ETHICS RESPONSE FORM

<table>
<thead>
<tr>
<th>Researcher name (student):</th>
<th>Faculty reviewer name:</th>
<th>Date of Review:</th>
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<tbody>
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Working title of the research: ..........................

Research Proposal attached? 
Yes or No

Is all supplementary documentation attached? (please remove Yes/No as appropriate)

This must include:
- Risk Assessment Yes/No
- PIS Yes/No
- Consent forms Yes/No
- Debrief forms Yes/No
- Letter of authorization Yes/No
- Local ethical approval Yes/No
- Questionnaire or interview schedule as relevant Yes/No

You should also include other relevant communications you intend to use such as flyers etc.

How to use this form

These 4 columns (on this page) contain an explanation of how the form is set out and how you should use it.

The questions you need to answer will be in this column below. You must answer all of these as directed.

You write your answers in the blue column. Some of the questions have links to footnotes you can follow for definitions for some of the terminology.

The Ethics committee reviewers will check your answers to the questions on this form alongside what you have written on all the other papers you submit.

You should make sure all the forms you submit to us are accurate and consistent.

There are 3 sets of questions.

The first 12 must be answered by ALL research students. The second set must be answered by researchers collecting new data. The 3rd set by researchers who hope to research with a vulnerable group or with sensitive information.

**Researcher's ethics self-check**

- You complete this blue column. (Also complete the blue boxes above).
- In this column, the RESEARCHER (student) should do a thorough self-check before submitting the ethics form to the faculty member supervising the study.
- In each row of the blue column, the RESEARCHER should enter YES, NO, or NA as well as a very brief explanation.

**Ethics Reviewer's assessment:**

- The ethics reviewer will read ALL your documents.
- In the yellow column, the ETHICS REVIEWER (Module 7 faculty member) will enter YES, NO, or NA to confirm or challenge the RESEARCHER'S self-check on each standard or principle.
- With each NO, the ETHICS REVIEWER will tell you what revisions are required for ethics approval. The reviewer will also make a decision at the end of this form and return the form to the RESEARCHER.

**Researcher's response to Ethics Reviewer**

- This column is only used if the form needs to be re-submitted.
- You will have to re-submit it if the REVIEWER has concerns about the ethics of your work.
- Normally, you will need to change some/all of your documents.
- If you do, then you must use this column to explain how and where each of the Ethics Reviewer’s concerns (from the yellow column) have been addressed in the re-submitted materials.

**PLEASE NOTE:** After approval is given, if there are any subsequent modifications to the study once it is underway a further Ethics Response Form and re-approval will be required
Examples of the use of this form are as follows:

<table>
<thead>
<tr>
<th>The question to answer:</th>
<th>The researcher answered this question by saying:</th>
<th>The reviewer was not satisfied with the fullness of that answer, so they said:</th>
<th>The researcher then clarified:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Will data be stored securely?</td>
<td>Yes. Data files will be kept on a password protected computer.</td>
<td>No. Please also address how the paper surveys will be secured prior to being entered as electronic files.</td>
<td>Paper surveys will be in a locked file cabinet. Research Proposal (page 4) has been updated.</td>
</tr>
<tr>
<td>Has the researcher identified and then managed any potential conflicts of interest?</td>
<td>Yes. Although I am the manager of this small clinic I will not be distributing the questionnaires. I will not know which of the clients has taken and returned a questionnaire. I have explained on the PIS that my clients’ care will not be changed in any way, regardless of whether they chose to participate in my research. They will know, that I won’t know, if they have participated or not.</td>
<td>No. You need to specify this more clearly on the PIS. I understand what you think you have said, but it needs to be VERY clear.</td>
<td>The PIS has been modified with a new and clearer sentence.</td>
</tr>
</tbody>
</table>

Hover the mouse over the blue footnoted words (in the questions below) to view information and definitions which we hope will help you further.
All researchers must complete all the first 12 questions below

