STUDIES INVOLVING NON-INVASIVE ASSESSMENT OF ELECTROPHYSIOLOGICAL RECORDINGS FROM THE SCALP OF TYPICALLY DEVELOPING INFANTS AND TODDLERS

1. SCOPE

Researchers in the Oxford Babylab conduct research into the language and cognitive development of typically developing infants involving measurements of electrical activity from the brain. This is known as electroencephalography (EEG) or event-related potential (ERP) recording. This approved procedure duplicates some aspects of the CUREC approved procedure used for EEG with adults (see CUREC_AP_IDREC_03).

The EEG (electroencephalogram) provides a readout of on-line brain activity while infants are presented with images and/or sounds. EEG measures the electrical voltage signals of brain activity directly from sensors (electrodes) that are placed on the scalp, and is particularly well-suited for studying the time-course of mental events. By averaging together several EEG records that follow a specific type of event, it is possible to extract a brain wave that is specific to the processing of that event type. The averaging procedure eliminates spurious signals from random electrical noise in the environment and from ongoing mental activity that is unrelated to the event of interest; and reinforces the consistent brain activity associated with the analysis of the event. The averaged waveform is known as an “event-related brain potential” (ERP). ERPs afford many advantages to the investigation of cognitive functions and their neural bases. They provide a direct measure of brain activity in real-time without requiring overt behavioural responses. The ability to measure information processing in the brain without requiring responses is of great value in the study of several cognitive functions, such as perception, attention, and language processing.

Sensor placement and preparation typically requires about half an hour. The procedure involves placing on the subject a snug fitting cap made of an elasticated cloth material and containing electrodes made up of a conductive metal (tin), and establishing electrical contact between the scalp and the electrodes by means of an electrolyte gel that contains conductive salts. In order to achieve a low-impedance connection, it is often necessary to prepare the area of the scalp under the sensor by cleaning it with a mildly abrasive substance using a cotton swab or by cleaning the surface of the scalp with a mildly abrasive implement. The procedure does not cause pain or harm to the participant. Cap placement is treated as a play session with the infants and toddlers, with ethically approved researchers of the Oxford BabyLab (and toys) often taking a turn to wear a cap.

The primary method of testing (i.e., EEG recording) is sometimes used in conjunction with secondary methods of data collection from the infant or the infant’s parent. This Approved Procedure is intended to cover situations where one or more of the following primary methods are used, and which may be used in combination with secondary methods listed below:

Primary testing method:
- EEG recording of electrical activity at scalp (infant)
Secondary testing methods include:
- Participant performs verbal task (infant)
- Questionnaire (parent)
- Structured interview (parent)
- Digital video recordings of testing session

This approved procedure is intended to be used in cases where:
- all responses in section D are in unshaded boxes, except for question D4
- where the participants are healthy infants, not recruited because of any clinical condition
- where the study involves no deception.

The purpose of the primary testing method is to assess infant and toddler responses to the presentation of images and sounds, in a controlled testing environment. This procedure allows systematic investigation of various aspects of infant cognitive and linguistic development, including category formation, phonological development, word learning, lexicon development, visual preference development, and associative or statistical learning.

As infants lack the capacity to give free and informed consent to these procedures, and ‘personal data’ about infants will be obtained from infants’ parents, (a ‘third party’), this Approved Procedure is designed to outline a set of procedures conforming to IDREC standards of ethical research for participants unable to give informed consent, and where parental consent will instead be sought.

1.1 Participants:
Participants included in this procedure will be sighted, hearing, typically developing infants and toddlers between the ages of three months- and three years-of-age. Parents of infants will be contacted (see Section 4, below) and invited to a dedicated testing facility in the Department of Experimental Psychology. On occasion, infants may be accompanied to the testing session by a caregiver other than the parent (grandmother, nanny, etc.). For the sake of simplicity, ‘parent’ henceforth refers to accompanying caregivers as well, on the understanding that they have been entrusted with guardianship of the child.

