# Section 4: Application for Ethical Approval

Who should complete this form?

The Cambridge Psychology Research Ethics Committee considers applications for ethical approval for research programmes in human psychology. Studies involving patients attending NHS clinics or administration of controlled or prescription pharmaceuticals or devices would normally seek ethical approval via the National Research Ethics Service. If you would like further advice on the suitability of a project for review, use the contact addresses given below.

How is the form completed?

Answer all questions using the notes and Handbook as guidance. Keep all responses to questions within the boxes. There is no limit to the length of responses; the boxes will expand to accommodate the text. However, be brief but precise. Clarity is important to effective and timely ethical review.

Any supporting information (e.g. questionnaires, advertising materials, Information Sheets, Consent Forms) should be clearly labelled as appendices to the application form and referred to as appropriate in responses to questions.

The primary applicant or any of the co-applicants can complete the form, although the Corresponding Applicant will be the first point-of-contact for communication between the Committee and the study team.

The Committee assumes that any application relating to a study that forms part of a taught course has been discussed with the Head of Department. Copies of all correspondence from the Committee relating to such applications will also be sent to the Head of Department.

All applicants must sign and date the form. Electronic signatures or scanned images of signatures are acceptable. Ink signed signatures should be scanned and submitted with the application form.

Once complete where is the form submitted?

Completed application forms and appendices can be emailed to: [Cheryl.Torbett@admin.cam.ac.uk](mailto:Cheryl.Torbett@admin.cam.ac.uk) or sent on digital media (e.g. CD, DVD) to: The Secretary of the Cambridge Psychology Research Ethics Committee, School of the Biological Sciences, University of Cambridge, 17 Mill Lane, Cambridge CB2 1RX.

If you have any queries regarding submission contact: [Cheryl.Torbett@admin.cam.ac.uk](mailto:Cheryl.Torbett@admin.cam.ac.uk)

or telephone: 01223 766894.

What happens next?

Refer to the web-site of the Cambridge Psychology Research Ethics Committee (<http://www.bio.cam.ac.uk/sbs/psyres/>) for information on the review process and time-lines for ethical approval.



COUNCIL OF THE SCHOOL OF THE BIOLOGICAL SCIENCES

Cambridge Psychology Research Ethics Committee

**Question 1: Title of the study**

*Notes: The title should be a single sentence*

Building a participatory citizen science platform to improve the lives of autistic people.

**Question 2: Primary applicant**

*Notes: The primary applicant is the name of the person who has overall responsibility for the study. Include their appointment or position held and their qualifications. Primary applicants cannot be research students or junior research assistants. For studies where students and/or research assistants will undertake the research, the primary applicant would normally be their supervisor.*

Dr. Kirstie Whitaker, Senior Research Associate, Department of Psychiatry, University of Cambridge and Research Fellow, Alan Turing Institute.

PhD in Neuroscience, University of California, Berkeley, 2012; MSc, Medical Physics, University of British Columbia, 2007; BSc, Physics, University of Bristol, 2004.

**Question 3: Co-applicants**

*Notes: List the names of all researchers involved in the study. Include their appointment or position held and their qualifications*

Dr. James Cusack, Director of Science, Autistica. PhD, Biological motion perception in Autism, University of Aberdeen 2012; MA (hons) Psychology, University of Aberdeen, 2008. Advanced Certificate, Autism in Education, 2005.

Bethan Davies, Discover Co-ordinator, Autistica. MA English Literary Studies, Victorian Studies. University of Exeter, 2015. BA English Literature with Proficiency in Italian, University of Exeter, 2014.

Georgia Aitkenhead, Citizen Science Lead, Autistica. M.Phil, Modern and Contemporary Literature, University of Cambridge, 2015. B.Phil, English language and literature, University of Oxford, 2012.

