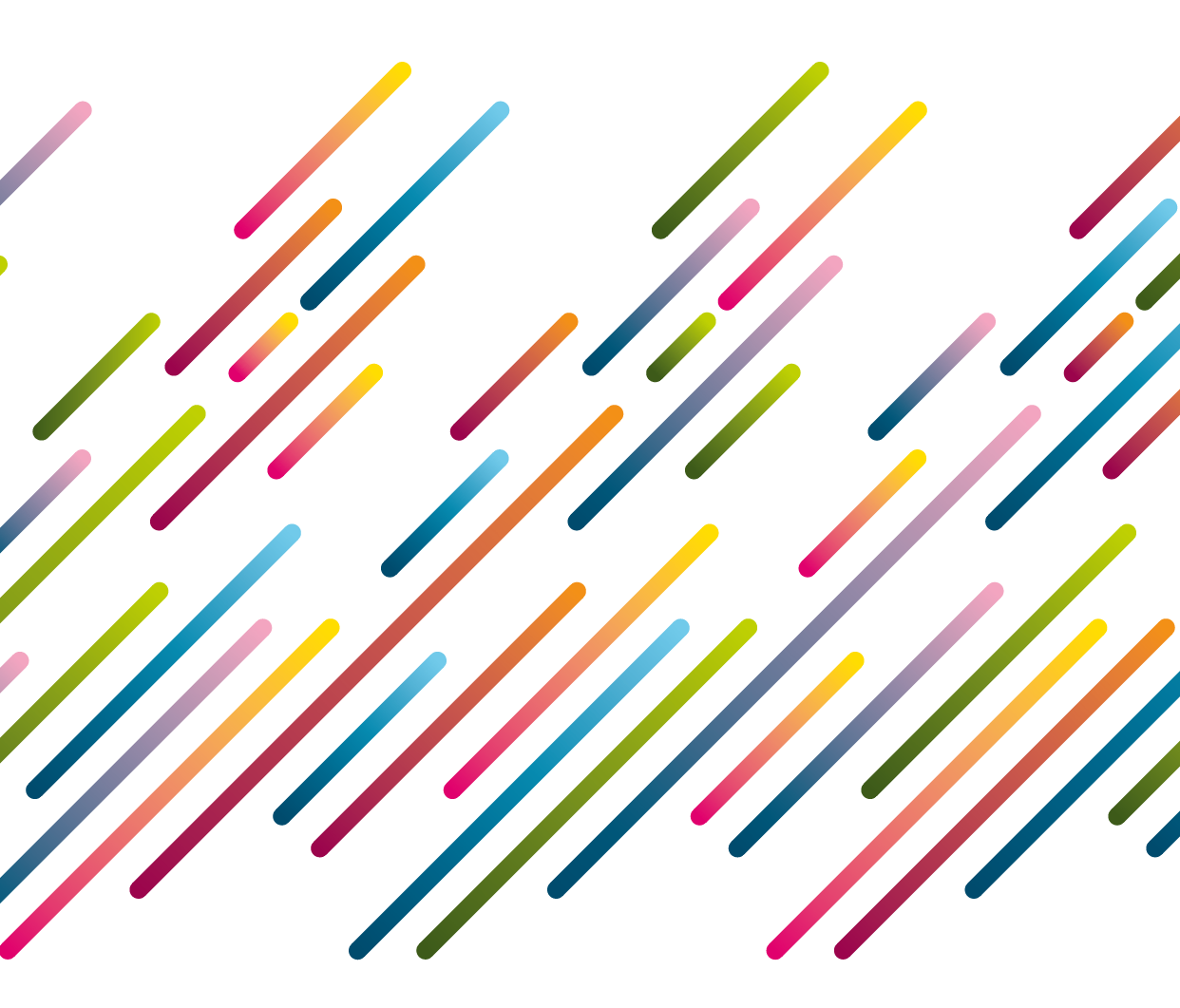
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**Ethics Handbook**

**School of Health & Social Care**

**Research & Integrity Committee**

**March 2021**





The Purpose of the Ethics Handbook:

* To make applicants aware of the standards of the [University Code of Practice for Research Integrity 2018](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf). It is essential that applicants read the code prior to completing the ethics application.
* To outline the University’s commitment to the [Universities UK’s Concordat to Support Research Integrity.](https://www.universitiesuk.ac.uk/policy-and-analysis/research-policy)
* To call attention to the important governance and regulatory requirements required for health and social care research studies involving human participants.