1.2 Procedure:
After arrival, formal consent of the parent is sought, with a reminder that the parent may choose to cease participation at any time without prejudice. During primary testing, parent and child will sit together in front of a large screen where images and sounds will be presented. The testing procedure, which lasts up to 20 minutes.

Secondary methods of data collection from the infant (such as elicitation of pointing or naming) will be conducted in playroom adjacent to the primary testing booth. Data collection of this type may occur before primary testing, between blocks of primary testing, or following primary testing. A short structured interview with the parent will typically precede primary testing, but may also follow testing. Other secondary methods of data collection from the parent, such as questionnaires, will typically be sought prior to the study visit, but on occasion may be sought at the time of the visit, or as a follow-up to the visit.

If infants appear unsettled during primary testing, they will be given a break in the main play room, followed by further opportunities to continue testing, if the parent is comfortable to continue. Parents
may choose to cease participation at any time. The procedure is non-invasive and presents no harm to parent or child.

1.3 Multiple studies:
A testing session can contain more than one short experiment. Different CUREC 1 approved researchers may have designed these experiments. To minimise discomfort and confusion to the infant, only one or two researcher are directly involved in collecting data during the laboratory visit. The researchers will be referred to as the Investigators Collecting Data. They will typically be the primary point of contact during the days leading up to a laboratory visit, and for any follow-up after the visit.

2. TRAINING OF RESEARCH STAFF
Researchers need to be sensitive to Child Protection issues, and avoid working in situations that could leave them exposed to accusations of abuse. They must follow the guidance set out in the University’s ‘Safeguarding Code of Practice’, including completing the online training course ‘An introduction to Safeguarding’ provided by the Oxford Safeguarding Children Board, as well as undertaking risk assessments of the proposed research. Any risk assessment should also include details of how research participants can report concerns about any member of the University with whom they will be interacting.

Researchers should also take responsibility for complying with safeguarding regulations and research practices which relate to the setting(s) (country, institution) of their research. As well as such compliance, researchers should consult guidance from the relevant professional associations. For example, for research settings in the UK, detailed guidance on obtaining safeguarding clearance can be found on the Disclosure and Barring Service (DBS) website (https://www.gov.uk/disclosure-barring-service-check).

Before beginning research, Oxford BabyLab researchers will:
- Sign a copy of the Oxford BabyLab Code of Conduct
- Read and agree to the relevant sections of the following professional guidelines:
  - CUREC Best Practice Guidance 09 ‘Management and Protection of Data Collected for Research Purposes’
  - DOH ‘Seeking Consent: Working with children’ (2001), Department of Health
- Undergo a British Disclosure and Barring Service (DBS) background check

While CUREC 1 and DBS approval are pending, new researchers may ‘shadow’ experienced researchers, but will not a) seek consent for infant participation from a parent, b) be alone in a room with an infant or child, c) gain access to identifiable infant data. During this period, new researchers will be able to familiarise themselves with the procedures of the Oxford BabyLab, according to current documentation, including the details of this approved procedure. Once ethical approval and DBS clearance have been obtained, the new researcher may conduct research independently and have full access to identifiable data concerning infant subjects.
An ethically approved experienced researcher should give training in setting up the laboratory and in dealing with parents and babies. Training in application of sensors and setting up the recording should be given by an experienced researcher, and no inexperienced person should be left in sole charge of an ERP study.

3. METHODS FOR RECRUITING PARTICIPANTS
Parents of infants relevant to the study will be identified through the Oxford BabyLab database. This database contains personal information for people who have expressed their interest in our research, and are approached in local maternity wards (JR hospital, and others), local playgroups, NCT sales, through the Oxford BabyLab website or publicity material regularly distributed to medical centres, doctors’ surgeries and child-care centres. The collected personal information contains names of parents, home address, home or work telephone numbers, name of their infant, date of birth, problems at birth, language developmental problems of close relatives and visual or hearing problems that their infants may have.

Recruitment for specific studies will be by phone, email or post. During this recruitment phase, the aims and method of the study will be discussed, and parents will be given the opportunity to ask questions. If parents are interested in participating, more detailed information will be sent by email or post and an appointment date will be arranged.

