# MERIT AND INTEGRITY

*"Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable." - National Statement*

## MERIT IN PRACTICE

What is the **potential benefit** that justifies this research? [1.1a]

Benefits can be to participants, the population from which the sample is drawn, or the wider community, now or in the future. Benefits should be realistically achievable from the research. [NS 3.1.1b]

Are the **methods** to be used **appropriate** for achieving the **aims** of the research? [1.1b]

There's further guidance about this in NS 3.1. If the proposed method is outside of your expertise, you may need to seek advice. "The merit and integrity of research should be assessed by criteria and standards relevant to the research field/s and methodology/ies." [3.1.2]. By citing literature or previous research findings the applicant should show how the methods will help achieve the aims. [3.1.1c,d].

What is the basis for the research in **current literature** or **previous studies**? [1.1c]

Is the research **designed** to ensure that respect for participants will not be compromised by the aims of the research, the way it is conducted or its results? [1.1d]

This relates to all methods and also the way interactions occur with participants during all phases of the work. Respect is embodied in the idea that human research involves *"participants"* and not "*research subjects*". [Section 1, Introduction]

Are the **facilities** and **resources** that will be used appropriate? [1.1f]

This includes facilities that might be necessary to support diverse participation, potential risks, and the general support and well-being of participants. [NS 1.1d; 1.7a,c]

Has the merit of the research already been evaluated by **peer review**? [1.2]

Has there been formal academic scrutiny of the proposal and the outcome? From NHMRC's perspective, this is taken to include, for example, peer review conducted as part of competitive grant funding, and should have been conducted on the specific research study rather than a broader level proposal.

## INTEGRITY IN PRACTICE

Are the **experience**, **qualifications** and **competence** of the researchers appropriate to this research? [1.1e]

Where there are students undertaking work for which they are not highly experienced, ensure that supervisors are committed to having oversight, and providing training and support. The experience and skills of supervisors should be appropriate to support the methods, procedures, and activities to be undertaken by the research team.

Are the researchers committed to undertaking the work **honestly**, and using **recognised principles of research conduct**? [1.3b,c]

This is also required under the *Australian code for the responsible conduct of research*, and relates to every aspect of the research.

How will the results be **disseminated** to permit **scrutiny** and contribute to **public knowledge** and understanding? [1.3a,d]

This applies irrespective of whether the study achieves its aims. Reporting "negative findings" may be equally informative to the research community. Researchers should explain if there may be external (commercial, or funding body) interests or conditions which could impact publication. [NS 3.1.69]

## TIPS

## EXAMPLE COMMENTS

*"Please indicate how the study design and methods will achieve the aims of the research (NS 3.1.1d)."*

*"The methods are likely to achieve the first aim, 'to determine [x]' , however it is less clear how the second aim will be achieved. Please clarify. (NS 1.1a,b,c)"*

*"Please justify the methodological approach and provide further detail in the protocol. (NS 3.1.1b,d; 3.1.2a,b)"*

*"Please indicate the outcome measures and how they will be used to respond to the research questions. (NS 3.1.1d; 3.1.2a)"*

*"Please explain the sample size considerations for Phase 1." (NS 3.1.2a)*

*"The design and detail of successive stages of this research project will be informed by preceding stages, so the total project cannot be described in advance. Please provide a description of the stages that are foreseen and how you intend to seek ethics approval for each stage. (NS 3.1.8)"*

*"Please confirm the funding. Securing adequate funding is considered to be crucial to fulfilling the expectations of the community."*

*"Participants will reveal personal/sensitive information. Please advise the names and qualifications of research team members who are qualified to interpret any recommendations relating to the health and wellbeing of participants." (NS 1.1b,e; 1.7a,c)*

*As well as the National Statement, these guides draw on work by Colin Thompson for Houston Thompson: Developing Best Practice in Human Research Ethics Review, Consultative Council for Human Research Ethics, Victoria, 2013*

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# BENEFICENCE

*"Researchers exercise beneficence in several ways: in assessing and taking account of the risks of harm and the potential benefits of research to participants and to the wider community; in being sensitive to the welfare and interests of people involved in their research; and in reflecting on the social and cultural implications of their work."*

