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AUSTRALIA
CREATE CHANGE

Human research Ethics Information session

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Outline

- Human Research
- Review Pathways
- Full review vs. LNR review process
- Principles of ethical research
- Internet research
- Common problems in applications
- HREA

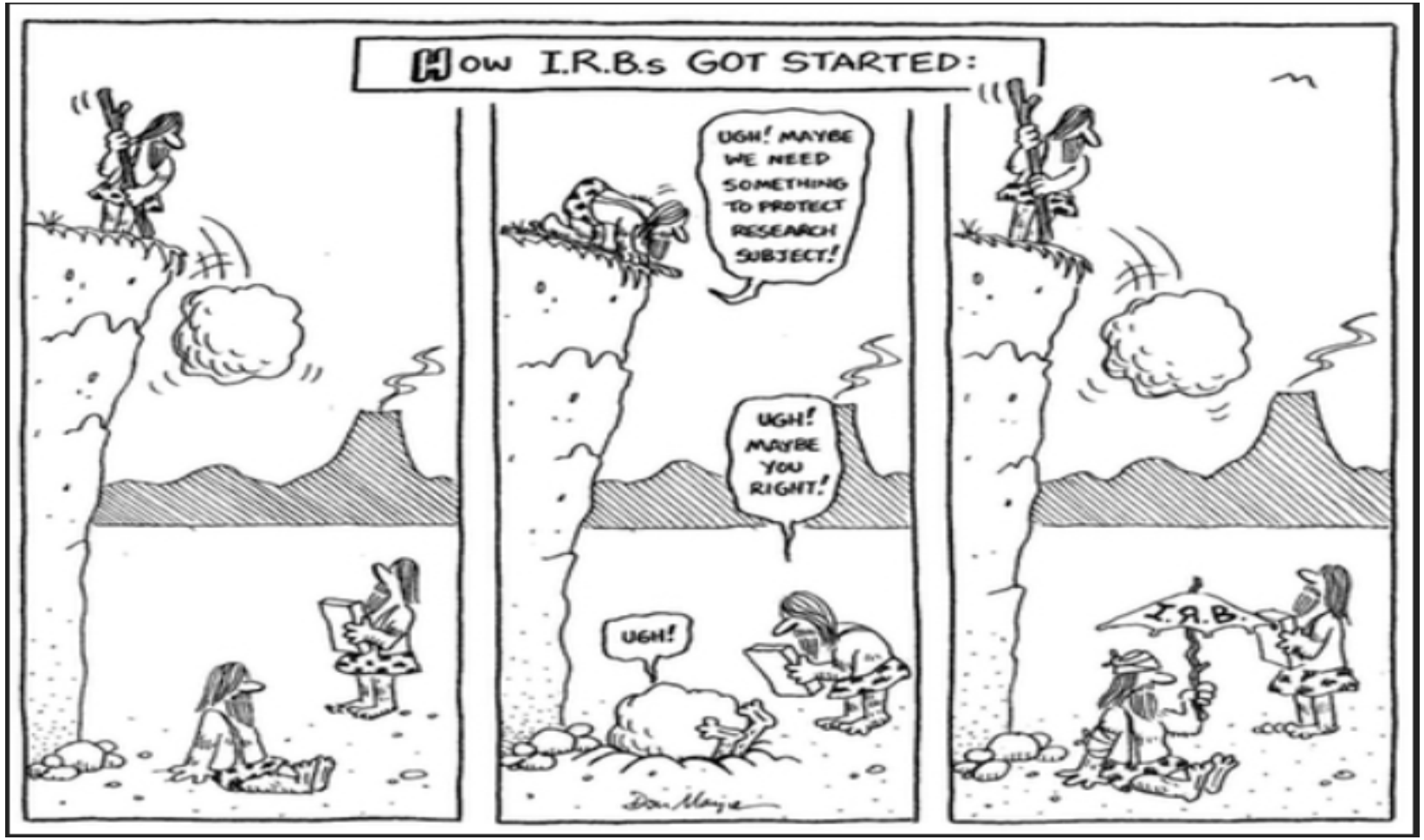
What is human research?

