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 (updated 2018)*, "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 if the researcher is later required by a court or similar order to disclose that information:

- **Research intended to study illegal activity (e.g. 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 illicit substance use)**
- **Research where illegal activity is inadvertently and unexpectedly discovered (e.g. a 'lifestyle' study where such information might 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 court order), 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. in legal actions related to 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 actions of a research participant, police might become aware of the participant's involvement in a research project where information related to the activity might have been recorded. The police might then seek a warrant from a court to require researchers to disclose the information. If the information is considered useful in prosecuting a criminal case, the evidence may be disclosed in court and 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, etc.

5. Consequences for researchers – breaking the law

It is possible that information a researcher collects might be required to be produced in a legal proceeding. In an effort to protect participants, a researcher might take steps to protect the confidentiality of research participants in a manner that 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.

Similarly, if a researcher *is aware* of legal proceedings and in response renders information non-identifiable they are likely to be committing an offense.

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 unless legally required to do so. This requirement is included in section 141(2) of the *Health Services Act 1988* (Vic) which states that information must be kept confidential, unless a specific statutory exception applies.
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 Office of Ethics & Research Governance.

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

If researchers 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 must design their research to elicit accurate information. However, participants are unlikely to want to take part in a research project, or to give honest answers, if this is likely to have adverse 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 essential
- minimise the possibility of identifying individuals and maximize data security at an early stage
- provide participants with accurate and appropriate warnings and reassurances in advance.

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
   - use month/year of birth or age rather than date of birth
   - store data in coded, rather than identified, form.

   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. Ensure that information, whenever possible, is collected in a general form (e.g. phrase questions so specific details of events such as names of people, specific dates or specific places that are not essential for the research are not included).

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 otherwise 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. provision of blood samples after 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, and the efforts that will be made to protect the information participants provide.

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 limited English proficiency.

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 '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. As per

usual practice, if the research is likely to uncover specific information that the researcher believes they have an obligation to, and may lawfully, disclose, 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:*
  We will also ask you about [*insert type of activity, eg. crime, your use of drugs*]. We will not disclose that information without your consent except in circumstances where we have to do so for legal reasons. In the unlikely event that this happens, the information you gave us could potentially be used against you in legal proceedings. For that reason, you should not tell us anything specific about events or activities such as *[insert appropriate example/s – e.g. crimes that you have not been charged with or you have not been to court about]*. Please don't tell us things like names, specific dates or specific places of illegal activities. *[Include if applicable]* Over many years of research, we have never been required by law to provide our research information under such circumstances. If we are requested to do so, we will do our best to let you know at the earliest opportunity.

- *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 not disclose that information without your consent except in circumstances where we are required by law to do so. In that case, the information could potentially be used against you in legal proceedings. *[Include if applicable]* Over many years of research, we have never been required by law to provide our research information under such circumstances. If we are requested to do so, we will do our best to tell you at the earliest opportunity.

- *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]
  We cannot keep this information confidential if we:
  - think you are going to seriously harm yourself
  - think you are going to seriously harm someone else
  - are required to provide this information by a court of law
  - learn information concerning the protective safety of children

  If we receive such information, 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 PICF (Section 7 or 9).

Required wording for **all** PICFs:

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. SUMMARY: KEY MESSAGES

1. Information collected by researchers may be required to be produced following a court order.
2. Information cannot be de-identified after one has become aware of a possible legal action.
3. If a researcher is collecting information potentially relating to illegal activity then (unless there are compelling reasons not to) it should be fully de-identified and scoured of potential inadvertent identifiers at the earliest possible stage.
4. The PICF should be explicit in explaining the way that confidentiality will be guarded.
5. If the above procedures are followed and the risk is appropriately mitigated then this should be indicated in the PICF.

H. REFERENCES

National Statement on Ethical Conduct in Human Research 2007 (National Health and Medical Research Council) – Note that the National Statement is periodically revised; please check the NHMRC website for the latest revision.

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