This document concentrates on School of Health & Social Care (SHSC) specific information and explains the requirements for NHS ethics application processes and sponsorship review. Members of the SHSC ethics committee will be happy to meet to discuss aspects of the ethics application processes in further detail as required. Information and supporting documents can be found on the [SHSC Research & Integrity Website](https://www.napier.ac.uk/research-and-innovation/research-search/school-research/school-of-health-and-social-care/research-ethics-shsc).

Please be aware that the [University Research Integrity Committee](https://staff.napier.ac.uk/services/research-innovation-office/Pages/Research-Integrity.aspx) (URIC) oversees the governance policies, procedures and practices across the University and will provide Cross University Ethics Review (please contact the URIC clerk for further information).

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Health Research Governance

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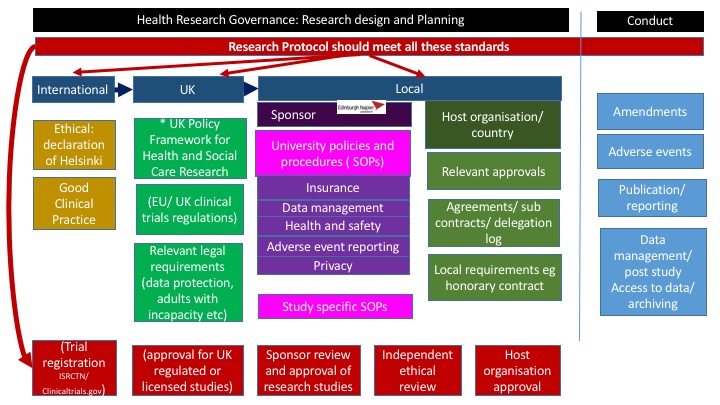
Research Governance concerns setting standards to improve research quality and safeguard the public.

It involves:

* + enhancing ethical and scientific quality
  + promoting good practice
  + reducing adverse incidents
  + ensuring lessons are learned
  + preventing poor performance and misconduct

A broad range of regulations, principles and standards of good practice exist to achieve, and continuously improve, research quality across all aspects of healthcare in the UK and worldwide.

Health research is required to meet the international, national and local standards outlined below:



How to Apply

3

***Applicant Responsibilities***

1. It is the applicant’s responsibility to determine if their study requires ethical review. However, it is important for researchers to consider the ethical risk of their study which involves human subjects or personal data. All research involving human participants, their tissue or personal data must be subject to research ethics review. This may also include studies where the intention is to submit to publication or coursework. If you are uncertain if your study requires ethical review, please contact [ethics.SHSC@napier.ac.uk](mailto:ethics.SHSC@napier.ac.uk) to discuss the ethics application prior to submission
2. Staff and post-graduate research (PGR) students will need to complete an online application provided in the [Worktribe Ethics Application Facilities](file:///Users/annerowat/Downloads/Please%20go%20to%20the%20system%20at:%20https:/napier-research.worktribe.com). The ethics application may relate to a funded project or can exist independently (i.e. non-funded project) as a stand-alone ethics application in Worktribe. Please note that the full ethics application is found using the Ethics menu. Applicants should only need to create a full ethics application after the project is awarded funding unless the funder requires ethical pre-approvals.
3. Undergraduate and postgraduate taught students will need to complete a word version of the application found on the [SHSC Research & Integrity Website](https://www.napier.ac.uk/research-and-innovation/research-search/school-research/school-of-health-and-social-care/research-ethics-shsc) and should submit an electronic version of the application and all supporting documents to [ethics.SHSC@napier.ac.uk](mailto:ethics.SHSC@napier.ac.uk) for review.



Online Worktribe Ethics Application

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The University has switched to using the online Worktribe Ethics system that provides facilities for submitting and managing ethical approval for research activity.

The online system will help applicants submit and track their application and will facilitate the Research Ethics and Integrity Committees to conduct reviews, provide feedback and approve applications. Managing ethics reviews and approvals on Worktribe system aims to ensure greater transparency, ethical compliance and research integrity.

This online system is available to Edinburgh Napier staff and PGR students only. The PGR student’s application will be assigned to both the student and the supervisor, but only the supervisor can submit for review.

