
**ALFRED HOSPITAL ETHICS COMMITTEE GUIDELINES:
RESEARCH THAT POTENTIALLY INVOLVES LEGAL RISKS FOR PARTICIPANTS AND RESEARCHERS**

These Guidelines should be read in conjunction with Chapter 4.6 of the National Statement on Ethical Conduct in Human Research 2007, "People who may be involved in illegal activities".

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A. INTRODUCTION

The National Statement identifies several types of research where information gathered in the course of the project may potentially lead to legal consequences for participants and researchers, should the information be disclosed:

- **Research intended to study illegal activity (e.g. heroin use, illegal sex work)**
- **Research not specifically intended to discover illegal activity but likely to do so (e.g. a study which includes collecting information about substance use)**
- **Research where illegal activity is inadvertently and unexpectedly discovered (e.g. a 'lifestyle' study where such information may be volunteered by a participant despite no specific questioning)**

The following guidelines are mainly applicable to research projects in the first two categories; however some of the information is also important for researchers to keep in mind for all research.

Also included is recommended wording to include in Participant Information and Consent Forms, which should be modified to suit the circumstances of the specific research project.

B. BACKGROUND INFORMATION ABOUT LEGAL RISKS

1. Why might research participation have 'legal consequences'?

When researchers record information about a research participant, they could subsequently be required by law to disclose the information (e.g. by search warrant), and the information could be used to prosecute the participant. Therefore, if a participant in a research project reveals illegal activity, there is a risk that the participant could be exposed to criminal sanction. There might also be research that investigates an activity that is not in itself illegal but information about it could be used against the research participant (e.g. causes of motor vehicle accidents).

2. Self-incrimination

Information a person gives about their own illegal activities (such as information about their illicit drug use) is categorised as being self incriminatory - as providing evidence against oneself of having committed a crime. The legal system usually considers evidence made by a person about their own activities to be very strong evidence of wrong doing. This is why the "right against self incrimination" is a basic right in our legal system and a person giving evidence in court is given the option of refusing to answer a question on the basis that the answer might be self incriminating.

3. Confidentiality cannot always be maintained

Potential participants in a study that is likely to collect information about illegal activities must be made aware of the risk that they accept by taking part (e.g. by answering some of the questions in the study, by undergoing certain tests, etc.).

Researchers should not give an undertaking to *always* keep information confidential because:

- Information might be required by law:
Researchers might have to provide information if it is ordered by a court or required by legislation (e.g. in the case of a search warrant or subpoena).
- Researchers might have a moral obligation to 'breach' confidentiality:

Researchers *may* legally disclose information in some circumstances; e.g. to prevent serious harm to the participant, another person, or the community.

4. Consequences for participants – sanctions and public exposure

In the course of a criminal investigation into the participant, the police might become aware of the participant's involvement in an illegal activity and that he/she has taken part in a research project related to the activity. The police might then seek a search warrant from the courts to authorise them to seize the information from the researchers. If the information is considered by the prosecutors to be useful in establishing a criminal case they can seek to produce the information in court. There may be legal argument about whether the information can be used but if the court decides that the information can be used, the evidence may be given in open court and may become public information. The researcher may also be required to give evidence on oath about the study and the way that the information was obtained.

Information about the illegal activity may also be considered to be relevant in other areas such as proceedings in the Family Court, child protection, matters before the Victorian Civil and Administrative Tribunal, matters in the Coroners Court or insurance claims.

5. Consequences for researchers – breaking the law

It is possible that information a researcher receives might be required in evidence in a legal proceeding. In an effort to protect participants, a researcher might take steps to preserve the confidentiality of research participants which could put the researcher him/herself at legal risk.

Under section 254 of the *Crimes Act 1958* (Vic), if a person knows that a document or any other thing is, or is reasonably likely to be, required in evidence in a legal proceeding, they should not destroy data, conceal it or render it illegible, undecipherable or incapable of identification. To do so may be an offence.

If a researcher *was aware* of legal proceedings and rendered information non-identifiable *in response*, they would be putting themselves at legal risk.

For most research, it is unlikely that this will be a concern. However, whether or not a research document is reasonably likely to be required in evidence in a legal proceeding will depend on the circumstances. Every situation is different and should be considered on its merits.

In most situations, it is appropriate for researchers to follow standard ethical practices to protect participants' confidentiality by ensuring that information is not readily identifiable (for e.g. by using pseudonyms or codes). Accepted methods of protecting confidentiality, such as those recommended in the National Statement [4.6.4], should not be discounted for fear of breaking the law. If in doubt, researchers should seek legal advice.

C. WHAT INFORMATION CAN I DISCLOSE ABOUT A RESEARCH PARTICIPANT?

1. Researchers **must not disclose** patient or participant information in most cases. The general rule regarding confidentiality is in section 141(2) of the *Health Services Act 1988* (Vic) - information must be kept confidential, unless a specific statutory exception applies. It is an offence to breach section 141(2).
2. Researchers **must disclose** participant information if required by law to disclose it, e.g.:
 - where they receive a court order, such as a subpoena or a search warrant; or
 - where they have a mandatory reporting obligation, such as in cases of notifiable infectious diseases or suspected child abuse.
3. Researchers **may disclose** (but are not required to disclose) patient or participant information where they are permitted by law to disclose it, e.g.:

- if they reasonably believe that disclosure is necessary to prevent a serious and imminent threat to anyone’s life, health, safety or welfare or a serious threat to public health, safety or welfare; or
- if legislation expressly permits disclosure (e.g. giving information to the hospital’s insurer regarding a potential claim, giving information required in connection with the further treatment of a patient/research participant).

