



Understanding lives –
now and for the future

Ethics and Information Governance Framework

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Forward

The Life Study Ethics and Information Governance Framework (EIGF) was developed and is owned as a policy by the Life Study Scientific Steering Committee (SSC; members listed below). It was developed and written by the authors with input from experts in ethics, regulation, law, and the biomedical, clinical and social sciences.

The SSC established an Ethics and Information Governance Subgroup in 2012 to assist in the development of the Life Study EIGF. The Subgroup (members listed below) was tasked with identifying the key ethical issues that Life Study should be prepared for, advising SSC on the high-level principles set out in the Life Study EIGF, and on the need (if any) for an independent ethics advisory body (as requested by the NHS Research Ethics Committee) to provide advice on any ethical legal or social issues that may arise – anticipated or otherwise - during the course of Life Study. The SSC and the Life Study Governing Board (subsequently the Strategic Advisory Committee) endorsed the draft EIGF based on this advice in 2013, and the Subgroup’s recommendation to establish a Life Study Advisory Group on Ethics (AGE). The Terms of Reference of the Life Study AGE can be found in Annex 1. Its members are listed below. In 2015, the Life Study AGE reviewed and advised on the EIGF, notably in relation to the introduction of financial incentives as a token of gratitude to participants.

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In developing the EIGF, the authors have drawn on the UK Biobank Ethics and Governance Framework and are grateful to Jonathan Sellors of UK Biobank for permission to do so.

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Introduction

The Life Study Ethics and Information Governance Framework summarises the key principles that govern how Life Study relates to participants, researchers and society. The focus of this Framework is on ethical issues, how the confidentiality of information given by the people taking part in Life Study will be preserved, and how access to their data and biological samples will be managed. The Framework is intended to be a document that will evolve over time, and is written for a diverse range of audiences.

It is essential that Life Study policies take account of relevant laws, and key policies and ‘good practice’ guides that have been published by others; links to these can be found in Annex 2¹.

More information on Life Study can be found on the Life Study website at:

<http://www.lifestudy.ac.uk/homepage>

A. Life Study

1. Overview

1.1 Aims and overview

A baby’s development is shaped by many influences, from the most immediate ones such as his/her parents, wider family and home environment; to the local environment, schools and services; as well as more distant influences such as Government policies. The overall aim of Life Study is to understand how the family, social and physical environment in very early life influences child development, health and wellbeing in the children being born in the UK today.

Life Study will follow the physical, social and emotional development, health and wellbeing of up to 80,000 UK babies and their families from pregnancy onwards; and the relationship with social, economic and environmental influences. Collecting information at different time points in a child’s early life will allow researchers to identify important pathways to health and well-being and the timing and sequence of different events and experiences early in life.

¹ In developing this Framework, we have drawn on the UK Biobank Ethics and Governance Framework v3, October 2007 in particular (accessed on 19th February 2016 at: <http://www.ukbiobank.ac.uk/resources/>): we are grateful to Jonathan Sellors of UK Biobank for permission to do so.

As well as mothers, Life Study also involves fathers and/or other partners, recognising their important role in a child's development and later life.

Life Study has been designed to address important gaps in earlier national cohort studies, for example Life Study will have greater insights into pregnancy and the first year of life and greater representation of families of black and minority ethnic backgrounds. It will also increase our understanding in the following areas in particular:

- Inequalities, diversity and social mobility in the Life Study generation
- Early life antecedents of school readiness and later educational performance
- Developmental origins of health and illness in childhood
- Social, emotional and behavioural development: the interplay between infant and parent
- Neighbourhoods and environmental pollutants: effects on child and family

In addition to these areas, the breadth of the information collected means that the Life Study will be useful for a wide range of future research, including research which cannot yet be foreseen.

The Life Study team will seek active engagement with participants², research users and society in general throughout the lifetime of the resource³. Data and samples will only be used for approved research consistent with the above purpose. Safeguards are in place and will be maintained to ensure the confidentiality of the participants' data and samples.

1.2 Organisation and funding

Funding for the Life Study has been provided through the UK Government Department of Business Innovation and Skills Large Facilities Capital Fund, with additional contributions from the Economic and Social Research Council, the Medical Research Council and University College London (UCL).

² 'Participant' refers to the child and to his/her mother or individual with legal parental responsibility for the child, and/or the mother's nominated father or partner who may or may not have legal parental responsibility for the child.

³ In this context, 'resource' refers to primary data and biological samples, and secondary data which has been derived from data, samples or linkage.

The management and governance structure of Life Study has been established by the funders to ensure that Life Study is developed, managed and maintained in a manner that maximises its benefit as a long-term scientific resource of importance both nationally and internationally. The overall strategic and scientific direction and objectives of Life Study are the responsibility of the Chief Investigator/ Director of the Study based at UCL, together with a Scientific Steering Committee of leading academic experts from various UK universities with a broad spread of scientific and technical expertise. In their contract with UCL, the funders of Life Study have delegated responsibility to the Director for custodianship of the data and samples, to ensure that policies and processes are put in place to safeguard the interests of the participants and society, and the scientific and ethical integrity of the resource.

Life Study will conform to the accepted standards for research involving human subjects, and therefore requires NHS Research Ethics Committee (REC) review, approval and reporting.

1.3 Principles of information governance

The Life Study team will collect information from the babies in the Study and their families, together with biological and environmental samples. It is of paramount importance that the data and samples are handled and archived securely, maintaining the confidentiality of people participating in Life Study, and managing access to the data and samples in a responsible way that respects these requirements and ensures responsible management of samples that are depletable.

The Life Study team will employ best-practice information security at all stages in the data management process. From participant recruitment, through data collection, curation, archival and dissemination, information security management systems will be independently audited to the ISO-27001 information security standard. In addition, for all aspects of handling of NHS-derived identifiable data, the team will ensure that systems meet the requirements of the NHS Information Governance Toolkit.

Any personal information held by the Life Study team will be held in strict confidence and in accordance with the Data Protection Act 1998.

B. Relationship with Participants

2. Recruitment

2.1 General principles

Life Study aims to recruit up to 80,000 babies and their families from around the UK. It is not intended to enrol people who are unable to give consent (for example, because of diminished mental capacity), those who are unable to take part in data collection (for example, because they are too ill), or those who are uncomfortable with any of the conditions of participation. Staff will be trained to judge each potential participant's capacity to give consent and take part in data and sample collection.

Participation in Life Study is voluntary, and all aspects of recruitment will be conducted in a way that preserves the voluntary nature of participation and respects cultural differences. In order to generate scientifically valid results, Life Study must also obtain agreement from participants for examination of the progress of their development and health or any illness over time.

