The National Statement

- Principles-based; mixture of high level guidance, prescriptive guidance and best practice
- Four key principles, main issues (e.g. consent, risk), research ‘category’ and population-based considerations, establishment and operation of HRECs, institutional responsibilities
- Applies to all human research
- Subject to ongoing review but the principles remain the same.
National Statement (updated 2018) including fully revised Section 3: Ethical considerations in the design, development, review and conduct of research was released on 9 July 2018

- Major changes in structure and content
  - 3.1. The elements of research: new structure, new content
  - 3.2. Human biospecimens in laboratory based research: new structure, unchanged content (reviewed in 2013),
  - 3.3. Genomic research: new structure, new content
  - 3.4. Animal-to-human xenotransplantation: new chapter
Chapter 3.1 The elements of research

- Relates to research in general
- Provides guidance related to specific types of research (e.g. clinical interventional research) as necessary
- Incorporates guidance previously provided in Chapters 3.1, 3.2 and 3.3
- Significantly increases guidance on ethical considerations related to collection, use and management of data and information in research
The elements of research

Guidance provided through the elements of research

- Element 1 – Research Scope, Aims, Themes, Questions and Methods
- Element 2 – Recruitment
- Element 3 – Consent
- Element 4 – Collection, Use and Management of Data and Information
- Element 5 – Communication of Research Findings or Results to Participants
- Element 6 – Dissemination of Research Outputs and Outcomes
- Element 7 – After the Project
Chapter 3.3

- Addresses genomic research (vs ‘human genetics’)  
- Significantly increases guidance on ethical considerations related to management and potential return of results and findings with hereditary implications or implications for health  
- Includes decision tree graphic and detailed *Ethically Defensible Plan*  
  - The Nature of Research Findings  
  - Determination of Whether Findings Will Be Returned  
  - Validation and Assessment of Findings  
  - Consent to Disclosure of Findings and Notification Requirements  
  - Communication process – Who, to Whom, How, When  
- Privacy Issues Specific to Genetic Information
**Question**

1. Was the investigation a validated test performed in a NATA accredited lab or overseas equivalent?

   Yes: Do not return findings

   No: Relevant for clinical practice only

2. Was the investigation requested by or on behalf of a primary treating clinician? (see Note 1)

   Yes: Are the results pertinent to the indication for testing?

     Yes: Follow standard clinical practice

     No: Do not return findings

   No: Did the patient consent to the return of findings, including secondary and/or incidental findings?

     Yes: Follow policy and/or patient preferences

     No: Consult current best practice or national clinical genomics guidelines

3. Was the investigation performed as part of an approved research project?

   Yes: Do not return findings

   No: Does the protocol include criteria and a process for the return of findings, including secondary and/or incidental findings? (see Note 4)

     Yes: Do not return findings (unless national/international standard or protocol is for mandatory return of some or all incidental findings)

     No: Follow process as described in protocol

   No: Are the findings pertinent findings? (see Note 5)

     Yes: Follow process as described in protocol

     No: Do not return findings

**Terms**

- **Primary findings**: Also known as a primary diagnostic or genetic finding, these are the findings that were specifically sought or anticipated as part of the primary target or indication.

- **Secondary findings**: Findings that were not the primary target of the investigation but were unexpected and not specifically sought or anticipated as part of the primary target or indication.

- **Incidental findings**: Findings of potential clinical significance unexpectedly discovered during the investigation. Without respect to the full spectrum of discovery investigations and direct-to-consumer testing, findings are not considered "unexpected."
Chapter 3.2 and 3.4

- 3.2- no content changes just format
- 3.4- Animal-to-human xenotransplantation
- This is a new chapter and I am yet to apply it to research that we have running at the Melbourne Children’s Campus.
- If you are going to do this I will be advising you to review the Chapter prior to submission and as a HREC we may need to seek additional expertise.
3.1 The elements of research

Guidance provided through the elements of research

- Element 1 – Research Scope, Aims, Themes, Questions and Methods
- Element 2 – Recruitment
- Element 3 – Consent
- Element 4 – Collection, Use and Management of Data and Information
- Element 5 – Communication of Research Findings or Results to Participants
- Element 6 – Dissemination of Research Outputs and Outcomes
- Element 7 – After the Project
The elements of research

Introduction
Human research can involve a wide range of methods and practices: it can be qualitative, quantitative or mixed; interventional, experimental or observational in nature; and involve various degrees of collaboration between researchers and participants. Each research project is shaped by the field to which the research question relates, the research question itself, the desired outcome, and the context in which it is conducted.

Chapter 3.1 (the elements of research) should be read in conjunction with other sections of the National Statement and is supplemented by the guidance in Chapters 3.2, 3.3 and 3.4.

