THE UNIVERSITY OF QUEENSLAND
AUSTRALIA
CREATE CHANGE

Ethics and Informed Consent

MND Clinical Research Learning Institute

Friday 11th November 2022

Anjali Henders
SALSA Project Manager

Outline

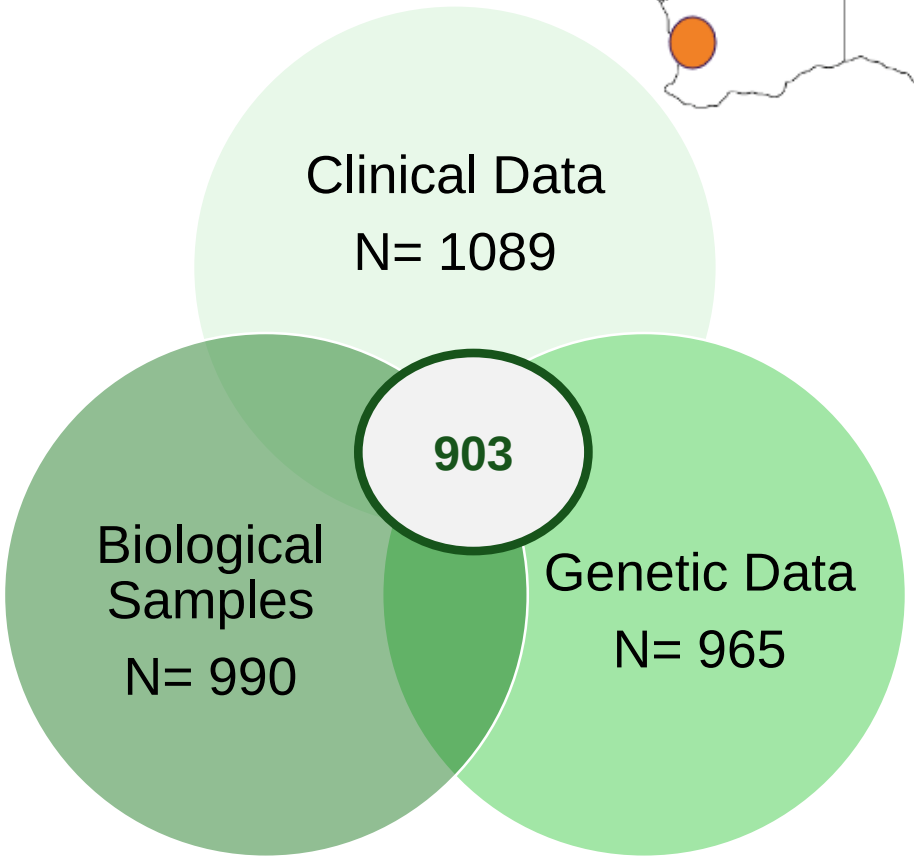
1. Sporadic ALS Australia - Systems Genomics Consortium (SALSA)
2. Introduction to Human Ethics
3. The NHMRC National Statement
4. Australian Code for Responsible Conduct in research
5. Considerations in obtaining HREC approval
6. The Study Protocol
7. Types of Informed Consent
8. Key Statements for genetics and Genomics Research
9. Research Governance Models
10. Ethics Everyday

The Sporadic ALS Australia –Systems Genomic Consortium

VISION: Try and understand the complexity that is sporadic MND

To build a resource that is:

- Visionary for future research
- Records the complexity of MND progression
- Accurately reflects the cohort of MND patients in Australia.
- Establishes a long-term genomics resource



What is Human Research

Is research conducted with or about people, or their data or tissue.

- Taking part in surveys
- Being observed by researchers
- Accessing personal information
- Collection of biological samples
- Accessing information held in a repository / database
- Analysis of data collected or generated

What is Ethical Research?

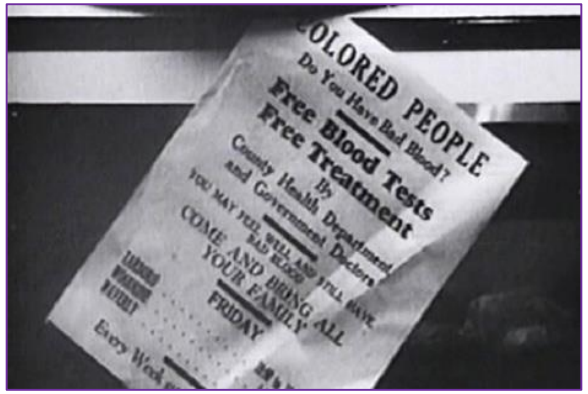
‘Ethical conduct is more than simply doing the right thing’

Ethos that permeates the way those engaged in human research approach all that they do in research.