## BENFICENCE IN PRACTICE

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| Do the likely **benefits** of the research **justify any risks** to participants? [1.6] | There must be a clear and realistic summary of the likely benefits and forseeable risks. Ensure that researchers have identified the range of risks that may apply: physical, financial, social, legal, and economic. [2.1] Risks are from the perspective of the participant (rather than the researcher). [1.7c; 2.1.3,4] Researchers should also consider risks to non-participants - e.g. the risk of distress for a participant's family member identified with a serious genetic disorder, or the possible effects of a biography on family or friends. |
| How does the design of the research **minimise** any risks to participants? [1.7a] | Each of the identified risks should be followed with a clear description of what will be done before, during, and after data collection to minimise potential harm for each of the identified risks. Prompt applicants to consider what would they want from researchers if they were a participant. Prompt applicants to reference scholarship in their responses where there is evidence that specific strategies are effective in minimising risks. |
| Will the potential **benefits and risks** of the research be made **sufficiently clear to participants**? [1.7b] | This requires more than a "yes or no" response. In what ways will the potential benefits and risks of the research be made clear to participants (e.g., in the PIS, in the interview preamble?) |
| How will the researchers fulfil their **responsibility** for the **welfare** of the **participants**? [1.7c] | Prompt applicants to describe how they will care for participants before, during, and after data collection to minimise harm arising from the identified risks. The quality of the recruitment and consent processes including attention to potential obligation or coercion are relevant to risk management. [NS 4.4.2; 4.5.3; 4.7.5] |
| How have the risks to participants been reduced for **participants that will not benefit**? [1.8] | If participants will not benefit directly from the research (and this is the case in most of our reserach), prompt applicants to explain the ways in which they have reduced risk. Clear information provision is relevant because it allows a participant to consider whether they wish to undertake a risk for altruistic reasons. |
| Will participants be reimbursed for any expenses incurred as part of their participation? [2.2.10] | If participants will be reimbursed, applicants should explain how this will be done. In their response, they should consider what is feasible within their context of the university. It is generally appropriate to reimburse participants for costs incurred taking part in research - e.g. travel. Sometimes participants may also be paid for time. However, payment that is disproportionate to the time involved, or any other inducement that is likely to encourage participants to take risks, is ethically unacceptable. |

## TIPS

## EXAMPLE COMMENTS

*"You state there are no risks. There is at least the risk of inconvenience, since you will invite participants to spend 30 minutes of their time to complete the survey. (NS 2.1) Further, please consider whether some participants may experience discomfort in answering questions about [x, y, z]."*

*"Please clarify what the proposed incentives are and provide the monetary value. Consider the degree to which any payment could result in pressure on individuals to consent to participate." (NS 3.1.22)*

*"You are asking questions that relate to potentially painful experiences. For example: "Do you remember how you felt when you failed your assignment?" These questions certainly carry risks beyond inconvenience. Pleae consider and revise."*

*"While it is noted that no individual survey results will be provided to the company, it should also be clear what form of report will go to the company, especially considering that a stated benefit could be improvements by the company. "*

*"In the participant information sheet, under the section, 'What are the possible benefits' , add details about the prize draw: who will provide the prizes, what will they be, how many will there be, when will the winners be announced?"*

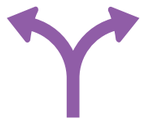
*"If risks are no more than normal day to day activities, is the reference to psychological support required in the participant information?" (NS 1.7a,b).*

*"When you report the research, will you name the companies from which the participants came? If so, consider risks to those companies, and any associated risks to their employees who are your participants."*

# JUSTICE

*"At a profound level, justice involves a regard for the human sameness that each person shares with every other. Human beings have a deep need to be treated in accordance with such justice, which includes distributive justice and procedural justice. In the research context, distributive justice will be expressed in the fair distribution of the benefits and burdens of research, and procedural justice in 'fair treatment' in the recruitment of participants and the review of research. While benefit to humankind is an important result of research, it also matters that benefits of research are achieved through just means, are distributed fairly, and involve no unjust burdens..."*

JUSTICE IN PRACTICE



Are the **inclusion and exclusion criteria** fair? [1.4a]

There will almost always be some criteria that a potential participant must meet to be eligible for participation in the research. Fairness involves considering whether some groups are being inappropriately excluded on the basis of attributes such as culture, language, gender, race, ethnicity, age, or disability. There should be consideration of how limiting or expanding the sample will influence the findings and the generalisability of the research. [3.1.15]

Is the **recruitment process** fair? [1.4b]

Dependency in relationships, a sense of obligation, established trust or a desire to please researchers or an institution can all impact the likelihood of participation and impact voluntary decision-making. [NS 2.2.9; 3.1.18a,d,e] Dependency in relationships etc. can also impact the quality of the data obtained/interacts with the merit of the methodology.

Is there any **unfair burden of participation** on particular groups? [1.4c]

Researchers should consider the degree to which those who are intended as participants may be over-researched, and the circumstances of particular target participants. A burden which might seem minimal from the perspective of the research team, might be far greater for a particular sample.

Is it clear that participants will **not be exploited**? [1.4e]

Have the applicants addressed the potential for coercion in participant recruitment? A sense of obligation or the influence of a prior relationship can be difficult to gauge when recruiting and during decision-making by a participant. Clear explanation in information material of possible burdens and risks will validate the recruitment process, and also assist in preventing withdrawal of participants.

Will there be **fair access to the benefits** of the research? [1.4f]

This requires consideration of long term benefits, such as the access to, and introduction of, a beneficial intervention to the population from which the sample is drawn.

How will **timely and clear access to the outcomes** of the research be provided to participants? [1.5]

This relates to the idea that participants can be regarded as colleagues in the research undertaking and demonstrates respect. [NS 1; 1.1d] Would it be better for participants to receive a lay summary rather than a journal article? The timeframe should be included.

