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| Section A. Research Details | | |
| 1. **Full title of research** | Investigation of Brain Structural Changes in Visual Impairment Among Healthy Population | |
| 1. **Short title of research** | Brain Changes in Visual Impairment | |
| 1. **Principal Investigator (PI) / Student Supervisor** | Dr. Elizabeth Johnson | |
| 1. **PI’s training in research ethics and/or research integrity**   Research integrity training within the past 3 years is compulsory for all University research staff and students. Please enter date of relevant course completion (one of 1a, 1b or 1c must be completed). | **Course Title** | **Date completed** |
| 1a. [Research Integrity Core Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (New researchers & students) | 15th March 2023 |
| 1b. [Research Integrity Refresher Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (Experienced researchers) | 20th April 2023 |
| 1c. Other (please specify title) |  |
| 2. [Supplementary Module](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) – Research involving human participants |  |
| 3. [Information Security Training](https://www.infosec.ox.ac.uk/do-the-online-training) |  |
| 1. **Student name and degree programme (if applicable)** |  | |
| 1. **Department/Institute name** | Department of Neuroscience | |
| 1. **University email address** | ejohnson@ox.ac.uk | |
| 1. **University telephone number** | +44 1234 567890 | |
| 1. **Funding Source**   (required for ethics team use) | This research is funded by the UKRI. Funding reference number: HM012345. | |
| 1. **State any** [**conflicts of interest**](https://researchsupport.admin.ox.ac.uk/governance/integrity/conflict) **and explain how these will be addressed** | None | |

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| Section B. Researchers | | |
| 1. **Researcher title and name** | Research Assistant - Emma Davies | |
| 1. **Department / Institute name** | Department of Neuroscience, University of Oxford | |
| 1. **Role in research** | Assisting in data collection and participant recruitment | |
| 1. **Training in research ethics and/or research integrity**   Research integrity training within the past 3 years is compulsory for all University research staff and students. Please enter date of relevant course completion (one of 1a, 1b or 1c must be completed). | **Course Title** | **Date completed** |
| 1a. [Research Integrity Core Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (New researchers & students) | 10th February 2023 |
| 1b. [Research Integrity Refresher Course](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) (Experienced researchers) | 25th March 2023 |
| 1c. Other (e.g. GCP - please specify title) |  |
| 2. [Supplementary Module](https://researchsupport.admin.ox.ac.uk/integrity-and-ethics-training) – Research involving human participants |  |
| 3. [Information Security Training](https://www.infosec.ox.ac.uk/do-the-online-training) |  |

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| Section C. Basic Information | |
| 1. **Provide a brief lay summary of the aims and objectives of the research. This should cover the questions it will answer, any potential benefits and what you will do to address the question.**   **(Maximum 300 words)** | This study aims to investigate structural changes in the brain among a healthy population displaying visual impairment. By utilizing MRI scans, we seek to answer questions regarding the adaptation of brain structures in response to visual deficits. Understanding these changes can provide valuable insights into neuroplasticity and potentially inform interventions for individuals with visual impairments. Participants will undergo MRI scanning sessions to allow for detailed examination of brain structures and their alterations. |
| 1. **List all places where research will be conducted (including any other countries and online)** | Department of Neuroscience, University of Oxford, United Kingdom |
| 1. **Anticipated research start date** | 1st May 2024 |
| 1. **Anticipated research end date**   (n.b. A maximum of 5 years approval can be granted) | 30th April 2026 |
| 1. **Please list any** [**CUREC Approved Procedure(s)**](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/ap) **you will follow** | AP17 CUREC approved procedure IDREC |
| 1. **Please list any CUREC** [**Best Practice Guidance**](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg) **used to develop your research** | BPG 01, BPG 09 |
| 1. **Name of departmental / peer reviewer (if applicable)** |  |

