

## **STUDIES INVOLVING NON-INVASIVE ASSESSMENT OF PHYSIOLOGICAL RECORDINGS 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 (known as electroencephalography (EEG) or event-related potential (ERP) recording), and other physiological measurements, such as electrodermal and heart-rate activity.

The EEG (electroencephalogram) provides a readout of on-line brain activity while infants are awake (e.g. presented with images and/or sounds) or asleep. 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 time-locked to an event is known as an “event-related brain potential” (ERP) or sometimes (when specific frequency bands are analysed in relation to events) “event-related oscillation” (ERO). 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 approved researchers of the Oxford BabyLab (and toys) often taking a turn to wear a cap. An alternate EEG system used in the BabyLab uses an elasticated net instead of a cap. The net contains sensors embedded in sponges. Before applying the net and starting the recording, the net is soaked in warm water containing a small amount of salt and baby shampoo (for better conductance). This EEG net takes 2 minutes to apply.

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/guardian. 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.

Where a study has the potential for risk to the child, this Approved Procedure may not be cited and a CUREC 2 application must be submitted.

Primary testing method:

- EEG recording of electrical activity at the scalp (*infant*)

Secondary testing methods include:

- Participant performs verbal, touchscreen and/or play tasks (*infant*)
- Questionnaires (*parent/guardian*)
- Structured interview (*parent/guardian*)
- Digital video recordings of the testing session
- Electrodermal activity (EDA) recorded using a wearable device (*infant*)
- Actigraphy monitoring using a wrist-watch-like device (*infant*)
- Heart-rate activity recorded by a wearable device placed on the chest (*infant*)

This Approved Procedure is intended to be used in cases where:

- the participants are healthy infants, with no clinical conditions
- 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 (but not limited to) category formation, phonological development, word learning, lexicon development, attention, executive functioning, visual preference development and associative or statistical learning. Another aim of the primary testing is to understand the physiology and regulatory processing underlying sleep in early childhood, and the role daytime sleep plays in the development of cognitive functions.

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/guardians, (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/guardian 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 one month and three years of age. Specific studies might look at development over a longer period of time and hence older participants could be included (pre-schoolers, school-age children and adolescents). 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 the 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, the parent and child will sit together either in front of a large screen in the testing booth, where images and sounds will be presented (this will sometimes be in the form of a video and/or animations), or in the sleep room, where the infant will go for a nap.

Secondary methods of data collection *from the infant* (such as elicitation of pointing or naming, or solving tasks with specially designed objects/toys) will be conducted in the primary testing booth, in the play area of the Developmental Science Reception, or in a separate behavioural testing room. Data collection of this type may occur before primary testing, between blocks of primary testing, or following primary testing. Secondary data may also be collected in parallel with the primary testing (i.e. data from wearable devices recording electrodermal activity, actigraphy and/or heart rate). 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 also be sought during the visit and/or after the visit.

If infants appear unsettled during primary testing, they will be given a break in the play area of the Developmental Science Reception, 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 study. Different approved researchers may have designed these studies. To minimise discomfort and confusion to the infant, only one or two researchers are directly involved in collecting data during the laboratory visit. The researchers will be referred to as the *Investigators Collecting Data*.

## 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.

Detailed guidance on obtaining safeguarding clearance can be found on the [Disclosure and Barring Service \(DBS\) website](#).

Before beginning research, Oxford BabyLab researchers **will**:

- Ensure that ethics approval has been granted
- 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
  - RCP 'Guidelines for the ethical conduct of medical research involving children' (2000): Compiled by the Royal College of Paediatrics, Child Health: Ethics Advisory Committee and Prof. Sir David Hull, *Arch. Dis. Child*, 82, 177-182.
- Undergo a British Disclosure and Barring Service (DBS) background check
- Complete the University of Oxford Online Integrity and Ethics Training
- Complete the University of Oxford Information Security Training Module

While DBS approval is 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 DBS clearance has been obtained, the new researcher may conduct research independently and have full access to identifiable data concerning infant subjects.