**Question 4: Corresponding applicant**

*Notes: Give the name of the person to whom correspondence regarding this application is to be addressed. This person should be the primary applicant or one of the co-applicants. An email address for correspondence must be provided.*

Kirstie Whitaker, [kw401@cam.ac.uk](mailto:kw401@cam.ac.uk)

**Question 5: In which Department(s) or Research Unit(s) will the study take place?**

*Notes: Indicate where the study procedures will take place as well as the location for the storage and analysis of data. If the study will use National Health Service facilities, give a contact name and address of the Trust R&D office.*

Researchers primarily located at The Alan Turing Institute, The British Library, 96 Euston Road, London NW1 2DB. KW employed through Department of Psychiatry, University of Cambridge.

Collaborators employed by Autistica at Autistica head office, St Saviours House, 39-41 Union St, London SE1 1SD.

This is an openly developed citizen science project, so our contributors will be located around the world.

The storage and analysis of anonymised data or data that has been consented to be made publicly available storage will be on cloud service providers.

Personal data will be stored on Alan Turing Institute or Autistica servers.

For more detail **see our answer to Q21**.

**Question 6: What are the start and end dates of the study?**

*Notes: If exact dates are unavailable, explain why and give approximate dates.*

Initial scoping for the project will start in spring 2019 (when ethical approval is received) and extend for 6 months to the autumn of 2019.

This part of the project will involve scoping the platform requirements and getting feedback on the design.

We will submit a separate ethics approval request for the final design. We expect this submission to happen in winter 2019.

**Question 7: Briefly describe the purpose and rationale of the research**

*Notes: Attach any detailed research proposals, if they have been submitted or will be submitted to a funding body. Make the objectives of the study clear.*

Numerous studies into sensory processing and autism have confirmed that autistic people experience sensory processing differences, and that this can significantly impact their lives. One aspect which is not yet fully understood is how sensory processing differences affect the ways in which autistic people navigate different environments. In order to help understand this area more fully, we aim to build a platform to gather a wide range of autistic people’s experiences. We imagine a secure, public platform where people can upload free text entries, photographs and demographic information about how they navigate different environments, any barriers they face and strategies to overcome them.

There are key challenges in the responsible and ethical management of data relating to personal and often upsetting experiences. **The purpose of this phase of the research is to scope and design the citizen science platform in close collaboration with members of the autistic community.** Our goal is to develop a framework for ethical participatory citizen science. The primary deliverable is an open access academic article describing the framework along with publicly available resources that can be easily re-used by others.

In order to ensure that the work achieves its goal of improving the lives of autistic people, they must be involved in the co-development of the platform from the start. Members of the autistic community – autistic people, their relatives and carers – are integral to the process of researching, building, and designing the platform, which will be modified iteratively based on their feedback. We will gather this feedback from in person focus groups and via online platforms such as Google Forms and GitHub project management tools (issues and pull requests).

The project described here relates to the design of the platform, the development of the data management processes – including who will have access to the data for secondary research purposes – and the evaluation of openly built protypes. We will seek **separate ethics approval** **at a later date** when launching the platform to gather and store data to answer specific research questions.

**Question 8: Who is funding the costs of the study?**

*Notes: Give the name and address of funding bodies or other sponsorship (other than the University of Cambridge) involved in providing resources for the study.*

The costs of the study will be funded by Autistica through a grant to The Alan Turing Institute to support a post-doctoral fellow to develop the platform and manage the dataset. Autistica will also finance other costs incurred, such as recruiting for the initial discovery phase of the project, paying expenses for participants travelling to focus group sessions, and making the autistic community aware of the platform.

Resources will also be provided directly by the Alan Turing Institute through partial (50%) overhead support for the research staff and in providing a venue to conduct focus group sessions.

Kirstie Whitaker is funded through a five-year Turing Research Fellowship under EPSRC Research grant (TU/A/000017). James Cusack and Bethan Davies are full time staff at Autistica. Georgia Aitkenhead is funded by Autistica for a two year postdoctoral fellowship at the Alan Turing Institute (May 2019 – April 2021).

