

Parkinson's UK is the largest charitable funder of Parkinson's research in Europe. So far, we've invested more than £80million in ground-breaking research.

We are committed to ensuring that the outputs of the research we fund, including research data, are managed and used in ways that maximise patient benefit. Making research data widely available to the research community in a timely and responsible manner ensures that these data can be verified, built upon and used to advance knowledge and its application to generate improvements in health.

We regard it good research practice for all researchers to consider at the research proposal stage how they will manage and share the data they will generate. Therefore, we require that applicants applying for funding provide a data management and sharing plan as part of their application. This plan will be reviewed as part of the funding decision.

Any applicants who consider that the data arising from their proposals will not be suitable for sharing must provide clear reasons for not making it available.

DATA SHARING AND PRESERVATION POLICY

1. In order to achieve the greatest impact, Parkinson's UK wishes to ensure that data arising from the research that it funds should be managed and made available as widely and freely as possible to maximise public benefit. Such data must be shared in a timely and responsible manner and researchers who are providing and receiving data are required to adhere to any relevant regulatory requirements including those relating to the ethical use of data.
2. A limited period, defined in consultation with the grantholder, of exclusive use of data for primary research is reasonable, according to the nature and value of the data and the way they are generated and used. Ongoing research contributing to the completion of datasets must not be compromised by premature or opportunistic sharing and analysis. Sharing should always take account of enhancing the long-term value of the data.
3. This policy is not intended to discourage filing of patent applications and recognises the need to safeguard intellectual property, to protect opportunities for commercialisation of research outputs and respect obligations of commercial confidentiality and that it may be necessary on occasion to delay publication or restrict the release of data.
4. Parkinson's UK believes that data sharers should receive full and appropriate recognition (eg by acknowledged collaboration) by funders, their academic institutions and new users for promoting secondary research.
5. For medical research involving personal data, the appropriate regulatory permissions - ethical, legal and institutional - must be in place before the data can be shared.
6. Data arising from Parkinson's UK-funded research should be properly curated throughout its life-cycle and made available with the appropriate high-quality metadata. This is the responsibility of the data custodians, who are usually those individuals that received Parkinson's UK funding to create or collect the data.
7. This data sharing and preservation policy applies to all Parkinson's UK-funded research while recognising that different fields of study will require different approaches. It does not prescribe when or how researchers should preserve and share data, but requires them to make clear provision for doing so when planning and executing their research.
8. New studies that result from this data-sharing should meet the high standards of all Parkinson's UK-supported research regarding scientific quality, ethical requirements and value for money. It should also add recognisable value to the original dataset. Such research is often most fruitful when it is a collaboration between the new user and the original data creators or curators, with the responsibilities and rights of all parties agreed at the outset.

DATA SHARING AND PRESERVATION GUIDELINES

Given the diverse nature of the research supported by Parkinson's UK, the guidelines below do not prescribe precisely how and when investigators should share research data. Instead they should be used to ensure that the principles of the policy are adhered to.

Applicability

Our 'Data sharing and preservation policy' applies:

- to the sharing of final research data for research purposes
- to basic research, clinical studies, surveys and other types of research supported by Parkinson's UK
- especially to unique data that cannot readily be replicated
- to projects that transform or link pre-existing datasets

Data management and sharing plan

All applicants seeking funding from Parkinson's UK will be required to submit a data sharing plan as part of their research grant application. If data sharing is not appropriate, applicants must include a clear explanation why. The data sharing plan will be reviewed as part of the funding decision. Grant assessment panels will assess the appropriateness and adequacy of the data sharing plan and provide specific feedback to applicants where necessary.

We recognise that data sharing strategies will vary according to the type of data collected and thus do not specify the exact content and format of the data sharing plan. We recommend that data should be shared using established standards and existing resources where possible. The following should be considered when developing a data sharing plan:

- the volume, type, content and format of the final dataset
- the standards that will be utilised for data collection and management
- the metadata, documentation or other supporting material that should accompany the data for it to be interpreted correctly
- the method used to share data
- the timescale for release of data
- the long-term preservation plan for the dataset
- whether a data sharing agreement will be required
- any reasons why there may be restrictions on data sharing, eg patient confidentiality
- development arrangements including intellectual property protection and commercialisation
- proprietary data – restrictions due to collaborations with for profit organisations International policies governing the sharing of data collected outside of the UK
- confidentiality, ethical or consent issues that may arise with the use of data involving human subjects.

Parkinson's UK will monitor grantholders' progress in implementing their data management and sharing plan. However, we understand that an investigator may need to adapt the method and timelines for sharing during the course of the study – for example, when potential intellectual property arises unexpectedly.

Intellectual property rights and proprietary data

Data which might have the potential to be exploited commercially or otherwise to deliver patient benefit should be discussed with the investigator's technology transfer office prior to data sharing.

We encourage the appropriate filing of patents and recognise that there may be a need to delay the release of data until patent applications have been filed. Whilst there may be a delay in the release of data due to the application process, appropriate intellectual property protection should not hinder data sharing and may be the best way of ensuring that patient (and public) benefit is delivered.