The Life Study team will act in accordance with the Data Protection Act 1998 and all other relevant legislation, and seek all necessary approvals that are required for the planned invitation, assessment and follow-up procedures (e.g. from relevant ethics committees, the Information Commissioner, Caldicott Guardians and other relevant bodies).

The Life Study team will seek to reduce barriers to participation (for example any barriers due to gender, ethnicity, social class, employment, language, disability) through, among other things, the location and opening times of Life Study Centres and translation of study information.

2.2 Selection and approach

There are two groups within Life Study – one group will be recruited during pregnancy and another group will be recruited after the birth of their baby. The Life Study team will seek to recruit as widely generalisable a sample as is practicable so that the research may ultimately benefit a wide diversity of people.

Group recruited during pregnancy

Pregnant women booking to deliver within one of the maternity units included in Life Study will receive information about Life Study as part of their routine booking information pack. At, or before, their 20 week ultrasound scan these pregnant women will be invited to take part in Life Study and to make an appointment to attend their local Life Study Centre when they are between 20 and 30 weeks pregnant or as soon as possible thereafter. Partners who

attend the scan with a pregnant woman will also be given information about the study and invited to make an appointment to attend a Life Study Centre.

If a woman has a partner whom she would like to involve in Life Study, she will be asked to provide contact information so the partner can be sent an information pack or she may choose to pass on the information pack herself to her partner. Women will be allowed to choose who they nominate as their partner (this may not be the baby's biological father and could be a same sex partner), or they may choose not to involve a partner at all.

Group recruited after the birth of the baby

Babies in this part of Life Study will be identified through a random sample of the births registered across the UK. Mothers will be invited to take part in Life Study by one of three UK Statistical Authorities with responsibility for registering births (the Office for National Statistics in England and Wales, National Records Scotland or Northern Ireland Statistics and Research Agency). Mothers recruited through this process will be offered a home visit when the baby is six months of age.

2.3 Enrolment

As well as the information packs distributed to participants, further information will be available from Life Study through a free telephone service and websites.

At the visits to Life Study Centres, or at home visits, trained staff will answer questions, provide clarifications and explain the consent process as required. If an individual decides to take part, their signed consent will be sought and recorded before they are enrolled.

Enrolment for the pregnancy group visiting Life Study Centres will involve computer-assisted self-complete questionnaires, as well as interviewer-based questionnaires for the mother and for the father/partner. Biological samples (such as blood and urine) will be collected, and physical measurements (such as height, weight and assessments of vision) carried out. Mothers (or a person with legal parental responsibility where this is not the mother) will be invited back for a similar visit at the same Centre when their baby is aged approximately six months and again at 12 months. At visits after the baby's birth, physical measurements of the baby will be made including the baby's length and weight, developmental assessments and observations, and samples of urine and saliva (but not blood) taken.

Biological samples will be collected from the mother and baby in the maternity unit shortly after birth, with maternal consent.

Enrolment for the group recruited after the baby has been born will involve a visit to their home when the child is approximately six months old. After consent has been obtained, the visit will include interviewer- and self-administered questionnaires for the mother and the

father/partner. No biological samples will be collected or physical measurements made in this group. It is intended that the home visit will be followed by a postal/web/telephone questionnaire when the baby is approximately twelve months old.

Mothers and fathers/partners will be asked questions on a number of topics including, for example, their health, wellbeing, lifestyle, identity, education, employment and income, parenting and childcare, housing, social networks, neighbourhoods, and personal environmental exposures to – for example - X-rays, noise and mobile phones. Parents will be asked questions about the baby's birth, health and development relating to, for example, sleeping, crying, and feeding.

3. Consent and Understanding

3.1 Consent

Individual written consent will be sought to participate in Life Study. Participation will be presented as an opportunity to contribute to a resource that will, in the long term, increase understanding of how to enhance the health, wellbeing and life chances of babies and children, and the adults that they will become. Because it will be impossible to anticipate all future research uses, consent will be sought for research in general that is consistent with Life Study's stated purpose (rather than for specific research).

3.2 Individual consents

Life Study will involve different types of participant. Individual written consent to participation will be sought from these participants as described below.

Pregnant women/new mothers⁴

Written consent will be sought from:

Women/mothers during pregnancy (pregnancy group) – at their visit to a Life Study Centre – for their own participation, including for biological samples from mother and child at birth; and for links to be made with a range of other routinely collected data relating to them and to their child, including that derived from health and education records or by linkage to other records (for example air pollution data) through their postcode data.

New mothers in the birth group – at the home visit – for their own participation and for linked access to a range of other routinely collected data relating to them and to their child,

⁴ Pregnant women or mothers under the age of 16 years will not be eligible for participation.

such as health and education records or by linkage to other records (for example air pollution data) through their postcode data.

Partners of women recruited to Life Study (includes fathers and partners⁵)

Written consent for their own participation and for linked access to a range of other routinely collected data relating to them, such as health and education records or by linkage to other records (for example air pollution data) through their postcode data, may be sought from the following:

- **Partners of women recruited to the pregnancy group** at their visit to a Life Study Centre (fathers or partners)
- **Partners of women recruited to the group enrolled after the baby's birth** at the home visit (fathers or partners)
- **New partners/step-parents from either group** if they are nominated by the mother

Children/young people

Written consent will be sought from children in Life Study when they reach an age when they are regarded as competent to provide their own consent to take part. Current legal and ethics advice suggests that formal written consent should be sought at the first contact with children after they reach 16 years of age, however this policy will remain under review by Life Study as appropriate. In line with good practice, age-appropriate and accessible information will be provided to child participants and assent may be sought at earlier ages.

Babies/children

Written consent will be sought for the child's participation from:

- Mothers (or the individual with legal parental responsibility) in the pregnancy group at the visit to a Life Study Centre when the child is aged approximately six months – including for biological samples to be collected and for linked access to a range of other routinely collected data relating to their child, such as health and education records or by linkage to other records (for example air pollution data) through their postcode data
- Mothers (or the individual with legal parental responsibility) in the group enrolled after the baby's birth at the home visit when the child is aged approximately six months –

⁵ A partner may be the mother's partner, or an adult who has become legally responsible for the child, for example a step-parent or grandparent, recognising that this may change as the family structure changes or the child grows older.

including for linked access to a range of other routinely collected data relating to their child, such as health and education records or by linkage to other records (for example air pollution data) through their postcode data

If the parent who originally gave written consent for the child to take part dies, loses capacity to consent or no longer has legal responsibility for the child, then further written consent will be sought (in order) from:

- a participating father/partner or other carer with legal responsibility, or
- a non-participating father/ partner or other carer with legal responsibility.