Tuskegge Syphilis Study 1932

Tuskegee Syphilis Study: Incentives for Participation

- Free physical examination
- Free rides to and from the clinic
- Hot meals on examination days
- Free treatment for minor ailments
- Payment of burial stipends to survivors



The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

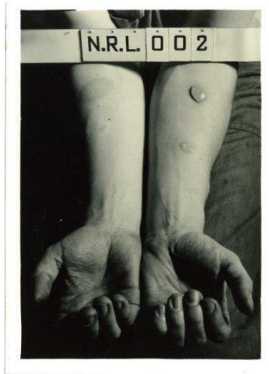
The study was conducted to determine from autopsies what the disease does to the human body.

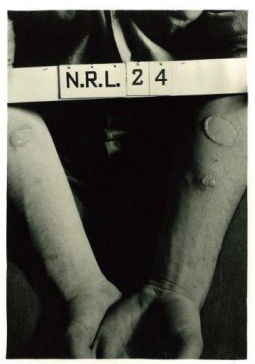
Officials of the health service who initiated the experiment have long since retired. Current officials, who say they have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

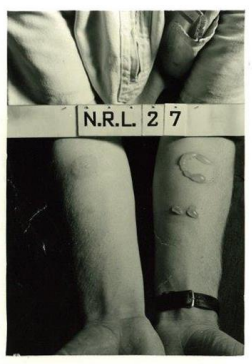
Doctors in the service say they are now rendering whatever other medical services they can give to the survivors while the study of the disease's effects continues.

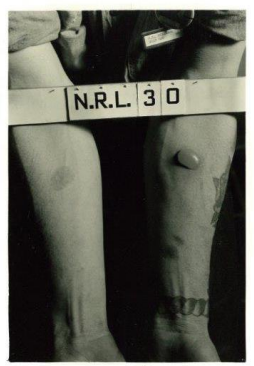
Dr. Merlin K. DuVal, Assistant Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning of the study. He said that he was making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men,









Timeline

Nuremburg Code of 1947 which developed 10 principles about permissible medical experiments

Helsinki Declaration was adopted in 1964 at the World Medical Association assembly after discussion of the Nuremberg principles.

NHMRC Statement on Human Experimentation in 1966

1999 the National Statement on Ethical Conduct in Research involving Humans

2007 NHMRC National Statement on Ethical Conduct in Human Research

→ Substantially updated in Nov 2018

Sr Regis Mary Dunne RSM

NHMRC National Statement on Ethical Conduct in Human Research (2007) Updated 2018

- Fulfils the NMHRC statutory obligation to issue ethical guidelines on research involving humans
- Provides guidelines for all human research
- Conformity is now part of institutional policy and funding agreements
- Legal status by reference in Therapeutics Goods Act

LIMITS:

- Compliance with legal obligations is not within its scope
- Responsibility of institution and researchers to be aware of relevant legal obligations

https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research
https://www.nhmrc.gov.au/guidelines-publications/e72

Four Principals of Ethical Research Practice

- Research Merit and Integrity

  Respect for participants is not compromised by the aims

  Disseminate / Communicate results to permit public scrutiny and to add to public knowledge and understanding

- Justice

  Research outcomes are accessible to the participants

- Beneficence

  To clarify the potential benefits and risks for the welfare of the participants in a research context

- Respect for human beings

  Empowering participants to make free decisions about participating

Australian Code for the Responsible Conduct of Research 2018

Promotes :

integrity in research for researchers and explains what is expected of researchers by the community.

Provides information where there has been a departure from best practice guidelines.

A strong research culture will demonstrate:

honesty and integrity

respect for human research participants, animals and the environment

good stewardship of public resources used to conduct research

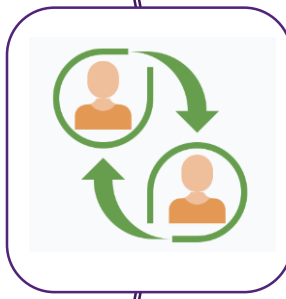
appropriate acknowledgment of the role of others in research

responsible communication of research results.