Research conducted with or about people, or their data or tissue. Per the *National Statement on Ethical Conduct in Human Research* (updated 2018) human participation includes the involvement of human beings in the following activities:

- ***surveys, interviews or focus groups;***
- psychological, physiological or medical testing or treatments;
- ***observation by researchers;***
- ***having their personal documents or other materials accessed;***
- collection and use of their body organs, tissues or fluids (e.g. skin, blood, urine, saliva, hair, bones, tumor and other biopsy specimens) or their exhaled breath, and;
- ***their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database being accessed.***
- ***Registries***

You MUST have Ethics approval ***BEFORE*** conducting research!

Why ethics approval?



National Statement on Ethical Conduct in Human Research (NS)

"Ethical conduct" is more than simply doing the right thing. […The National Statement] is oriented to something more fundamental than ethical 'do's' and 'don'ts' – namely, an **ethos** that should permeate the way those engaged in human research approach all that they do in their research." (National Statement, p. 3)

https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018


Human research ethics
Ratification
Already have non-UQ ethics approval
Exemption
Quality assurance
Evaluation activity
*Research
Negligible risk
Existing collection of non-identifiable data
Apply for Ethics approval (HREA)
Full Committee (HREC)
Low and Negligible Risk (LNR)

What is Risk?

The potential likelihood and severity for **harm**, **discomfort** or **inconvenience**.

***Physical harms*:** e.g. injury, pain

***Psychological harms*:** e.g. feelings of worthlessness, distress, guilt, anger or fear

***Social harms*:** e.g. damage to social networks; discrimination in access to benefits

***Economic harms*:** e.g. the imposition of direct or indirect costs on participants;

***Legal harms*:** e.g. discovery and prosecution of criminal conduct.

***Discomfort*:**

- less serious than harm and can involve body and/or mind. e.g. anxiety induced by an interview.

Inconvenience:

- less serious again is inconvenience. e.g.:
  - filling in a form,
  - participating in a street survey,
  - giving up time to participate in research.

Low and Negligible Risk (LNR)

Low Risk: A project in which the only ***foreseeable*** risk is one of discomfort. If there is any chance that the research may result in anything more serious than discomfort, the research cannot be called low risk.

Negligible Risk: A project in which there is no ***foreseeable*** risk of discomfort or harm and if there is any foreseeable risk, it will not be more than an inconvenience. If there is any chance, no matter how small, that the risk will exceed inconvenience, then the research cannot be classified as being of negligible risk.

HREC is always required for …

Projects with greater than low risk ***or*** projects involving any of the following categories:

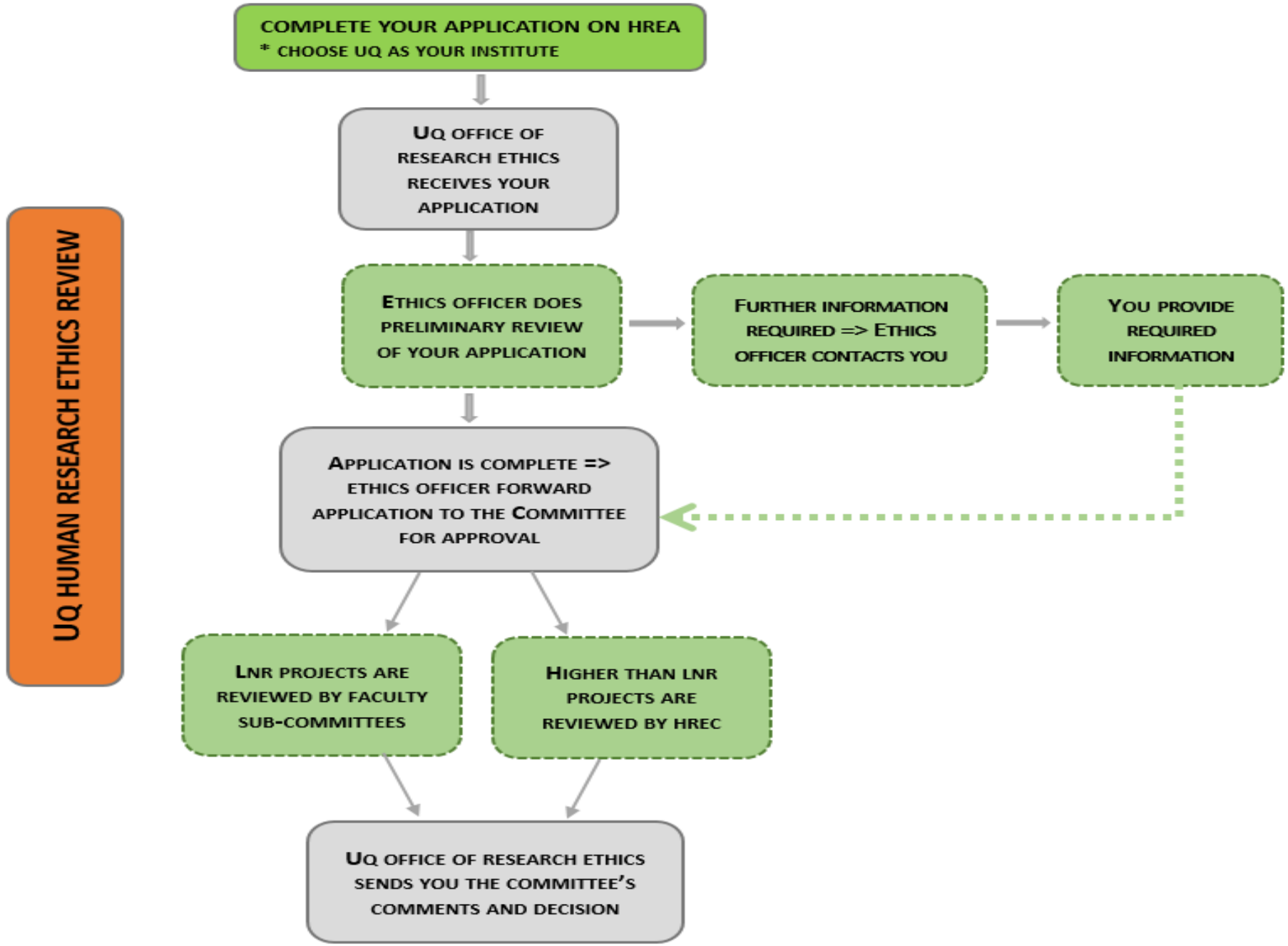
- *"Deception" or concealment (e.g. some psych experiments) (Ch. 2.3.4)*
  - **"Limited disclosure" could be considered as LNR*
- *Aims to expose illegal activity (Ch. 2.3.4)*
- *Waiver of consent (e.g. using personal information in medical research or personal health information (Ch. 2.3.9)*