To access the Worktribe system via the Virtual Private Network (VPN, please see: [https://staff.napier.ac.uk/services/cit/OffCampusServices/Pages/RemoteNetwork.aspx)](https://staff.napier.ac.uk/services/cit/OffCampusServices/Pages/RemoteNetwork.aspx), please use the following links and log in with your ENU username and password to Worktribe at: [https://napier-research.worktribe.com/](https://napier-research-test.worktribe.com/)

To help create the ethics application please use the [ethics applicant user guide](https://livenapierac.sharepoint.com/sites/rio/Worktribe/Worktribe%20Training%20Documents/Forms/AllItems.aspx?id=%2Fsites%2Frio%2FWorktribe%2FWorktribe%20Training%20Documents%2Fworktribe%2Dethics%2Duser%2Dguide%2Djun%2D20%2Epdf&parent=%2Fsites%2Frio%2FWorktribe%2FWorktribe%20Training%20Documents), which can be found on the [Worktribe Training page](https://staff.napier.ac.uk/services/research-innovation-office/rms/Pages/RMS-Training.aspx). [Worktribe training videos](https://onlinevideo.napier.ac.uk/Browse/Category/5501) are also available to provide guidance on how to complete the online application.

Any errors in completion of forms on worktribe can results in delays in ethical approvals so please contact [ethics.SHSC@napier.ac.uk](mailto:ethics.SHSC@napier.ac.uk) [for advice](mailto:https://staff.napier.ac.uk/services/corporateaffairs/photography-logos-branding/Pages/Data-protection.aspx) if you are uncertain of when and how to create your full ethics application using the worktribe system.

Please be aware that ethics applications should not be linked with a funded project unless it has received external funding or RIE competitions funding. Applicants should only need to create a full ethics application after the project is awarded funding unless the funder requires ethical pre-approvals. Pre-awards requirements you will complete a “checklist” that needs to be completed on the worktribe project records only (please note the pre award checklist is not reviewed by the ethics committee).

The ethics application can be created as a standalone application if the project is unfunded, it should **not** be linked with a project on the worktribe system.

The ethics application can be found in the Ethics menu item and then select **create application** in order to generate the application form that you need to complete for review by the ethics committee. The number of questions you need to complete will be based on the answers you provide on the project tabs. The majority of ethics applications submitted to SHSC is likely to include the following tabs:

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Summary | Details | Scope | Methodology | Human Participants | Data Management | Documents | Versions | Comments |

It is recommended that you read the “Additional guidance for some questions” section in the worktribe [ethics applicant user guide](https://livenapierac.sharepoint.com/sites/rio/Worktribe/Worktribe%20Training%20Documents/Forms/AllItems.aspx?id=%2Fsites%2Frio%2FWorktribe%2FWorktribe%20Training%20Documents%2Fworktribe%2Dethics%2Duser%2Dguide%2Djun%2D20%2Epdf&parent=%2Fsites%2Frio%2FWorktribe%2FWorktribe%20Training%20Documents) (see page 8), because how you answer the question may increase or reduce the number of tabs and questions that you will be required to complete. For instance, it is expected that all projects except those that require NHS REC/external ethical review will be required to complete the **Human Participants** section on the form. If this section is missing it may be because you have not selected “**no**” to external ethical review. Please note that external “permissions” to recruit NHS staff as participants or use secondary data (i.e. PBPP; eDRIS) are not considered external NHS REC ethical review for purposes of Worktribe application, but these services do provide “permissions” to access NHS staff, sites or data. Therefore it will be expected that the full SHSC ethics application is completed including the section related to **Human Participants**.

Incomplete applications or failure to provide sufficient detail in the free text boxes within the form (e.g. it is not sufficient to just refer to supporting documents such as the data management forms in the application) or if there are missing supporting documents will result in the application being returned for completion before it will be reviewed by the SHSC ethics committee.

Taught Student Application

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All undergraduate and postgraduate taught projects carried out as part of a research or dissertation module fall under the [University Code of Practice for Research Integrity 2018](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf). Within the terms of the code of practice all research involving human subjects, their data or human tissue, requires ethical review. Evaluation studies, Public Engagement and audit that include human subjects or projects that collect any identifiable personal data also require ethical review.

Students on undergraduate and postgraduate taught programmes do not have access to the worktribe system. Applications for undergraduate or taught postgraduate student projects must be completed using the SHSC Ethics Application form found at [SHSC Research & Integrity Website](https://www.napier.ac.uk/research-and-innovation/research-search/school-research/school-of-health-and-social-care/research-ethics-shsc). The application, all supporting documents (see the Documents Checklist, section 15) and permissions to recruit participants must be submitted to [ethics.SHSC@napier.ac.uk](mailto:ethics.SHSC@napier.ac.uk) for proportionate review that will depend on whether the research is deemed to be low, medium or high risk.