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| Section D. Participants | | | | |
| 1. **Age range of participants** | 18 - 50 years | | | |
| 1. **Are research participants people who may not be able to give free and informed consent?**   e.g. those under 18, prisoners, or adults ‘at risk’ | No | | | |
| 1. **Anticipated number of participants** | 40 | | | |
| 1. **How was the number of participants decided?** | The number of participants was determined based on similar previous studies and the statistical power required to detect significant structural changes in the brain. | | | |
| 1. **Inclusion criteria** | Aged between 18 and 50 years  Good general health  Presence of visual impairment (e.g., corrected vision worse than 20/20) | | | |
| 1. **Exclusion criteria** | History of neurological or psychiatric disorders  Current use of psychoactive medications  MRI contraindications (e.g., metal implants) | | | |
| 1. **Please mark ‘X’ against all planned recruitment methods**   Provide copies of all recruitment material for review | Poster advert | |  | |
| Flyer | |  | |
| Email circulation | |  | |
| In-person approach | |  | |
| Website | |  | |
| Social media (e.g. twitter, Facebook) | |  | |
| Snowball sampling (recruiting through contacts of existing participants) | |  | |
| Newspapers | |  | |
| Research recruitment sites (e.g. Prolific Academic, Amazon Turk) | |  | |
| Existing departmental contacts or volunteer database | |  | |
| Other (please specify) | |  | |
|  | | | |
| 1. **How will potential participants be identified and approached?** | Recruitment material will be distributed within university premises, including posters in common areas and emails circulated through departmental mailing lists. Social media platforms will also be utilized to reach a broader audience. Potential participants will be directed to a dedicated website for further information and to express their interest in participation. | | | |
| 1. **Will informed consent be obtained from the research participants or their parents/ guardians?**   If not, please explain why not in the box below | | Yes | | No |
|  | | | | |
| 1. **For each activity or group of participants, explain how** [**informed consent**](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent) **will be obtained from the participants themselves and/or their parents/guardians, if applicable. How will their consent be recorded?** | Informed consent will be obtained from each participant before any study procedures commence. Participants will receive detailed information about the study, including its purpose, procedures, risks, and benefits. Consent will be recorded using a written consent form, which participants will sign prior to their involvement in the study. Additionally, all participant-facing materials, including recruitment material and information sheets, will be reviewed by the ethics committee to ensure clarity and transparency. | | | |

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| Section E. Research methodology | | | |
| 1. **Please mark ‘X’ against the methods that will be used in your research**   Ensure you address each method you will use in your informed consent documents and on this form | | | |
| Use of casual or local workers (e.g. interpreters) |  | [Audio recording](https://researchsupport.admin.ox.ac.uk/covid-19/data#collapse2299901) of participant |  |
| Interview (refer to guidance in [BPG 10: Conducting research interviews](https://researchsupport.admin.ox.ac.uk/files/bpg10conductingresearchinterviewsv10pdf)) |  | [Video recording](https://researchsupport.admin.ox.ac.uk/covid-19/data#collapse2299901) of participant |  |
| Focus group |  | Photography of participant |  |
| Participant completes questionnaire in hard copy |  | Physiological recording from participant |  |
| Participant completes online questionnaire or other online task (refer to guidance in [BPG 06: Internet-mediated research](https://researchsupport.admin.ox.ac.uk/files/bpg06internet-basedresearchpdf)) |  | Taking a sample of blood or other bodily fluid from a participant |  |
| Use of social media to recruit or interact with participants (refer to guidance in [BPG 06: Internet-mediated research](https://researchsupport.admin.ox.ac.uk/files/bpg06internet-basedresearchpdf)) |  | Participant observation |  |
| Analysis of existing records |  | Covert observation |  |
| Participant performs verbal or aural task |  | Systematic observation |  |
| Participant performs paper and pencil task |  | Observation of specific organisational practices |  |
| Participant performs computer based task |  | Other (please specify below) |  |
| Measurement/recording of motor behaviour |  |  | |
| 1. **Provide a lay description of the research design and methods. In particular, describe clearly what participants in the research will be asked to do.** | | | |
| The research will be conducted at the Department of Neuroscience, University of Oxford. Participants will be briefed on the study objectives, procedures, and risks involved before providing informed consent. The study will involve a single session of MRI scanning, during which participants will undergo structural brain imaging. Participants will also complete standardized questionnaires assessing visual impairment and general health status. The duration of the MRI scanning session will be approximately 45 minutes to 1 hour. Standardized questionnaires to be utilized include the Visual Functioning Questionnaire (VFQ-25) and the Short Form Health Survey (SF-36). | | | |
| 1. **Will the research include any audio, video or photographic recordings?** | | | |
| No | | | |
| 1. **Biological sample handling** | | | |
| No samples will be taken. | | | |
| 1. **Please detail all expenses or gifts that will be offered to participants.**   Guidance is available in [Best Practice Guidance: 05 Payments and incentives in research](https://researchsupport.admin.ox.ac.uk/files/bpg05paymentsandincentivesinresearchv10pdf). | | | |
| Participants will receive a £20 Amazon voucher as a token of appreciation for their time and contribution. | | | |