Note: before disclosing participant information under this discretionary option, researchers should - if practicable - consult the Ethics Committee via the Ethics Office.

D. WHAT SHOULD I DO IF I RECEIVE A LEGAL ORDER TO PROVIDE INFORMATION?

If researchers should ever receive a legal request for information such as a subpoena, summons or search warrant, it is recommended that they seek advice from the Alfred Health legal office before responding to the request.

E. HOW CAN I DESIGN MY RESEARCH TO MINIMISE LEGAL RISKS TO PARTICIPANTS?

In order to conduct sound and effective research in areas that may have an associated legal risk for participants, researchers need to design their research to best elicit accurate information. People are unlikely to want to take part, or to give frank and honest answers, if this is likely to have bad consequences for them. It is also unethical to ask participants to put themselves at risk for the sake of the research, particularly when they are unlikely to derive any personal benefit.

The rule of thumb is to:

- keep the collection and retention of ‘risky’ information to that which is necessary
- minimise the possibility of identifying individuals and maximize data security
- provide participants with accurate and appropriate warnings and reassurances

Recommended strategies

1. Avoid obtaining information that is not directly necessary for the research project
2. Record only that information which is relevant to the research project (e.g. written notes recording the essential information may be preferable to an audio-recording which captures everything said)
3. Protect the confidentiality of participants by ensuring identities are not ascertainable. This could include one or more of the following:
 - do not collect names and other identifying information (e.g. where the risks are particularly high, verbal consent may be preferable to written consent)
 - use pseudonyms
 - store data in coded, rather than identified, form
 - protect (and store separately from other research materials) links between names and data.

The **Australian Code for the Responsible Conduct of Research**, Chapter 2, Introduction, requires the “retention of durable records *derived* from recordings and questionnaires”, rather than the actual recordings and questionnaires.

The **National Statement** [4.6.4] says: “Consideration should be given to ... the removal of links between names and data, for participants whose illegal activities may be revealed or discovered in research.”

However, you need to be cautious about destroying data, concealing it or rendering it illegible, undecipherable or incapable of identification. If the data might be required in evidence in a legal proceeding, you may be in breach of the Crimes Act 1958. If in doubt, seek legal advice.

4. When considering the extent to which research data are non-identifiable, researchers and ethics committees may need to weigh the importance of data verification against the importance of participant confidentiality/anonymity.
5. Collect information in the most 'general' form possible (e.g. month/year of birth rather than date, phrase questions to elicit opinions rather than personal disclosures)
6. Ensure that people considering participation are appropriately warned about the limits to confidentiality and the potential legal consequences of participation. In other words, provide them with enough information to assess the extent of any risk to themselves. The existence or level of risk often depends on the individual's personal circumstances which may not be known to the researchers.
7. Ensure that information and alerts are appropriate to the participant group (e.g. a 16 year old may not understand what a subpoena is or what 'as required by law' means). Examples or expanded information may be required.
8. Reiterate the most important points relating to risks verbally as part of the consent process and/or pre-interview discussion. In cases where it is possible that participants may reveal information that is not relevant to the research and is 'legally problematic', it may be appropriate to specifically advise them not to broach certain topics or not to provide individually-specific details.

F. ADDITIONAL INFORMATION FOR PARTICIPANT INFORMATION & CONSENT FORMS (PICFS)

In the PICF, a standard general statement advising participants about confidentiality and its limits is not considered sufficient for some research.

Additional information needs to be included in the PICF if there is a reasonable likelihood that participants may reveal, and/or the research will collect, information about

- their involvement in an illegal activity or
- an activity/behaviour that in itself may not be an illegal activity but could potentially have legal implications, e.g. in the case of a motor vehicle accident

Three key sections of the PICF need to be considered:

- **Section 3 – What does participation in this research involve?**
- **Section 7** (Health and Social Science template) or **Section 9** (Non-interventional or Interventional templates) – **What are the possible risks and disadvantages of taking part?**
- **Section 11** (Health and Social Science template) or **Section 16** (Non-interventional or Interventional templates) – **What will happen to information about me?**

When addressing these sections, researchers need to ask themselves what information the specific participant group needs in order to understand the project and the consequences of their involvement.

Factors that should also be considered with the specific participant group in mind are: the length of the PICF, its formatting/appearance, language used, the setting in which it will be provided. The recommended wording below may be adapted as appropriate for participants with low literacy or English as a second language.

POINTS TO CONSIDER AND RECOMMENDED WORDING

Section 3 'What does participation in this research involve?'