<table>
<thead>
<tr>
<th>Beneficence</th>
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| **1.** Is your research of benefit, and in the public interest? Explain how it is.  
(For example, what new knowledge will come from the work?)| Research should be focused towards some type of good or benefit. Use 2-3 sentences to state how your research will be likely to be beneficial and to whom. |

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<th>Non-maleficence</th>
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| **2.** Are participant recruitment and data collection steps described clearly? | Researchers should aim to do no harm and not be exploitative.  
These questions (2 – 5) are concerned with the risk that: you, your research questions, or any of your research activities could do harm in some way.  
These are risks to others and for you too.  
Tell us how you have thought about your research work and identify and then minimize all possible harm. |
| **3.** What burdens are you placing on participants?                       | For example, are you asking them to take a long journey – when they are unwell?  
Are you asking them to spend time with you, reflecting on, and then revealing, difficult things.  
Are you asking workers to spend their short break times answering a long questionnaire? |
| **4.** Is the benefit of your research, worth the burden on/to participants?  
Explain how.                                                               | Research receiving ethical approval must demonstrate that it will add to the scientific knowledge around the topic and that this knowledge is potentially of value to the scientific community and/or to a group/groups of people.  
The benefits of the research must outweigh any risks to participants. |
| **5.** Have you completed the Risk Assessment Form and evaluated risk thoroughly and carefully? Have all:  
  Actual and potential risks  
  Direct and indirect risks  
  Risks to yourself and others  
  • psychological,  
  • relationship,  
  • legal, | Spend time on your risk assessment. Make sure you understand the different types of risks that come about because of the way you want to do the research.  
These may exist now, and may be made worse, they may be direct to people, or indirect.  
They may also be risks to people’s welfare, their relationships and so on. Think about ALL of these, know you have identified as many possible risks as you can and have attempted to manage them in different appropriate ways. |
- **economic/professional**, 
- **physical**, 
- and other risks (such as accidental disclosure of information, or the creation of stigma) have been fully **acknowledged** and described?

### Potential overall gain

6. Are the benefits of this research worth the overall risks and **burdens** of it? Explain why?  
   - There are usually many different ways a research project can be designed to study an area. Once you have worked out the risks and burdens of your design you have to be sure the gain, or benefit, is worth it. State how this is the case.

### Data security, privacy and confidentiality for people in the research

7. Will the data be stored for at least 5 years? 
   - Will data be stored **securely** and how will you maintain the confidentiality of the data?  
   - You must protect the data you collect and the people you are working with in different ways.  
   - Show how you have planned for this.

8. Are participants' names or contact information to be recorded in the research records?  
   - They should not be. If they are, then why are they? You should avoid this if possible.

9. Will the research procedures ensure **privacy** during data collection?  
   - For example, will interviewees be able to participate without everyone else knowing? Could the location of your research cause the names of people to be linked with your research topic and with any data they may provide? (For example, if this is a sensitive area, and there is a small sample selected from a small population?) If you are using secondary data you should state exactly how you will remove the identifiers from the data and when.
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<tr>
<th></th>
<th>Question</th>
<th>Answer</th>
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<tr>
<td>10</td>
<td>Do the research procedures and analysis/write-up plans include procedures to ensure that participant identities are not directly or indirectly disclosed? How will you do this?</td>
<td>Then, when you have collected your data, you still have to protect people’s identities. You need to show you have thought through how you will do this successfully. Tell us how this will be achieved at different stages of management of the data.</td>
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<tr>
<td>11</td>
<td>Has the researcher identified and then managed any potential conflicts of interests? (These can arise for many reasons, and cannot be managed by a student using a research assistant).</td>
<td>COI is important, especially if you are in a position of power or authority (or were). Also, a COI can be direct and relating from your role or indirect. You must explore how you relate to the research sites and participants. You must show you can identify and then manage a COI. Remember, a student researcher cannot use research assistants to recruit participants or collect research data on their behalf).</td>
</tr>
<tr>
<td>12</td>
<td>Has the research site provided an Authorisation Letter (or email) granting permission for: • all relevant data access, • access to participants, • facility use, • and/or use of personnel time for research purposes?</td>
<td>The permission you have gained must fit with and be consistent with your methodology and the type of data you want to collect. The letter of authorisation must be issued with the organisation’s official confirmation (e-mail, signed letter etc.). It must say that you can: recruit participants within this organization and then collect a specific type of data, in a specific form. This letter should be obtained in order to get ethical approval and this MUST be prior to your data collection process. If such a letter is not obtained, students can only use public means to collect data and to identify participants.</td>
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Only researchers whose work involves recruiting participants to collect new data (such as surveys, interviews, observations) should answer the following questions.