Supervisors are responsible for the conduct of the research and should approve the application prior to submission. A formal research protocol, which should be proportionate to the level of studies, must be developed and agreed prior to completion and submission of the ethics application. We recommend the HRA guidance at <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/> that includes protocol templates for qualitative and CTIMP studies and NIHR templates for clinical protocols at <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>.

For the purposes of processing research data as part of a degree course, supervisors will advise on good research practice and data protection issues and make suggestions about how the research is conducted. Undergraduate and Postgraduate Research/Dissertation advice related to processing research data can be found at: <https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx>

NHS Research

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Research involving the following is likely to be classed as clinical and requires approval from an NHS Research Ethics Committee (REC) and/or R&D approvals using the Integrated Research Application System (IRAS), including:

* Patients and users of the NHS
* Relatives or carers of patients and users of the NHS
* Access to data, organs or other bodily material of past and present NHS patients
* The use of, or potential access to, NHS staff and/or premises/facilities (please contact the local NHS R&D office for formally confirming management permission for research including their staff or site). For further information go to the [NHS Research Scotland Permissions Co-ordinating Centre](https://www.nhsresearchscotland.org.uk/services/permissions-co-ordinating-centre/permissions).
* Individuals under the care of social or community care professionals, local authorities or prison, including adults who lack mental capacity.

Note even if NHS REC ethical approvals are required, the SHSC ethics committee is required to review a draft of the IRAS application for sponsorship review

All research undertaken with the NHS must comply with the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)and will need review and permissions from [NHS/HSC R&D Scotland](https://www.nhsresearchscotland.org.uk/services/research-ethics) before it can go ahead.

**Applicant Responsibilities**

* 1. All NHS research projects require sponsorship review by the University before they can be forwarded to an NHS REC for ethical review. Where Edinburgh Napier University is not the research sponsor then written confirmation from the agreed sponsor is required prior to submission.
  2. Decide if the project is classed as research. This can be established from guidance from the [Health Research Authority (HRA)](https://www.hra.nhs.uk/) UK Policy Framework for Health and Social Care Research using the [HRA decision tools](http://www.hra-decisiontools.org.uk/research/) to determine if research and/or requires [NHS REC review](http://www.hra-decisiontools.org.uk/ethics/).
  3. If you are unsure if the study is classed as research, service evaluation or audit please consult the [NRS defining research table](http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf). It is also recommended that you discuss the proposal with the SHSC ethics committee convenor and/or send your protocol to the local [R&D office/nodal](http://www.nhsresearchscotland.org.uk/services) for advice prior to completing the [IRAS form](https://www.myresearchproject.org.uk/Signin.aspx).
  4. If the project is deemed research the application should be completed using the [IRAS form](https://www.myresearchproject.org.uk/Signin.aspx), which should be uploaded via the worktribe system for sponsorship review (please note this will not be signed off by the University sponsor until they have been notified that sponsorship review has been completed and approved by SHSC ethics. Supervisors must submit an IRAS application for sponsorship review on behalf of a student.

* 1. It is important to be aware that if the study is classed as service evaluation or audit ([NRS defining research table](http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf)). Audit and service evaluation projects do not require NHS REC review, but they will still require SHSC ethics approval that must gain relevant permissions from the Quality Improvement Team (QIT) or Clinical Effectiveness Facilitator from the relevant health board/s (please make that the sure the online worktribe ethics application includes a **Human Participants** tab prior to submission of these projects).
  2. Studies that apply to the Public Benefit and Privacy Panel (PBPP) for Health and Social Care (PBPP) research requesting access to NHS Scotland data will need to engage with eDRIS to develop an application that will provide authorisation, permissions and certifications to access the data. A PBPP study will still require SHSC ethics approval (please make sure the online worktribe application includes a **Human Participants** tab)
  3. Check who is should be the Chief investigator for the NHS REC study and if the named principal investigator of the project is a staff member at Edinburgh Napier University. For PGR or PG/UG taught projects the supervisor must be the named the Chief Investigator and take responsibility for the IRAS process and submission of the project for ethical review. There are some exceptions when a PGR student with clinical expertise may be the named Chief Investigator, but only on an educational IRAS form, but this should be checked if appropriate in advance prior to completion of the form (see section 9.3 in the [HRA guidance](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/) related to chief investigator and exceptions).
  4. If you are non-NHS staff wishing to carry out research in the NHS, identify whether you need an NHS Research Passport. The research passport provides a mechanism for pre-engagement information about the researcher to be shared with the relevant NHS organisation.
  5. Ensure your research has adequate insurance. All projects need to enclose a [certificates of insurance](https://staff.napier.ac.uk/services/finance/Pages/InsuranceCertificates.aspx) with their IRAS application. Please check these in advance of submission of your application and contact
  6. Post award please send a copy of the authorisation letter to the committee administrator and post on worktribe if required.