Points to consider:

- Disclosing information that may incriminate the participant or others:

When describing the nature of the questionnaires, interviews, focus groups, etc. it may be appropriate to specifically alert participants that:

- they will be asked questions about their personal involvement in certain 'legally problematic' activities (e.g. substance use, acts that could result in the transmission of HIV),

OR

- they will be asked for more general information/opinions/understandings and should avoid disclosing information of personal nature;

AND (in either case)

- they can choose not to answer if a question makes them feel uncomfortable or concerned.

- Other relationships between participants and researchers [Refer to NS 4.6.5]:

It is important to avoid any confusion on the participant's part between the research and other kinds of contact (e.g. their clinical care). What a person is willing to disclose in a clinical situation where the benefit to them is likely to be greater may not be the same as a research situation where the risks associated with disclosure could outweigh any benefit to the individual.

Another consideration is the potential for coercion where there is also a clinical relationship between researchers and participants (i.e. patients may feel obliged or pressured to take part).

In the PICF, state whether the interviewer/researcher is independent of the clinical staff, or also has contact with participants in another professional role, e.g. their doctor.

- Video/audio-taping:

Participants must be advised if researchers intend to record interviews for the research. They also need to be told:

- whether the recording of interviews is optional or essential.
- whether the recording will be destroyed after transcription or kept. (Note that you may need to seek legal advice about destroying the recording. Refer to the information in "Consequences for Researchers" on p.2.)

Where interviews might contain sensitive information that is not needed for the research, it is recommended that researchers consider alternatives to video/audio taping, such as taking a hand-written summary of the information.

Recommended wording:

- No specific wording has been recommended for Section 3 because information provided to participants in this section is project-specific. However, the information needs to take into account the above 'points to consider'.

Section 7

‘What are the possible risks and disadvantages of taking part?’ (or **Section 9** in Non-interventional or Interventional templates)

Points to consider:

- The extent of the risk/seriousness of consequences will depend on participants’ individual circumstances. For example, the consequences of illicit drug use being revealed may be considerable for someone facing a child custody hearing; on the other hand, they may not be of particular concern to someone whose drug use is already known to the police.
- Potentially incriminating information about a participant could be disclosed in either of the following circumstances:
 - a) Researchers could be required by law to disclose information (e.g. if research records are subpoenaed).
 - b) Researchers may disclose information about a participant if legislation expressly permits disclosure; for example, they reasonably believe this is necessary to prevent a serious and imminent threat to anyone’s life, health, safety or welfare or a serious threat to public health, safety or welfare. If the research is likely to uncover specific information that the researcher believes they have an obligation to, and may lawfully, disclose (e.g. suicide risk, dangerous sexual practices), the possibility of disclosure and reasons for the disclosure should be made clear in the PICF.
- If researchers are issued with a subpoena or search warrant, attempts should be made as appropriate to notify the individual/s whose information is involved *before releasing the documents*.

Recommended wording for the PICF [to be adapted as appropriate]:

- *Where the research involves collection of information:*

This study involves the collection of information about *[insert type of activity, eg. your use of drugs]*. We will generally not disclose that information without your consent but there may be circumstances where we have to do so for legal reasons. In that case, the information could potentially be used against you in legal proceedings or otherwise. *[Give a relevant example/s, such as: Information about drug use may be considered relevant in a criminal investigation, proceedings in the Family Court, child protection, matters before the Victorian Civil and Administrative Tribunal, matters in the Coroners Court, insurance claims.] [Include if applicable]* To our knowledge, researchers at this institution have not been required by law to provide information. If we were ever required to do so, we would do our best to notify you before disclosing it.
- *Where the research involves drug testing of samples:*

Participation in this study includes *[blood and /or urine analysis]* to determine the presence of *[name of substances]*. The test may reveal evidence that you have previously used illegal drugs. We will generally not disclose that information without your consent but there may be circumstances where we are required by law to do so. In that case, the information could potentially be used against you in legal proceedings or otherwise. *[Include if applicable]* To our knowledge, researchers at this institution have not been required by law to provide information. If we were ever required to do so, we would do our best to notify you before disclosing it.
- *Where the nature or subject matter of the research means that there is a reasonable possibility that the researcher will receive information that they feel obliged, and are legally permitted, to disclose:*

[For example] If, based on the information you give us, we become concerned that you are at risk of harming yourself or someone else we would *[briefly explain what action you would take]*.

Section 11 ‘What will happen to information about me?’ (or **Section 16** in Non-interventional or interventional templates)

Points to consider:

- Risks associated with the limitations to confidentiality should be covered in the Risks section of the PDCF (Section 7 or 9).

Required wording for **all** PDCFs:

- Any information obtained for the purpose of this research project [*include if applicable:* and for the future research described in section *xx*,] that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or in compliance with the law.

G. REFERENCES

National Statement on Ethical Conduct in Human Research 2007 (National Health and Medical Research Council)

Australian Code for the Responsible Conduct of Research 2008 (National Health and Medical Research Council, Australian Research Council and Universities Australia)

Approved by: Alfred Hospital Ethics Committee

Date approved: October 2010

Reviewed & updated: September 2016

Next Review date: April 2018 (To be reviewed bi-annually)