**Recognising power and autonomy, and ensuring informed consent**

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| 13 | Are participants recruited in a way that is non-coercive? | All humans are in power relationships with each other. We want people to be as autonomous as possible and for them to give informed consent freely. They must know that they can say yes or no and it will not impact on their care or education etc. They must not be coerced.

Coercion can include:
- using an existing relationship to "encourage" participation,
- recruiting in a group setting,
- extravagant compensation,
- recruiting individuals in a context of their treatment or evaluation.

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<tr>
<td>14</td>
<td>If anyone is to be excluded from participating in the research is their exclusion justified? Is their exclusion handled respectfully and without stigma?</td>
<td>You will select a sample from a population. Those who will not be included, and those who do not give consent, must not experience negative consequences, such as stigma. How will you manage the situation for people who are not recruited?</td>
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**Other risks**

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<tbody>
<tr>
<td>15</td>
<td>Where the researcher proposes to use an interpreter to assist with communication tell us how the interpreter has been trained regarding: confidentiality and respect, the principles of informed consent, reporting accurately what is said, how they will be appropriately debriefed</td>
<td>You should avoid using an interpreter where possible. Where this is necessary you need to demonstrate you have paid attention to important areas such as these. Your research should not place the interpreter or participants under risk as a consequence of your work. Show us you can identify potential risks and how these can be managed.</td>
</tr>
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</table>
### Will this researcher be appropriately qualified and supervised in all data collection procedures?

We must be sure you can and should be in contact with your participant group, and that you are qualified to collect the data in the way you propose.

