BOOKLET 33

Griffith University Research Ethics Manual

Observation without consent, limited disclosure, deception, and/or qualified or waived consent

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Contents

1.0 Introduction

The ethical principle that potential human research participants should be asked to provide voluntary and informed consent has a long historical basis. Generally withholding or 'modifying' the information that is provided to potential participants has been considered a matter of significant community concern (see Commentary Inset 1 for more on this).

One of the reasons why such research designs can be so ethically problematic is the degree to which they can undermine an individual's or even the wider community's trust in researchers and willingness to support, fund or participate in our research.

Nevertheless, there can be circumstances where it could be considered ethically justifiable to not seek consent, not fully disclose all of the pertinent facts to a potential participant, or in some way to'qualify' that information.

Commentary Inset 1 – Community concern about less than full disclosure to potential participants

Scandals such as the Tuskegee Syphilis trial, Milgram's obedience to authority, Humphrey's tearoom trade and Project Camelot have generated considerable community concern and a climate of regulatory caution.

In many cases such major scandals relate to less than full disclosure to potential participants about the purpose, demands and risks associated with the research. When such matters come to light there has often been a formal investigation, considerable media interest, and some form of regulatory response.

When reflecting upon the consequences of the community and regulatory response to such incidents, it should be noted that there is often an apparent diminishing of support for research, impacts upon trust in research as a profession, and a reduced willingness to participate in research.

Consequently, there must always be a persuasive justification for less than complete disclosure to potential participants. This is also one of the reasons why demanding ethical standards apply to research of this kind.

Essentially the ethical justification for such a situation rests upon questions such as: is this the only way to conduct the research; do the anticipated benefits of the research justify such an approach; does this expose participants to increased risk; what will be done after the data collection has occurred (i.e. will there be a disclosure and the opportunity for individual participants to withdraw the data?); and is it reasonable to assume that a person would agree to participate if they were aware of the full facts about the project? It is not valid to argue for a limited disclosure, deception or waiver of consent just because of the burden on the research team associated with seeking informed and voluntary consent.

This Booklet is intended as a source of advice and assistance to researchers who are planning research involving some form of deception, covert observation or qualified consent. It does not replicate the content of other booklets of the Griffith University-REM (such as the guidelines on informed consent found in Booklet 22). Instead, where appropriate this booklet will provide links to the other relevant booklets.

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2.0 National guidelines

The National Statement on Ethical Conduct in Human Research (2007 updated 2018) is the Australian reference for human research ethics matters. Potential participants providing their voluntary and informed consent is an important component of the core ethical principle of 'respect for persons' – as discussed in Chapter 1.1 of the *National Statement*. Chapter 2.3 of the *National Statement* discusses the ethical issues associated with 'limited disclosure' and ethics committees granting a 'waiver' of the informed consent requirement.

Chapter 2.3 provides guidance to researchers and ethics reviewers with regards to:

- the deception of participants;
- covert observation; and
- waiver of the informed consent requirement.

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3.0 Limited disclosure: no deception or active concealment

This refers to situations where there is limited or no disclosure to potential research participants, but where deception will not be used and there will not be 'active' concealment (see Commentary Inset 2 for further commentary on how to define whether concealment is active).

Commentary Inset 2 – Is the concealment active?

As was noted at 4.0 of this Booklet, the National Statement articulates additional ethical considerations where a project involves either deception or active concealment.

Unhelpfully the term 'active concealment' is not otherwise defined.

The University defines concealment as being active when a researcher will utilise a 'blind' or some other mechanism to conceal their presence and data collection activity. In effect, even if a participant was looking for someone conducting research, they would not be able to perceive the researcher, because of this active concealment.

In contrast, concealment is not active if the researcher is not hiding or otherwise disguising themselves / the data collection. For example, a researcher who was seated in a public place, may not be announcing her or his presence (so is concealed), but the absence of any strategies to hide the researcher means that this concealment is not in fact active.

An example of such an activity is a researcher who is sitting in a public place monitoring the ways in which members of the public interact with that space. Whilst the researcher probably would not overtly

communicate her/his data collection, they are equally not pretending to collect data about something else and are not in 'hiding'.