4. INFORMATION PROVIDED TO PARTICIPANTS
The specific details provided to parents will vary depending on the study, but will always be on University headed paper and will always include:

- the name of the study
- the name(s) and status(es) (e.g. doctoral student) of the researchers carrying out the study and how to contact them
- a brief rationale of the study, including its purpose and value
- why potential participants are being invited to take part in the research
- an explanation of what the potential participant would do, including estimated duration of the test session and where it would take place
- that potential participants can ask questions about the study before they decide whether to participate
- that potential participants can choose whether they participate and, if they agree, they may withdraw from the study without penalty at any time by advising the researchers of this decision
- information about any additional personal information that would be obtained
- information about who would have access to the data, how it will be stored and what will happen to the data at the end of the study
- statement that the data would be anonymised
- what benefits (direct or indirect) may accrue to the participants in the study
- what risks are involved in the study
- that the project has received ethics clearance through the University of Oxford’s ethical approval process for research involving human participants.
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- where applicable, a note to explain that the research will be written up as a student’s thesis and how the personal data included in that thesis will be published and stored
- the procedure for raising a concern or making a complaint

The Information Sheet is written in simple but non-patronising language. Most word-processing packages provide readability statistics for a document, and one should aim for a 12-year-old (Year 7) reading level for adults. The information sheet will also explain that the study carries no significant personal risk and that publishable data will be anonymous. A verbal explanation will also be given to parents when they visit, to ensure they are fully aware of the procedures involved before they give consent.

In addition to general information, from time to time, the Investigator Collecting Data may choose to add a plain language description of one or more of the short tests, in order to give the parent more detail. This information will be written informally, may include pictures of stimuli, and is included purely for the interest of the parent.

Please refer to the Template Participant Information Sheet associated with this Approved Procedure.

The current guidance for Participant Information and consent can be found at [http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent](http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent).

5. **CONSENT OF PARTICIPANTS**

When parents of infant participants are recruited for a specific study (by phone, post or email), they will be given the opportunity to ask questions about the procedure and about participation in general. If they express an interest in participating, an appointment will be made for a study visit, and written information (including the participant information sheet), will be sent by post or email, at least two days before the testing session. On arrival at the testing session, the Investigator Collecting Data will verbally review the testing procedure prior to requesting written consent. Parents will also be given the opportunity to review the written information, and to ask questions prior to signing the consent form (attached). Parents will also be verbally reminded that they may cease participation at any time, for any reason, without penalty.

Parents of participants sign a consent form which will always be on University headed paper and will always include:

- the name of the study
- the name and status (e.g. doctoral student) of the researcher collecting the information and how to contact him/her
- the name and contact details of the Director of the Oxford BabyLab
- the purpose of the study
- declarations that the parent of the participant:
  - has read the participant information sheet
  - has had the opportunity to ask questions about the study and has received satisfactory answers to questions, and any additional details requested
Parental consent is an essential component of any research involving human participants, especially when studying infants and toddlers. The consent process aims to ensure that parents are fully informed about the study and that their participation is voluntary. Here are some key points to consider:

- Parents understand that they may withdraw from the study at any time without penalty by advising the researchers.
- The project has received ethics clearance through the University of Oxford’s ethical approval process.
- Participants’ personal data will be stored and used in accordance with the approved procedures.
- Consent is obtained from both the parent and the infant.

Parents will sign, print, and date their names, and the researchers will do the same. Consent forms can be found at the provided link. In the event of late receipt of the written information, consideration will be given to reading time and verbal description of the procedure to ensure informed consent.

5.1 Consent for audio, photographic or video data

While it is useful to illustrate lectures with still-frames or videos of infants, these materials are classified as ‘potentially identifiable’, and separate consent must be obtained from parents for their use. Without this additional consent, only anonymous data may be presented to others apart from study-approved researchers in the Oxford BabyLab. This includes training videos for ‘offline scoring’ for new researchers whose CUREC status and DBS check are pending.

Please refer to the Consent Form associated with this Approved Procedure.

