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, 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. 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 methods:
- Visual recording of the infant (inter-modal preferential looking (IPL), or head-turn procedures)
- Measurement of motor behaviour of the infant (i.e., remote eye-tracking)

Secondary testing methods:
- Participant performs verbal task (infant)
- Questionnaire (parent)
- Structured interview (parent)

This Approved Procedure is for use where:
- participants are infants whose parents 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 category formation, phonological development, word learning, lexicon development, visual preference development, 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 (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 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. In some cases, sounds and lights will be presented to the right or the left of the infant. Parents will be requested to close their eyes and to wear headphones throughout the primary testing procedure, which lasts up to 20 minutes. During primary testing, images of the infant will be recorded using CCTV or digital video cameras. 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.

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 study 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 researcher is directly involved in collecting data during the laboratory visit. This researcher will be referred to as the Investigator 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, BabyLab researchers will:

- Sign a copy of the BabyLab Code of Conduct (attached)
- 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 CUREC 1 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 ethical approval and DBS clearance have 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 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

A general information sheet will be provided to parents of participants. This information sheet will be applicable to all of the tests planned for a single laboratory visit. If an information sheet differs from the one associated with this Approved procedure, it will be on University letterhead paper, and will include:

- the name of the study
- the name and status (e.g., doctoral student and postdoctoral researcher) of the Investigator Collecting Data
- the name and contact details of the Director of the Oxford BabyLab
- the purpose and value of the study
- what the study will involve for participants (description in plain language of all procedures including purposes, duration, frequency and location)
- that parents can ask questions about the study before they decide whether to participate
- that parents can choose whether they participate and, if they agree, that they may withdraw from the study without penalty at any time by advising the researchers of this decision.
- that the project has received ethics clearance through the University of Oxford’s ethical approval process for research involving human participants
- who will have access to personal data provided, how the data will be stored; and what will happen to the data at the end of the project
- what benefits (direct or indirect) may accrue to the participants in the study
- what adverse events are involved in the study.
- information about how to raise a concern or make a complaint

The information sheet will 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 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 Information Sheet associated with this Approved Procedure.

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 general 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 participant:
  - has read the general information sheet
  - has had the opportunity to ask questions about the study and has received satisfactory answers to questions, and any additional details requested
  - understands that s/he may withdraw from the study without penalty at any time by advising the researchers of this decision
  - understands that this project has received ethics clearance through the University of Oxford’s ethical approval process for research involving human participants
  - understands who will have access to personal data collected, how the data will be stored; and what will happen to the data at the end of the project
  - agrees to participate in this study

Parents of participants will sign, print and date their names and the investigator who secures the consent will also sign, print and date their name.

In the event that the parent did not receive the written information in a timely manner, 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, 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 anonymous data may be presented to people other than 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.

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

As part of the normal behaviour pattern of healthy, typically-developing infants, infants may become restless or upset during the experiment. To minimise distress to the infant, the investigator informs the parent that they can abort the experiment at any time. Because the parent has their eyes shut and wears headphones playing a sound track during the experiment, 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 experiment 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. There are no risks to anyone else or the investigator collecting data.

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 will occasionally shadow the running of an experiment to check that the Investigator is adhering to the procedures outlined in this approved procedure.

During an experiment, the Investigator 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, 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 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, the Investigator 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, digital video recording of the infant (anonymous, potentially identifiable), Coded Behavioural Data derived from Visual Recording (anonymous).

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 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 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 video recordings of infant participants, use only the infant participant code. Original video recordings are stored on a password-protected standalone PC in a secure laboratory. These recordings can only be accessed by BabyLab researchers with CUREC 1 approval and DBS disclosure. Back-up video recordings on CD/DVD are kept in a locked filing cabinet in a secure office and all other electronic data are stored on a password-protected PC in a secure office. Only 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 identifiable or potentially identifiable data (i.e., digital video recordings 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.

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#collapse4-0](http://researchsupport.admin.ox.ac.uk/governance/ethics/resources/ap#collapse4-0):

- BabyLab Code of Conduct
- BabyLab Public Sign-up Sheet
- AP11 Information Sheet template
- AP11 Consent Form template

13. CHANGE HISTORY

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<td>2.1</td>
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