**2019**

**DEPARTMENT OF PSYCHOLOGICAL SCIENCES**

**BIRKBECK UNIVERSITY OF LONDON**

**ETHICAL APPROVAL FORM FOR RESEARCH INVOLVING THE USE OR COLLECTION OF DNA AND/OR RNA FOR GENETIC ANALYSIS (INCLUDING SECONDARY ANALYSES OF GENETIC DATA)**

**MINORS (16 YEARS OF AGE OR UNDER)**

**Please fill out this application carefully and ensure that you answer EVERY question and that it contains all relevant signatures. Incomplete forms will be returned.**

**Research involving the use or collection of human tissue**

It is the researcher’s responsibility to check that the proposed research does not fall under the remit of the UK Health Departments’ National Research Ethics Service (NRES). It is recommended that all researchers check that NRES approval is not required for the proposed project by using their online decision tool: http://www.hra-decisiontools.org.uk/ethics/.

I confirm that to the best of my knowledge this project does not fall under the review requirements of a research ethics committee from within the National Research Ethics Service.

**The Human Tissue Act**

Birkbeck does not have a Human Tissue Act license, which is required for the storage (traceability, disposal, consent) of human *cellular* material. Acellular material (i.e., DNA and RNA) is exempt from the act, as is all material (including cellular) that has been approved by a research ethics committee from within the National Research Ethics Service.  **If you are collecting human biological samples at Birkbeck for the purposes of genetic analysis and DO NOT have NREC approval, all samples must be processed into acellular DNA and/or RNA immediately after collection**. If you are receiving human biological, DNA and/or RNA samples from another institution you must have verified that the samples were collected in accordance with the Human Tissue Act. Please contact Dr Emma Meaburn (e.meaburn@bbk.ac.uk) if you are unclear on these requirements.

I confirm that the project DOES NOT fall under the remit of the Human Tissue Act (for example, secondary genetic analyses or moving DNA samples from another institution to Birkbeck

I confirm that I am aware that the project DOES fall under the Human Tissue Act and procedures are in place to extract DNA and/or RNA within 48 hours of arrival on site at Birkbeck, in

accordance with the Human Tissue Act

***Please submit all applications electronically to*** ***ethics@psychology.bbk.ac.uk*** ***Please indicate in the subject title if the application is ROUTINE or NON ROUTINE***

**Question 1: Is this application routine or non-routine? If routine, the relevant approval number(s) MUST be provided**

*Notes: An application is non-routine if the proposed research raises ethical issues for which the applicant/supervisor does not have existing approval. An application is routine if the proposed study is so close to a previous one which has received ethical approval that there are no new ethical issues to be considered. Students should discuss this with their supervisor.*

*Routine applications may be submitted at any time. The chair of the ethics committee reviews these monthly and you will not receive any correspondence from the committee. Dates for submitting NON ROUTINE applications are on the departmental ethics webpage. You will receive an email informing you of the committee’s decision.*

***ALL STUDENT APPLICATIONS FOR RESEARCH WITH MINORS ARE NON ROUTINE***

***A***

**Routine/non-routine (please delete one)**

**Question 1a: Please detail why this application is routine.**

*Notes: Explain the difference between this application and the already approved one (e.g. a change in age range, a change in stimulus on the computer screen – in other words, changes which would not be considered significant).*

**Routine:**

**Previous approval number and date:**

**Question 2: Title of the study**

*Notes: The title should be a single sentence*

**Title:**

**Question 3: Primary applicant**

*Notes: The primary applicant is the name of the person who has overall responsibility for the study. If you are a student or research assistant, the primary applicant will be your supervisor.*

**Primary applicant:**

**Question 4: Co-applicants**

*Notes: List the names of all researchers involved in the collection and/or analysis of the DNA/RNA material, their specific role (e.g. Undergraduate, Masters, PhD) and their relevant experience. If the co-applicant(s) has no experience, an experienced collaborator must be named here and their experience briefly described.*

**Co-applicants:** *Sample text: Dr XXXX previously conducted a gene expression study of 10 healthy children, which involved the collection of blood samples (ref). Dr XXX is a trained phlebotomist.*

*Dr XXX and Dr XXX have experience in all stages in the proposed study (i.e., using the PAXgene blood collection system, the extraction of RNA from blood, gene expression microarrays and analysis of genomic data).*

**Question 5: Contact details**

*Notes: Please provide email addresses for all applicants. The approval certificate will be sent via email and must be retained*