Please contact SHSC ethics convenor for school queries related to healthcare research governance and sponsorship review for NHS research studies.

For further information related to NHS research ethics structures in Scotland and contacts, see: <http://www.nhsresearchscotland.org.uk/services>.

The [Academic and Clinical Central Office for Research Development](https://www.accord.scot/) (ACCORD) for NHS Lothian also has specific guidance related to:

* IRAS: <https://www.accord.scot/research-access/study-development>
* R&D approvals: <https://www.accord.scot/research-access/approvals>
* Caldicott Guardian: <https://www.accord.scot/research-access/go-study-mangement>
* Public Benefit and Privacy Panel (PBPP) for Health and Social Care (PBPP): <https://www.informationgovernance.scot.nhs.uk/pbpphsc/>
* ISD Scotland and electronic Data Research and Innovation Service (eDRIS) is found at Public Health Scotland: <https://www.isdscotland.org/Products-and-Services/eDRIS/>

Vulnerable Groups

7

It is important to ensure respect for the dignity and autonomy of research participants. Certain people or groups of people may be considered potentially more vulnerable than others, for example: children and young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship (see the [University Code of Practice for Research Integrity 2018](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf) - [guidance Note 5](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/CoP%20version%203%20-%20Research%20Guidance%20Note%205.pdf): Research involving vulnerable groups).

#### Approval of research involving adults lacking mental capacity

Research involving adults lacking mental capacity must be approved by an ethics committee, which will depend on the type of study and where in the UK is taking place. Guidance can be found at <http://www.hra-decisiontools.org.uk/consent/principles-ALC-Scotland.html>

Legal frameworks and national requirements in Scotland include:

* [Adults with Incapacity (Scotland) Act, 2000.](https://www.legislation.gov.uk/asp/2000/4/contents)
* [Medicines for Human Use (Clinical Trials) Regulations, 2004](https://www.legislation.gov.uk/uksi/2004/1031/contents/made) – applicable to CTIMP research only.

Applications under the Adults with Incapacity Act relating to research including those outside the NHS will be accepted for review by NHS Research Ethics Committees. [Scotland A Research Ethics Committee](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/scotland-research-ethics-committee/) can only provide ethical opinions for the purposes specified in section 51 of the Adults with Incapacity (Scotland) Act 2000.

***Approval of research involving children and young people***

All studies involving children and young people should seek to be inclusive and accessible and pay due regard to the child’s best interests, especially with respect to safeguarding the health and wellbeing of the child participant. There is specific [HRA guidance](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-involving-children/) on the requirements for participant information, consent and assent in Scotland. It is best practice to ensure that all research participants fully understand the research and can provide informed consent. A child under 16 cannot legally consent and the researcher should ask a parent or guardian for consent. Wherever possible, consent should also be sought from any children involved in the research, so they have opportunities to make their own decisions as well as ensuring they're willing participants.

Overseas Research

8

All research carried out overseas (in part or entirely) must uphold the University’s ethical standards while also being cognisant of local expectations, practices and laws. Any research that would require ethical review when carried out in the UK should similarly be subject to appropriate ethical review when carried out overseas and must meet UK standards. Please see (see the [University Code of Practice for Research Integrity 2018](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf) – [guidance note 8](https://staff.napier.ac.uk/services/research-innovation-office/Pages/Research-Integrity.aspx)).

Review must be sought from the SHSC/University ethics committee and also from a research ethics committee in the country in which the research is to take place. This will require partnership with an institution within that country. University approval to start the research will be subject to evidence of in-country ethical/ governance approval. It is advised that researchers should always seek advice from their school-level research ethics committee and University governance before seeking ethical approval for a project through an overseas ethical review process.