Targeted, Likely / Foreseeable vs. Incidental Recruitment

- ***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)*

UQ HUMAN RESEARCH ETHICS REVIEW



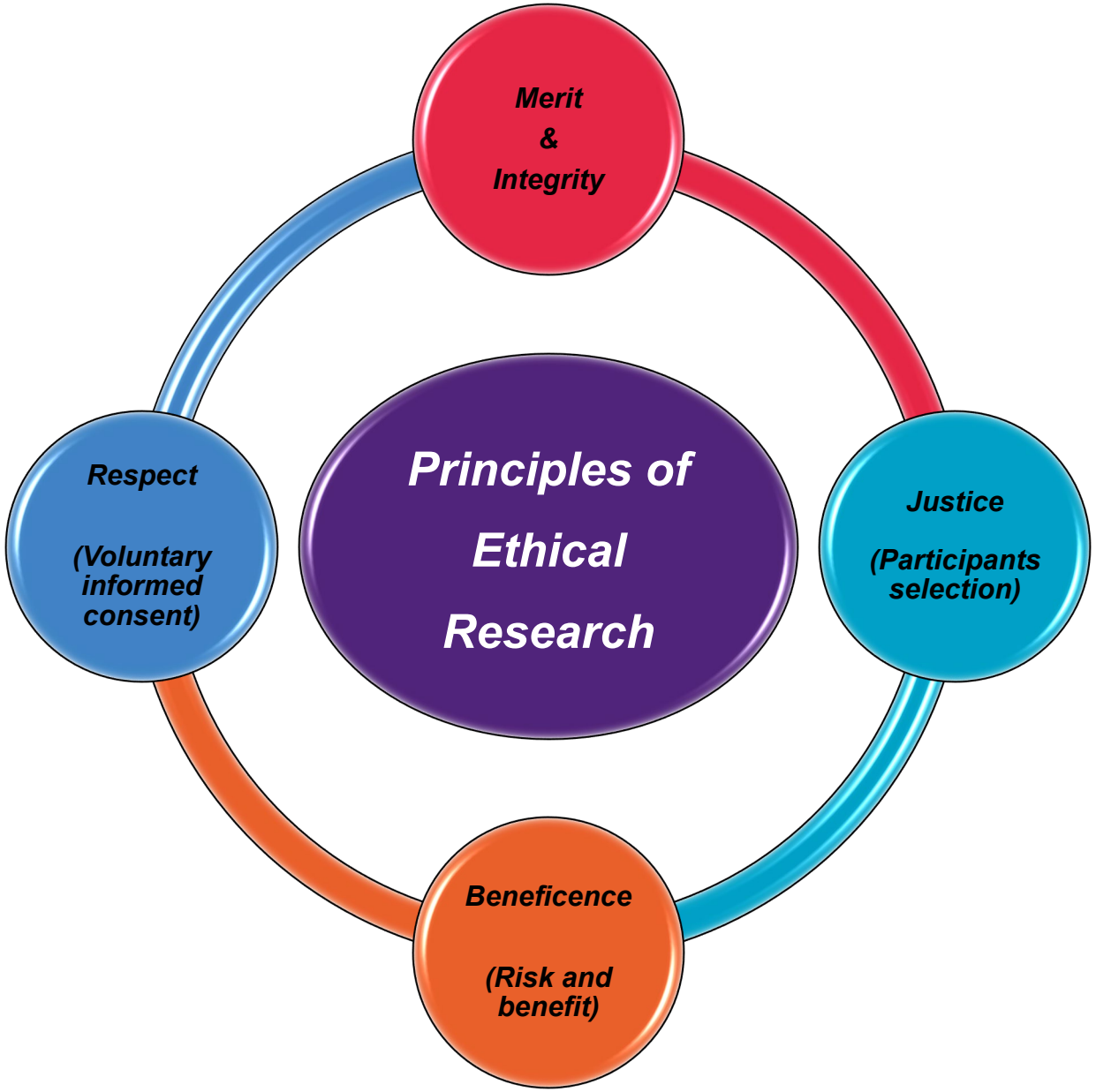
Human Research Ethics Committee (HREC)

At least 8 people on an HREC;

- equally men and women;
- at least 1/3 of the members external to the reviewing institution
- members are from different categories;

  - a committee chair
  - at least 2 lay people, a man and a woman (not themselves researchers, no affiliation to the research institution)
  - at least 1 person with experience in counselling or treatment of people;
  - at least 1 person who performs pastoral care in the community, e.g. an Aboriginal elder or minister of religion;
  - a lawyer;
  - at least 2 researchers.

Layperson Language!



- Direct benefits to the research participants, their families or community,
- Gains in knowledge, insight and understanding,
- Improved social welfare and individual wellbeing,
- Gains in skill or expertise for individual researchers/teams/ institutions.