Process of Obtaining Ethical Approval

Study Proposal

- Study Protocol / Instruments / Consent Forms



Scientific Review

Research Design / Methods / Power

Ethical Review

Risk / Special Considerations

Levels of Review – Primary Submission

Negligible / Low Risk Research

Negligible – research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.

Low - Research in which the only foreseeable risk is one of discomfort

High Risk Research

Anything above Negligible or Low Risk Research

Full HREC Review is always required for…

Projects involving any of the following :

- "Deception" or concealment (e.g. some psych experiments) (Ch. 2.3.4)
  - *Noting that some "Limited disclosure" could be considered as LNR*
- Aims to expose illegal activity (Ch. 2.3.4)
- Waiver of consent –risk is negligible and using de-identified secondary data (Ch. 2.3.9)
- Women who are pregnant and the human foetus (Ch. 4.1)
- People highly dependent on medical care who may be unable to provide consent (Ch. 4.4)
- People with a cognitive impairment, an intellectual disability, or a mental illness (Ch. 4.5)
- People who may be involved in illegal activities (Ch. 4.6)
- Aboriginal and Torres Strait Islander Peoples (Ch. 4.7)
- Interventions and Therapies, including clinical-and non-clinical trials and innovations
- Human Genetics (Ch. 3.5)

The Research Study Protocol

A protocol describes the objectives, design, methodology, population, statistical considerations, ethical conduct, and organization of a research project

- Background and Rationale
- Research Objectives (Specific Aims or Goals)
- Participant Selection and Recruitment (addressing collection of informed consent)
- Research Methods & Procedures
- Study Visits (if applicable)
- Risks and Benefits
- Statistical Analysis
- Data Management & Privacy/Confidentiality
- Data & Safety Monitoring

What is Informed Consent?

- Is one of the founding principles of ethical research
- Its intent is that human participants can enter research freely with full information about what it means for them to take part, and that they give consent **before** they enter the research.
- there must be no undue influence on participants to consent
- The minimum requirements for consent to be informed are that the participant understands what the research is and what they are consenting to.

Two distinct stages to obtaining informed consent for participants:

1. Giving information
2. Obtaining Consent

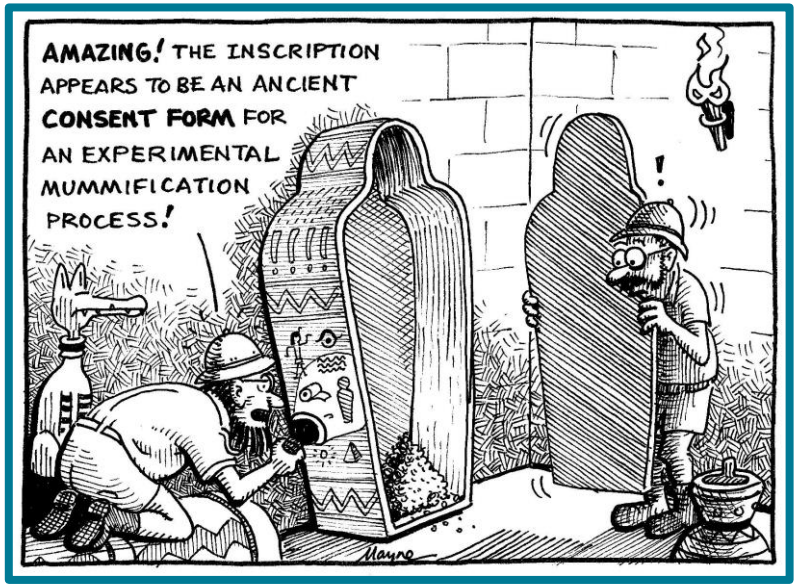
Types of Consent

1. Implied
2. Written
3. Verbal
4. Online
5. eConsent
6. Retrospective consent

Management of Informed Consent
1. HREC - as part of an amendment
2. Opt-in Vs Opt-out (*often used in Registries*)
3. Dynamic consent

Must contain…..