**Contact details:**

**Question 6: Give details of DBS applications and approval numbers (or equivalent) for all applicants involved in collecting data**

*Notes: Include name of applicant, date of application, date of approval and DBS number.*

*Anyone carrying out research with minors must undergo a DBS check and research MUST NOT begin until DBS approval is in place. Please see departmental ethics webpages for further information.*

**DBS approval numbers and dates:**

**Question 7: Collection of biological samples**

*Notes: If the study involves the collection or receipt of new biological materials for genetic analysis, please provide* ***full details*** *on the types of samples, the processing protocols to be used (if applicable) and the storage location(s). Please state the name of the researcher who will do the extraction and the planned timetable for this extraction AND who will be the custodian for the samples (usually this is the institution or funding body)*

**Collection of biological samples:** *Sample text:* ***Whole blood samples for DNA analysis:*** *A phlebotomist will perform blood collections for each participant (state location). A total of 15.5mls of blood will be taken across four tubes (single venipuncture). The blood samples will be stored at 4 degrees at BRIDGE Lab for approximately ~24 hours before RNA is prepared from the blood using standard procedures. The RNA will then be stored at -80 degrees at the BRIDGE laboratory for the duration of the study. Only Dr XXX XXX will have day-to-day access to the RNA samples.*

**Question 8: Where will the study take place?**

*Notes: Indicate where the study procedures will take place (e.g. CBCD, Babylab, schools, nurseries, home) as well as the location for the data storage and analysis of data.*

**Location:** *Sample text: On the day of the visit, blood samples will be taken from participants by a trained phlebotomist in a dedicated phlebotomy room (state location). Venous blood samples will be collected using a standard phlebotomy protocol in conjunction with the PAXgene Blood RNA System (Becton & Dickinson, Oxford), which allows the collection, stabilization and transportation of a whole blood sample in a closed evacuated system. The PAXgene Blood RNA System collects 2.5 mls of blood per tube. Three PAXgene Blood tubes will be collected for each participant. Two further EDTA tubes (4 mls each) will be collected for DNA and complete blood cell counts. Differences in the blood cell composition could influence the gene expression profiles obtained from whole blood; therefore it is important to take a complete blood cell count as a control for the influence of different cell types on gene expression profiles. The total amount of blood taken per individual will be 15.5 mls (i.e., one tablespoon). It should be noted that for the five tubes collected per participant, a single venipuncture would be required. It is estimated that each venipuncture will take 10 minutes.*

**Question 9: Briefly describe the purpose and rationale of the research**

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

**Purpose and rationale:**

**Question 10: Who is funding the costs of the study?**

*Notes: Give the name and address of funding bodies or other sponsorship*

**Funding:**

**Question 11: Describe the methods and data generation**

*Notes: If relevant, include full details of planned experimental methods (e.g. DNA genotyping arrays) and genetic analyses (e.g. Genomewide association)*

**Methods and data generation:** *Sample text: In order to examine gene expression profiles in the blood, RNA will be extracted from the PAXgene blood samples using commercially available standard protocols. RNA will be extracted (within 48 hours) from whole blood by a standardised procedure using PAXgene RNA processing kit buffers (Becton & Dickinson, Oxford). RNA will then be concentrated using the Genechip Blood RNA Concentration Kit (Affymetrix, CA). cDNA is then prepared from the total extracted RNA samples by reverse transcriptase using the Affymetrix One-cycle Target Labelling kit (Affymetrix, CA) in conjunction with a globin reduction step (Affymetrix, CA). cDNA will then be cleaned using the Genechip Sample Cleanup Module (Affymetrix, CA). cRNA is then prepared from the cDNA using the Affymetrix One-cycle Target Labelling kit (Affymetrix, CA). Gene expression levels for 47,000 transcripts throughout the genome will be assessed by assaying a single cRNA per individual on an Affymetrix HG-U133 plus 2.0 expression array. The gene expression data will be processed using Robust Multiarray Average (RMA) as implemented in the Bioconducter R package to produce normalized, background-adjusted, perfect-match, log-transformed probe set summaries.*

**Question 11a: If relevant, describe any other methods and procedures of the study**

*Notes: Do not merely list the names of measures and/or their acronyms; summarize them briefly (e.g. Buss-Durkee Hostility Inventory: a standardized self-report measure of trait aggression). Include any information about any interventions, interview schedules, duration, order and frequency of assessments.* ***It should be clear exactly what would happen to participants.***

