within the Organisation

Personal and Sensitive Personal Data is only to be used to meet the purposes of the Registry, these purposes are as follows:

- Develop and encourage the development of more research into Muscular Dystrophy
- Facilitate research by collecting relevant data and making it available for specified research projects
- Use the information provided to understand the disease better
- Establish contact between clinicians, other health professionals, researchers and Registry participants
- Enhance clinician's and other health professional's ability to deliver treatments for this disease

These purposes have been notified to the Information Commissioner.

b) Uses of Existing Personal Data for New Purposes

When it is proposed that Personal data is to be used for new purposes then consent will be sought from the Steering Committee. The Steering Committee consists of senior advisors, from clinical and clinical research backgrounds and Action Duchenne Director of Research (see Governance Policy Document for more information). A check will be made to determine whether, in accordance with the requirement of fair processing, further consent may need to be obtained and/or further information provided to the data subject. Appropriate notification will be given to the Information Commissioner.

The agreed criteria for Action Duchenne Ltd are:

1. The research proposal is in line with the stated aims of Action Duchenne Ltd.
2. The research grant has been peer reviewed by other notable Scientists, with a reputation in the field.
3. The project will help as many boys as possible across the spectrum to achieve a balance in the funding which is made available to separate bids.
4. The response time and the assessment of whether the research appears to be promising, in terms of likely outcome.
5. The opportunity to work with other organisations and to fund jointly with other organisations longer term research projects and/or research projects requiring more substantial funds.
6. The ability of Action Duchenne to justify its decisions on funding to its members, in terms of demonstrating that it has been fair, equitable and even handed.
7. Taking into account funding of research proposals which other organisations may not fund.
8. Taking into account the views of the members of Action Duchenne, the Person with Parental responsibility for children with Duchenne and adults living with Duchenne.

c) Disclosures of Data

Each different role in the Registry will be allowed to view (or edit) different views of the Data

- **Administrators**

Administrators can edit and view all the data in the Registry.

- **Clinicians and other Health Professionals**

Clinicians and other Health Professionals can view all data (including sensitive personal data) authorised by the Steering Committee. They cannot view administrative data, such as passwords or researcher's data, such as research assessments that have not completed.

- **Researchers**

Researchers can view all data authorised by the Steering Committee, but all the data they view will be anonymous. This means they cannot see contact information or personal identifiers of any Participant, Parent or Guardian.

- **Participant or person with Parental Responsibility**

Participant or Person with Parental responsibility can view their own data. They cannot view administrative data, such as passwords or research assessments that have not completed. They can view their own Participant Assessments as part of a research project, using the privacy scoping rules (see 6c).

The Third Principle

The third principle states that the data held must be adequate, relevant and not excessive for the purposes for which it was collected.

a) Adequacy and Relevance of Personal Data

Action Duchenne has taken great care only to seek to obtain and to hold such Personal Data which can be justified for the purposes for which the Registry has been set up and which is adequate for that purpose. In particular the personal Health data has been selected for the reasons listed above.

Genetic variation data has been selected to match selection the upcoming treatments and research questions. There are a number of standards for recording human genetic variations, some of which has not been considered necessary.

Genetic variation data includes the following:

- Variation and surrounding DNA
- Exon Skipping
- Stop Codon
- Genetic Inheritance

** See Database definition for more details.

The Fourth Principle

The fourth principle states that data must be “accurate and up to date”. Action Duchenne have set up a process to avoid inaccurate or out of date data being held.

a) Accuracy of Personal Data

The following procedures have been put in place to ensure that personal data is accurate:

- **Data entry**

Data is entered online voluntarily by Participant or person with parental authority. The data collection has been carefully designed to reduce ambiguities.

- **Validation**

When data is entered onto the system the data is validated to ensure that it is within defined boundaries.

- **Verification**

All sensitive records are initially entered voluntarily by participant or person with parental authority and the DMD Registry Curator verifies the accuracy with the Participant or person with parental authority. Geneticists enter the gene variation data which is verified independently by a geneticist for accuracy and this is recorded.

- **Access**

Participants and Parents/Guardians can pro-actively view their own information using a password protected account and secure web pages.

b) Keeping Personal Data up-to-date

All subjects on the Registry will have agreed to the Terms and Conditions and consented at the time of registration. It includes a clause that asks that participants agree to be contacted to check their personal data is up-to-date.

Participants, Parents / Guardians are asked to pro-actively provide updated contact information using their password protected account and secure web pages.