If the parent who originally gave written consent for the child to take part withdraws from Life Study, then the consent for the child will stand unless the parent also withdraws consent for the child to take part⁶.

Where consent for a child to take part has been withdrawn before that child's 16th birthday then, if appropriate and feasible, the child may be re-contacted after reaching 16 years of age and asked if they would like to provide their own consent to take part in Life Study.

3.3 Capacity to provide consent

As stated in **Section 3.2**, young adults who have participated in Life Study as babies or children will be asked to provide written consent to continued participation once they reach an age at which they are deemed competent to do so.

When adults provide individual consent, consideration will be given to their competence to provide consent. If there are concerns about a potential participant's understanding of consent, for example due to language or mental capacity issues, then consent may not be taken.

In considering whether a potential participant can provide consent, Life Study will take account of the four principles for assessing an individual's capacity to make decisions as set out by the Royal College of Psychiatrists in their guidance.⁷ An individual will be considered to have capacity to provide consent if they can:

⁶ See Section 3.9 on withdrawal from the Life Study.

⁷ Royal College of Psychiatrists provides guidance on assessing capacity to make healthcare-related decisions: *Mental Capacity and the Law*. Accessed on 19th February 2016 at: <http://www.rcpsych.ac.uk/expertadvice/problems/mentalcapacityandthelaw.aspx>

- Understand the information provided
- Retain information
- Weigh up the benefits and harms, and
- Communicate their response clearly

3.4 Understanding

The information provided to potential participants when inviting them to take part and seeking consent will provide a clear understanding of, amongst other things:

- The purpose of Life Study, the fact that it is a long-term research resource (not a healthcare programme), and any risks and benefits of taking part
- The kinds of information and biological samples that will be collected from the family during pregnancy and the first year of the baby's life, which may include data that some participants would regard as especially sensitive (with options to avoid certain questions, measurements and/or biological or environmental samples)
- The fact that permission will be sought for linked access to a number of other records on the baby/child as s/he grows older, for example medical and other health-related information (past and ongoing), and education records; and the need for participants to allow such linkage for as long as possible to maximise the benefit of the Life Study as a research resource. The proposed links will be explained in detail during the consent process, together with information on how possible future changes to such records (e.g. due to changes in the way such records are obtained and maintained) will be managed in relation to the consent given.
- The fact that additional consent is being sought for linked access to a number of other records on the mother and/or the father/partner, for example on postcode data or employment records. The proposed links will be explained during the consent process, together with information on how possible future changes to such records (e.g. due to changes in the way such records are obtained and maintained) will be managed in relation to the consent given.
- The fact that Life Study will act as custodian of the Life Study database and biological sample collection, and that participants will have no property rights in the biological samples.

- The kinds of safeguards that will be maintained, including secure storage of data and biological samples in reversibly anonymised⁸ form (as explained in **Section 4**) and restrictions on access to data and biological samples that are not anonymised
- The assurance that data and biological samples will be anonymised before being provided to research users
- The expectation that commercial entities will apply to use Life Study data and samples and the principles governing any commercial access
- The expectation that Life Study will continue into the future with the possibility of further contacts such as invitations to provide further information in person or by phone/internet/post.
- The intention to hold and allow research access to data and samples in future, including if participants lose mental capacity or die, as such data and samples are crucial for research on severe illnesses
- The right to withdraw at any time without having to give a reason and without penalty, and the meaning of different levels of withdrawal
- The Life Study team’s commitment to maintaining active engagement with participants and society in general.

The points listed above are some elements of what it means “to participate in Life Study”. These are discussed in more detail later in this document. These elements and other customary undertakings will be addressed in information provided to participants during the consent process.

The Life Study protocols will be designed to ensure that participants understand to what they are consenting when they agree to take part, through participant information and staff training and will have been tested and evaluated with focus groups.

The consent to participate in Life Study will apply throughout the lifetime of the Study unless the participant withdraws. Further consent will be sought for any proposed activities that do not fall within the existing consent, such as additional record linkages.

⁸ The information that can identify an individual will be removed and replaced with a code so that the person receiving the data or samples does not receive any information that identifies a specific individual. See Section 4.2 and 4.3 for more detail.

3.5 Collection of data from relevant records

In order to ensure we can follow children through their life course and fully understand the wide range of influences on children's lives, the Life Study team will seek agreement from Life Study participants for linked access to and collection of information from other routinely-collected data sources including education and health records. This is essential for the success of Life Study which aims to track events that relate to the child's development, education, and health. Sources of information will be diverse and include, for example: screening results from the screening programme; diagnostic codes for disease or operations from GP or hospital records; and educational attainment from educational records.

The range of different records that can be accessed will be determined by availability of suitable electronic records systems and the practical requirements of linking to these systems, and by considerations such as the importance of maintaining secure information and maintaining confidentiality. In the consent process, the Life Study team will explain to participants the kinds of record systems to which it will seek access, and will keep participants generally informed of progress with accessing different types of records in Life Study, seeking views from sub-groups of participants as appropriate.

It is not possible to specify in detail and in advance which data from these various records will be needed. Although, in general, only certain data from these records may be requested, it is proposed that consent will cover access to information from the full records. This will include information from past records, since these will help to characterise participants and to understand later child-related outcomes more completely. Information derived from the full records may also be required when it is necessary to verify the accuracy of data.

3.6 Provision of health-related information to participants

General considerations about providing health-related information⁹

Provision of health information to participants is possible at various stages of Life Study:

- At the visits to Life Study Centres: It may be impractical to conceal from participants some of the measurements taken in their enrolment or subsequent visits (for example, height, weight, estimated amount of body fat). Consequently, a printed report will be provided at the end of their visit as a means of feeding back such measurements. By

⁹ In some cases health-related information might include educational findings or other findings relating to an individual in the study.

reporting standard ranges, the participant should be provided with sufficient information to give meaning to the measurements taken.

- As a research study, Life Study does not have the same duty of clinical care that would apply for health professional and other staff working in a clinical service. The duty of care for Life Study research staff enrolling and interviewing participants applies mainly to considerations of child and adult safeguarding, and to ensuring the safe and competent collection of questionnaire data, baseline measurements, and blood or other samples. Concerns about child or adult safeguarding will be actioned in line with the processes operating at the host NHS organisation or as agreed with any third parties providing research survey services.
- Standard operating procedures will be provided to alert staff to the limited number of situations in which they should actively encourage participants to contact a relevant health professional. Participants may act at their discretion on the printed report provided or on the encouragement to contact a health professional and arrange to see their general practitioner or other relevant health professional.
- Summaries of research findings and implications of findings that derive from information provided by Life Study participants as a group will be made available to participants and the wider community to explain how they will or have been used to inform relevant public health and policy strategies in line with the objectives of Life Study.