**Other methods and procedures:**

**Question 12: Does this project involve secondary analysis of genetic data?**

*Notes: Complete this section if the project ONLY involves secondary analysis of genetic data. Please provide details of the committee which approved the original study and attach any relevant documentation.*

**yes/no (please delete one)**

**Question 13: What materials and techniques (e.g. EEG, imaging) are to be used in the study?**

*Notes: Please list any materials described in Q11a and confirm that they are attached (e.g. questionnaires, specific information given to parents about particular techniques such as EEG. These are in addition to the general information sheet about the study which is dealt with in Q19)*

**Materials and techniques:**

**Question 14a: For Researchers, describe any potential risks or adverse effects resulting from participation and what measures have been taken to address them?**

*Notes: Describe any discomfort or inconvenience that researchers may experience. Include information about location of the study, when the study is taking place, and possible safety risks to the researcher. Please ensure that your methods have a valid safety and risk assessment. Risk assessment forms/examples can be found on the ethics website or from the ethics committee.*

**Risks or adverse effects for researchers:**

**Please indicate that the risk assessment associated with your research is attached: yes/no (please delete one)**

**If ‘no’, please explain why:**

**Question 14b: Describe any potential risks or adverse effects resulting from participation and what measures have been taken to address them?**

*Notes: For example, pain or discomfort from collection of whole blood samples, and possible risks to researchers (e.g. needle stick injuries)*

Sample text: *The health risks associated with the planned blood collections are not above or beyond what would be expected from a routine blood test. The participant will be told to expect minor stress or discomfort at the time of blood collection and possible light bruising, but should experience no long-term effect on their mental or physical health. Parents will be asked in advance about any pre-existing medical conditions, or previous history of venipuncture difficulties or adverse outcomes that would prevent blood collection. No genetic manipulation of DNA prepared from blood will take place, and the participant’s risk for a genetic disease/trait will not be modified in any way.*

*The blood collections will be terminated if the participant feels unwell or appears distressed, or the phlebotomist is unable to reach a vein and obtain blood easily.*

*The potential health risk to the researcher due to handling blood is minor. The blood is evacuated into a closed system and DNA and RNA will be extracted from blood in a class II safety cabinet whilst wearing a lab coat, gloves and eye protection. Once the DNA and RNA have been extracted, samples are no longer infectious. All researchers handling blood samples have been vaccinated against Rubella and Hep B.*

**Question 14a: What other ethical issues do this study raise, if any, 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 procedure, tasks with high failure rate, personal experience questions.*

*Describe what you would do if a participant became distressed during the study (e.g. an infant crying, a child becoming anxious during school testing, a parent becoming upset when completing a sensitive questionnaire)*

**Ethical issues:**

**Question 15: Who will the participants be?**

*Notes: Describe (a) the groups of participants that will be recruited; (b) the main inclusion and exclusion criteria and (c) make clear how many participants you plan to recruit into the study in total.*

**Participants:**

**Question 16: Describe the recruitment procedures for the study**

*Notes: Give 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 procedures (e.g. collecting medical history, SES information) and explain why they are necessary*

**Recruitment procedures:**

**Question 17: Describe the procedures to obtain informed consent**

*Notes: Describe when and how consent will be obtained. 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, adolescents with depression, children who may have suffered significant trauma), say how you will ensure that consent is voluntary and fully informed.* ***Please note that students are not allowed to carry out research with vulnerable groups and on sensitive topics.***

*When obtaining consent for collecting biological material for genetic analysis it is important the participants have sufficient understanding of the process of sample collection, associated physical risks (if any), what the samples are to be used for, and how the research results might impact on them. Note that individual results of genetic analyses (e.g., genotyping data) should not be given to participants.*

*For general guidance about consent procedures for research involving DNA, see here:*

<http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice/code1consent.cfm>

*Where there is potential for future research of the samples outside the remit of the study for which consent is being sought, a two-part consent form should be used; The first form requests consent for the planned research and the second form requests consent for storage and future use of the sample for further research.*

*There are different rules for different age groups:*

*0-4 Formal signed consent obtained from parent/guardian*

*5-12 Formal signed consent from parent/guardian and informal verbal consent from the child that they understand what the study involves and that they are happy to participate*

*13-16 Dual but independent signed consent from parent/guardian and the young person. Both are required for participation to go ahead.*