Provision 2.3.1 of the *National Statement* specifies circumstances where ethics reviewers can approve such research. Parts (a) – (e)ii of this section specify the exact matters which will determine whether such research can be approved. Even though this section specifies that ideally there should later be a disclosure to participants and an opportunity for them to withdraw their data, this is not articulated as an absolute requirement. In situations such as the example above it would simply be impractical to provide such a disclosure. However, the nature of the research means that this is likely not to be considered much of a concern.

A project that involves limited or no disclosure without active deception or concealment can be reviewed by the expedited system if the project otherwise qualifies for: Negligible Risk review (NR); review via the Expedited Ethics review Level 1 (E1) pathway; or review via the Expedited Ethics review Level 2 (E2) pathway.

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4.0 Limited disclosure: with deception or active concealment

This refers to situations where there is limited or no disclosure to potential research participants, and where deception will be used and/or there will be 'active' concealment (see Commentary Inset 2 for more on how to define whether concealment is active).

An example of such an activity is a researcher who tells participants they are to undertake a group task so that the researcher can look at the process of collective problem solving. Instead the researcher is in fact interested in the 'natural' interaction between two personality types, and has hidden webcams to make an audio and video recording of the interactions.

Provision 2.3.2 of the *National Statement* specifies circumstances where, if the project does not involve the intention to expose illegal activity (see 5.0 of this Booklet), ethics reviewers can approve such research. Items (a) – (c) of provision 2.3.2 specify the exact matters which will determine whether such research can be approved. Unlike provision 2.3.1 of the *National Statement* (see 3.0 of this Booklet), 2.3.2 of the National Statement specifies that where there will be deception or active concealment, as soon as possible there must be a subsequent disclosure to participants of the genuine purpose of the research. Although not explicitly stated it is recommended that the instruction at provision 2.3.1 e(ii) should also be applied (i.e. that once the deception has been disclosed to the participants they should be afforded the opportunity to withdraw their consent – so her / his data must then be deleted).

Depending upon the participant group and context, there may be legal constraints associated with filming individuals without their prior consent. This is one of the reasons why such projects require full ethics review by a Human Research Ethics Commitee and will be a matter carefully considered by the ethics reviewers.

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5.0 Limited disclosure: Illegal conduct

Not surprisingly, provision 2.3.3 of the *National Statement* specifies additional ethical considerations and challenges where research involving disclosure (whether of the kind discussed in 3.0 or 4.0 of this Booklet) aims to expose illegal behaviour (see Booklet 40 of this

Manual **for further discussion in regards to both the exposure of, and interest in, illegal behaviour.)**

Before approving such research, the ethics reviewers will carefully consider the risks to the participant pool and the degree to which the limited disclosure is justified, specifically in regards to the exposure of illegal activity. When designing such a project, researchers are urged to consult with the Research Ethics Advisor for their element (see contacts).

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6.0 Research ethics review

The University's research ethics arrangements are based upon the guidelines and standards discussed in the *National Statement*. More information about Griffith University's ethics review arrangements can be found in Booklet 2 of the Griffith University-REM**. In some cases the *National Statement* directs the types of research that must be reviewed by a Human Research Ethics Committee (HREC), rather than a proportional review pathway.**

Provision 2.3.4 of the *National Statement* directs that where research involves either: an active concealment or deception; or where research involves an intention to expose illegal behaviour, it must be reviewed by a HREC. Depending upon the presence of additional risk issues or significant ethical concerns, other research involving a degree of limited disclosure (see Commentary Inset 2) can be reviewed via the University's NR, E1 or E2 pathways.

As per provision 2.3.9 only a HREC can approve a waiver of the informed consent requirement. See 7.0 of this Booklet for more about waivers of the informed consent requirement.

Hints & Tips – Avoid common problems and omissions

Below is a suggested list of items to consider when designing a project that involves deception or limited disclosure. Many projects will not address all of the issues outlined here, but there must be a clearly articulated justification for any unresolved matters. Failure to do so may result in unnecessary delays with the ethics review of the project.