A clear explanation of this policy is included in the participant information material.

Future policy on feedback

Science is progressing and new findings and potential interventions are and will continue to be identified, although their implications may often not always be known in the early stages of their use. While largely applicable to biomedical data and samples, there may be times when such findings also arise from the educational and psychosocial research data that are collected. Accordingly, the Life Study policy on feedback should be flexible in order to respond to new information, to scientific progress and/or to any other exceptional scenario – possibly unpredictable at the outset of Life Study – in which feedback to an individual (or individuals) becomes highly desirable or imperative.

Principles of information provision

- The Life Study policy will take account of any relevant UK Research Council policies and other widely accepted standards of ‘best practice’ (see Annex 2).
- Life Study protocols will aim to ensure that participants understand that enrolment in Life Study does not provide the parent(s) or the baby with a health check. (This will be

clarified in information materials and participants will be advised to consult a healthcare professional if they have concerns about their own or their baby's health).

- In principle, feedback will not be given to Life Study participants on any result, except where it is impractical to conceal measurements from participants (for example, measures of body height, weight or fat) AND their interpretation for a healthy, asymptomatic population sample is well-understood.
- The Life Study team will generally not provide individual health information to participants, and a clear explanation of this policy (and the few exceptions) will be provided in the participant information material. This policy is based on the following reasoning:
 - There is a lack of understanding of the spread of results in the general population for many investigations. Although these tests may be routinely used in sick patients, the clinical or health-related significance of these tests can be impossible to interpret reliably when they are undertaken in an asymptomatic and otherwise healthy population.
 - Results communicated outside of a clinical setting will not have been evaluated in the context of the individual's full medical record.
 - Feedback of results might be potentially harmful, for example, may cause undue alarm, trigger unnecessary further investigation or treatment or have potentially adverse effects on insurance and employment status.
 - Samples may not be analysed until many years in the future meaning that the timeliness and relevance of the information for the individual is difficult to judge.
 - Samples and data may be used in experimental or pilot studies where the interpretation of results is unclear for individuals.
 - The clinical implications and significance of some data - such as that assessing exposure to environmental pollutants - for health, now and in the future, may not be known.
- There may be exceptional circumstances when it is appropriate to feedback individual clinical results. All potential research results or findings considered for feedback must
 - be appraised in terms of any benefits or harms of feedback
 - meet the criteria of scientific and clinical validity, clinical significance and perceived benefit to the individual

- be confirmed independently for that specific individual (for example through analysis of a second sample) and prior to consideration of communicating the finding to an individual participant.

The Life Study feedback policy will be reviewed regularly and updated as necessary.

3.7 Ongoing provision of information to participants and the public

Regular communication will be important to inform participants of general findings from research based on the resource and to encourage continued participation. The Life Study team will, therefore, look for a variety of ways for communicating with (including listening to) participants, the general public, research users and the scientific community.

A variety of media, such as websites, helplines, newsletters, and public meetings will be used to inform participants about the development and use of the resource, and of ways to contact Life Study (including, for example, how to withdraw). Systems will be put in place to allow participants to indicate how, and whether, they would like to receive such information. Life Study will also maintain procedures for responding in a timely fashion to any enquiries or complaints.

3.8 Expectation of re-contact

It will be explained to participants that they may be re-contacted by the Life Study team for various reasons, including:

- For a further ‘sweep’ or contact with participants in order to collect new information (such as questionnaire data, measures or samples) as part of the ambition of Life Study to follow babies recruited to the study throughout their lives. It is anticipated that further contacts will be made every few years (more frequently in the early years which are a critical time in a child’s development). These contacts could include invitations to visit the Life Study Centres, and/or receive home visits. Invitations to provide additional information that does not require such visits (e.g. questionnaire data collected by mail or internet) might be sent to all participants at various times during Life Study.
- To seek consent for proposed new uses of existing data that have passed scientific and ethics review, but do not fall within the existing consent; or for consent to linkage to other records not specified at the initial consent.

It will be emphasised that participation in future Life Study research is entirely voluntary, and that any further contact of participants will only be undertaken by the Life Study team.

3.9 Right to withdraw

Participants will be advised at enrolment that they have the right to withdraw from Life Study at any time without having to explain why and without penalty. This is essential to preserve and demonstrate the voluntary nature of participation.

A parent who has provided consent for a child to participate in Life Study may choose to withdraw the child at a later stage (selecting one of the options below). In certain circumstances, such as when a parent has withdrawn the child before the child reaches 16 years of age, it may be appropriate to contact the child after they reach 16 years of age to confirm their withdrawal or participation. If a child is withdrawn from the study by a parent, then the parents/carers will also be assumed to have withdrawn on the same basis (see below).

When a child participating in Life Study reaches an age where consent is sought, the child may choose not to take part in Life Study any longer. In this situation, no further information would be collected on that child or his/her family.

Where one parent or partner chooses to withdraw themselves from Life Study, this participant's data and samples will be the only data to be withdrawn, where practicable to do so. Should participants become incapacitated or die, they would no longer be able to withdraw themselves (see **Section 3.10**).

When seeking consent, the Life Study team will provide information to participants about the options for indicating withdrawal from Life Study as follows:

- **“No further contact”**: Life Study would no longer contact directly the participant who withdraws, but would still have their permission to use information and samples provided previously and to obtain further information from the relevant linked records.
- **“No further access”**: Life Study would no longer contact the participant or obtain further information from the relevant linked records in the future, but would still have their permission to use the information and samples provided previously.
- **“No further use”**: In addition to no longer contacting the participant or obtaining further information about them, any information or samples collected previously would no longer be available to researchers. The Life Study team would destroy any biological samples as far as is practicable (although it may not be possible to trace and destroy all distributed anonymised sample remnants) and would only hold their information for archival audit purposes. The participant's signed consent and withdrawal would be kept as an auditable record of their wishes. Such a withdrawal would prevent information about them from contributing to further analyses, but it would not be possible to

remove their data from analyses and/ or reports that had already been completed. Although data from participants who choose the “No further use” withdrawal option can be made unusable, it may not be possible to destroy it completely. This is due to the development of complex IT systems designed to protect the integrity and security of the data and the confidentiality of participants.