*There is one narrowly defined exception to the above: for studies conducted in schools where the researcher is known to the school (e.g. one of their own teachers) and which involves activities which might take place as part of normal school curriculum activity (e.g. awareness of phonemes in written text, counting strategies, memory tasks). In such cases, the head teacher should be asked if she/he wants to have parental opt-in or opt-out consent. In all other cases parental opt-in consent is required. Please state which form of consent is to be used and if it is opt-out consent, please explain why.*

**Informed consent procedure:**

**Question 17a: Do you explain the exception to confidentiality rule?**

*Notes: There is an exception to confidentiality with respect to minors because of the need to consider child protection. A researcher who thinks a child may be at risk of harm must report this to the supervisor (if applicable) and the Chair of the ethics committee. Parents/guardians and young people over 13 should have this exception to confidentiality explained to them in the information sheet and consent form prior to taking part in the study.*

*Here is an example of default text for children aged 0-16 which can be modified if appropriate: Your child’s involvement in the study will remain confidential except in the highly unlikely event that the researcher has a serious concern regarding a child protection issue.*

*If you explain the exception please provide the text you will use. If you do not, please explain why not.*

**Exception to confidentiality:**

**Question 18: Will consent be written?**

*Notes: If yes, please include a consent form.* ***A draft consent form is at the end of this application, please complete/adapt as necessary and attach as an appendix****. If no, describe and justify an alternative procedure (verbal, electronic etc.)*

*Please provide sample informal verbal consent text for children aged 5-12. Here is an example which can be modified if appropriate: I just need to check that you understand that you can take part in the study if you want to but if you don’t, it’s fine not to. Your parents have said it is ok for you to do it but you also have a choice about whether you want to or not. Is there anything you would like to ask me about? Are you happy to go ahead and take part?*

**Written consent: yes/no (please delete one)**

**Informal verbal consent text (if necessary):**

**Question 19: What are participants told about the study? Will any information on procedures or the purpose of the study be withheld? If any information is to be withheld, justify this decision.**

*Notes:* ***A draft information sheet that sets out the purpose of the study and what will be required of the participants is at the end of this application. Please complete/adapt as necessary and attach as an appendix.***

**Study information for participants:**

**Question 20: Describe the procedures in place for maintaining that participant personal information and data collected will be treated with confidentiality and their anonymity respected. Please list all people who will have access to the data.**

*Notes: Personal identifying information is defined as:*

* ***Biographical information or current living situation****, including dates of birth, Social Security numbers, phone numbers and email addresses.*
* ***Looks, appearance and behaviour****, including eye colour, weight and character traits.*
* ***Workplace data and information about education****, including salary, tax information and student numbers.*
* ***Private and subjective data****, including religion, political opinions and geo-tracking data.*
* ***Health, sickness and genetics****, including medical history, genetic data and information about sick leave.*

*Supply information about the storage (e.g. specific physical location where the samples will be stored, who will have access) and transport of any biological materials. If relevant, include how any identifying information will be kept separate for data collected; where data will be stored and for how long; what use will be made of the data. Say who will have access to participants’ personal data and for how long personal data will be stored or accessed after the study has ended. If using interview data, describe how you will ensure that all identifying information will be removed from the transcripts.*

*Sample text: All RNA samples will remain on-site at Birkbeck and King’s College London and are stored in anonymised form in lockable freezers. Only central researchers on the project have day-to-day access to the samples. The RNA samples will be anonymised from the start via the participant ID number, with only the date, time and order of blood collection known to the researcher (via a label on the blood collection tube).*

**Please state your data management plan:**

**Procedures for confidentiality and anonymity:**

**Are you recording personal identifying information: yes/no (please delete one)**

**Why do you need to record personal identifying information:**

**How long will personal identifying information be kept:**

**How are you ensuring that personal identifying information will be kept separate from research data:**

**Will you be uploading your anonymised data to an online repository? Yes/no (please delete one)**

**Question 21: 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.*

**Payments:**

**Question 22: At the end of the study, what will participants be told about the investigation?**

*Notes: Give details of debriefings, ways of alleviating distress that might be caused by the study.*

**Debrief document attached: yes/no (please delete one)**

**Question 23: Has the person carrying out the study had previous experience of all of the procedures to be used in the study? If not, who will supervise and/or train 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.*

**Researcher:**

**Training:**

**Question 24: Signatures of the study team (including date)**

*Notes: The primary applicant and all co-applicants must sign and date the form. Scanned or electronic signatures are acceptable. Alternatively typing the full name represents your hand-signed signature*

*press <enter> to enlarge the size of the box*

*Primary applicant*

*NAME: SIGNATURE: DATE:*

*Co-applicant 1*

*NAME: SIGNATURE: DATE:*

*Co-applicant1*

*NAME: SIGNATURE: DATE:*

**DEPARTMENT OF PSYCHOLOGICAL SCIENCES**

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**CONSENT FORM FOR:** *State title of the study and ensure it is informative and user-friendly*

I have had the details of the study explained to me and willingly consent for my child to take part. My questions have been answered to my satisfaction and I understand that I may ask further questions at any time.