The Fifth Principle

The fifth principle states that data should not be kept for longer than is necessary for the purposes for which it was collected for the Registry.

a) Retention Policy

Action Duchenne considers that it will be necessary to hold the data concerned for as long as it remains relevant for the purposes of the development of the effective treatments and the continuation of research into Muscular Dystrophy. Participants of the Registry have been informed that their data will be kept until effective treatments or cures have become established. At this stage it is difficult to predict the time span for which data will be held, but Action Duchenne will ensure that data it holds is reviewed on a regular basis to ensure that redundant or out of date material is no longer held.

b) Review and Deletion of Personal Data

The data which is held will be reviewed at least annually. When notification is received of the death of a Participant, the next-of-kin will be asked if they want the data to be removed or made irreversibly anonymous. When data is made irreversibly anonymous all personal data, such as name address and reference information is removed. The reason for keeping anonymous data is for the continuing purpose of research.

The Sixth Principle

The sixth principle states that data is "processed in accordance with the individual's rights"

a) Subject Access

All subject access to the Registry is online over a secure web connection.

In their consent documents (Terms and Conditions as part of registration process) all participants have been told of their right to access their data.

Participants have been told that they can either do this in one of two ways:

- By writing to Action Duchenne and receipt of a written reply.
- A data subject has access to a secure dedicated user login and view this personal data online.
- The processes will secure that only individuals who can prove their identity and their right to access information will have access to their personal data

b) Appropriate withholding of Personal Data in response to a Subject Access Request

All Participants, Parents or Guardians may be told that there is the possibility that they may not be told about their research assessments until after the research has completed.

The Researchers have the option of restricting access to the Participant Assessments tables using one of the following scoping rules: -

- Private. Only researchers entering data into the Participant Assessment tables can see the data on the tables. In other words, those researchers running the trial.
- Protected. If Participants are given an account, then they can see their own Participant Assessment data (Participant and their Guardians can only ever see their own data). Plus those with private scope can see protected data.
- Public. Registered users can see the research data.

c) Processing that may cause Damage or Distress

There are at least two legitimate reasons for concern.

- Selecting Participant wrongly. In this case, the Registry is used to select Participant wrongly for a research or treatment. This is a false-positive error.
- Not selecting Participant. In this case, the Registry omits to select a Participant for research or treatment. This is an omission error.

To help prevent these errors from happening Researchers and Health Professionals have been warned not to rely exclusively on The Registry as a source of information, but to check their own records.

d) Dealing with Notices served by Individuals

Every member of staff has been told how to deal with subject access request notices.

This means either:

- Create and return a printed reply within 2 weeks.
- Create an online account within 2 weeks.

e) Automated Decision Taking

See 6.c)

f) Rectification, Blocking, Erasure and Destruction

Every member of staff has been trained how to rectify, block, erase and destroy data.

Training will be initially given to Angela Stringer of Action Duchenne by Nvisage Ltd. For any new features added by Nvisage Ltd, further advice or training will be received.

g) Staff Awareness

Every member of staff involved has been given all relevant policy documents and consent forms to read.

The Seventh Principle

The seventh principle states that appropriate technical and organisational measures to be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data Action Duchenne has carried out a risk assessment of the appropriate security measures required and has adopted a Security policy to manage these issues and to ensure appropriate procedures are in place to manage security. The policy will ensure that Action Duchenne's working practices comply with the Act and that staff understand how data should be protected and how to prevent unauthorised disclosure.

a) Unauthorised or unlawful processing of data

The security policy document covers security in more detail.

b) Ensuring Reliability of Staff

The security policy document covers security in more detail.

c) Destruction of Personal Data

The security policy document covers security in more detail.

d) Contingency Planning - Accidental loss, destruction, damage to personal data

The security policy document covers security in more detail.

The Eighth Principle

The eighth principle states that data is "not transferred to countries outside the European Economic area unless the country has adequate protection for the individual."

a) Adequate Levels of Protection

In the event that a research project outside the Registry needs your data it will only be transferred when the following conditions are met.

- The research cannot be done within the Registry database. For example, computing the frequency of genetic variants can be done on the Registry database.
- If data is transferred is transferred anonymously.
- The Steering Committee (consisting of senior medical professionals) has validated that the research will help achieve the goals of the Registry.
- The Registry Manager has authorised the transfer.

In addition, under the Data Protection Act and GDPR a transfer can only be made of data outside the European Economic Area where there is “adequate protection” for the rights and freedoms of the individuals. Before any decision to transfer data outside the European Union is made the Action Duchenne will take legal advice for the test of adequacy in addition to the criteria above.