



## **STUDIES USING NON-INVASIVE ASSESSMENT OF INFANT EYE MOVEMENTS AND HEAD MOVEMENTS IN RESPONSE TO IMAGES AND SOUNDS - FOR TYPICALLY DEVELOPING INFANTS AND TODDLERS**

### **1. SCOPE**

Researchers in the Oxford BabyLab conduct research into the language and cognitive development of typically developing infants using non-invasive assessments of eye-movements and head-movements in response to pictures, videos and lights, presented with or without sound. These primary methods are 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 the research 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 methods:

- Visual recording of the infant (where the infant is looking, inter-modal preferential looking (IPL - presenting pairs of images on a screen and playing a target word or carrier sentence) or head-turn procedures) Measurement of motor behaviour of the infant (i.e., remote eye-tracking)

Secondary testing methods:

- Participant performs verbal, touchscreen or manual play tasks (infant)
- Questionnaire (parent/guardian)
- Structured interview (parent/guardian)

This Approved Procedure is for use where:

- Participants are infants whose parents/guardians have volunteered to participate, not recruited because of any clinical condition;
- the study involves no deception.

The purpose of this procedure 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, visual preference development, executive functioning, and associative or statistical learning. As the control of eye- and head-movements develops early in infancy, the primary procedures are infant-friendly. From time to time, secondary procedures will be used in conjunction with the primary procedures, in order to link behavioural performance to other aspects of development.

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 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/guardians 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, parent and child will sit together in front of a large screen in a testing booth where images, lights and/or sounds will be presented. This will sometimes be in the form of a video and/or animations. In some cases, sounds and lights will be presented to the right or the left of the infant. In some instances, parents will be requested to close their eyes and/or to wear headphones in order to prevent them from accidentally 'cueing' their child; if this is necessary, parents will be informed beforehand. During primary testing, videos and or images of the infant will be recorded using CCTV or digital video cameras. Given the nature of the setting, the videos and images of the infant might also capture the parent. In addition, in the remote eye-tracking procedure, low-level infrared light will be emitted from a remote eye-tracking device to enable automatic tracking of the infant's eye movements. This infrared light is non-invasive, and the eye-tracker is a standard piece of equipment used in many infant testing facilities around the world. The eye-tracker also outputs pupil size information for each eye, allowing an external software to record the pupil size variation during an eye-tracking session.

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 either in the play area of the Developmental Science Reception, in the primary testing booth, 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. 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, even when there are more researchers involved in running the study, there will always be a primary researcher who interacts with the child most of the time during the visit. This researcher will be referred to as the *Investigator 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, BabyLab researchers **will**:

- Ensure that ethics approval has been granted
- Sign a copy of the BabyLab Code of Conduct (attached)
- Read and agree to the relevant sections of the following 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 approved 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 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 participants.

## 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 were approached in local maternity wards (JR hospital, and others), local playgroups, NCT sales, through the Oxford BabyLab website, BabyLab 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 the 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 using the BabyLab's online 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**

A general information sheet will be provided to *parents of infants*. This information sheet will be applicable to all of the tests planned for a single 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, and use, the Information Sheet template associated with this Approved Procedure.

#### **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 general 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 completely *optional* on the consent form.

Both the *Investigator Collecting 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 for 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.

Separate consent will always be sought from parents for use of the images and videos recorded during the testing sessions to illustrate lectures, training material or academic presentations and publications, as well as for any advertising or other public use. Without this additional consent, only anonymous data may be presented outside the group of study-approved researchers in the 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.

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). The procedure for this will need to be specified in the lead researcher's full CUREC application. Parents of participants can 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.

Consideration should be given to how and when participants are told about any recompense. Participant information sheets and recruitment materials should state that recompense will be made so that potential participants are not discouraged from participating by the associated costs. As a general rule, recruitment material should not state the value. However, if this is necessary (e.g. it is a requirement of a third-party recruiter), advertisements must not emphasise the value of the payment (for example, through the use of formatting). Further guidance is available within CUREC's [Best Practice Guidance 05 on Payments and incentives in research](#).

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

As part of the normal behaviour pattern of healthy, typically-developing infants, infants may become restless or upset during the testing session. To minimise distress to the infant, the Investigator informs the parent that they can abort the testing session at any time. Because the parent has their eyes shut and wears headphones playing a soundtrack during the session, there is a slight possibility that they may not be aware of their child's distress. In such cases, the *Investigator Collecting Data* will draw attention to the infant's behaviour either by speaking to the parent over the headphones or by pausing the session and approaching the parent. After providing the parent with an opportunity to comfort and settle their child, the parent can decide whether or not they wish to continue. The procedures pose no risks to the infant, parent or the *Investigator Collecting Data*.

## 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 testing sessions 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 session 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, 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 their parent. Any problems with an infant that could possibly be noticed within a study session should be detectable through the NHS health visitor system. Hence, the *Investigator Collecting Data* 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 Collecting Data* will indicate that they are not qualified to make such an assessment, and recommend that the parent speaks with their health visitor or GP if they are concerned.

## **11. DATA MANAGEMENT AND 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, digital video recordings of the infant (potentially identifiable), eye-tracking data (anonymous), coded behavioural data derived from visual recording (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 stored on a University-approved server. All electronic data, including images and video recordings of infant participants, use only the infant participant code and, for longitudinal studies, also the date of birth. Original video recordings are stored on a network drive which can only be accessed by BabyLab researchers with DBS disclosure. Back-up video recordings are kept in one or more of the following locations:

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

All other electronic data are stored on a password-protected PC in a secure office or in University-approved cloud storage. Only BabyLab researchers with DBS disclosure have access to the paper records 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.

### ***Sharing of Data***

Research teams will be encouraged to make their data available for reuse and validation. In all cases, the data will be shared as openly as possible and as closed as necessary in order to protect the privacy of participants. Online repositories will be assessed by research teams for their appropriateness with regard to:

- the required treatment and de-identification of unique brain and biometric data in line with UK GDPR;
- control of how the data are accessed and re-used, including terms to protect the ongoing privacy of participants;
- required attribution of the data to the originating research team, the University and funding bodies;
- management of data withdrawal requests made by participants.

## **12. FURTHER INFORMATION**

Please see the [University's Approved Procedures webpage](#) for more resources:

BabyLab Code of Conduct  
 BabyLab Sign-up Forms  
[Online version of the BabyLab Sign-up form](#)  
 REDCap version  
 BabyLab Flyer  
 Image Release Agreement  
 AP11 Parent/Guardian Information Sheet template  
 AP11 Consent Form template

### 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
2.2	Removed reference to sections of the old CUREC 1 checklist	2.1
3.0	Addition of touchscreen and/or manual play tasks; Clarification of procedures conducted during a research visit; Clarification of the use of video recording; Update to researcher training requirements; Update of sections 4 (Information provided to participants) and 5 (Informed Consent) to refer researchers to use template documents associated with the Approved Procedure; Update to details of remuneration for participation; Clarification of data protection procedures; General administrative amendments	2.2
3.1	Updated to improve accessibility	3.0
3.2	Administrative revisions Reference to BPG05 added Information about Data Sharing added	3.1