9

Research Requests from External Researchers

All researchers from other institutions who request to recruit Edinburgh Napier University (ENU) staff or students as participants in their research studies should provide evidence that they have been through ethical review at their institution prior to submitting a request. The SHSC ethics will not require then to duplicate ethical review. However, the University needs to be satisfied that there has been appropriate ethical review and will request copies of the approved ethics application, supporting documents and approval letters from the researcher’s institution for review, including:

* There should be justification why ENU staff and/or students need to be recruited for the study.
* Potential risks to participants or conflicts of interest are identified
* Details of the intended recruitment method(s), including study-specific documents such as participant information sheets, consent forms, privacy notice, data management plan, data collection forms, posters etc.
* Include reference to the ethics committee that has reviewed and approved the study

The researcher must provide assurance that suitable governance and sponsorship, insurance arrangements and data management processes are in place as ENU will not be liable for the research. If the research is targeting a specific group of SHSC staff or students (e.g. students taking a particular course, specific student societies or groups) the researcher must first obtain the relevant approval, e.g. from the Dean of School (to access staff) and/or programme leader or appropriate module leaders (to access students). When requesting permissions to recruit staff or students the following questions should be addressed:

* How many staff/students involved?
* How will participants be recruited?
* When and where would their participation take place?
* How long will the study take?
* Are there resource implications in terms of staff time?
* Would the involvement of staff/students likely cause disruption to teaching/studies?

Upon review by the SHSC ethics committee a letter will be sent to the researcher(s) stating that the proposed research has been judged as meeting appropriate ethical standards and it is expected that the research will be conducted to the same ethical standard as those expected of ENU staff and students. The letter will also make clear that in the case of any queries, advice should be sought from the relevant institution’s research ethics committee.

Public Involvement and Engagement

10

Patient and public [involvement](https://www.spcr.nihr.ac.uk/PPI/resources-for-researchers/involvement-in-research) (is usually defined as actively involving people on a specific research project) and [engagement](https://www.spcr.nihr.ac.uk/PPI/resources-for-researchers/engagement-with-research) (usually encompasses the various ways in which the activity can be shared with the public) is an important and expected component of health-related research. PPIE can also include opportunities for the public to contribute to the design and conduct of the research, provide input to interpret the findings and advise on dissemination activities.

[PPE activities](https://www.spcr.nihr.ac.uk/PPI/resources-for-researchers/engagement-with-research) that include human data, for example through interviews, focus groups or questionnaires, are likely to include the collection of personal information. The [General Data Protection Regulation (GDPR) 2018](mailto:https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) regulates the type of personal data that can be held and has stricter regulations on where data can be stored. Therefore, it is important to think about what information you may require for your PPIE activity. Best practice is to not ask for any personal information for which you do not require to collect. It is important to be transparent on what and how personal data will be used and where it will be stored. Therefore, a detailed information sheet, privacy notice and consent may be required prior to collection of data.

It is also important to be aware that photographs, videos and any digital image of a person are also considered personal data. All pictures taken by University staff are subject to the GDPR and Data Protection. The University [consent forms](https://staff.napier.ac.uk/services/corporateaffairs/photography-logos-branding/Pages/Data-protection.aspx) that must be signed by participants before any picture and video can legally be used.

For any further questions on how GDPR might affect you PPIE activities please go to [Public Engagement](https://www.napier.ac.uk/research-and-innovation/public-engagement) webpage or contact [ethics.SHSC@napier.ac.uk](mailto:ethics.SHSC@napier.ac.uk) for advice.

Social Media Research

11

[Social media](https://staff.napier.ac.uk/services/corporateaffairs/pr-and-social-media/Pages/Social-media.aspx) platforms are increasingly being used by researchers to collect data. Social media does not mean public domain and it may not be intended for a general public audience. Researchers using social media data should always seek ethical approval to ensure an ethical approach is taken in data collection, analyses and re-use of data collected using social media platforms.

The following should be addressed in the application:

* The data collection must be compliant with all terms and conditions of the University.
* Researchers must read through the relevant terms and conditions of the specific platform that will be used to obtain data, in particular consider terms relating to third parties wishing to access data. Some services restrict viewing messages/posts only to those who log in, which indicates an intention of only sharing the data amongst users of the service. Permissions from the platform may be required to access data.
* Please note using personal data for research equals using it for another purpose. Just because personal data is in the public domain does not mean that individuals expect it to be used for another purpose. Therefore, you will need to inform and seek consent from your intended research participants.
* Traditional informed consent may be difficult when collecting social media data, however the researchers should aim to be transparent and open about their research, including how the data is being used, processed and shared.
* A Privacy Impact Statement must be included and should identify privacy and risks for the social media user, including whether the data is in public domain, inclusion of vulnerable groups or sensitive data.
* Suitable data management, storage, security and copyright provisions need to be in place.
* State if the data is anonymised and how it will be published.