### Autonomy and informed consent (consent forms and PIS)

<table>
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<tr>
<th>Question</th>
<th>Response</th>
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<tr>
<td>Do the proposals to gain informed consent provide participants with enough time to review the study information and ask questions before they give consent?</td>
<td>We want people to want to participate in research. What will you do to make sure that people give you informed consent, freely? Specify the time people will have, and the privacy they will have, while they think about agreeing to participate. Will they be able to reflect and consult with others to help them decide?</td>
</tr>
<tr>
<td>Do the consent documents preserve the participant’s legal rights?</td>
<td>This is particularly relevant to the country that the research is conducted within.</td>
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<tr>
<td>Will informed consent be appropriately documented, and where?</td>
<td>Tell us about your consent form.</td>
</tr>
<tr>
<td>Is the Participant Information Sheet (PIS) written using language that will be understandable to the potential participants? Is it written in direct language and addressed to “you”?</td>
<td>Tell us about the population you are recruiting from. You should use local language that people will understand in your PIS. If this is not English – there needs to be an accurate English translated copy too. Don’t use jargon or specialist terminology. But, do be accurate and honest.</td>
</tr>
<tr>
<td>Does the PIS explain the sample’s inclusion criteria in such a way that the participants can understand how/why THEY are being asked to participate?</td>
<td>Be clear about the group they belong to and why you want them to participate in your work.</td>
</tr>
<tr>
<td>Does the PIS clearly state that participation is voluntary?</td>
<td>Make this very obvious.</td>
</tr>
<tr>
<td>Does the PIS disclose all potential conflicts of interest?</td>
<td>You must specify how this study is separate from your other professional roles, if this is relevant.</td>
</tr>
<tr>
<td>Does the PIS include an understandable description of the data collection procedures?</td>
<td>Make this very obvious (e.g. that they will be interviewed for one hour with a tape recording made, or will answer 20 questions on paper, for example).</td>
</tr>
<tr>
<td>Does the PIS convey that the participant has the right to decline or discontinue participation at any time?</td>
<td>Make this very obvious that people can leave your study. Tell them how you will destroy their data you have already collected up to 2 weeks after you have collected it.</td>
</tr>
<tr>
<td>Does the PIS include an estimate of the time commitment for participation?</td>
<td>This must be specific about how much time, how many times and so on.</td>
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<td></td>
<td>Does the PIS describe:</td>
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<tr>
<td>26</td>
<td>any thank you gifts, compensation, or reimbursement to participants (for travel costs, etc.) or lack of?</td>
</tr>
<tr>
<td>27</td>
<td>Does the PIS include a description of reasonably foreseeable risks or discomforts?</td>
</tr>
<tr>
<td>28</td>
<td>Does the PIS include a description of anticipated benefits to participants and/or others?</td>
</tr>
<tr>
<td>29</td>
<td>Does the PIS describe how privacy will be maintained?</td>
</tr>
<tr>
<td>30</td>
<td>Does the PIS explain how the participant can contact the researcher's supervisor and the Dean of Online Studies?</td>
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</table>
Only researchers whose work involves sensitive content and/or working with vulnerable participants need answer these questions.

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<th>Answer</th>
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<tbody>
<tr>
<td>31</td>
<td>If vulnerable individuals will be specifically sought out as participants, is such targeted recruitment justified by a research design that will specifically benefit that vulnerable group at large?</td>
<td>These questions regarding sensitive content and vulnerable populations should be reviewed and addressed by the researcher (student) and faculty reviewer. They must also be confirmed by the Roehampton Online Research Ethics Committee before the study may go ahead. You started to state this earlier. If you have chosen to work with people in a vulnerable group you must be clear about why this work is essential. It must be clear there will be minimal/no risk of harm to them and also that this will benefit the group as a whole in an important way. It must be worth it to them. The benefit must be clearly describable.</td>
</tr>
<tr>
<td>32</td>
<td>If the researcher is in a trusted or authoritative role to the participant (e.g., health care provider, teacher etc.), do the recruitment procedures ensure voluntary participation?</td>
<td>You also started to state this above. But if your group is considered vulnerable you must be particularly clear about this here too.</td>
</tr>
<tr>
<td>33</td>
<td>If the research procedures might reveal or create an acute psychological state that necessitates referral, are there suitable procedures in place to manage this?</td>
<td>Research must do minimal/no harm. Sometimes we can do harm without having intended to. How will you know if you have caused your participant any distress? Are there appropriate, confidential and accessible services people can access if they need to? How will you tell them about these?</td>
</tr>
<tr>
<td>34</td>
<td>Are limits to confidentiality (i.e. your duty to report) appropriately mentioned in the Participant Information Sheet? If the research procedures might reveal:</td>
<td>Research must do minimal no harm. Sometimes a researcher may find out that a law has been broken or that some kind of abuse is taking place. You are obligated to report this appropriately. Thus, participants must know the limits there are to the confidences you will keep. Tell us how you will tell participants about this.</td>
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### Education Programmes only