An experienced researcher should give training in setting up the laboratory and in dealing with parents and babies. Training in the 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 and social media or publicity material regularly distributed to medical centres, doctors' surgeries, child-care centres, and at public engagement events. The collected personal information contains names of parents, home address, home or work telephone numbers, name of their infant and the infant's siblings, if any, due date, date of birth, problems at birth, language developmental problems of close relatives and visual or hearing problems that their infant may have.

Recruitment for specific studies will be by phone, email, private messages on social media platforms or post. If interested parents contact the BabyLab directly, (e.g. in response to a Facebook advert), they are encouraged to sign up on the BabyLab's web form (which is subsequently entered into the Oxford BabyLab database), before being booked in for a specific study. During this recruitment phase, the aims and method of the study will be explained to the parents, and they 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.

The Information Sheet should be 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 lay 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, which should be adapted for the research

## 5. CONSENT OF PARTICIPANTS

When *parents of infant participants* are contacted about a specific study, 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, prior to the testing session. On arrival for the testing session, the *Investigator Collecting Data* will verbally review the testing procedure and parents will be given the opportunity to review the written information and ask questions prior to being asked to sign the consent form. Parents will also be verbally reminded that they may cease participation at any time, for any reason, without penalty.

For some studies, parents may be given the option to allow data sharing of research data only, to promote data transparency and collaboration across labs. This will be presented as optional on the consent form.

Both the *Investigator Collecting the Data* and the parents of participants will sign, print their names and date the consent form. In the event that the parent did not receive the written information in a timely manner before coming to the testing session, consideration will be given to reading time and verbal description of the procedure to ensure that the parent is able to provide informed consent.

While it can be useful to illustrate lectures with still-frames or videos of infants, as well as for advertising or other public use, these materials are classified as 'potentially identifiable', and separate consent must be sought from parents for use of these materials. Without this additional consent, only fully anonymous data may be presented to people other than approved researchers in the Oxford BabyLab. This includes use of such images in 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.

Please also see CUREC's [guidance on the informed consent process](#).

## 6. COMPENSATION

Participation in studies is voluntary, thus there is no default financial reward for parents of infant participants. However, some more demanding studies (e.g. longitudinal studies) do offer some compensation for parents' time in the form of vouchers or by covering their travel expenses (45p/mile or up to £10). Parents of participants may claim reimbursement for the cost of parking if we are unable to offer a free reserved parking space. At the end of a testing session, parents of participants are offered 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. Regular newsletters are sent out to parents of participants, detailing the findings of studies conducted in our laboratories. News about study findings are also shared via the BabyLab's social media accounts.

## **7. POTENTIAL RISKS TO PARTICIPANTS/RESEARCHERS/OTHERS AND WHAT WILL BE DONE TO MINIMISE**

### **7.1 Risks to participants**

EEG/ERP 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 study. 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 some studies, there is the occasional risk that they may not be aware of their child's distress. Since the *Investigator Collecting Data* monitors the infant during the study, the investigator can, in such cases, draw attention to the infant's behaviour by speaking to the parent via a microphone and pausing the study. After providing the parent with an opportunity to comfort and settle their child, they can decide whether or not they wish to continue. The procedure will be interrupted or aborted 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/nets, 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 or by cleaning the scalp with warm water and baby shampoo. Syringes used to apply the gel on the sensors are disposed of safely after a single use. For the EEG system involving a net instead of a cap, the parent is offered a towel to dry the infant's head after the session.

### **7.2 Risks to Investigators Collecting Data**

The main way to avoid risks 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 UNFORESEEN EVENTS**

The *Director of the Oxford BabyLab* or other senior researcher conducting BabyLab studies 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* or other senior researcher will occasionally shadow the running of a study to check that the *Investigator Collecting Data* is adhering to the procedures outlined in this Approved Procedure and ethics application.