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| Section F. Ethical Considerations For guidance on ethical issues, please see <http://researchsupport.admin.ox.ac.uk/governance/ethics/resources>  (N.B. To complete, double click on the check boxes and select ‘checked’) | | |
| 1. **Will the research involve any participants considered** [**vulnerable**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#V) **in the context of the research (e.g. children, elderly, prisoners)?**   **If yes,** please describe how they are defined as vulnerable and detail any CUREC Approved Procedures or guidance that will be applied to the research (for current documents and templates see <https://researchsupport.admin.ox.ac.uk/governance/ethics/resources>).  **If yes, and you cannot apply any Approved Procedure, please cease completion of this form** – a CUREC 2 application is required | Yes | No |
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| 1. **Will** [**unequal relationships**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#U) **exist between participants and those obtaining informed consent?**   **If yes,** describe the nature of the unequal relationship and how arising ethical issues will be addressed | Yes | No |
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| 1. **Will the research involve questions and/or discussions of contentious and/or sensitive issues (e.g. information relating to ethnicity, political opinions, religious beliefs, physical/mental health or sexual life)?**   **If yes,** please justify why this is required and provide a copy of the questionnaire raising the issues that will be used in your research. | Yes | No |
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| 1. **Will the research involve deliberate** [**deception**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary/#D) **of participants?** | Yes | No |
| **4b. If you answered yes to F4, is the deception outside the scope of** [**CUREC Approved Procedure 07**](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/ap#collapse397216)**?**  **If yes, please cease completion of this form** – a CUREC 2 application is required | Yes | No |
| 1. **Could the proposed research affect your own physical and/or psychological safety as a researcher?**   **If yes,** describe how you will manage this. Explain what safety procedures, structured mentoring or other ongoing support will be in place during this research. Include details of lone working procedures, if applicable. | Yes | No |
|  | | |
| 1. **How will you ensure the research is conducted according to the details given in this form?** | | |
| Weekly meetings to discuss progress involving the principal investigator and research assistants  Supervisory process for students, if applicable, with regular check-ins and feedback sessions  Adherence to protocols will be ensured by the principal investigator and research team members. Any deviations will be reported promptly to the ethics committee.  Procedures for handling adverse events, such as injury to participants or data breaches, will be clearly outlined and followed. | | |
| 1. **Please give details of any other research-specific ethical and/or safety considerations, including whether there might be any risks or benefits to the wider community.** | | |
| The research poses minimal risks to participants and the wider community. However, participants will be informed about the potential risks associated with MRI scanning, such as claustrophobia and discomfort. | | |
| 1. **How do you propose to deal with / handle any incidental findings?** | | |
| Not applicable. | | |
| 1. **Will any data or information from this study be provided to individual participants?** | | |
| No | | |