Risk Assessment and Level of Review

12

The risk will be determined from the application and will dictate the level of review as follows:

|  |  |  |
| --- | --- | --- |
| **Risk** | **Criteria** | **Review parameters** |
| Low | Literature only; Public Anonymised data | 1 reviewer |
| Medium | Not identified as low or high risk | 2 reviewers |
| High | Vulnerable groups; Deception; Special category personal data; Research involving deceased persons, human tissues or cells; Research of Interventions; Overseas studies | 2 reviewers and committee or convenor |

Even once risk level has been set it can be escalated or reassessed based on the specifics of the project.

Reviewing Processes

13

All applications for ethics approval received by the committee will be considered carefully. All incoming applications will initially be screened to ensure completeness. It is recommended that ethics applications are submitted in the first week of the month to be considered for the next SHSC ethics committee meeting held at the end of the month.

Members of the Committee must withdraw from consideration of any submission in which they are researchers or supervisors.

The lead reviewer/s will comment on the application and recommend the decision, highlighting any issues to members of committee/convenor.

The Committee decisions, include:

1. **Favourable ethical opinion and approval to proceed with study:**  the research is able to proceed. Any such authorisation is granted on the basis of the project as stated on the research submission. Any changes after this date must be notified to the Committee updated on worktribe or using the amendment form and will be reviewed and approval obtained prior to proceeding with changes to study.
2. **Refer**: clarification or modification of parts of the research submission will be highlighted on the feedback form. The revisions will generally be returned to the original reviewers for confirmation. The updated and version number should be resubmitted in advance of the meeting and any changes to documents highlighted and the changes clearly stated on the feedback pro-forma.

* If the requests for minor/moderate revisions are required, applicants are instructed to provide revised materials to the lead reviewers within two weeks.
* If the proposal requires major revision, applicants are instructed to resubmit via SHSC ethics for full committee review within six weeks and prior to the bi-monthly meeting.
* If issues with application remain unresolved within the allocated timeframes, the application will not be approved and will require to be rewritten and submitted for full review.

1. **Defer:** if substantial modifications are required or where significant additional information is required until that information is supplied and reviewed.
2. **Reject:** the research proposal in whole or in part.

The applicant can be invited to meet with the lead reviewers, convenor and/or attend the committee meeting to discuss the application if required. Once the application is approved the lead applicant provides convenor’s recommendation for approval and papers are forwarded to the SHSC administrator for storage on the ethics share-point. When applications have been reviewed and approved by the committee, the approval letter will be sent to the applicant within three working days of the committee meeting by email (see Timescale for applications).

Reviewing Timescale

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The following timescale aims to ensure the smooth running of research within the SHSC and avoid undue delays:

|  |  |  |
| --- | --- | --- |
| **Action** | **Timescale** | **Comments** |
| Application to be reviewed | 2 weeks |  |
| Resubmission | Within 2 weeks (minor)  Up to 6 weeks (major) | Changes to be highlighted by applicant |
| Final Approval | Within 1 week |  |
| Overall time scale for Approval | 3-8 weeks |  |

Application Form and Document Checklist

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It is the lead researcher’s responsibility to check the application is complete and is submitted with all the required supporting documents and permissions from outside organisations required for the study. Please make sure the following checklist is complete and included with your ethics application. Incomplete applications will be returned to the researcher.

Only once all the research governance tasks (Data Management Plan, Privacy Impact Assessment and Privacy Notice) are in place and have been fully reviewed by University Research Data Management and /or Governance should you proceed to School ethics/integrity review.