**Question 9: Describe the methods and procedures of the study**

*Notes: Attach any relevant material (questionnaires, supporting information etc.) as appendices and summarise them briefly here (e.g. Cognitive Failures Questionnaire: a standardised self-report measure on the frequency of everyday cognitive slips). Do not merely list the names of measures and/or their acronyms. Include information about any interventions, interview schedules, duration, order and frequency of assessments. It should be clear exactly what will happen to participants. If you are collecting any human tissue samples (for example, saliva, urine, blood, breast milk), please confirm that they will be stored at a location that has an appropriate licence from the Human Tissue Authority.*

For this project is it necessary that we consult with the autistic community to find out about their needs, priorities, desires and concerns for the citizen science platform. We will base the process by which we build the platform, as well as the type of platform we decide to build, on the results of this consultation.

It is also necessary that we seek input from the software development and open source data science communities to ensure that we design a platform that can implement the needs articulated by the autistic community.

We will collect feedback and recommendations in person and online. Details of participant identification and recruitment are answered in **Q11** and **Q12**, informed consent processes in **Q13** and data management in **Q21**.

Our methods to collect information **in person** are:

* A series of discussion sessions with up to 16 participants, including autistic adults and the relatives and carers of autistic people. We will record and transcribe these sessions and extract high level summary information.
* A series of one to one feedback interviews (in person and via video conferencing software) on the prototype design of the platform.

Based on the research team’s experience with focus groups, we will also offer the opportunity for participants to submit additional comments by email after the session. These comments will be incorporated into the focus group content and incorporated into the high-level summary reports. If they are received after the report is published, the participant will be invited to submit their feedback via the online survey described below.

Our methods to collect information **online** are:

* An “always open” online survey asking for feedback via Google Forms: <https://goo.gl/forms/dDu0CDCLiXOm32GH3>
* Via online discussion around specific development points at our GitHub repository (through issues and pull requests): <https://github.com/alan-turing-institute/AutisticaCitizenScience>

The online survey will not collect publicly identifying (names, addresses) or demographic (ethnicity, age) information except for the contributor’s personal connection to autism. The form asks contributors to acknowledge that “I understand that the information I provide in this form will be made publicly available.” See appendix 1 for a PDF copy of the form (**A1\_OnlineSurvey.pdf**).

The key insights will be synthesised and shared by members of the research team, in collaboration with the online and in-person community. We will publish all academic papers in an open access format and will have an autistic co-author on all outputs from the project.

**Question 9a: Does the study involve any pharmaceutical or other compounds with physiological effects?**

*Notes: This includes all compounds licensed under the Medicines Act. However, some compounds may be considered as Investigational Medical Products and studies of them, therefore, as clinical trials (CTIMPs). If there is any ambiguity, investigators should contact the Medicines and Healthcare Products Regulatory Agency (MHRA) for guidance. Include any response from the MHRA in your application. CTIMPs must seek NRES approval.*

No.

**Question 10: What ethical issues does this study raise and what measures have been taken to address them?**

*Notes: Describe any discomfort or inconvenience that participants may experience. Include information about procedures that for some people could be physically stressful or might impinge on the safety of participants, e.g. noise levels, visual stimuli, equipment; or that for some people could be psychologically stressful, e.g. mood induction procedures, tasks with high failure rate. Indicate what procedures are in place if clinically relevant information arises from the study (e.g. from brain scans or questionnaire responses that might indicate that a participant is at risk).*

There has been a history of autism research that has not included the voices or considered the needs of autistic people. We are led by the “nothing about us without us” philosophy of ensuring representation of the affected community at all points in our research process. This means balancing the needs of a potentially vulnerable population with an ethos of transparency. We are committed to building and providing open source resources that can be used and re-used by anyone for any purpose. This also requires clear communication of the principles and values of the project community.

In asking for their feedback on the design of the project we will ensure that we are building a platform that is of use to autistic people and that is accessible to as many members of their community as possible. We ask for ethical approval to capture their contributions so that we can publish academic papers to inform future projects that wish to explore participatory citizen science solutions.