TIPS

## EXAMPLE COMMENTS

*"Please justify the selected age range. At protocol, section 6.2 please clarify why women who are not menstruating are excluded. Does this mean 'no longer able to menstruate', or 'not currently menstruating'? (NS 1.4a, b; 3.1.15)"*

*"How will prospective participants become aware of the study, be identified and approached? This is unclear. (NS 3.1.12,13)."*

*"Will pregnant women be excluded from working with the toxin? if they can, will additional precautions need to be undertaken? If they are unable to work with the toxin in Stage 2, can they still particpate in the Stage 1 survey?"*

*"This study carries substantial burden to the schools involved. Please note that this may be a concern of the Department of Education. (NS 1.4c,e)."*

*Are patients/carers made aware when they opt for the Palliative Care services that their data may be used for a research purpose? (NS 1.4b; 3.1.18d,e).*

*"How will it be determined that potential participants are 'healthy' (a requirement in the PIS for QUT participants). What is the definition of 'healthy'. (NS 1.4a; 3.1.13.)"*

*"Please explain how the approach with the businesses will work, and how you will avoid any sense of obligation to participate among employees. For example, will a supervisor know whether someone they supervise has participated?"*

# RESPECT

*"Among [all the] values, respect is central. It involves recognising that each human being has value in himself or herself, and that this value must inform all interaction between people. Such respect includes recognising the value of human autonomy – the capacity to determine one's own life and make one's own decisions. But respect goes further than this. It also involves providing for the protection of those with diminished or no autonomy, as well as empowering them where possible and protecting and helping people wherever it would be wrong not to do so."*

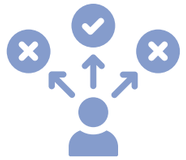
## RESPECT IN PRACTICE

How does the research give due respect for **participants' welfare, beliefs, perceptions, customs and cultural heritage**? [1.10]

Particular cultural, racial or community groups may have views about the research. This is particularly important when considering methodologies and also benefits. Additional guidance may need to be accessed (e.g. the AIATSIS Code) to inform due respect.

Will the research respect the **privacy**, **confidentiality**, and **cultural sensitivities** of participants and their communities? [1.11]

NS 3.1 is helpful here. If data is collected in a face-to-face interaction with a participant, it is considered to be identifiable. What do the researchers intend to do with the data that may make it more or less identifiable? These considerations also apply to accessing data for a secondary research purpose. The intent of the research team not to do harm but to generate new knowledge is not a sufficient reason not to gain the agreement of the people to whom data or artefacts relate.



How will the research give due scope to the capacity of participants to **make their own decisions**? [1.12]

This can require attention to how prospective particpants are identified, screened and approached for research - even before recruitment and consent occurs. It relates to recruitment and consent strategies (e.g. who approaches and when), and the quality of the information provided. Participant information should be correct, clear and free of typographic mistakes, since these can impact participant understanding. Determination of capacity to reach a decision can vary with the participant and the study, and should be explained in the submission.

How will participation be **voluntary**, and **based on sufficient information** and **adequate understanding** of the purpose, methods, demands, risks and potential benefits of the research? [2.2]

NS 2.2.6 provides a helpful list of information that should be provided to participants. Information must be presented in ways suitable to each participant. [2.2.3] Has the applicant considered, for example, the participants' ages, communication impairments, and education levels. Is there a need for reliable transcription? Is the information provided in a way that is culturally appropriate? [5.2.7] This requires consideration of the steps in achieving voluntary consent. The possibility for coercion or obligation to impact a decision should be explored. [Beauchamp & Childress 1979; NS 2.2.9; 3.1.18a,d,e]

Where **participants cannot** make their own decisions, how will researchers **empower and protect them?** [1.13]

This may entail involving an advocate, or establishing who is the statutory health attorney, guardian or parent. Legislation is relevant, and the 'next of kin' cannot be assumed as fulfilling these roles.

## TIPS

## EXAMPLE COMMENTS

*"In the participant information, please include a summary of why this study is being conducted."*

*"What is the nature of data that you propose to make available in a public repository? Please also explain this in the participant information sheets. (NS 2.2.14-16)."*

*"Please address the aspects of power imbalance whereby the Unit Coordinator and lecturers request participation of students. How (and by whom) will students be informed about the research, be approached about it, and how will a sense of coercion or obligation in participation be avoided?"*

*"In the participant information, indicate that several risks have been identified and list them."*

*"Explain limits to confidentiality that apply in relation to disclosures of harm to a child, and any other legal reporting requirements. (NS 1.7b)."*

*"Please provide more information about what you will do with the data to make it less identifiable. For example, what identifiers will you remove? (NS 3.1.40-2)"*

*"Since you will be conducting face-to-face interviews, the data will be identifiable (not re-identifiable) at the time of collection."*

*"The questionnaire asks students whether they identify with any of the following groups: "Single parent, person with a disability, Aboriginal or Torres Strait Islander, Mature Age... Please explain why collecting this infromation is necessary to answer your research question."*

*"You say participants will provide written consent, yet the recruitment email says interviews with interstate particpants will be via video-conference. How will this work?"*

*"Consider piloting the information sheets with the different ages to gauge comprehension and to adjust if required. (NS 2.2.3,4)."*