<table>
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<tr>
<th>35</th>
<th>Does the research fall under the definition of usual curriculum or other institutional activities (see definition below) and do you have (or will obtain before research begins) the written approval for your research project from a senior member of school staff (or organization) with legal responsibility?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition of usual curriculum:</strong></td>
<td><strong>Usual curriculum</strong> is invoked when a student researcher wishes to conduct research with a vulnerable population, e.g. under 16 years old, or where a power relationship exists, e.g. teacher and their student, but may be granted if certain criteria are fulfilled.</td>
</tr>
<tr>
<td>• The research involves the preparation, delivery and assessment of classes that are part of assigned class/subject allocation for the academic year;</td>
<td>The full definition and guidelines for Usual Curriculum are available in the Centre for Student Success Research Project pages (ethics section).</td>
</tr>
<tr>
<td>• The content being delivered to students during the research follows the standard curriculum for the subject;</td>
<td></td>
</tr>
<tr>
<td>• Work is conducted with the entirety of the student group with whom the instructor normally works.</td>
<td></td>
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- criminal activity,
- child/elder abuse,
- employer policy non-compliance that necessitates reporting, are there suitable procedures in place for managing this?
This whole document must be posted in the ‘ethics’ thread/forum in the student researcher’s classroom after the supervising faculty member has made a decision.

The Research Proposal faculty member will mark an **X** next to box A, B, or C.

If box A or B is marked, then the Research Proposal faculty member will also mark an **X** next to the applicable subcategory (1,2,3)

### A. APPROVED VIA EXPEDITED (LIGHT TOUCH) ETHICS REVIEW:

- As the Research Proposal faculty member, I confirm that all questions above are answered with either a “Yes” or “N/A.”
- I understand my responsibilities, and will ensure to the best of my abilities that the student investigator abides by the University’s policy on Research Ethics at all times.
- I affirm that the research activities fall entirely within the parameters of the design indicated with an X below (1, 2 or 3) that the Roehampton Online Research Ethics Committee has authorized faculty members to approve via the expedited (light touch) review:

**For Education programmes only:** Where 35 is met with a “Yes”, Programme Director approval is indicated below

<table>
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<tr>
<th>Date:</th>
<th>PD Name:</th>
<th>PD Signature:</th>
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1. The proposed study is analysis of **public** documents, artifacts, behaviour or data.

2. The proposed study is secondary analysis of **existing** data that is privately held but released for research purposes (with all identifiers removed).

3. The study will use surveys or interviews of **non-vulnerable** adults on **non-sensitive** topics (i.e., there is no potential to participants of coercion, distress, loss of work/school time, damage to professional reputation etc).

**Note:** Vulnerable populations include children, clinic patients, prisoners, military personnel, facility residents, anyone over whom the researcher holds authority (e.g., students, subordinates etc), anyone who might feel undue pressure to participate in the study, and any individuals with severe enough mental disabilities to interfere with their capacity to consent to the study.
## B. REFERRED TO ETHICS COMMITTEE BY THE MODULE 7 FACULTY:

- **As the initial reviewer, I am referring this study to the full ethics committee (ROREC) as indicated below [please mark 1, 2, 3, 4 or Other below].**
- **I will email the student’s ethics application and all attachments as a single zip file to the ethics committee via Ethics@roehampton-online.com, copying the Programme Director.**

  The ethics committee can accept applications at any time, but only meets every 2 weeks. Applications will need to be with reviewers for one week prior to the meeting where they will be considered. Decisions and feedback will be emailed to the student and Research Proposal faculty member within 5 business days after the 4th Thursday of the month.

1. Referred because the researcher proposes to collect data from vulnerable individuals such as children, clinic patients, prisoners, military personnel, facility residents, anyone over whom the researcher holds authority (e.g., students, subordinates etc), anyone who might feel undue pressure to participate in the study, or any individuals with severe enough mental disabilities to interfere with capacity to consent to the study.

2. Referred because some (potential) participants may find the research topic or premise sensitive.

3. Referred because participants’ jobs or livelihoods may be placed at risk by the study activities.

4. Referred because the participants’ culture and/or international location suggest that extra participant protections may be necessary.