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| Section G. Other Considerations | | |
| 1. **Is any part of this research being conducted overseas?**   **If yes,** please give details below. Explain how you will address any ethical issues specific to the local context. Please provide details of the local review, approval or permission obtained or required. If there will be no local review, explain why not. You may find it helpful to refer to CUREC’s [BPG 16: Social science research conducted outside the UK](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg).  Ensure you complete and submit a [travel risk assessment](https://safety.admin.ox.ac.uk/travel-and-fieldwork) to your departmental safety officer, if your department requires this. (This is necessary to ensure the travel/ fieldwork is covered by the University’s travel insurance – see [http://www.admin.ox.ac.uk/finance/insurance/travel](http://www.admin.ox.ac.uk/finance/insurance/travel/))Please also address any physical or psychological risks for Oxford researchers and local fieldworkers in the ‘Ethical Considerations’ section above and discuss these with your safety officer. | Yes | No |
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| 1. **Please list any stakeholder or community engagement that has been, or will be, undertaken in relation to the research** | | |
| Stakeholder engagement will involve discussions with local organizations working with visually impaired individuals to ensure the research aligns with their needs and interests. | | |
| 1. **Does your research raise issues relevant to the Counter-Terrorism and Security Act (**[**the Prevent Duty**](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445916/Prevent_Duty_Guidance_For_Higher_Education__England__Wales_.pdf)**), which seeks to prevent people from being drawn into terrorism?**   **If yes,** please say how you plan to address any related risks. Please see advice on this on our [Best Practice Guidance Web Page](http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg). | Yes | No |
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| Section H. Data Management and Handling | | | | | |
| All information provided by participants is considered **research data** for the purpose of this form. Any research data from which participants can be identified is known as [**personal data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P); any personal data which is sensitive is considered [**special category data**](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#S).  Management of personal data, either directly or via a third party, must comply with the requirements of the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018, as set out in the [University’s Guidance on Data Protection and Research](https://researchsupport.admin.ox.ac.uk/policy/data).  In answering the questions below, please also consider the points raised in the [Data Protection Checklist](https://researchsupport.admin.ox.ac.uk/policy/data/checklist) and whether, for higher-risk data processing, a separate [Data Protection Impact Assessment](https://compliance.admin.ox.ac.uk/privacy-by-design) may also be required for the research. Advice on research data management and security is available from [Research Data Oxford](http://researchdata.ox.ac.uk) and your local IT department. Advice on data protection is available from the [Information Compliance team](mailto:information.compliance@admin.ox.ac.uk).  **Please mark ‘X’ against the data you will collect for your research** | | | | | |
| Screening documents |  | Audio recordings | |  | |
| Consent records including participant name or other identifiers (e.g. written consent forms, audio-recorded consent, assent forms) |  | Video recordings | |  | |
| Consent obtained [anonymously](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#A) (e.g. via online survey) |  | Transcript of audio/video recordings | |  | |
| Opt-out forms |  | Photographs | |  | |
| Contact details for the purpose of this research only |  | Information about the health of the participant (including mental health) | |  | |
| Contact details for future use ([guidance](https://compliance.admin.ox.ac.uk/mailing-lists#collapse1041266)) |  | Physiological test results / measurements | |  | |
| Field notes |  | MRI scans | |  | |
| Task results (e.g. questionnaires, diary completion) |  | IP addresses (refer to [Best Practice Guidance 09: Data collection, protection and management](https://researchsupport.admin.ox.ac.uk/files/bpg09datacollectionandmanagementpdf) for guidance) | |  | |
| Data already in the public domain.  Specify the source of the data: |  | Other (please specify below) | |  | |
| Previously collected (secondary) data |  |  | | | |
| Bank details for payment |  |
| **How and where will each type of data be stored whilst the research is ongoing (until the end of all participant involvement)?**  List each type of data selected above, and explain how each will be physically transferred (including movement/sharing of audio files, paper records, electronic downloads etc.) from where it is collected to a suitable storage site (e.g. [Nexus365 OneDrive for Business](https://help.it.ox.ac.uk/nexus365/which-onedrive), SharePoint, University servers). State the storage location for each. Do not store unencrypted data in freely available cloud services or unprotected USB drives.  Refer to Best Practice Guidance on data collection, protection and management ([BPG09](https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/bpg)). | | | | | |
| Consent records, screening documents, questionnaire results: Paper consent records will be stored securely in a locked filing cabinet within the researcher's office.  MRI scans: Digital MRI scans will be stored on encrypted servers within the University network. | | | | | |
| **Will you use a unique participant number on research data instead of participant name?**  **If yes,** state whether or not you will retain a list of participant names against numbers ([pseudonymisation](https://researchsupport.admin.ox.ac.uk/governance/ethics/faqs-glossary/glossary#P) via a linkage list).  **Where will the list be stored, and when will it be destroyed?** | | | | | |
| Yes, participant numbers will be used. A pseudonymisation list linking participant names to numbers will be securely stored on encrypted computers within the University network and destroyed at the end of the study. | | | | | |
| **Who will have access to the research data?** | | | | | |
| Researchers listed on the form will have access. Access will also be granted to the MS IDREC for monitoring and audit purposes. | | | | | |
| **If research data is to be shared with another organisation, how will it be transferred / disclosed securely?** | | | | | |
| If data is shared, it will be transferred securely using encrypted methods to ensure confidentiality. | | | | | |
| **When and how will identifiable data (including audio/video recordings & photos) be destroyed or deleted?**  N.B. If any identifiable data will be retained beyond the end of the study and/or indefinitely, please state what data this is, and the reasons for retention (e.g. contact details for future studies; photos used in publication). This must be clearly stated on participant information, and specific consent obtained. | | | | | |
| Identifiable data, will be destroyed within 2 years after completion of the study, unless specific consent for retention is obtained. | | | | | |
| **Please confirm that you will store other (non-identifiable) research data safely for at least 3 years after final publication or public release and adhere to any** [**additional research funder policies.**](http://researchdata.ox.ac.uk/funder-requirements/)  For more information about the University policies, please see the University’s web pages on [research data management](http://researchdata.ox.ac.uk/).  **If ‘Yes’**, please give details of who will store the data and on storage format, location and security.  **If ‘No’**, please provide further details. | | | Yes | | No |
| Yes, non-identifiable research data will be stored securely for at least 3 years after final publication or public release. Data will be stored in encrypted format on University servers. | | | | | |