Researchers conducting clinical interventional research should also refer to additional guidance in Chapters 5.2 and 5.5.
How it looks 3.1
Element 1: Research Scope, Aims, Themes, Questions and Methods

• Key questions include:
  – What is the research theme or question that this project is designed to explore?
  – Why is the exploration of this theme or answer to this question worth pursuing?
  – How will the planned methods explore the theme or achieve the aims of the research?
3.1.4 For interventional research conducted in the context of health care or public health, researchers should additionally determine and state:

a) whether the project involves the systematic investigation of the safety, efficacy and/or effectiveness of an intervention;

b) if the research involves exposure to an intervention for which the safety or efficacy, or both, is not well understood:
   i. whether it is likely or possible that the intervention will be of therapeutic benefit and
   ii. whether there is a realistic possibility that the intervention being studied will be at least as beneficial overall as standard treatment, taking into account effectiveness, burden, costs and risks;

c) where patient care is combined with intent to contribute to knowledge, that any risks of participation should be justified by potential benefits to which the participants attach significance. The prospect of benefit from research participation should not be exaggerated, either to justify to the reviewing body a higher risk than that involved in the participant’s current treatment or to persuade a participant to accept that higher risk;

d) whether the intervention or other research procedures are without likely benefit to participants. For such research to be ethically acceptable, any known or emerging risks to the participants must not be greater than the risks that would be associated with the health condition and its usual care.
3.1.5 Where current and available treatments are known or widely believed to be effective and/or there is known risk of significant harm in the absence of treatment, placebo or non-treatment groups are not ethically acceptable. Non-treatment (including placebo alone) groups may only be used:

   a) where the existing standard of care comprises or includes the absence of treatment (of the type being evaluated); or
   b) where there is evidence that the harms and/or burdens of an existing standard treatment exceed the benefits of the treatment.

3.1.6 In health research involving an intervention, the risks of an intervention should be evaluated by researchers and reviewers in the context of the risks of the health condition and the treatment or treatment options that would otherwise be provided as part of usual care.
Element 2: Recruitment

• Key questions include:
  – Who will be recruited?
  – How will participants be identified and recruited?
  – Will the potential participants be screened?
  – What is the impact of any relationship between researchers and potential participants on recruitment?
  – How will the recruitment strategy facilitate obtaining the consent of participants?
  – How will the recruitment strategy ensure that participants can make an informed decision about participation?
  – Are there any risks associated with the recruitment strategy for potential participants or for the viability of the project?
Element 3: Consent

Key questions include:

- What strategy(ies) for obtaining consent, or alternatives to consent are appropriate for the specific project?
- Does the nature of the project design, the participants or the context necessitate the use of more than one strategy?
- Do the proposed strategy(ies) satisfy the relevant requirements of Chapters 2.2 and 2.3?
- Are there any project-specific matters that warrant specific attention (e.g. whether the research could generate results of significance to participants, whether the data will be added to an open or mediated access repository or whether the data or materials will be used for any other purpose)?
Element 4: Collection, Use and Management of Data and Information

- Key questions include:
  - What data or information are required to achieve the objectives of the project?
  - How and by whom will the data or information be generated, collected and/or accessed?
  - How and by whom will the data or information be used and analysed?
  - Will the data or information be disclosed or shared and, if so, with whom?
  - How will the data or information be stored and disposed of?
  - What are the risks associated with the collection, use and management of data or information and how can they be minimised?
  - What is the likelihood and severity of any harm/s that might result?
  - How will the collection and management of the data or information adhere to the ethical principles in Section 1 of this National Statement?
Element 4: Collection, Use and Management of Data and Information

- What is data and what is information?
  - The terms often used interchangeably.
  - 'Data' is intended to refer to bits of information in their raw form.
  - 'Information' generally refers to data that have been interpreted and analysed/contextualised.

- Examples:
  - what people say in interviews, focus groups, questionnaires/surveys, personal histories and biographies;
  - images, audio recordings and other audio-visual materials;
  - records generated for administrative purposes (e.g. billing, service provision) or as required by legislation (e.g. disease notification);
  - digital information generated directly by the population through their use of mobile devices and the internet;
  - physical specimens or artefacts;
  - information generated by analysis of existing personal information (from clinical, organizational, social, observational or other sources);
  - observations;
  - results from experimental testing and investigations; and
  - information derived from human biospecimens such as blood, bone, muscle and urine.
Element 4: Collection, Use and Management of Data and Information

- Identifiability of Information
  - Categorical terms 'identifiable', 'potentially re-identifiable', 'anonymised' no longer used.
  - Identifiability of information exists on a continuum and varies with contextual and technological factors:
    - Context: e.g. who has access to the information and potentially other related information.
    - Technology: e.g. measures in place to protect anonymity of individuals, or alternatively technological mechanisms that reduce anonymity.
  - "Researchers should adopt methods to reduce the risk of identification ...
    Methods ... may include:
    (a) minimising the number of variables collected for each individual;
    (b) separation and separate storage of identifiers and content information; and
    (c) separating the roles of those responsible for management of identifiers and those responsible for analysing content."
Element 4: Collection, Use and Management of Data and Information