I understand that my child will remain anonymous and that all the information given will be used for this study only.

I understand that I may withdraw my consent for the study at any time without giving any reason and to decline to answer particular questions. Furthermore I understand that I will be able to withdraw my child’s data and samples up to the point that the anonymised data can no longer be identified.

I understand that audio/video recordings will be made *(Say something about: how recordings will be identified by a code, and will not be used or made available for any purposes other than the research project; when the recordings will be destroyed.)*

I understand that all information given will be kept confidential (*Say something about: who will have access to the data. For example: All data will be identified by a code, with personal details kept in a locked file or secure computer with access only by the immediate researchers. If personal data is being collected, explain how personal data will be kept separate from research data. Say have long data will be kept for, and whether it will be uploaded to an online repository).*

Your child’s involvement in the study will remain confidential except in the highly unlikely event that the researcher has a serious concern regarding a child protection issue.

I give consent for my child’s DNA to be genotyped for this study and I understand that I will not receive any results about his/her own genotype.

I understand that my child should not participate if [Exclusion list]

I understand how the results of the study will be used. ((*Say something about what will happen to the study results. For example: Results will be written up for a project/thesis or results will be presented at conferences and written up in journals. Results are normally presented in terms of groups of individuals. If any individual data are presented, the data will be totally anonymous, without any means of identifying the individuals involved).*

I confirm that I am over 16 years of age

**There should be two signed copies, one for the participant, one retained by the researcher for records.**

Name (participant): Signature: Date:

Name (researcher): Signature: Date:

Contact details of a named investigator for further information as well as the primary applicant (if investigator is a student or research assistant)

**DEPARTMENT OF PSYCHOLOGICAL SCIENCES**

**BIRKBECK UNIVERSITY OF LONDON**

**INFORMATION SHEET FOR:** *State title of the study and ensure it is informative and user-friendly*

Before you decide to take part in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish. A member of the research team can be contacted if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

This research project looks at (*state the aim of the study in user-friendly terms)*. This study will be completed by *(expected completion date).*

Your child has been chosen to participate in this study (*state any inclusion criteria*).

In this study, (*explain in detail what the participant will do if s/he takes part*). This study will take place (*state location of study - in your child’s school, in our laboratory*).

Describe any possible disadvantages/risks and benefits of taking part

The results of this project will be (*written up for an undergraduate final year project, written up for a masters’ dissertation, written up for a PhD dissertation, written up for publication, disseminated at conferences*). *Please describe the arrangements for anonymity and confidentiality*.

Your child’s involvement in the study will remain confidential except in the highly unlikely event that the researcher has a serious concern regarding a child protection issue.

You and/or your child have the right to withdraw participation at any point up until the point that the anonymised data can no longer be identified.

*Further information if samples are to be kept for further analyses*

The project has received ethical approval from the Department of Psychological Sciences Research Ethics Committee of Birkbeck University of London

Primary investigator contact details:

Co-applicant contact details:

For information about Birkbeck’s data protection policy please visit:

http://www.bbk.ac.uk/about-us/policies/privacy#7

If you have concerns about this study, please contact the School’s Ethics Officer at: ethics@psychology.bbk.ac.uk

School Research Officer

School of Science, Department of Psychological Sciences

 Birkbeck, University of London

London WC1E 7HX

You also have the right to submit a complaint to the Information Commissioner’s Office

https://ico.org.uk/

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**DEBRIEF SHEET FOR:** *State title of the study and ensure it is informative and user-friendly*

The following should be included:

The motivation for the research (why is this study being run?)

The hypotheses of the research (what are the expected results?)

Any information not available to the participant before participating in the study (e.g., what condition they were in, why they were selected etc).

(If necessary) ways to alleviate any possible distress (e.g., numbers and details for supervisor and/or appropriate school contacts)