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| Section I. Publication and Dissemination of Results | |
| 1. **How will you disseminate and feedback project outcomes at the end of the research?** | Project outcomes will be disseminated through academic publications, conference presentations, and public talks. Participants will receive summaries of the results upon request. Open science practices will be followed, including open access to research data and publications through institutional repositories. Additionally, findings will be shared with relevant stakeholders and community organizations. |

# Declarations and signatures

**In providing signatures, the MS IDREC Secretariat will accept either:**

**Option 1:** Email confirmations sent from a University of Oxford email address. Separate emails should be sent by each of the relevant signatories as outlined below, indicating acceptance of their responsibilities.

**Option 2:** That the form be fully-signed with handwritten (wet-ink) signatures. Please scan these and the rest of the form pages to create a single PDF document and email to us.

# Principal Investigator (and student if applicable)

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| --- | --- |
| I/We, the researcher(s):   1. Understand our responsibilities as outlined on this form and in the CUREC glossary and guidance 2. Agree to start this research only after obtaining approval from the MS IDREC; 3. Understand that the Principal Investigator must ensure that all researchers are suitably qualified and trained to conduct the research described, or are appropriately supervised until deemed qualified/trained; 4. Agree to provide additional information as requested by the MS IDREC before approval is secured and as research progresses; 5. Agree to maintain the confidentiality of all data collected from or about participants; 6. Agree to notify the MS IDREC in writing immediately of any proposed change to the research, and await approval before proceeding with the proposed change; 7. Agree to notify the MS IDREC if the Principal Investigator changes and supply the name of the successor; 8. Will use the data collected only for the research for which approval has been given; 9. Will grant access to data only to authorised persons; and 10. Have made arrangements to ensure that [personal data](https://www.admin.ox.ac.uk/curec/faqs-glossary/glossary/#d.en.163302) collected from participants will be held in compliance with the requirements of the GDPR and the Data Protection Act 2018. | |
| **Principal Investigator (Name)** |  |
| **Principal Investigator (Signature)**  Pasted images of signatures cannot be accepted |  |
| **Date** |  |
| **Student (Name)** |  |
| **Student (Signature)**  Pasted images of signatures cannot be accepted |  |
| **Date** |  |

# Acceptance by Head of Department/Faculty or Designated Nominee\*

\*Another senior member of the department may sign where the head of department is the Principal Investigator, or where the head of department has appointed a nominee. Example nominees include Deputy Head of Department, Director of Research, or Director of Graduate/Undergraduate Studies.

* I have read this application, and am aware of the research proposed.
* To the best of my knowledge, the proposed design and scientific methodology do not raise concerns.
* I support this research in principle, subject to ethical and other necessary reviews.

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| **Head of Department or designated nominee (Name)** |  |
| **Head of Department or designated nominee (Signature)**  Wet-ink signature (not pasted electronic image)  *or*  The Head of Department/nominee can send an email (including PI name and study title) to [ethics@medsci.ox.ac.uk](mailto:ethics@medsci.ox.ac.uk) confirming the above |  |
| **Date** |  |