For our in-person interactions:

* The lead researcher at any focus group will have a current disclosure or barring service (DBS) or Disclosure Scotland certificate.
* We will hold events such that they can be accessed outside of peak travel hours and provide clear directions to alleviate the stress of travelling to the venue. We will adjust light and sound levels as requested by the participants to ensure they are comfortable during the session.
* We will have multiple facilitators available to ensure all participants’ needs are met – such as providing them with additional food or water, a quiet space to decompress, or access to the bathroom. We will make clear from the beginning that they can leave the room – and the focus group itself – at any time without giving a justification.

For our online interactions (most likely via GitHub conversations):

* We have a clear set of values which we will link to from any online spaces that are used for the project (see appendix **A2\_ValuesAndOutcomes.pdf**). All collaborators will be expected to abide by these values in all online interactions.
* We have a community code of conduct and enforcement process (<https://github.com/alan-turing-institute/AutisticaCitizenScience/blob/master/CODE_OF_CONDUCT.md> and **A3\_CodeOfConduct.pdf**). Kirstie Whitaker will act as the moderator of the online space, and will ask the contributor to remove any content that infringes our values. If necessary, the research team will bar (temporarily or permanently) individuals from further contributing to the project if they persistently violate the code of conduct.

We will proactively and iteratively design our online working space so that it is supportive and inclusive of contributors, based on seeking continuous feedback. Dr Whitaker has expertise in creating inclusive and supportive online communities. She will be responsible for managing the project’s online engagement and ensuring that any bullying, discrimination, or other infringements of our values code is appropriately dealt with.

We have a clear reporting pathway to ensure all participants can escalate complaints about their experience within the project (appendix **A4\_BuildingASafeCommunity.pdf**). This pathway can be followed by any participant, contributor, or researcher. We will email all consultation session participants a link to the referral pathway, explain it in person, and we will feature a prominent link to the referral pathway on our online spaces, so that it is transparent to all.

**Question 11: Who will the participants be?**

*Notes: Describe the groups of participants that will be recruited and the principal eligibility criteria and ineligibility criteria. Make clear how many participants you plan to recruit into the study in total.*

For the in person workshops, we plan to run 3-4 events and recruit a total of up to 16 members of the autistic community for each consultation, including autistic people and their carers and relatives. All participants will be over 18 years of age and have capacity to give informed consent. The workshops will be based in the UK.

We will recruit from Autistica’s Discover Network (<https://www.autistica.org.uk/our-research/discover-network>; 11,000 people) and Insight Group (<https://www.autistica.org.uk/get-involved/calmer-christmas/help-shape-research>; 250 people). Both communities are members of the autistic community who have volunteered to be contacted by Autistica for the purposes of research. The eligibility criteria is that participants must be over the age of 18, and must be either autistic or the carer or relative of an autistic person.

For the online participation, we will promote the project within the Discover Network and through the Turing and Autistica’s online and social media networks. We will not be able to control the demographics of who provides us with online information – whether publicly through a GitHub comment or review, or privately through the online survey. We will make clear that the information submitted through the online survey will be summarised and shared publicly before anyone submits their information.

We anticipate that we will receive input from a global community of autistic and neurotypical people. In particular we hope to receive feedback on both the design and goals of the project and contributors to the open source development of the software and infrastructure.

**Question 12: Describe the recruitment procedures for the study**

*Notes: Gives details of how potential participants will be identified or recruited. Include all advertising materials (posters, emails, letters etc.) as appendices and refer to them as appropriate. Describe any screening examinations. If it serves to explain the procedures better, include as an appendix a flow chart and refer to it.*

For the in person events we will recruit from Autistica’s Discover Network and Insight Group. Recruitment materials are available online at <https://www.autistica.org.uk/get-involved/take-part-in-research> and in appendix **A5\_AutismInsightGroupRecruitmentForm.pdf**.

For the online recruitment we will encourage people to openly share their feedback and suggestions via social media, our GitHub repository, and via project pages on the Turing Institute and Autistica’s websites.

We do not have pre-prepared materials for promoting this project. This is because we anticipate that how we communicate the project as it is designed will change over time.

We note that we are following standard recruitment practice for participation and feedback on open source project development, which has not traditionally been covered by university ethics approval.