- ✓ Rationale for the project
- ✓ What is involved in participating
- ✓ Risks and benefits of participation
- ✓ Potential outcomes
- ✓ Return of results
- ✓ Sharing of data and/ or samples
- ✓ Use in related or non-related future projects



The Patient Information and Consent Form (PICF)

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Program in Complex Trait Genomics

Participant Information Sheet/Consent Form

Non-Interventional Study - *Adult providing own consent*

Title
Short Title
Protocol Number
Project Sponsor
Coordinating Principal Investigator/
Principal Investigator
Associate Investigator(s)

Location Institute for Molecular Biosciences
University of Queensland

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in the *ATHENA CV19-G research project.* This is because *you have or have had a positive test for the COVID-19 infection.* The purpose of this research is to determine if there are genetic and/or environmental factors that cause some people to experience more severe COVID-19 infection symptoms than others.

This Participant Information Sheet/Consent Form tells you about this research project. It explains what is involved. Understanding what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether or not to take part, you might want to talk about this research project with a relative, friend or local doctor.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in this research project, you will be asked to sign the consent form. By signing the form, you are telling us that you:
• Understand what you have read
• Consent to take part in this research project
• Consent to the tests and research that are described
• Consent to the use of your personal and health information as described

You will be given a copy of this Participant Information and Consent Form to keep.

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Consent Form - *Adult providing own consent*

Title
Protocol Number
Coordinating Principal Investigator/
Principal Investigator
Associate Investigator(s)
Location

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand. I agree to participate and provide information and biological samples as required. I consent to participate under the following conditions:

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I have agreed to provide biological samples and their use has been explained and accepted by me including the generation of genetic information by sequencing my genome.

I understand that all data pertaining to me including my DNA I have provided (but **not** my name or address) may be made available to researchers in the future, some of whom may have commercial interests. I donate my biological sample freely for these purposes and waive any claim to commercial rights arising from this work.

I understand that I will be given a signed copy of this document to keep.

I give permission for the ATHENA COVID-19 research team, my doctors, other health professionals, hospitals or clinical laboratories to release information to *The University of Queensland* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Please select only one option:

- I request that genetic research findings of validated health significance identified in my DNA be shared with my clinician and understand that validation of these will require an additional biological sample to be provided.

OR

- I **do not** want genetic research findings of validated health significance identified in my DNA to be shared with my clinician. I understand this means I **will not** receive any information through my participation in this project of genetic research findings that may be of importance to me and/or my family.

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AUSTRALIA

Program in Complex Trait Genomics

Form for Withdrawal of Participation - *Adult providing own consent*

Title
Short Title
Protocol Number
Project Sponsor
Coordinating Principal Investigator/
Principal Investigator
Associate Investigator(s)

Location Institute for Molecular Biosciences, UQ

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *University of Queensland*

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Delegated research personnel
† (please print) _____

Signature _____ Date _____

† A senior member of the research team or delegate must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.

Key Statements in the PICF

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Consent Form - *Adult providing own consent*

Title
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I understand. I agree to participate and provide information and biological samples as required. I consent to participate under the following conditions:

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I have agreed to provide biological samples and their use has been explained and accepted by me including the generation of genetic information by sequencing my genome.

I understand that all data pertaining to me including my DNA I have provided (but **not** my name or address) may be made available to researchers in the future, some of whom may have commercial interests. I donate my biological sample freely for these purposes and waive any claim to commercial rights arising from this work.

I understand that I will be given a signed copy of this document to keep.

I give permission for the ATHENA COVID-19 research team, my doctors, other health professionals, hospitals or clinical laboratories to release information to *The University of Queensland* concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

Please select only one option:

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OR

- I **do not** want genetic research findings of validated health significance identified in my DNA to be shared with my clinician. I understand this means I **will not** receive any information through my participation in this project of genetic research findings that may be of importance to me and/or my family.

In respect to the storage and use of my samples, I give permission for the use of my samples and its derivatives for the purpose of:

1. this research project only — Yes ☐ No ☐
2. this research project and any closely related future research projects — Yes ☐ No ☐

No ☐

Declaration - for participants unable to read the information and consent form

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9, witness * required
Witness to the informed consent process
Name (please print) _____
Signature _____ Date _____
* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Researcher†