1. *Is this the only practical way to pursue the objectives of the research? The question of practicality needs a stronger justification than merely ease or preference.*
2. *The extent of, and the reasons for, the deception or limited disclosure must be well defined. This includes both what participants will be initially told, how this is a deception, what in reality is the case and why it is considered necessary to deceive participants.*
3. *Do the anticipated benefits of the research justify the use of deception or limited disclosure? This should be considered a higher standard than the general requirements of beneficence in human research. When research participants are to be deceived there will often be a clear risk of harm so that there should be a more significant level of anticipated benefits.*
4. *Will the deception or limited disclosure expose participants to a greater risk of harm? This includes psychological, professional, social, legal, economic and other risks.*
5. *Is it likely that the participants would have consented to the research if they had known all of the details? Researchers should consider in good faith the degree to which individuals might have avoided participating in the research if they knew its actual objectives / what participation entailed. This reflection might better prepare the researchers to consider matters such as: what is the likelihood that participants will feel cheated and ill used; and how best to approach the disclosure of the deception.*
6. *Will the full details of the research be provided to participants at a later point? This is often in the form of a supplementary consent form that not only discloses the deception but explains the reasons for the deception.*
7. *Will participants be able to withdraw their consent and data at this point? In the event an individual withdraws consent her / his data should be deleted. This should be explained when the deception is disclosed to participants (see 6 above).*

Careful consideration of these matters during the planning of a project can not only assist with the ethics review of a project it may minimise the degree to which individuals withdraw consent when the deception is disclosed. It may also reduce the possibility that participants complain about the deception.

Researchers considering the use of deception in a project are encouraged to discuss this matter with their local research ethics advisor (see contacts).

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7.0 Waiving the requirement for consent

There can be circumstances where, for a number of reasons, a researcher wishes to conduct research without the prior consent of the individuals. Two examples of this are below.

> EXAMPLE ONE: Accessing the medical records of a health service to identify persons whose medical history makes them appropriate potential participants for a project – to then approach them for consent.
>
> EXAMPLE TWO: Trialling the use of a new pressure sore management regime for unconscious patients in intensive care.

Section 2.3.9 of the *National Statement* discusses the limited circumstances where the requirement for consent from participants can be waived. In the case of medical research using personal information from a Commonwealth agency, or personal health information from an APP entity, sections 95/95A of the Commonwealth Privacy Act specifies that a HREC can grant such a waiver but: i) only when a specific test can be met; and ii) the HREC must provide an annual report to the NHMRC on the granting of waivers under these provisions. Similar provisions appear in State and territory privacy legislation.

In the case of non-medical research there may be other regulatory mechanisms where bodies or agency officers (e.g. a Director General) can grant such a waiver.

Further discussion about regulatory privacy issues can be found in Booklet 23 of the Griffith University-REM. The tests described in Booklet 23 derived from the National Statement can also be used for other situations where a researcher wishes to obtain a waiver of the informed consent requirement.

7.1 Ethical considerations when waiving consent

Provision 2.3.10(a)-(i) of the *National Statement* outlines the ethical considerations that apply when research does not involve the aim of exposing illegal conduct and it is proposed that the requirement of consent be waived. These provisions only apply to research that qualifies for either: NR (Negligible Risk); E1 (review via the Expedited Ethics Review Level 1 pathway); or E2 (review via the Expedited Ethics Review Level 2 pathway). **Research using personal health information or personal information from a Commonwealth agency in medical research, where a waiver of the consent requirement is proposed, must be reviewed by a Human Research Ethics Commitee.**

It is worthwhile noting that in addition to the ethical provisions (e.g. it is impractical to obtain prior consent, the benefits of the research justify any risks associated with not seeking consent, and there is sufficient protection of the privacy of participants) there is also direction that such a waiver can only be approved where the waiver is "not prohibited by state, federal or international law" (NS2.3.10). Accordingly, in these circumstances, it will be necessary to consider relevant privacy legislation.

7.2 Ethical considerations when waiving consent for research that intends to expose illegal conduct

Section 2.3.11(a)-(d) of the *National Statement* outlines the ethical considerations that apply when research involves the aim of exposing illegal conduct and it is proposed that the requirement of consent be waived.

Such research must be reviewed by the Griffith University HREC rather than by the NR, E1 or E2 pathways.