During a testing session, the *Investigator Collecting Data* will continuously monitor the infant participant to ensure that adverse or unforeseen events are rapidly detected. The *Investigator Collecting Data* 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 of the Oxford BabyLab* 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 for which consent was given, see Section 6 above). The outcomes of BabyLab research will be publicly available to academic audiences through presentations 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 and social media, the Oxford BabyLab newsletter (e-)mailed to parents of participants, 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. If the parent expresses concern about their infant, the Investigator Collecting Data should suggest that they speak to their GP for advice. 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**

Type of information collected: name of parent, name of infant, date of birth, due date, medical history on birth problems/prematurity, vision/hearing problems, languages spoken at home, number of siblings, contact details, family history on language impairments, developmental problems, visual or hearing problems. Questionnaires on infant vocabulary and object familiarity, sleep and nap diary and digital video recording of the infant (potentially identifiable) EEG, EDA, HR and actigraphy recordings (pseudoanonymous).

Since our research involves infant participants, questionnaire information cannot be obtained directly from the infant. Such information will be collected from the parent of the infant participant.

The secure database containing contact details of parents and details about infants is password-protected and can only be accessed through registration with a specific password-protected server. It can only be accessed by BabyLab researchers who have received DBS disclosure (see Section 3), and are therefore provided with the required passwords.

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 and/or an electronic copy of that information is also stored on a University approved server. All electronic data, including EEG recordings and digital videos of infant participants, contain details of the infant participant code (and for longitudinal studies also the date of birth). Original EEG recordings and digital videos will be stored on a network drive which can only be accessed by Oxford BabyLab researchers with DBS disclosure. Back-up recordings are kept:

- on CD/DVD/external hard drives in a locked filing cabinet in a secure area
- in a University approved cloud storage

All other electronic data, such as the output of data analysis and statistical analyses, are stored on a password-protected PC in a secure office or in a University-approved cloud storage . Only Oxford BabyLab researchers with DBS disclosure have access to the paper record and electronic data stored in these locations.

All data may be made available only to future, ethically approved, studies conducted by BabyLab researchers with DBS disclosure. The minimum retention period for research data and records is three years after publication or public release of the work of the research according to University policy, though funders and regulators may require longer retention periods. For longitudinal studies, retention of data may be up to 30 years after completion of the study, as long as parents are informed of this in the study-specific information sheet. All anonymised data (the output of data coding and statistical data) will be retained indefinitely.

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 inform the relevant university administration staff (i.e. the Information Compliance Team and MS IDREC) to assess the breach, mitigate the consequences and ensure that such circumstances are never repeated.

## 12. FURTHER INFORMATION

Please see the resources on the University's [Research Ethics webpages](#):

BabyLab Code of Conduct

BabyLab Sign-up Forms:

[Online BabyLab Sign-up Form](#)

REDCap version

BabyLab Flyer

Image Release Agreement

AP12 Information Sheet

AP12 Consent Form

## 13. CHANGE HISTORY

Version No.	Significant Changes	Previous Version No.
2.0	Incorporates reference to the University Safeguarding Code of Practice and related requirements. Retitled 'Approved Procedure' (previously 'Protocol'). Approved by CUREC, 19 November 2015	N/A
2.1	Updated hyperlinks for new CUREC website	2.0



Version No.	Significant Changes	Previous Version No.
2.2	Removed reference to sections of the old CUREC 1 checklist	2.1
3.0	<p>Name change to “Studies involving non-invasive assessment of physiological recordings of typically developing infants and toddlers;</p> <p>Expand the scope to include additional physiological methods such as electrodermal activity, heart-rate monitoring and use of wearable devices;</p> <p>Include details of the alternate, elasticated net, EEG system;</p> <p>Addition of touchscreen and/or manual play tasks;</p> <p>Update to researcher training requirements;</p> <p>Update of sections 4 (Information provided to participants) and 5 (Informed Consent) to refer researchers to use template documents associated with the Approved Procedure;</p> <p>Update to details of remuneration for participation;</p> <p>Clarification of data protection procedures;</p> <p>General administrative amendments</p>	2.2
3.1	Updated to improve accessibility	3.0