Merit & Integrity

- The design will meet the project's aim and produce generalizable knowledge
- The research team have appropriate qualifications, skills and experiences
- Appropriate facilities & resources are available to conduct the research
- Appropriate plan for dissemination of results

Justice

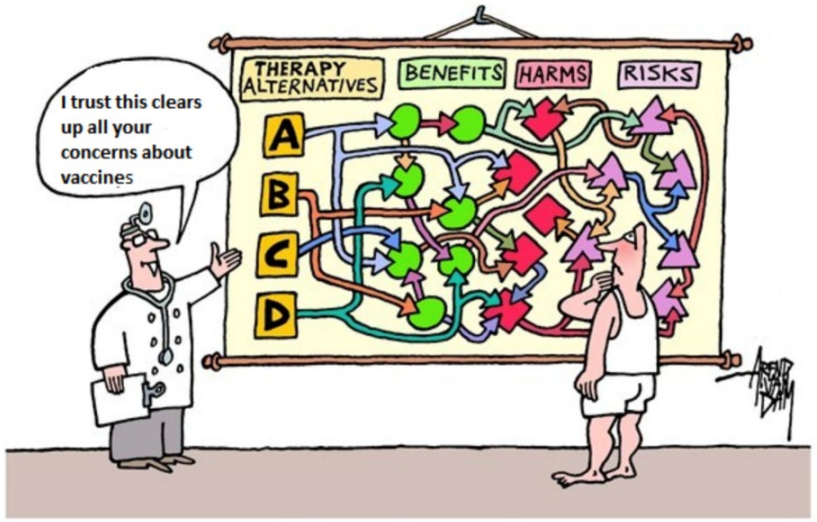
- Participants are selected for reasons directly related to the problem being studied **NOT** easy availability or their compromised position. ➔ **Vulnerable groups**
- Fair distribution of the risks and benefits of research. Not be fair if one group bears the **risks** of research while another group reaps its **benefits**.

Beneficence

- Risks are identified/mitigated and justified by the benefits
- Is there another way to obtain the same knowledge but with lower risks to participants?

Respect

- Regard for participants' welfare, beliefs, customs, cultural needs
- Protection of privacy, confidentiality and cultural sensitivities of participants
- Informed consent ➔ **watch out for therapeutic misconceptions**
- Right to withdraw



informed consent

Requirements for voluntary informed consent

- Voluntary
  - Relationship
- Sufficient information
  - What information
  - Method of disclosing information
- Adequate understanding
  - Capacity
- Right to withdraw

Participant Information Sheet and Consent Form CHECKLIST

This checklist is supplied for use as an additional means of ensuring all aspects of the proposed study have been considered and adequately detailed before submission to a reviewing Committee. A copy should be attached to the original application form for the reviewing Committee to support your submission.

Project Title:
Principal Investigator:

Participant Information Sheet (PIS)

	YES	NO	IF NO, WHY?
1. Version for each participant group *(if applicable)*			
2. On letter-headed paper *(if applicable)*			
3. Full title of project			
4. Lay title of project *(if applicable)*			
5. Names, positions, & affiliations of all investigators			
6. Clear purpose of study			
7. Non-technical language - appropriate lay language and length for PIS			
8. Details of participation/ procedures			
9. Duration of participation			
10. Location for participation			
11. Risks outlined *(% explanation needed?)*			
12 Benefits to participants			
13 What support if something goes wrong			
14. Statement that participation is entirely voluntary and that participants are free to withdraw without penalty			
15. Assurance of confidentiality			
16. Access to results			
17. Debriefing			
18. Reimbursement to participants *(if any)*			
19. Contact details for further questions			
20. Ethical Clearance Paragraph *(refer below)*			

University of Queensland Ethical Clearance Paragraph
The following paragraph is to be incorporated into all Participant Information Sheets given to participants in human research:

"This study adheres to the Guidelines of the ethical review process of The University of Queensland and the *National Statement on Ethical Conduct in Human Research*. Whilst you are free to discuss your participation in this study with project staff (contactable on .....), if you would like to speak to an officer of the University not involved in the study, you may contact the Ethics Coordinators on +617 3365 3924 / +617 3443 1656 or email humanethics@research.uq.edu.au."