Any intellectual property issues or plans for commercialisation that may affect data sharing should be addressed in the data sharing plan. We understand that unexpected intellectual property may arise during the course of the study and investigators may need to depart from their data sharing plan to protect intellectual property and for any other necessary steps to be taken.

Data sharing may also be affected when co-funding is provided by the private sector (eg by a pharmaceutical company) or host institution, resulting in some restrictions on the disclosure of data. Any restrictions should be outlined in the data sharing plan and applicants should explore ways data sharing requests can be considered by the body that owns the data.

Standards, metadata and documentation

For data sharing to be a success it is important that data are prepared in such a way that those using the dataset have a clear understanding of what the data mean so that they can be used appropriately. To enable this, applicants are encouraged to include with the dataset all the necessary information (metadata) describing the data and their format. This information should include such information as the methodology used to collect data, definitions of variables, units of measurement, any assumptions made, the format of the data, file type of the data etc. To support this researchers are strongly encouraged to utilise community standards to describe and structure data, (eg common terminology, minimum information guidelines and standard data exchange formats).

Methods for data sharing

The methods used to share data will be dependent on a number of factors such as the type, size, complexity and sensitivity of data. Data can be shared by any of the following methods:

- **Under the auspices of the grantholder:** Investigators sharing under their own auspices may securely send data to a requestor, or upload the data to their institutional website. Investigators should consider using a data-sharing agreement (see below) to impose appropriate limitations on the secondary use of the data.
- **Through a third party:** Investigators can share their data by transferring it to a data archive facility (for instance [Critical Path for Parkinson's](#)) to distribute more widely to the scientific community, to maintain documentation and meet reporting requirements. Data archives are particularly attractive for investigators concerned about managing a large volume of requests for data, vetting frivolous or inappropriate requests, or providing technical assistance for users seeking to help with analyses. This may be particularly suitable for legacy data collections and for studies that no longer actively collect data or receive funding.
- **Using a data enclave:** Datasets that cannot be distributed to the general public due to confidentiality concerns, or third-party licensing or use agreements that prohibit redistribution can be accessed through a data enclave. A data enclave provides a controlled secure environment in which eligible researchers can perform analyses using restricted data resources.
- **Through a combination of methods:** Investigators may wish to share their data by a combination of the above methods or in different versions, in order to control the level of access permitted.

Timeframe for data sharing

As the value of data is often dependent on its timeliness, we expect that data sharing should occur in a timely manner. We acknowledge that the investigators who generated the data have a legitimate interest in benefiting from their investment of time and effort and we therefore support the initial investigator having a reasonable period of private use of the data but not prolonged exclusive use.

We expect data to be made available once published (unless restrictions from third party agreements or IP protection still apply) or on a timescale in line with the procedures of the relevant research area. We recognise that different types of data may be managed differently and refer investigators to [NIH guidance](#) on what might be considered reasonable standards for some common data sharing situations.

With experiments carried out over an extended period of time (eg population based studies) it is reasonable to expect that subsets of data analysed by the investigator(s) be made available for sharing. The investigator(s) can then continue to benefit from further reasonable periods of exclusive analysis while the dataset as a whole matures.

Research involving human participants

Investigators carrying out research involving human participants must ensure that consent is obtained to share information; furthermore the necessary legal, ethical and regulatory permissions regarding data sharing should be in place prior to disclosing any data. Every effort must be made to protect the identity of participants and, prior to sharing, data should be anonymised. In addition, any indirect identifiers that may lead to deductive disclosures should be removed to reduce the risk of identification. In most instances, sharing data should be possible without compromising the confidentiality of participants but if there are

circumstances where data needs to be restricted due to the inability to protect confidentiality this should be fully addressed in the data management and sharing plan.

Where datasets may be valuable for sharing with the [Critical Path for Parkinson's](#) project, the data sharing plan should specifically address the strategy for achieving this. The Parkinson's UK project co-director can advise on this.

Data sharing requests

When a principal investigator is contacted with a request to share his/her data, they may ask the requestor to provide a brief research proposal on how they wish to use the data. It could include the objectives, what data are requested, timelines for use, intellectual property and publication rights etc. This may form the basis of a data sharing agreement (see below). If the principal investigator has doubts over scientific validity of the proposal or the requestor's ability to analyse/interpret data correctly, this should be discussed with the requestor. A refusal to share data in such circumstances must have clear justification.

Data sharing agreements

To ensure that data are used appropriately investigators may consider implementing a data sharing agreement that indicates the criteria for data access and conditions for research use. This can ensure the responsibilities of both parties, along with intellectual property, citation and publication rights are agreed at the outset. It may incorporate privacy and confidentiality standards, as needed, to ensure data security at the recipient site and prohibit manipulation of data.

Data acknowledgement

As a minimum, researchers using shared data are expected to acknowledge the investigators who generated the data upon which any published findings are based. When both parties have collaborated using a shared dataset, co-authorship on publications may be more appropriate. Researchers using shared data are also expected to acknowledge Parkinson's UK for supporting the original study.

Data preservation

Once the funding for a project has ceased researchers should preserve all data resulting from that grant to ensure that data can be used for follow-up or new studies. We expect that data be preserved and available for sharing with the science community for a minimum period of five years following the end of a research grant.