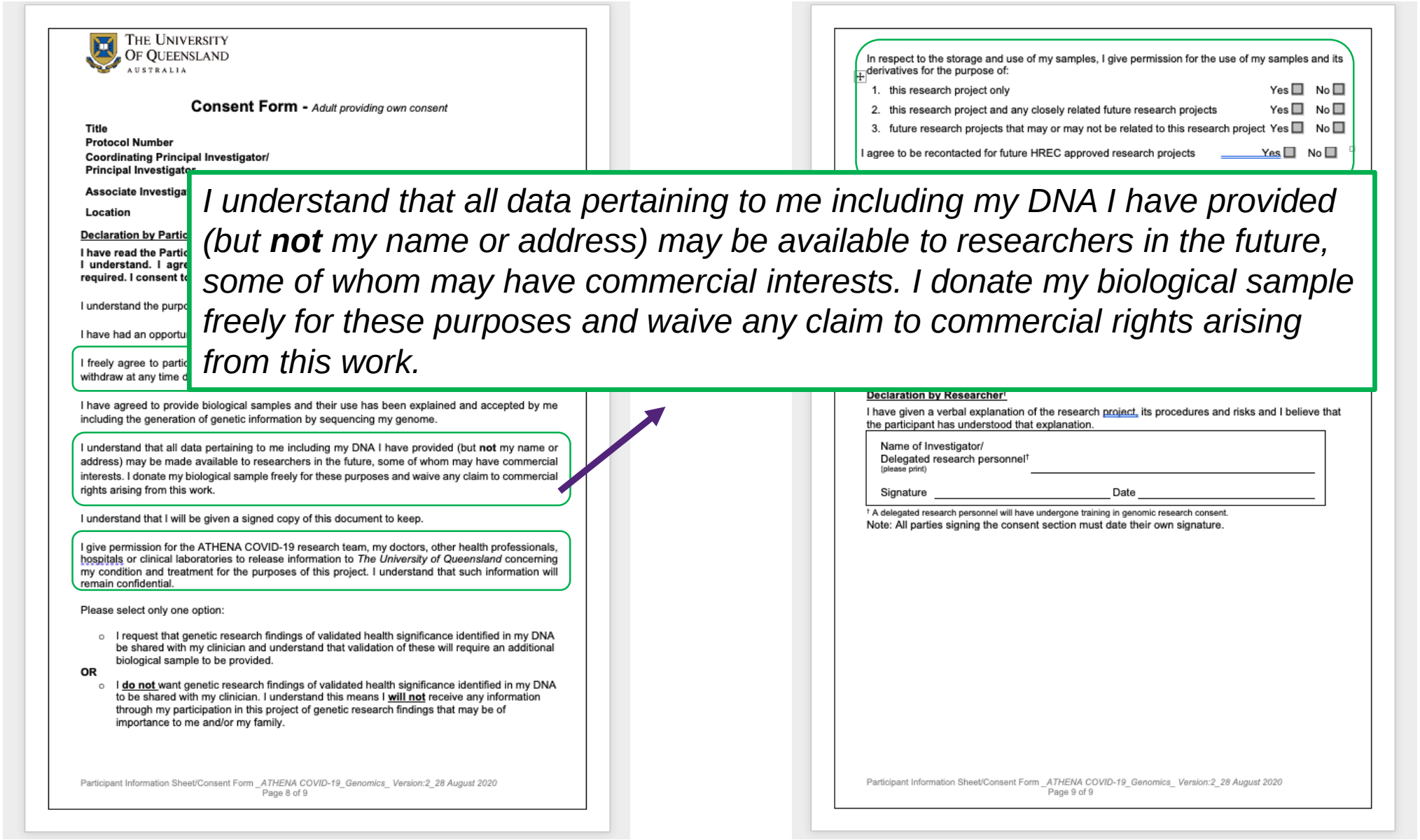
I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Investigator/
Delegated research personnel†
(please print) _____

Signature _____ Date _____

† A delegated research personnel will have undergone training in genomic research consent.
Note: All parties signing the consent section must date their own signature.

Key Statements in the PICF



THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

Consent Form - *Adult providing own consent*

Title
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Associate Investiga

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Declaration by Partic

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Participant Information Sheet/Consent Form _*ATHENA COVID-19_Genomics_ Version:2_28 August 2020*
Page 8 of 9

In respect to the storage and use of my samples, I give permission for the use of my samples and its derivatives for the purpose of:

1. this research project only — Yes ☐ No ☐
2. this research project and any closely related future research projects — Yes ☐ No ☐
3. future research projects that may or may not be related to this research project — Yes ☐ No ☐

I agree to be recontacted for future HREC approved research projects — Yes ☐ No ☐

Declaration by Researcher[†]

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Investigator/
Delegated research personnel[†]
(please print) _____

Signature _____ Date _____

[†] A delegated research personnel will have undergone training in genomic research consent.
Note: All parties signing the consent section must date their own signature.