Participant Consent Form (PCF)

	YES	NO	IF NO, WHY?
1. Version for each participant group *(if applicable)*			
2. Full title of project			
3. Lay title of project *(if applicable)*			
4. Names, positions, & affiliations of all investigators			
5. Provision of space for full name of participant			
6. Written declaration of informed consent, eg, *"I have read/"I understand..."*			
7. Freedom to withdraw without penalty			
8. Assurance of confidentiality			
9. Provision for signature of participant and date			
10. Provision for signature of parent/guardian, relationship to Participant, and date *(if applicable)*			

http://www.uq.edu.au/research/integrity-compliance/human-forms-resources

The elements of research

Chapter 3.1 of the National statement guideline identifies 7 elements highlighting the manner in which the core principles outlined in the document should be reflected in the elements of research project design.

- Element 1: Research Scope, Themes, Questions and Method
- 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

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?

E1: Research Scope, themes, Qs and methods

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?

E2: Recruitment

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)?

E3: Consent

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?

E4: Data Collection, use and management

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 parties and/or the public?

E5: Communicating results to participants

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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?

E6: Dissemination of results

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?

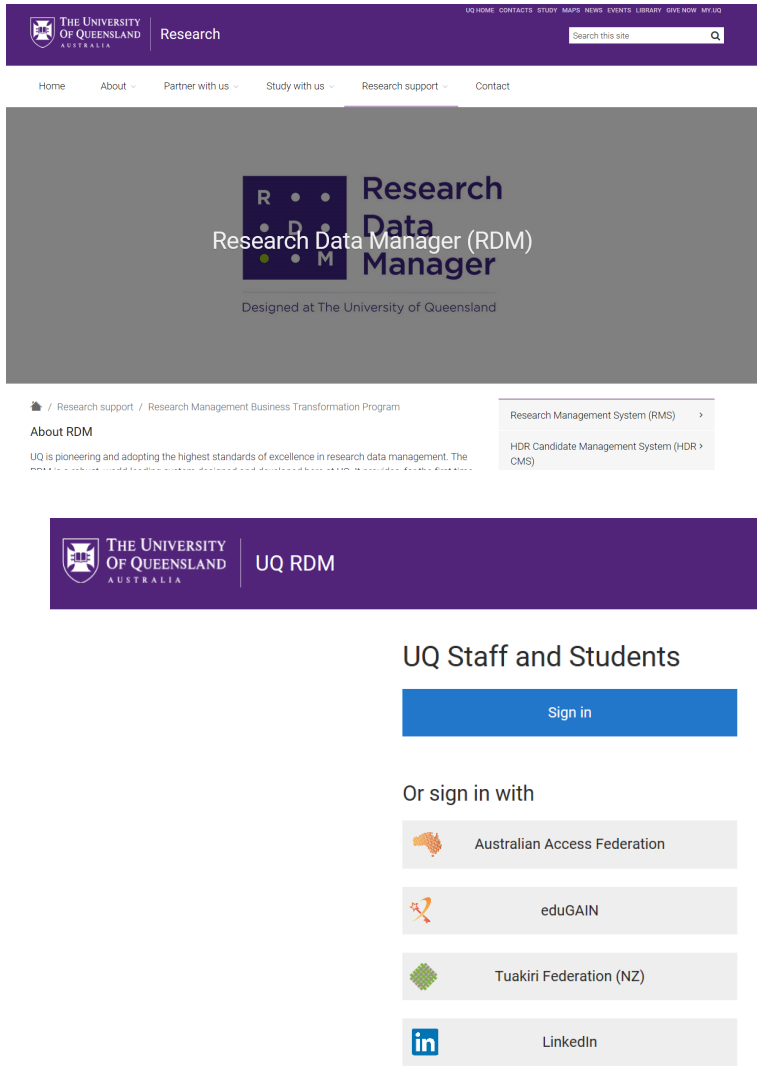
E7: After the project

Data management *(Everything you do with your data throughout its life cycle.)*

Research Data Manager (RDM)

Safe and secure large-scale storage facility for UQ research community.