   Other: _____

## C. REVISIONS REQUIRED:

The student needs to revise the proposal and ethics materials to address the concerns in the yellow columns and resubmit to me before I can select A or B above.
A conflict of interest is caused when the researcher has some additional role or roles in the research context, such as being a parent, teacher, therapist, investor, business-owner, manager, etc. Conflict of interest must be managed to ensure that the research reveals “truth,” not just the outcome that the researcher might desire to see due to their other role.

Examples of “new knowledge” include: effectively addressing a gap in the literature, generating new theory, enhancing understanding of a phenomenon, assessing effectiveness of a particular professional practice, addressing a local practical problem via data analysis.

In order to weigh potential risks against benefits, the researcher first needs to plan and clearly articulate all of the following that apply:

- how existing data or contact information of potential participants will be obtained, format and context of the initial contact with potential participants, informed consent procedures, assignment to groups (if applicable), description of any pilot activities, data collection steps, transcript review and/or member check (if applicable), and how results will be shared with stakeholders.

All research activities place some degree of burden on the participants by asking the participants to share personal information, volunteer time, and assume risks.

Examples of “minimal risk” include: data collection delivered outside of regular activities. It is important to maintain an “opt in” dynamic rather than implying that employees/students/group members are expected to participate.

Examples of “minimal risk” include: data collection delivered outside of regular activities. It is important to maintain an “opt in” dynamic rather than implying that employees/students/group members are expected to participate.

Footnotes

1. Any research activity must take extra precautions to ensure that potential participants are not pressured to take part in their study.
2. The responsibility of the researcher is to protect the identity of a participant. So the researcher must be cautious about proposing data collection that could be used in ways that would potentially lead to the identity of a participant. For example, an EAP worker may have access to personal information about a student, but may not want to collect data on that student because they fear that the data could be used to identify the student.
3. Relationship risks are present if the recruitment or data collection process is likely to alter the existing dynamics between the researcher and participant (who may be coworkers or have some professional relationship), among participants (if they know one another), or between the participant and the participant’s friends, coworkers, or family members.
4. Minimal risks are acceptable but must be identified upfront. Minimal risk is defined as when: “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.”
5. All research activities place some degree of burden on the participants by asking the participants to share personal information, volunteer time, and assume risks.
6. Psychological risks include stress greater than what one would experience in daily life (e.g., materials or topics that could be considered sensitive, offensive, threatening, degrading).
7. Economic/professional risks are present if data collection could result in the participant disclosing violation of workplace policies, disagreement with leadership decisions, poor work performance, or anything else that could be damaging to the participant’s relationship, professional reputation, promotability, or employability. Risks are acceptable but participants need to be made aware of professional risks during the consent process so they can make an informed decision.
8. Physical risks are not common in social science research but would involve risk of serious physical injury to the participant or the researcher.
9. Legal risks are present if data collection might result in a participant’s disclosure of violation of laws.
10. A conflict of interest is caused when the researcher has some sort of dual role in the research context, such as being a teacher, therapist, investor, business-owner, manager, etc. Conflict of interest must be managed to ensure that the research reveals “truth,” not just the outcome that the researcher might desire to see due to their other role.
11. No documentation of permission is required (a) if the researcher will simply be asking organizations to distribute research invitations on the researcher’s behalf, or (b) if the researcher is using only public invitations. If the researcher is using private invitations (e.g., email), then permission is required (c) if the researcher is using public invitations and the researcher is a manager researcher who must have the authority to authorize the study, or (d) if the researcher needs to have the authority to author a study, but cannot obtain permission to do so from another psychologist’s practice; a manager researcher may conduct ANONYMOUS data collection so that subordinates do not perceive their responses or [non]participation as being associated with their job standing.
12. It is not ethically acceptable to invite a “captive audience” to participate in research on the spot (i.e., to ask an entire class or a group of meeting attendees to complete a survey during their session). Such a dynamic would not provide sufficient privacy or respect for their right to decline research participation. However, a researcher may use the last few minutes of a meeting to introduce a study and distribute materials, such that the potential participants can then take their time to decide later about participation.
13. Generally, data collection cannot be approved during work hours or school hours unless a “free period” has been identified (e.g., lunch) so the research activities can be separated from the participants’ regular activities. It is important to maintain an “opt in” dynamic rather than implying that employees/students/group members are expected to participate.
*When applicable, the exclusion criteria should be listed on the recruitment material (flyer, invitation email, etc.) or participant information sheet (PIS) to prevent situations in which the researcher rejects volunteers in a stigmatizing manner.