To be considered ethically justifiable, such research must be able to meet a test where the value of exposing the illegal conduct justifies the adverse effects to the persons exposed. As per research that does not involve exposing illegal conduct (see 7.1 of this Booklet), in addition to the need for an ethical justification, a waiver can only be granted where the waiver is "not prohibited by state, federal or international law" (NS2.3.11).

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8.0 Institutional reporting

Provision 2.3.12 of the *National Statement* **specifies that institutions must make publicly available (e.g. in annual reports) those projects approved under** 2.3.10 or 2.3.11 of the *National Statement***.** The *National Statement* specifies that this reporting should include a summary of the project.

As of 2007/08, this information has been included in the annual reports from the Griffith University HREC to the University, which are publicly available documents.

In the case of the reporting of projects approved under s.2.3.11 of the *National Statement* this will occur after the listed completion date of the project.

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9.0 Application to deception and the testing of non-sensitive variables

Some projects, especially in areas such as Psychology, will involve a degree of deception when administering a test (e.g. participants might be told an exercise is intended to assess memory recall strategies, when it is instead interested in the impact of performance anxiety on memory related tasks).

As a general principle, the relevant sections of the *National Statement* apply to such work (e.g. refer to 3.0 of this Booklet). Such research would normally require at least review via the E2 online process. However, where the variables of interest are innocuous, the deception is **minor**, and the research otherwise involves either negligible or no more than low risk it may be possible for the research to be deemed NR or reviewed via the E1 online process.

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10.0 Queensland Human Rights Act

In 2019, the Queensland state parliament enacted the Human Rights Act**. The Act has direct implications for research involving deception and waiver of the consent requirement. The Act applies to Griffith University research, even if a research project is conducted in another jurisdiction.**

See Booklet 26 (at 11.0) of this Manual for further information about the Act.

10.1 Human experimentation without consent

Despite the waiver of the consent requirement permitted by Chapter 2.3 of the National Statement 2007 updated 2018), in accordance with the Queensland Human Rights Act (17c), human research involving

medical or scientific experimentation or treatment cannot occur without the full, free and informed consent of the participant or a legally authorised alternate (e.g. a legal guardian).

This prohibition does not apply to other kinds of non-interventional clinical research such as chart audits.

10.2 Deception

In accordance with the Queensland Human Rights Act (17c) and sections 2.3.1 and 2.3.2 of the National Statement, Griffith University researchers cannot use active deception in research projects without:

(i) there being later a mechanism to disclose the deception to participants and an explanation of why the deception was necessary; and

(ii) the mechanism providing participants with the ability to withdraw their consent and for their data/information to be erased after the deception is disclosed.

This prohibition does not apply to other kinds of limited disclosure.

The use of deception in projects involving greater than a low risk of harm is already prohibited by the National Statement.

11.3 Further information

Researchers who wish to clarify the degree to which these provisions apply to their work should contact the Research Ethics & Research Integrity team (see Contacts).

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Contacts

There are a number of resources available to assist researchers formulate an appropriate response to a question or challenge about the design and/or conduct of a project. This includes the Griffith University Research Ethics Manual and the Human Research Ethics Information Sheet Series. These documents are available from the URL below.

Research students – The first point of contact for research students for advice on any research ethics matter is always your supervisors.

REAs – All academic elements of the University have been asked to appoint at least one member of academic staff as a Research Ethics Advisor. REAs are a local contact for advice, information and suggestions. The contact details of all the current REAs can be found on the URL below.

Office for Research – Staff in the Office for Research (see below) are available to advise with the process of lodging an application or other administrative matters, procedural or policy questions. However, you will be asked what advice you have sought or received already (e.g. consultation with the REA for your area).

Manager, Research Ethics and Integrity

Tel: (07) 373 54375
research-ethics@griffith.edu.au

Policy Officer, Research Ethics and Integrity

Tel: (07) 373 58043

Research Ethics Systems and Support Officer

Tel: (07) 373 5 2069

On the ethics web site you will find:

https://www.griffith.edu.au/research/research-services/research-ethics-integrity/human

- The other booklets of the *Griffith University Research Ethics Manual*
- The *Griffith University Human Research Ethics Information Sheet Series*
- Either downloadable copies of, or links to, the various application forms
- Contact information for the Research Ethics Advisers (REA) and other contacts
- Educational and other resource material
- Useful external links

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