If, having considered their concerns and options, a participant decides to withdraw from Life Study then written confirmation of the level of withdrawal would be requested from the participant using a standard proforma. Life Study would need to retain some minimal personal data for a number of reasons, including ensuring that participants who have withdrawn are not re-contacted and/or assessing the determinants of withdrawal and any impact on research findings. Participants who withdraw will be assured that this administrative record will not be part of the main database that is available to others.

Despite the Life Study team’s efforts to stay in touch with participants, contact may be lost with some participants as they relocate, emigrate, or do not respond to communications. Where a participant has not actively withdrawn, the Life Study team will continue to use the samples and data and maintain linkages, although it will not be able to update some data (e.g. those collected by repeat questionnaire).

3.10 Incapacitated or deceased participants

In the event that a participant dies or loses mental capacity the Life Study team will continue to use information and samples provided previously, unless the participant has withdrawn. Should a participant express the view sometime after enrolment that s/he would wish to be withdrawn from Life Study in the event of mental incapacity or death then this request will be honoured, provided written confirmation of their preferred option for withdrawal (see **Section 3.9**) has been provided and loss of capacity or death is notified by a family member or someone with legal parental responsibility for the child. Otherwise, participants will not be withdrawn if they lose mental capacity or die. In all events, the Life Study team will continue to safeguard the confidentiality and security of all participants’ data and samples as long as it holds them, including after a person’s mental incapacity or death.

3.11 Financial remuneration

Participants may be offered a small financial remuneration or token of gratitude for entering Life Study if approved by the Research Ethics Committee (REC). Reasonable expenses incurred through participation (such as travel and parking) will be reimbursed in accordance with the Life Study policy on expenses.

As is explained in **Section 5** “Custodianship of data and samples”, we will explain to participants that their involvement will not create or confer any property rights in biological samples.

4. Confidentiality

The Life Study will protect the confidentiality of participants, their data and samples. Systems will be in place for secure data flow and for protecting confidentiality, (reversibly) anonymising data and biological samples, and enforcing data and physical security. Assurance that these measures are in place will be given to participants during the consent process. Some principles and comments on these matters follow in this section.

4.1 Commitment to maintaining confidentiality

The Life Study team will maintain strict measures to protect confidentiality, and will ensure that data and samples are (reversibly) anonymised, linked and stored to very high standards of security. The same protection will be extended under contract for any handling or analysis of data or samples by third parties engaged to provide services necessary for developing the resource. Research users will only be given access to anonymised data and samples.

Life Study takes confidentiality very seriously. Participants will be informed that in some rare circumstances it may be necessary to breach confidentiality in a research study, for example when a participant is considered to be at risk of harm or a child safeguarding issue arises. Life Study will aim to ensure all staff are trained to identify and raise concerns appropriately in the rare situations when such issues arise.

4.2 Anonymisation

During enrolment, the Life Study Centre will need to hold identifying information on the pregnancy group (such as name, address, birth date, NHS number) together with information collected from the participant during the visit. This information will be encrypted for security when data are transferred. When the information is no longer needed for operational purposes, it will be removed from the Life Study Centre system at the first available opportunity.

Information collected from the group recruited after the baby’s birth will be similarly encrypted for transfer to the Life Study central system.

On receipt at the Life Study coordinating centre or other data handling facility, all personal identifying information will be separated from participant data and samples and only linked using a unique identifier of relevance only to Life Study (for example, not the NHS or National Insurance number).

All identifying information will be held centrally by the Life Study team in a restricted access database that is controlled by senior Life Study staff. Only a few people within Life Study will have access to the “key” to the code for re-linking the participants’ identifying information with their data and samples (i.e. “reversible anonymisation”). It is necessary to retain this link with identifying information to allow follow-up of participants, to eliminate redundant data (e.g. duplicate cases), to verify correctness and completeness of data against original records, to establish correct linkages among databases, and to find specific data or samples for removal should a participant wish to withdraw from Life Study.

4.3 Re-identification

Access to the “key” to the code re-linking participants’ identifying information with their data and samples will be restricted to a limited number of Life Study staff in order to allow proper follow-up of participants including linkage of follow-up data and for other necessary procedures. All Life Study staff will receive appropriate Information Governance training and will be required to maintain participant confidentiality as part of their contracts. All efforts will be made to ensure that researchers cannot identify individual participants from the anonymised data or samples that are provided to them.

4.4 Security

A wide variety of measures will be put in place to ensure the security of data, samples, the database and the information technology system in general. These include staff training and contractual sanctions, physical and electronic controls on access to data, cyber- security, and physical security. This should prevent identifiable information from being used – inadvertently or deliberately – for any purpose other than approved research (see **Section 6** below).

4.5 Self-identification as a participant

Life Study understands that participants may wish to disclose to others that they are participating in the study and respects their right to make such decisions. As part of the study communications strategy, Life Study will develop a guide to media and identity disclosure for participants, and will provide support and advice to any participants who are considering whether to discuss their participation.

C. Relationship with Research Users

5. Custodianship of Data and Samples

A number of different types of data and samples will be collected in the Life Study.

The data collected or created as part of Life Study will include:

- Questionnaire data from participants
- Biomedical assessment data e.g. anthropometric measurements, accelerometer data
- Video and audio recordings of mother and baby.
- Paradata e.g. data concerning the process of collection of information or samples from individual participants.
- Metadata e.g. catalogue data on the questionnaire instruments or biomedical assessments chosen, or on the collection and storage requirements for biological samples.
- Linked data, e.g. routine health and other administrative data.
- New secondary data or derived variables e.g. data derived from statistical analysis of Life Study data.
- New secondary data derived from the biological samples, e.g. genomic data or biological assay results.

The samples collected include:

- biological samples such as blood, saliva and urine from parents; urine and saliva from babies, discarded biological materials such as placenta and umbilical cord samples following birth; left-over screening samples from antenatal or newborn screening programmes; microbiome samples, such as faeces and vaginal swabs collected from mothers and babies at or shortly after birth;
- environmental samples may also be collected, for example samples of dust from the participant's home.

In their contract with the Research Organisation (RO; currently UCL), the funders of Life Study have delegated responsibility to the Director who is accountable and responsible for custodianship of the database and the sample collection and for ensuring that policies and processes are put in place to safeguard the interests of the participants and society, and the scientific and ethical integrity of the resource.

Custodianship conveys certain rights, such as the right to take legal action against unauthorised use or abuse of the database or samples, and the right to sell or destroy the samples. Participants will not have property rights in the samples.