Guidance on the informed consent process can be found at: http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent

6. FINANCIAL AND OTHER REWARDS TO PARTICIPANTS

Participation in studies is voluntary, thus there is no financial reward for parents of infant participants. However, parents of participants may claim reimbursement for travel expenses (25p/mile or up to £6) and the cost of parking if we are unable to offer a reserved parking space. At the end of a laboratory visit, parents of participants are offered a choice between reimbursement of expenses or a small gift for their child, such as a t-shirt or drinks bottle. It is not acceptable for gifts of sweets to be offered to infant participants.

Additional benefits include the opportunity for parents of participants to learn about the development of language and cognitive abilities in infants. The completion of a vocabulary questionnaire enables the parent to assess what words their child is able to understand and say. A newsletter is sent out twice a year to parents of participants, detailing the findings of studies conducted in our laboratories.
7. **POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE**

7.1. **Risks to participants**
ERP/EEG recording has been used safely for many years with infants, and we are aware of no cases of adverse events. EEG equipment comes from certified suppliers of medical equipment, who are obliged by law to adhere to published guidelines on electrical and mechanical safety (IEC-601).

During the session, if the infant becomes unduly distressed or uncomfortable, parents of infants are asked to indicate if they want to stop the experiment. As part of the normal behaviour pattern of healthy, typically-developing infants, infants may become restless or upset during the experiment. To minimise distress the infant stays seated on the parent or caregiver’s lap throughout the study. However, because the parent has their eyes shut during the study, there is the occasional risk that they may not be aware of their child’s distress. Since the Investigator collecting data sits next to the parent and infant during the study, the investigator can, in such cases, draw attention to the infant’s behaviour by speaking to the parent and pausing the experiment. After providing the parent with an opportunity to comfort and settle their child, they can decide whether or not they wish to continue. It is possible to pause the procedure if a participant needs to take a break or visit the bathroom, or if a fire alarm goes off.

Brain potentials vary widely from individual to individual. The investigator collecting data undertakes not to make any judgemental comments on the type of brain potentials seen in individual participants, to avoid causing unnecessary anxiety. For example, the investigator collecting data should not make a comment such as “you’ve only got very small brain responses”.

An important consideration for the investigators is hygiene: the sensors, caps and instruments used to apply gel are soaked in a disinfectant solution after each use. In the majority of cases, investigators or parents of participants will remove the gel from the infants’ hair using a wet-wipe. Syringes and needles used to apply the gel on the sensors are disposed of safely after a single use.

7.2. **Risks to Investigators collecting data**
Again, the main way to avoid risk is to adhere to a regime of hygiene. Hands are washed after any contact with the scalp of a participant.

8. **MONITORING AND REPORTING OF ADVERSE OR UNFORSEEN EVENTS**
The *Director of the Oxford BabyLab* will meet regularly with the *Investigator Collecting Data* to discuss how the experiments are being conducted and whether any specific difficulties have arisen. The *Director of the Oxford BabyLab* will occasionally shadow the running of an experiment to check that the *Investigator Collecting Data* is adhering to the procedures outlined in this approved procedure.

During an experiment, the *Investigator Collecting Data* will continuously monitor the infant participant to ensure that adverse or unforeseen events are rapidly detected. The investigator will report any adverse events to the *Director of the Oxford BabyLab*, who will make further decisions and discuss with the investigator how the event will be managed. The parent of the infant participant will have the opportunity to speak with the *Director* if they and/or their child are involved in an adverse event. In the case of an adverse event, the parent will be given the opportunity to continue with the study or to terminate the session.
In case a parent or an infant participant becomes unwell, the Investigator collecting data will immediately report the event to the Departmental First Aid Officer or call Emergency Services according to the severity of the event. Such a case would be reported in the Departmental Safety Book.

9. COMMUNICATION OF RESULTS

No identifiable details of infant participants will be disclosed in any publications arising from research conducted at the Oxford BabyLab, thereby maintaining the anonymity of the infant participants (with the exception of photographic materials, see Section 6 above). The outcomes of BabyLab research will be publicly available to academic audiences through presentation at academic conferences, publications in peer-reviewed journals, and end-of-award reports to research funding councils. Outcomes of research written in accessible, non-technical language will be made publicly available on the Oxford BabyLab website, the Oxford BabyLab newsletter mailed to parents of participants twice a year, funding council websites and newsletters, and occasionally in the local and national media (e.g., parenting websites, radio, newspapers).