Participant Information Sheet/Consent Form _*ATHENA COVID-19_Genomics_ Version:2_28 August 2020*
Page 9 of 9

*I understand that all data pertaining to me including my DNA I have provided (but **not** my name or address) may be available to researchers in the future, some of whom may have commercial interests. I donate my biological sample freely for these purposes and waive any claim to commercial rights arising from this work.*

Key Statements in the PICF

THE UNIVERSITY OF QUEENSLAND AUSTRALIA

Consent Form - *Adult providing own consent*

Title
Protocol Number
Coordinating Principal Investigator/
Principal Investigator

Associate Investigator(s)

Location

Declaration by Participant

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2. this research project and any closely related future research projects — Yes ☐ No ☐
3. future research projects that may or may not be related to this research project — Yes ☐ No ☐

I agree to be recontacted for future HREC approved research projects — Yes ☐ No ☐

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Declaration by Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Investigator/
Delegated research personnel†
(please print) _____

Signature _____ Date _____

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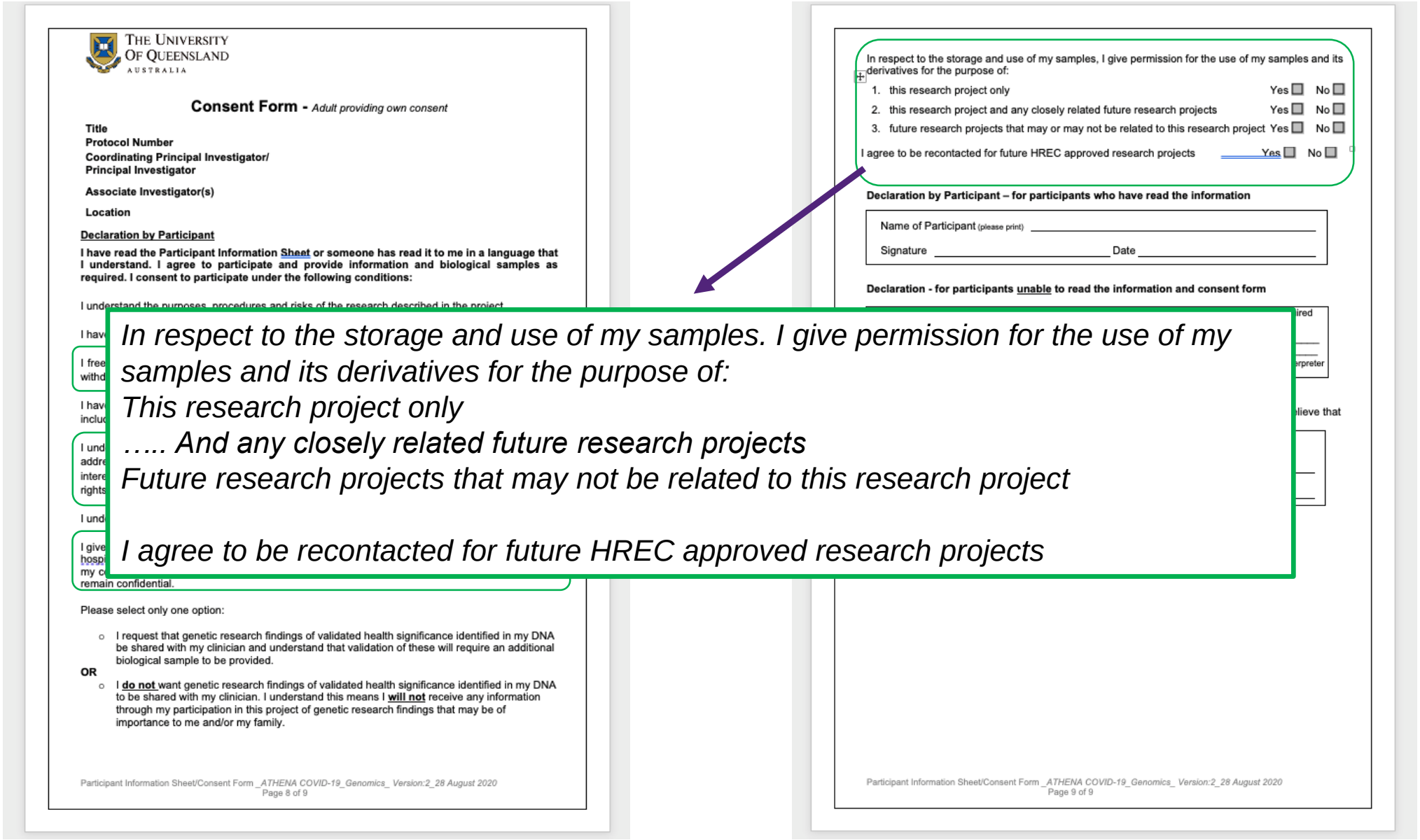
Key Statements in the PICF