**Question 13: Describe the procedures to obtain informed consent**

*Notes: Describe when consent will be obtained. If consent is from* ***adult participants****, give details of who will take consent and how it will be done. If you plan to seek informed consent from* ***vulnerable groups*** *(e.g. people with learning difficulties, victims of crime), say how you will ensure that consent is voluntary and fully informed.*

*If you are recruiting* ***children or young adults*** *(aged under 18 years) specify the age-range of participants and describe the arrangements for seeking informed consent from a person with parental responsibility. If you intend to provide children under 16 with information about the study and seek agreement, outline how this process will vary according to their age and level of understanding.*

*How long will you allow potential participants to decide whether or not to take part? What arrangements have been made for people who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*

*If you are not obtaining consent, explain why not.*

At the beginning of the **in person events** the lead facilitator will explain the purposes of the workshop and the participants’ role. They will then give a brief overview of what to expect during the session. They will make clear to participants their rights to withdraw at any point. The facilitator will give each participant a copy of the consent form detailing their rights and making clear the terms of participation, and ask them to check the boxes and sign and date the form (appendix **A6\_ConsentForm.pdf**).

If we are obtaining information about vulnerable autistic adults who are unable to legally consent on their own behalf, we will seek such information from their relatives or carers as representatives, and will ask for the signed consent of their representatives.

For the online survey, we ask contributors to check a box that they “understand that the information I provide in this form will be made publicly available” before the survey questions appear, and to check a box to answer yes to “Q3: Can we use the information above to inform how we design and build the platform?” (appendix **A1\_OnlineForm.pdf**)

For contributions via GitHub, we are not able to obtain informed consent before contributors interact with the project, but we will make clear that their contributions are public and may be used for research purposes in a prominent location in the repository.

**Question 14: Will consent be written?**

|  |  |
| --- | --- |
| Yes/No (delete as appropriate) |  |

*Notes: If* ***yes****, include a consent form as an appendix. If* ***no****, describe and justify an alternative procedure (verbal, electronic etc.) in the space below.*

*Guidance on how to draft Participant Information sheet and Consent form can be found on the Psychology Research Ethics Committee website.*

**In person**: Yes (appendix **A6\_ConsentForm.pdf**)

**Online**: No, via online form (appendix **A1\_OnlineForm.pdf**)

**Question 15: What will participants be told about the study? Will any information on procedures or the purpose of study be withheld?**

*Notes: Include an Information Sheet that sets out the purpose of the study and what will be required of the participant as appendices and refer to it as appropriate. If any information is to be withheld, justify this decision. More than one Information Sheet may be necessary.*

The purpose of the study will be made transparent to all participants. We will inform them directly of the research topic we are investigating, the overall aims of the project, and how we would like to collaborate with them on the project. Our projected outcomes for the whole project can be found in appendix **A2\_ValuesAndOutcomes.pdf**.

All summary materials will be made publicly available at our GitHub repository and we will send regular (likely monthly) newsletter updates to anyone who signs up to our mailing list (<https://tinyletter.com/AutisticaTuringCitizenScience>).

Participants will be able to send continuous feedback as the project develops via the “always open” online survey.

We have additionally created a participant information sheet (appendix **A7\_ParticipantInformationSheet.pdf**) that will be attached to all email communications, available printed out at in person events and in our online spaces.

**Question 16: Will personally identifiable information be made available beyond the research team?**

*Notes: If so, indicate to whom and describe how consent will be obtained.*

Contact information for participants who attend in person workshops will be managed by the Autistica Discover Network cohort management team. This information will not be made beyond the research team.

Summary information from in person events will not contain any personally identifiable information.

Information shared through the google form will have names and locations redacted before it is made publicly available. The team will not keep a copy of the original submission.

The research team cannot control what personally identifiable information is shared directly by the contributor via GitHub. Sharing someone else’s personal information violates our code of conduct and will be removed by the moderators.