The Director and the RO do not intend to exercise all of these rights; for example, they will not sell samples. Rather, they will serve as the custodian of the resource, maintaining and building it for the public good in accordance with its purpose. This implies both the judicious protecting and sharing of the resource. It also extends to the careful management of any transfer of parts or all of the database or sample collection (see **Section 10** Transfer of assets, or closure). If at some future time it is necessary for the funders to transfer the custodianship of Life Study to another RO, for example on the retirement of the Director, then the RO will work with the funders to ensure a managed transfer to the new custodian that takes account of the principles set out in this Framework.

Life Study will explain its committed role as custodian of the resource to participants. Even when this role is understood clearly, it is likely that many participants will continue to be interested to know how their data and samples are used; for this reason, among others, Life Study will inform participants periodically about the kind of research that is being or will be done using the resource and its findings and relevance (see **Section 3.7**).

In addition to respecting the commitments made to participants in the consent agreement, Life Study will strive to build a relationship of trust with participants and the wider public, in order to foster acceptance of the ways the resource is developed and used. A Framework for Managing, Sharing and Accessing the Life Study Resource has been developed and a detailed Access Policy for use of the resource will be developed, which will evolve in response to users, participants and the wider public.

6. Research Access to Data and Samples

6.1 General principles of access

Life Study will manage access to the resource in accordance with contractual obligations to the funders, and according to the principles of this Framework.

Users of data and/or samples will be subject to appropriate registration and license agreements. For some proposed uses of data and/or samples, a research proposal will be required, and this will be reviewed. If approved, the approval may be subject to a formal agreement that sets out terms and restrictions for the use of these data or samples.

Exclusive access to the fully developed resource will not be granted to any party. Use of the biological samples will have to be carefully coordinated and controlled because they are limited and depletable. While the resource is being developed, Life Study may use the early data and samples to validate and improve methods of data collection and analysis.

Access to the resource by the police or other law enforcement agencies will be acceded to only under court order.

It may be appropriate for anonymised and/or aggregated data or anonymised biological samples¹⁰ to be sent abroad, for example where a new technique for analysing biological samples is not available in the UK to the same standard, or where Life Study data are being pooled with or compared to other overseas studies. In these situations, steps will be taken to ensure appropriate governance mechanisms are in place through a formal material transfer or data transfer agreement.

6.2 Decisions on access and use

Contractually, the Director of Life Study as custodian of the data and samples will have delegated decision-making authority over access to and use of the resource in line with the agreed Life Study Access Policy and subject to the established Life Study governance processes and ethics approvals. In practice, the Director may delegate decisions on routine applications to suitable bodies or persons (such as the UK Data Archive or an Access Committee). The Director and the Scientific Steering Committee will own the Life Study Access Policy subject to endorsement of the Policy by the Life Study Strategic Advisory Committee.

Life Study will ensure that it explains and communicates through a variety of media, to participants and the public, the policies and procedures for research access. An overall policy and detailed terms of access have been, and will continue to be, developed (i.e. the Life Study Access Policy) which address fairness and transparency of decision-making, the handling of conflicts of interest and the prioritisation of use of samples.

The Director will ensure that use of the resource is kept under review through the Scientific Steering Committee as well as the established Life Study governance processes in

¹⁰ In some cases it will be appropriate to fully anonymise data and/or samples so that no link can be made back to the individual. In other cases data and/or samples will be reversibly anonymised, i.e. the information that can identify an individual will be removed and replaced with a code so that the person receiving the data or samples does not receive any information that identifies a specific individual. Aggregation is the pooling of data - information is no longer at the individual level.

conformance with this Framework and the Access Policy and any other relevant Life Study policies, and through reports on its use to provide assurance to participants and society that the resource is being used in the public interest.

6.3 Contractual arrangements

Access to samples will be licensed for approved specific research consistent with Life Study's purpose. Licensed use of the resource will be for specific uses under strict terms and conditions in standard access agreements, including compliance with the consent given, the provisions of this Framework and other policies. Fees may be charged to cover the costs of providing access to samples or any additional work required on the data supplied.

6.4 Sharing of data and findings

Life Study seeks to augment the value of the resource in order to ensure that the greatest potential public benefit may be realised from it.

All research users will be required to provide the results from analyses of participants' data and samples, and any relevant supporting information, to Life Study for possible inclusion in the database, so that they are subsequently available for use to all researchers with appropriate scientific and ethics approval.

There will also be a requirement on all research users to place the findings (whether positive or negative) from all research based on Life Study into the public domain so that people can benefit from them. Publication should be in the peer reviewed scientific literature whenever possible. Life Study will also explore further strategies for dissemination of findings (such as through accessible electronic archives or in other formats accessible to the public and other stakeholders for example policymakers).

Researchers will only be permitted to keep results based on Life Study confidential for a limited and reasonable period as described in the Life Study Access Policy. This policy will apply to all research users, whether non-commercial or commercial.

D. Relationship with Society

7. External Governance

7.1 Ethics approval and review by relevant ethics committees

The core scientific protocol and operational procedures of the Life Study resource, as well as proposed uses of it, will have approval from appropriate ethics committees in accordance with guidance from relevant bodies (such as the Health Research Authority) and with

relevant provisions (such as the Research Governance Frameworks of England, Wales, and Scotland; Governance Arrangements for Research Ethics Committees; and Standard Operating Procedures for Research Ethics Committees in the United Kingdom. Participants will be told that such independent ethics approval will be obtained.

7.2 Compliance with Research Governance Frameworks

With respect to the core protocol, the Life Study team will assume the responsibilities stipulated by the Research Governance Framework for Health and Social Care in England and the corresponding frameworks in Wales and Scotland.

In England, for example, at present these responsibilities are as follows¹¹:

- **Sponsor** is the Research Organisation (or RO, currently University College London): responsible for confirming that proper arrangements are in place for initiating, managing, monitoring and financing the project.
- **Chief Investigator is the Director:** responsible for the overall conduct of Life Study in the UK.
- **Principal Investigator:** each Life Study research site will have a principal investigator who is responsible for any site-specific research governance or other processes.
- **Life Study senior management:** responsible for the day-to-day conduct of the project and ensuring it follows the protocol, and for ensuring the training and monitoring of all staff involved in its conduct.
- **Staff in Life Study Centres, Biorepository, fieldwork agencies:** responsible for carrying out key aspects of project delivery on behalf of the central Life Study team.

Typically, external researchers will act as the sponsor of particular research using the resource and will take on the relevant responsibilities. But, if the RO acts as the sponsor of some research then it will take on these responsibilities.

As required under the Human Tissue Act 2004, the premises procured by Life Study to manage the biological sample archive will be appropriately licensed with a named Designated Individual with responsibility and accountability for conformance with the Act.