*Researchers must be able to document their training in the data collection techniques and the ethics committee might require the researcher to obtain additional training prior to ethics approval. For most student researchers, the research course sequence is sufficient but some research procedures (such as interviewing people with mental disabilities) may require additional training. For psychological assessments, the manual indicates specific qualifications required. Data collection from children requires a background check/clearance through a local agency.

Remote supervision is suitable for most studies but onsite supervision may be required for certain types of sensitive data collection (e.g., interviews or assessment regarding emotional topics).

Informed consent is not just a form; it is a process of explaining the study to the participant and encouraging questions before the participant makes a decision about participation.

The consent forms/process should not ask a participant to waive any legal rights.

While documenting consent via signature is common, note that anonymous surveys can obtain “implied consent” by informing the participant, “To protect your privacy, no consent signature is requested. Instead, you may indicate your consent by clicking here/returning this survey in the enclosed envelope.” It is also acceptable to audio record verbal consent for interviews, in order to not have any record of the interviewee’s name.

The ethics committee encourages tailoring the language to the readers as long as a professional tone is maintained.

People receiving the PIS should not be left wondering, “How did the researcher get my name?” or “Why am I being invited and not others?” or “Does the researcher already know private information about me?” The means by which the researcher has identified and contacted the potential participant needs to be made clear, if it is not already clear from the context. Sample explanations of inclusion criteria in PIS: (a) The human resources department has forwarded this invitation to all employees who meet the researcher’s study criteria (i.e., have been with the organization at least 2 years and have transitioned into a managerial role within the past year); or (b) The researcher is inviting all attendees of the past year’s XYZ professional conference to be in the study; or (c) The researcher will be randomly selecting possible participants by approaching the residents of every 5th home in this neighborhood until 100 responses are obtained.

When the researcher is already known to the participant, the PIS must include written assurance that declining or discontinuing will not negatively impact the participant’s relationship with the researcher or (if applicable) the invitee’s access to services.

Provide an estimate (in minutes or hours) of each component of data collection (e.g., survey, interview, member checking, etc.)

Describe only the possible harms that go beyond the risks of daily life.

For most social science studies, it is appropriate to state that there are no particular direct benefits to the individual. In this case, just present the benefits to society.

The PIS should explain that the research report will not include names and that the data will not be used for any purposes other than research. It is not always clear to participants how a research interview is different from a journalistic interview, in which informants might be named. So the PIS should also describe any coding system that will permit the researcher to not use names. For sensitive interviews, the researcher might also want to assure participants that recordings will be destroyed immediately after transcription.

Vulnerable participants include children, clinic patients, prisoners, military personnel, facility residents, anyone over whom the researcher holds authority (e.g., students, subordinates), anyone who might feel undue pressure to participate in the study, and any individuals with severe enough mental disabilities to interfere with capacity to consent to the study. Pregnant women (and their unborn children) are only considered a vulnerable population when a study involves physically risky data collection.

Targeted recruitment of vulnerable participants can only be approved when the ethics committee determines that the study’s benefits justify its risks/costs.

A researcher with a dual role must use anonymous surveys or some other method that permits potential participants to opt out without fear of negative consequences. Patients, students, and subordinates of the researcher need explicit assurance that their decision about participation will in no way impact their ongoing relationship with the researcher.

Any limits to confidentiality (i.e., duty to report) must be mentioned in the participant information sheet (PIS).