**Question 17: What payments, expenses or other benefits and inducements will participants receive?**

*Notes: Give details. If it is monetary say how much, how it will be paid and on what basis is the amount determined.*

Participants will be paid for their time as well as for reasonable travel expenses. Autistica will pay £75/half day (focus group), £20/hour (1:1 user testing) or £10/30 minute (1:1 user testing). This will be paid by Autistica to the participants directly into their bank account. The amount will be the same for all participants, and is not dependent on their responses nor on successful completion of the session.

We will provide refreshments for participants.

We will not financially reimburse online contributors.

We will acknowledge members of the community prominently at our GitHub repository. Participants **do not need** to be publicly acknowledged. They will be asked when contributing (in person on online) if they would like to be included in the public list or not. Their decision on this point will not affect their input to the project. We will permit the use of pseudonyms when crediting an individual’s contribution. (Appendix **A4\_BuildingASafeCommunity.pdf**).

**Question 18: At the end of the study, what will participants be told about the investigation?**

*Notes: Give details of debriefings, ways of alleviating any distress that might be caused by the study and ways of dealing with any clinical problem that may arise relating to the focus of the study.*

The participants will be kept informed of the progress of the study if they consent to being contacted via the newsletter mailing list (<https://tinyletter.com/AutisticaTuringCitizenScience>). There will be no information about the study hidden from the participants at any point throughout the process.

**Question 19: Has the person carrying out the study had previous experience of the procedures? If not, who will supervise that person?**

*Notes: Say who will be undertaking the procedures involved and what training and/or experience they have. If supervision is necessary, indicate who will provide it.*

The lead researcher, Dr. Kirstie Whitaker, has experience running scientific studies involving seeking and upholding standards of consent. She has extensive experience in building online communities and mediating the challenging conversations that can arise from open contributions.

Autistica as an organisation has extensive experience running similar consultation sessions recruiting from the same community (via. the Insight Group and Discover Network).

The initial sessions will be co-facilitated by Autistica’s Discover co-ordinator, Bethan Davies, who has direct experience of running focus groups and similar sessions. Dr Whitaker has experience facilitating inclusive groups and will mentor and train members of the research team who facilitate in person interactions.

**Question 20: What arrangements are there for insurance and/or indemnity to meet the potential legal liability for harm to participants arising from the conduct of the study?**

*Notes: Insurance would normally be provided by the University's or Medical Research Council's insurance for persons employed by them or working in their institutions. Please contact the appropriate Insurance Office to arrange for insurance. If you do not have an appropriate institutional affiliation, say how you will provide public indemnity insurance, including insurance against non-negligent injury to participants. Evidence of insurance is required before a Letter of Approval can be issued.*

The research team will be covered by Dr Whitaker’s insurance as a member of the Department of Psychiatry at the University of Cambridge. We are simultaneously applying for a letter from the Insurance Section and for ethical approval. We will provide the letter as soon as possible.

**Question 21: What arrangements are there for data security during and after the study?**

*Notes: Digital data stored on a computer requires compliance with the General Data Protection Regulation; indicate if you have discussed this with your Departmental Data Protection Officer and describe any special circumstances that have been identified from that discussion. Say who will have access to participants' personal data during the study and for how long personal data will be stored or accessed after the study has ended.*

When consent is provided for data to be **made publicly available**, the data will be stored on the platform provider’s servers. For example, survey responses via Google Forms or feedback on open source development on GitHub.

Survey responses may also be downloaded from the platform provider and stored on the Autistica or Alan Turing Institute servers.

Data where informed consent is given, **but not** **for public use**, will be stored on the Autistica and Alan Turing Institute servers. For example, this will include full transcripts from focus group recordings or contact information for participants. Only members of the research team (as detailed in **Q2** & **Q3**) will have access to this information.

Recordings and written responses from focus groups will be collected on standalone devices and deleted once they have been transcribed. This will usually be less than 1 month from the date of recording and will certainly be within 3 months from the date of recording. The transcription will be done either by a member of the core research team directly from the standalone device, or by a professional transcriber, in which case the recordings will be transferred to the transcriber using the transcriber’s online, encrypted upload system.