¹¹ <http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilities/>

8. Public and Participant Involvement

All Life Study participants should have an opportunity to access publicly available information and summaries about Life Study findings provided in an accessible format and in non-technical language appropriate to a lay audience, for example through the Life Study website.

In a longitudinal cohort study of this kind, there is a necessity for broad consent because of the difficulty in predicting changes in specific requirements for consent. In view of the importance of maintaining support and trust, Life Study will seek participant views through a variety of engagement initiatives, such as focus groups or participant panels, particularly when considering the impact of future developments in Life Study.

9. Benefit Sharing

9.1 Dissemination of knowledge generally

The purpose of Life Study is to learn from the collective health, development and wellbeing experience of the participants over time, in order to generate and disseminate new knowledge to benefit the health and wellbeing of children in the UK and elsewhere.

Knowledge¹² derived from studies based on Life Study will be:

- Published in the world's peer-reviewed scientific literature ;
- Communicated to Life Study stakeholders, including participants, funders, NHS and other policy stakeholders, and others (as appropriate);
- Accumulated and made available by Life Study as a resource for further research, for example via archives of the findings of studies and initiatives such as the Cohort and Longitudinal Studies Enhancement Resources¹³.

¹² This does not refer to knowledge about an individual within the study. For information about individual feedback see Section 3.6.

¹³ CLOSER: see <http://www.closer.ac.uk/> (Accessed 19th February 2016)

Such knowledge may also be applied to the development or improvement of social, health, education or environmental policies, healthcare techniques, technologies, materials or routines.

9.2 Intellectual property, income generation and royalties

The Life Study Access Policy will ensure that the Life Study resource is accessible to all bona fide research users, and that intellectual property is used to the benefit of society and the economy, and that ownership and licensing of IP is not exercised in such a way as to prevent or restrict the conduct of Life Study or the dissemination of the outcomes of Life Study. Terms of access where appropriate will be embodied in formal agreements that reflect Life Study's objectives.

The data generated from Life Study are intended to become a valuable common resource for research, and are not expected in itself to lead to patentable inventions that return significant income either to researchers or Life Study. Nevertheless, it is possible that research conducted using the resource (which might be conducted by researchers in the public or commercial sector, as well as the academic and charity sector) will subsequently lead to the development of intellectual property that generates revenues.

The biotechnology and pharmaceutical industries can play an important role in realising health benefits in a practical sense by developing and improving the use of biomedical products. Commercial organisations will be allowed access to the Life Study resource only if their proposal is in accordance with the aims of Life Study to benefit the health of children and families, and compliant with the usual scientific and ethics requirements as well as with regard to any contractual requirements in relation to IP.

10. Transfer of Assets, or Closure

Contractual obligations agreed between the funders and the Research Organisation in the event that there is a transition in the custodianship or control of the resource will respect this Framework and other relevant agreed Life Study policies. A more detailed policy may need to be developed to support this which might for example address partial or full transfer of the resource and differentiate between processes appropriate for data and those for samples in order to preserve the integrity of the latter (as a depletable resource) in line with the original purpose of Life Study. The objective will be to ensure that the protection and respect for the rights of the participants provided by this Framework continues to be maintained. Information about such measures will be made available to participants.

E. Adoption, Implementation and Revision

11. Adoption

The Scientific Steering Committee has adopted this Framework, with the endorsement of the Life Study Strategic Advisory Committee or equivalent body, and will be responsible for ensuring that all Life Study policies and activities conform to it.

12. Implementation

The Life Study senior management under the direction of the Director of the Life Study will be responsible for implementing the Framework. Compliance with this Framework will be included as a contractual condition for continued funding of Life Study by the Funders. A Life Study Advisory Group on Ethics has been established to provide a source of expertise and advice to Life Study on ethics issues arising in relation to the Study (see Annex 1).

13. Revision

The Life Study Advisory Group on Ethics will be responsible for reviewing this Framework. The Scientific Steering Committee, the Life Study Strategic Advisory Committee or equivalent body, the Funders and other interested parties (including participants and members of the wider public) may also propose amendments or revisions of the Framework. In particular, the Advisory Group on Ethics, or any subcommittee of the Scientific Steering Committee established for this purpose, will advise on outstanding issues, and may propose adjustments in response to new developments. Adoption of any substantive amendment or revision will require endorsement by the Life Study Strategic Advisory Committee.

Annex 1: Life Study Advisory Group on Ethics

Terms of Reference

Taking into account the fact that Life Study has been established for the public good as a resource for research, and taking into account the broader legal and ethical landscape, the Life Study Advisory Group on Ethics will serve as a source of expertise to Life Study, its Director and Scientific Steering Committee (SSC) and will:

- Advise on the Life Study Ethics and Information Governance Framework (EIGF) and relevant strategies, policies, and processes;
- Review and advise on *general* ethics issues arising in relation to the Study, including those that are relevant to other Life Study strategies or policies;
- Advise on *specific* ethics and information governance issues that arise; for example on feedback of health-related findings;
- Anticipate and advise on issues that are likely to arise in future;
- Consider any ethics issues relating to the overall use being made of the resource¹⁴;
- Advise more generally on how to ensure there is appropriate consideration of the interests of Life Study participants in relation to ethics issues.

Specific functions

1. To consider the content and development of the Life Study Ethics and Information Governance Framework in relation to the development of Life Study and recommend any changes or action needed;
2. To consider any general ethics and information governance issues that arise relating to the Study and its relevant policies and strategies and recommend any changes or action needed;
3. To consider and advise on *specific* ethics and information governance issues arising. Such issues might include, for example, those relating to an enhancement to the Study or the feedback of research findings;
4. To consider the processes needed to ensure that any Ethical Legal Social Implications and Information Governance issues arising unexpectedly or that are anticipated during the conduct of the study can be addressed promptly, taking proper account of the legal and ethical framework;
5. To consider and advise on revisions to the Life Study EIGF that may be required to respond to changes in the legislative or regulatory context, developments in ethics or advances in science or technology;
6. To advise on Life Study policies that relate to or flow from the EIGF (such as those on recruitment, access, or complaints handling);

¹⁴ Note: The Advisory Group on ethics will not be involved in the adjudication of individual applications for access to Life Study data and samples.

7. To advise on any ethical aspects relevant to Life Study policies relating to applications for access to the Life Study resource with regard to the interests of research;
8. To consider any ethics and information governance issues arising from any proposed transfer of the custodianship of the Life Study resource (or substantial parts of it);
9. To receive and sign-off on annual reports from the Director on ethics issues arising.

Reporting

The Advisory Group on Ethics¹⁵ will report to the Director and SSC.