- https://research.uq.edu.au/rmbt/uqrdm
- https://cloud.rdm.uq.edu.au



Internet research

- Internet as a *tool for research*
    - *E.g.* Surveys (Qualtrics, Survey Monkey, etc.)

- Internet as a *site or venue of research*

Public vs. Private data

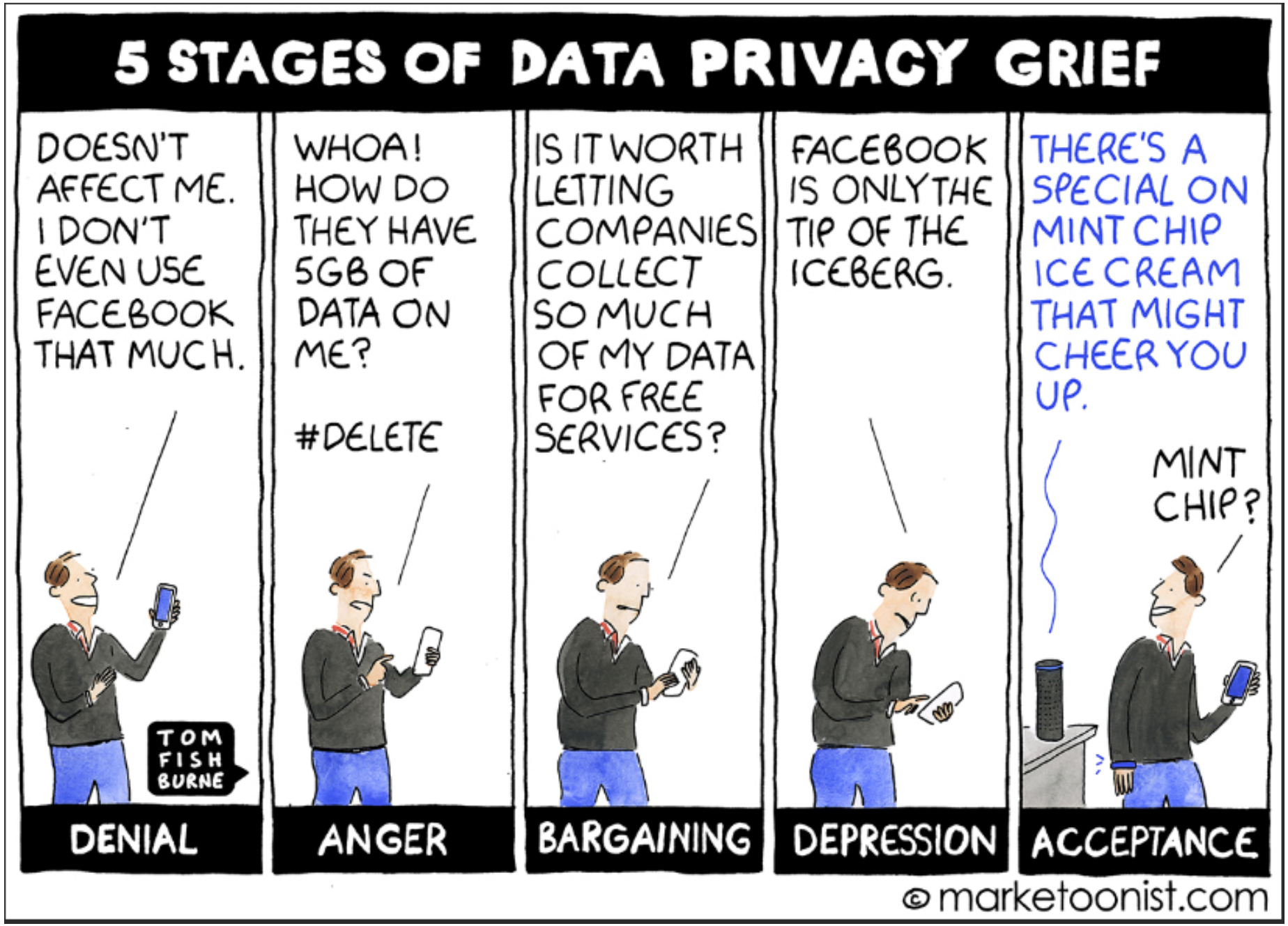
Publicly available data

- Information that is legally available to any internet user, without special authorization or access permission.

Private data

- Identifiable information that is available only with a subject's permission, or by using a password or other access mechanism under the subject's control.

- **Private information** is considered *identifiable* if the identity of the subject is or may be ascertained.


5 STAGES OF DATA PRIVACY GRIEF
DOESN'T AFFECT ME. I DON'T EVEN USE FACEBOOK THAT MUCH.
TOM FISH BURNE
DENIAL
WHOA! HOW DO THEY HAVE 5GB OF DATA ON ME?
#DELETE
ANGER
IS IT WORTH LETTING COMPANIES COLLECT SO MUCH OF MY DATA FOR FREE SERVICES?
BARGAINING
FACEBOOK IS ONLY THE TIP OF THE ICEBERG.
DEPRESSION
THERE'S A SPECIAL ON MINT CHIP ICE CREAM THAT MIGHT CHEER YOU UP.
MINT CHIP?
ACCEPTANCE
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Privacy in Internet research

Problematic for researcher and participant

Is the space being researched seen as private by its users?

- Are they aware they are being observed?
- What is the researcher's role?

How do researchers ensure their participants really are anonymous?

- IP Addresses are (usually) traceable
- Tweets may contain identifiers….

Core considerations

Preserving privacy and confidentiality

- Traceability (~loss of confidentiality)
- Anonymity
    - E.g. if you were to quote a Twitter post verbatim, the user can then be identified with a search engine.

Recruitment & Consent related issues

- Verifying identification
- Ensuring comprehension
- Obtaining appropriate documentation when needed