**Anonymised summary reports will count as publicly available data** and will be stored in the cloud provider’s servers (eg on GitHub or Google Drive). For example, summary reports of the focus group conversations and survey responses that cannot be identified back to the participants. These will include likert scale measures or group demographic measures such as age ranges, gender or autism diagnosis status.

The summary reports will be sent to focus group participants before they are made public and all participants will have 2 weeks to give feedback on the report. This will include the option of removing information that they provided in the conversation but that they do not wish to be made public.

**Contact and payment information** will be managed through Autistica’s customer relationship management (CRM) system. Only members of Autistica’s core staff will have access to this information.

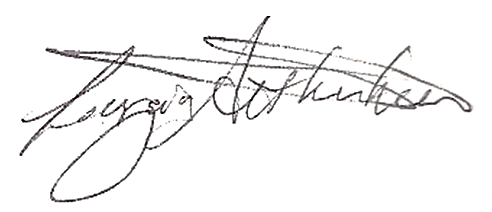
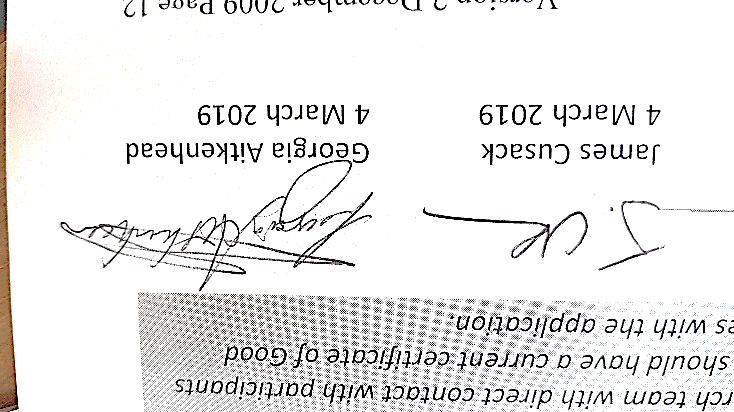
**Ongoing contact with the study** will be through a mailing list powered by MailChimp which has an extensive GDPR compliant privacy policy (<https://mailchimp.com/legal/privacy>). All members of the community can remove themselves from that list at any time.

Please see appendix **A8\_DataManagement.pdf** for detailed text and flow charts to explain to our participants how we will manage their data.

**Signatures of the study team (including date)**

*Notes: The primary applicant and all co-applicants must sign and date the form. Scanned signatures are acceptable.*

*The Principal Investigator and anyone on the research team with direct contact with participants during the administration of the active compounds should have a current certificate of Good Clinical Practice (GCP). Please include the certificates with the application.*



Kirstie Whitaker Bethan Davies James Cusack Georgia Aitkenhead

4 March 2019 4 March 2019 4 March 2019 4 March 2019

**Appendix A:** Additional information for studies involving the administration of pharmaceuticals or compounds with physiological effects. Include the study protocol with the application.

**Question A1: Specify the compound(s) to be used in the study**

*Notes: Include the trade name, marketing authorisation product licence holder, its form (for example, capsules, liquid) and concentration, any modifications (for example, over-encapsulation), and any other relevant details. If more than one compound is to be used, give details for each separately.*

**Question A2: How will the compound(s) be used in the study?**

*Notes: Give details of the intended dose, the maximum dose, the frequency of administration, and route of administration.*

**Question A3: What are the known side-effects and interactions with other compounds?**

*Notes: List each of the known side-effects and the corresponding risk of encountering them. Are there any known side-effects with commonly prescribed products, over-the-counter products, foods, and so on?*

**Question A4: What will participants be told about the compound(s)?**

*Notes: Describe what and how participants will be told about the risks of the compound***.**

**Question A5: What procedures are in place to mitigate the risks?**

*Notes: Give details of what emergency procedures are in place. Confirm that a medical qualified person is available when the compound is administered. Will there be an antidote available, and who will administer it? What procedures are in place for follow-up care? If the compound is blinded, how can the blind be broken if necessary?*