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Consent Form - *Adult providing own consent*

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Associate Investigator(s)

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2. this research project and any closely related future research projects Yes ☐ No ☐
3. future research projects that may or may not be related to this research project Yes ☐ No ☐

I agree to be recontacted for future HREC approved research projects Yes ☐ No ☐

Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

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Participant Information Sheet/Consent Form _ATHENA COVID-19_Genomics_ Version:2_28 August 2020
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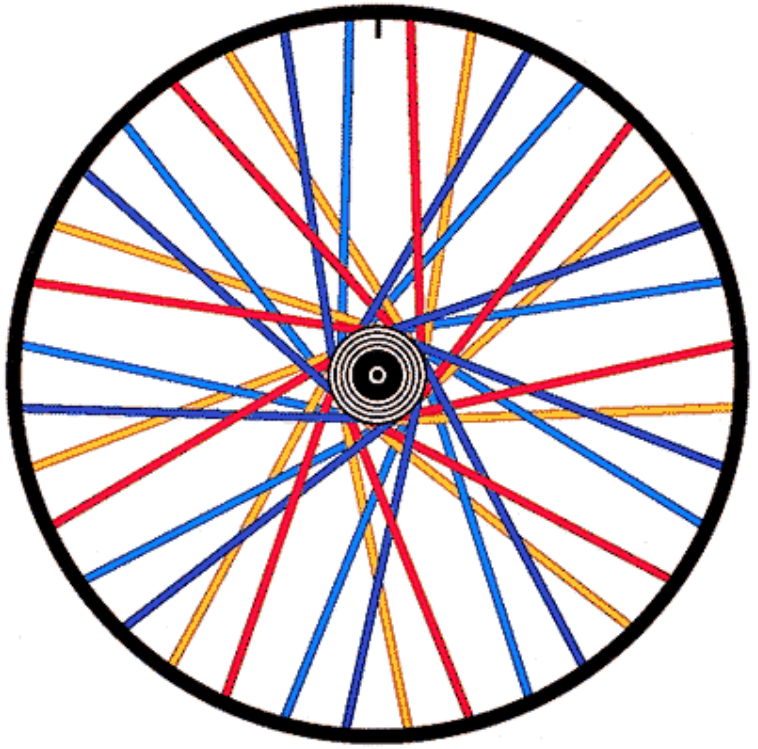
In respect to the storage and use of my samples. I give permission for the use of my samples and its derivatives for the purpose of:
This research project only
….. And any closely related future research projects
Future research projects that may not be related to this research project

I agree to be recontacted for future HREC approved research projects

One project many spokes……

Gone are the days….

Ideal model but……
Who is the hub?



Reality and several hubs…..

Research Governance Models

Ethical frameworks for patient partnership in research

Research Projects / International Consortia

Registries

Biobanks

Data Linkage

Clinical Trials

Martineau, J.T., et al. *BMC Med Ethics* **21**, 34 (2020).

Ethics Matters

Grant writing time:	Budgets
At the bench:	Protocols, QC standards, sample handling, lab books
Data collection:	Clinic and community
Collaborations:	Same systems and protocols, QC standards, data security
Data Analysis:	Local, network, HPC
Data sharing:	Internally, externally, international, databases
Manuscripts:	Methodology sections
Presentations:	Respectful and maintain confidentiality

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CREATE CHANGE

Thank you

Anjali Henders| SALSA Project Manager
Institute for Molecular Biosciences
a.henders@uq.edu.au

Anjali Henders

North Stradbroke Island 27.5323° S, 153.4626° E