Relationship to the Research Ethics Committee

The Group will advise the Director and SSC who will decide on any amendments required to LS policies, processes or materials. The Director will submit relevant proposed amendments to the REC as required. The REC will remain the point of formal approval for any material changes to the protocol, consents or participant information

Relationship to the Life Study Strategic Advisory Committee (LSSAC)

The Group will advise the Director and SSC, who will refer matters to the LSSAC where appropriate. The Director will report annually to the LSSAC on the ethics issues relating to Life Study. Funder observer status on the Advisory Group on Ethics will provide an additional mechanism for funder members of the LSSAC to be informed about ethics issues.

Meetings

The secretariat will be provided by Life Study.

Membership

Members will be appointed for two years in the first instance renewable for a further term. SSC will agree membership, normally this would be a small group with a broad spread of expertise relevant to the stage of the study and the age and type of participants. SSC may additionally appoint one or two Public and Participant Involvement (PPI) members.

The Advisory Group on Ethics will meet as required. It is envisaged that this may include one or two initial meetings, followed by ad-hoc meetings or other consultation (such as by telephone or email) as required. Life Study may also consult individual members for advice on a specific issue.

The minutes of meetings will provide a detailed and accurate record of decisions and an account of the deliberation that led to these. A public record of business will be provided that is consistent with an open approach but appropriately allows for the discussion of sensitive issues.

¹⁵ Note: Any allegations of malpractice, improper conduct or unethical behaviour will be covered by the responsibilities and policies of the research sponsor, and will not be in the remit of the Life Study Advisory Group on Ethics

Annex 2: Links to external documents

Note: All links were accessible on 19th September 2016.

A2.1 Relevant legislation

This includes:

- *Human Tissue Act*
England, Wales and Northern Ireland
<http://www.legislation.gov.uk/ukpga/2004/30/contents>
Scotland
<http://www.legislation.gov.uk/asp/2006/4/contents>
- *Data Protection Act*
England, Wales, Scotland and Northern Ireland
<http://www.legislation.gov.uk/ukpga/1998/29/contents/enacted>
- *Freedom of Information Act*
<http://www.legislation.gov.uk/ukpga/2000/36/contents/enacted>
- *Human Fertilisation and Embryology Act 2008*
<http://www.legislation.gov.uk/ukpga/2008/22/contents/enacted>
- *Children Act 1989*
<http://www.legislation.gov.uk/ukpga/1989/41/contents/enacted>
- *Section 251 of the NHS Act 2006*
(Originally enacted under Section 60 of the Health and Social Care Act 2001)
<http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/what-is-section-251/>

A2.2 NHS and other regulations, requirements and organisations

This includes:

- *Integrated Research Application System (IRAS)*
<https://www.myresearchproject.org.uk/Signin.aspx>
- *National Institute for Health Research (NIHR) governance, advice and ethics systems*
<http://www.nihr.ac.uk/policy-and-standards/research-management.htm>
- *Confidentiality Advisory Group (Health Research Authority)*
<http://www.hra.nhs.uk/resources/confidentiality-advisory-group/>
- *Public Benefit and Privacy Panel (previously the Privacy Advisory Committee), Scotland*
PBPP: <http://www.informationgovernance.scot.nhs.uk/>
PAC: <https://nhsns.org/how-nss-works/policies-and-statements/privacy-advisory-committee/>
- *Health Research Authority*
<http://www.hra.nhs.uk/>

A2.3 Ethics and access policies of relevant funding organisations

These include:

- *ESRC*
<http://www.esrc.ac.uk/about-esrc/information/index.aspx>
- *MRC*
<http://www.mrc.ac.uk/research/policies-and-resources-for-mrc-researchers/>
- *Wellcome Trust*
<http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/index.htm>

A2.4 other relevant groups, reports and activities

- *Expert Advisory Group on Data Access (EAGDA)*

Established by the Wellcome Trust, MRC, ESRC and Cancer Research UK to provide strategic advice on the emerging scientific, legal and ethical issues associated with data access for human genetics research and cohort studies. Professor Martin Bobrow chairs the Group which comprises thirteen other experts with expertise spans genetics, population research, social sciences, statistics, IT, data management and security, law and ethics.

<http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/EAGDA/index.htm>

- *Administrative Data Task Force*

The Administrative Data Taskforce, established in December 2011, was established to propose new mechanisms and collaborative agreements to enable and promote the wider use of administrative data for research and policy purposes. Chaired by Sir Alan Langlands, with members drawn from ESRC, Wellcome Trust, Medical Research Council, Department for Education, Department for Work and Pensions, Ministry of Justice, Department of Health, Her Majesty's Revenue and Customs, Office for National Statistics, Cabinet Office, NHS Information Centre, The Information Commissioner's Office, Government Office for Science, Scottish and Welsh government, it reported in 2013.

<http://www.esrc.ac.uk/research/our-research/administrative-data-research-network/administrative-data-taskforce-adt/>

- *MRC Ethics Regulation and Public Involvement Committee*
<http://www.mrc.ac.uk/research/research-policy-ethics/erp/c/>

- *Independent Information Governance Review*

An independent panel of experts chaired by Dame Fiona Caldicott conducted a review of Information Governance on behalf of the Secretary of State for Health. The Review (also known as Caldicott 2) made recommendations aimed at improving the sharing of personal information to support the care of individuals, enabling the further use of information more widely to improve health and social care services and protecting individuals' confidentiality and respecting their wishes in relation to how their information is used. A further review by Dame Fiona Caldicott is due to report in 2016.

<http://webarchive.nationalarchives.gov.uk/20130805112409/https://www.gov.uk/government/publications/the-information-governance-review>

- *Academy of Medical Sciences: A new pathway for the regulation and governance of health research*

<http://www.acmedsci.ac.uk/policy/policy-projects/a-new-pathway-for-the-regulation-and-governance-of-health-research/>

- *EU Data Protection Directive*

EU Data Protection legislation with implications for data sharing.

http://ec.europa.eu/justice/data-protection/index_en.htm

- *Wellcome Trust and MRC Framework on the feedback of health-related findings in research*

Guidance on feedback of health-related findings to individual participants in research studies.

<https://www.mrc.ac.uk/documents/pdf/mrc-wellcome-trust-framework-on-the-feedback-of-health-related-findings-in-researchpdf/>

<https://wellcome.ac.uk/funding/managing-grant/wellcome-trust-policy-position-health-related-findings-research>

- *Royal Society report 'Science as an Open Enterprise' (June 2012)*

The Royal Society produced a report which defines the terms used to describe data generated by scientific research within the context of debates around 'open data'.

<https://royalsociety.org/topics-policy/projects/science-public-enterprise/Report/>