10. DUTY OF CARE ISSUES / CONFIDENTIALITY

Because the Oxford BabyLab does not conduct clinical research or research with atypical populations, it is unlikely that procedures will identify a problem with an infant participant that had passed unnoticed by the parent of the infant participant. Any problems with an infant that could possibly be noticed within a study session should be detectable through the NHS health visitor system. Hence, we will always refrain from commenting on any apparent problems with an infant. However, such circumstances are unlikely to arise in the first place.

A parent might ask the investigator collecting data whether their child’s cognitive or language development is normal for their age. In these circumstances, the investigator will indicate that they are not qualified to make such an assessment, and recommend that the parent speak with their health visitor or GP if they are very concerned.

11. DATA PROTECTION ISSUES

Type of information collected: name of parent, name of infant, date of birth, due date, medical history on vision/hearing problems, languages spoken at home, number of siblings, contact details, family history on reading or language impairments. Questionnaires on infant vocabulary and object familiarity, EEG recording and digital video recording of the infant (anonymous, potentially identifiable).

Since our research involves infant participants, much of this information cannot be obtained directly from the infant. Therefore, information about the infant will be collected from the parent of the infant participant.

A secure database containing contact details of parents and details about infants can only be accessed by Oxford BabyLab researchers who have received CUREC 1 approval and DBS disclosure (see Section 3). The database is password-protected and can only be accessed through registration with a specific
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password-protected server. Only BabyLab researchers with CUREC 1 approval and DBS disclosure are provided with the passwords to access this database.

For a specific study, a single paper record of anonymous numeric infant participant codes linked to participant names is kept in a locked filing cabinet in a secure office. All electronic data, including EEG recordings and digital videos of infant participants, contain details of the infant participant code. Original EEG recordings and digital videos will be stored on a password-protected standalone PC in a secure laboratory. These recordings can only be accessed by Oxford BabyLab researchers with CUREC 1 approval and DBS disclosure. Back-up recordings on CD/DVD are kept in a locked filing cabinet in a secure office and other electronic data, such as the output of data analysis and statistical analyses, are stored on a password-protected PC in a secure office. Only Oxford BabyLab researchers with CUREC 1 approval and DBS disclosure have access to the paper record and electronic data stored in the secure office.

All data will be available only to future studies conducted by BabyLab researchers with CUREC 1 approval and DBS disclosure or an authorised peer-review body. However, all potentially identifiable or identifiable data (i.e., EEG recordings, digital videos of infant participants, and the paper record linking infant participant codes and infant participant names) will be destroyed or deleted after a period of five years has elapsed after the project has finished. All anonymised data (the output of data coding and statistical data) will be retained indefinitely. All data will be available only to future studies conducted by Oxford BabyLab researchers with CUREC 1 approval and DBS disclosure or an authorised peer-review body.

Should there be unforeseen disclosure of any identifiable or potentially identifiable information, the investigator collecting data will immediately inform the Director of the Oxford BabyLab. The investigator and/or the Director will then immediately inform the parents involved and relevant university administration staff to ensure that such circumstances are never repeated.

12. **FURTHER INFORMATION**

Please see [http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/ap#collapse4-1](http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/ap#collapse4-1):

- BabyLab Code of Conduct
- BabyLab Public Sign-up Sheet
- AP12 Information Sheet
- AP12 Consent Form

13. **CHANGE HISTORY**
### Title:

Studies Involving Non-invasive Assessment of Electrophysiological Recordings from the Scalp of Typically Developing Infants and Toddlers

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<td>Incorporates reference to the University Safeguarding Code of Practice and related requirements. Retitled ‘Approved Procedure’ (previously ‘Protocol’). Approved by CUREC, 19 November 2015</td>
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<td>2.1</td>
<td>Updated hyperlinks for new CUREC website</td>
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