Terms of service

- Who owns the data you create in a social networking site?

HREA terminology

Participant / Data privacy

- Identifiable
- Re-identifiable
- Not identifiable

Type of data (Q3.1-3.2))

- Personal information

Consent

- Written
- Verbal
- Implied
- Re-negotiate vs. Right to withdraw
- Opt out

Scope of consent

- Specific
- Extended
- Unspecific

Common problems in applications

- **Missing signatures;**
    - In case of student research, **the superviser is ALWAYS the Chief investigator and sign the application**.

      As the signatory of the application, the supervisor is responsible for;

  - Briefing students about the ethics requirements when preparing the project
  - Guiding the student in the completion of the application
  - Guiding the student in the ethical conduct of your research
  - Monitoring the project
- **Supporting documentation missing**
  - **Project description/Protocol**
  - Participant Information Sheet and Consent form (translations)
  - Questionnaire/survey (translations)
  - Any other relevant document
- **Risks not identified!**
- **Conflict of interest not identified/disclosed!**

- Use lay-language (non-technical language) in describing your project
- Avoid giving your personal mobile phone numbers in Participant Information and Consent Forms. Give a Departmental landline or a project-specific mobile phone number.
- Read each question in the application and answer carefully.
    - Eliminate guesswork! If any questions contact Office of Research Ethics.
    - Avoid providing information not directly relevant to the question.
    - **Be clear, concise and accurate!**
- ***Proof-read your application.***
- Meet submission deadlines (**Full committee review**).
- Follow the committee's advice: this is the ***fastest*** way of gaining clearance!

Contact details

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