• Data Management
  – Data management requirements expanded in revision.
  – Data Management Plan (DMP) should be created for all research projects
  – Address data/information generation, collection, access, use, analysis, disclosure, storage, retention, disposal, sharing and re-use
  – Detail the security arrangements for both physical and electronic data, license & confidentiality agreements, training.
  – CEBU intranet pages have DMP template.
  – Data & information should be stored for use in future research – not making data accessible must be justified.
Element 4: Collection, Use and Management of Data and Information

- Secondary Use of Data or Information
  - "Use of data/information collected for previous research or non-research purposes"
  - 2018 version further addresses main issues e.g. scope of initial consent & impracticability of re-consenting
  - Suggested strategies to address:
    - Ensure research translated into practice
    - Publicise research results in a location & language suitable for general community
    - Acknowledge source of data/information in publications
  - Data/information publicly available on internet/social media:
    - Cannot assume that the individual has granted permission for use in research.
    - Use needs to be considered by reviewing body in relation to risks in use of this data/information.
Element 4: Collection, Use and Management of Data and Information

• Sharing of Data or Information
  – Emphasised in 2018 version.
  – Contrasts with previous version of National Statement.
  – "most data collected... for single purpose" and "permission...sometimes sought for possible use in future research"

NOW reads

"data or information may collected... for an initial purpose, it is common for researchers to ‘bank’ data/information for possible use in future research projects or to otherwise share with other researchers... Also common for funding agencies to require sharing of data."
What is a data breach?

A data breach is any incident in which identifying personal information (including health information) is compromised, disclosed, copied, communicated, accessed, removed, destroyed, stolen, lost or used by unauthorised individuals, whether by accident or intentional.

What is a data breach in the context of research?

- Lost USB containing interviews from clinical trial participants;
- Survey containing name of child sent by an educator to our researchers where they were only allowed to collect de-identified information;
- Email sent to many participants of a study using ‘Cc’ instead of ‘Bcc’;
- Test results or research data sent to the wrong email address internally (staff having identical or similar name) or externally;
- Researchers receiving the name of a child when the referring GP was only supposed to share the parent’s name;
- Researcher with dual appointment collects personal information with his MCRI hat and shares that personal information with colleagues from another institution where he also holds an appointment without the individual’s consent.
Data Breach: what to do if it occurs?

- **Actions required**
  - Containment and mandatory notification to MCRI Data Breach Response Team (databreach@mcri.edu.au) - follow the process in MCRI’s Data Breach Response Plan (available on MCRI intranet).
  - MCRI Data Breach Response Team will review the Data Breach Notification Form and decide whether there is a need to notify the affected individuals and/or the Office of the Australian Information Commissioner (OAIC).

- **Early detection and response essential**
  - To protect affected individuals and MCRI
  - To meet MCRI’s obligations under Privacy Act:
    1. MCRI must take reasonable steps to protect the personal information that it holds, including having a data response plan and, where necessary, notifying the affected individuals or the OAIC in case of a data breach.
    2. Breaches of Privacy Act can incur fines up to AUD $1,800,000.
Data Breaches at MCRI (Feb 2018 – May 2019)

- **Notifications made by MCRI researchers to the Data Breach Response Team**
  - 29 notifications.
  - 26 confirmed cases of data breach.

- **Notifications made by a third-party**
  - 1 notification.

- **Actions undertaken by the Data Breach Response Team**
  - Ensuring appropriate steps are taken to contain the breach and avoid similar breach from happening in the future.
  - Ensuring notification is made to the affected individuals if appropriate.
  - So far, 0 notification made to the OAIC.
Element 5: Communication of research findings or results to participants

Key questions include:

– Could the research generate findings or results of interest to participants?
– Could the findings or results be of significance to the current or future welfare or wellbeing of participants or others?
– Are potential participants in the research forewarned of this possibility?
– Will the consent of participants be obtained to enable any planned or necessary disclosure of findings or results?
– Who will communicate the findings or results and how?
– Will the findings or results be disclosed to third
Element 6: Dissemination of project outputs and outcomes

Key questions include:
- What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?
- Will participants in the research be offered a timely and appropriate summary of the project outputs/outcomes?
- How will the planned dissemination of the outputs/outcomes contribute to knowledge or practice or serve the public?
Element 7: After the project

Key questions include:

- Will the data or information be retained only for the minimum period required by relevant policy?
- Do the data or information have cultural, historical or other significance that could warrant longer, or perpetual retention?
- Are the arrangements regarding intellectual property (individual, community, organisational, commercial) and copyright related to the outputs of the research clearly understood and communicated?
- Will the data or information be banked or added to a repository, such as an open or mediated access facility, for future use?
- Is any follow up or monitoring of research participants required and is this clear in the research plan and consent information?
Final words of wisdom

**Take Home Messages**
1. The underlying ethical principles of the National Statement remain unchanged in this version.
2. Specific, detailed guidance should be read and interpreted in the context of the broader ethical framework.
3. Section 3 aims to address contemporary issues in research ethics and to anticipate future issues.
4. The new structure of Section 3 is designed to assist researchers and HREC members to address ethical issues in research in a transparent and systematic way.
5. As always, high quality ethical review relies on thoughtful consideration of the research, by all parties.