|  |  |
| --- | --- |
| **Application must be complete**  *All relevant fields are complete* |  |
| **Application is submitted 4 weeks in advance of data collection**  *Please ensure that the date of data collection is clearly stated and allows for sufficient time for ethical review and any updates/amendments that may be required. Data collection should not start before ethical approval is given.* |  |
| **Includes a Participant Information Sheet (plain language summary) on headed paper**  *For examples we recommend that you use the HRA*[*: http://www.hra-decisiontools.org.uk/consent/*](http://www.hra-decisiontools.org.uk/consent/) |  |
| **Includes an Informed Consent Form on headed paper**  *For examples we recommend that you use the HRA:* [*http://www.hra-decisiontools.org.uk/consent/*](http://www.hra-decisiontools.org.uk/consent/) |  |
| **Includes protocol (as required)**  *Please use your own protocol or use a protocol template, i.e. the HRA:* [*https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/*](https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/) |  |
| **Includes Interview/Survey Questions/Audio/Video-recording/Poster/Debrief (as required)**  *Provide a copy of questionnaire/s; interview themes/online questionnaire URL or observation proforma (an indicative list can be sent, but final version must be sent as amendment prior to data collection if not provided in the initial application).*  [*Please ensure to check the list of University approved tools here*](https://livenapierac.sharepoint.com/:w:/r/sites/rio/RDM/_layouts/15/Doc.aspx?sourcedoc=%7Bda6c20f1-5cc8-47e4-96da-ef0aed3d4536%7D&action=edit&wdPreviousSession=235de8cf-1355-4167-aeb7-ee239f6c5f36)*.*  *Researchers are responsible for obtaining all necessary licences or copyright agreements needed to use any data collection tools, diagnostic tools or software platforms used in the research project. Failure to do so may impact your ability to publish data collected without an appropriate licence from the licence owner.*  *If audio/video-recording are used please make sure the permission is evidenced in the consent form*  *The recruitment poster, social media statement etc must include the researcher/supervisor contact details; statement that the named individual can be contacted for further information about project; and a statement that the study has received relevant ethical approvals*  *A debrief may be required for some studies in order to sign-post participants to relevant support services at the end of the study* |  |
| **Includes relevant data management form**  *It is mandatory to complete the relevant data management form for your study prior to submitting the ethics application. This document should be sent for review to* [*RDM@napier.ac.uk*](mailto:RDM@napier.ac.uk)*details and templates can be found here:*[*https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/introduction.aspx*](https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/introduction.aspx) |  |
| **Includes a privacy notice (PN) and Privacy Impact Assessment (PIA)**  *It is mandatory to complete the privacy notice and privacy impact statement for studies that collect personal data from the participants. It is the researcher’s responsibility to get these checked prior to submission to the ethics committee by contacting* [*dataprotection@napier.ac.uk*](mailto:dataprotection@napier.ac.uk)  *The PN and PIA forms can be found at:* [*https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) |  |
| **Has attached written permission(s) from relevant outside organisation(s) (as required)**  *Written permissions are required from external organisations to recruit participants, collect data or use of premises* |  |
| **Includes data sharing agreement (as required)**  *If required please contact Research Data Management (*[*RDM@napier.ac.uk*](mailto:RDM@napier.ac.uk)*) and Governance (*[*dataprotection@napier.ac.uk*](mailto:dataprotection@napier.ac.uk)*) f*o*r advice* (*i.e. use of secondary data sets, data sharing with other universities, NHS or other organisations (nationally or internationally).* |  |
| **Includes completed risk assessment form (as required)**  *Please see risk assessment template in list of ethics application documents* |  |
| **All students require to provide an oath of confidentiality**  *Please see oath of confidentiality template in list of ethics application documents, please see:* [*https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) |  |
| **The declaration is signed and dated** |  |
| **The Director of Studies/Supervisor(s) have read, signed and dated the declaration (student requirement)** |  |

Please contact the SHSC committee administrator ([ethics.shsc@napier.ac.uk](mailto:ethics.shsc@napier.ac.uk)) if you require advice or support (including templates of supporting documents listed)

Managing Research Data

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Data Management Planning (DMP) must occur early in the project development stage and prior to ethics review to allow any additional checks and advice by the relevant University Services. By ensuring these checks are in place early this will assist the ethics/integrity review prior to starting the work.

***Project development tasks***

1.       Consider the methodology required to deliver the project aims. It is important to remember that personal or sensitive data may not be suitable for sharing with other researchers, depending on whether informed consent has been obtained from participants. The [HRA](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/what-law-says/consent-research) has an authoritative and comprehensive guide on ethics, consent and confidentiality.

2.       Develop a DMP and send for review to [RDM@napier.ac.uk](mailto:RDM@napier.ac.uk) details and templates can be found here: <https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/introduction.aspx>

3.       During the review Research Data Management (RDM) will provide feedback, highlight risks and direct you to other colleagues in the University as necessary.

4.       If you are using [personal data](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/what-is-personal-data/what-is-personal-data/) (about/collected from people directly or indirectly e.g. from online sources such as websites/social media) you will need to do a Privacy Impact Assessment (PIA) <https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx>

5.       If you have complex IT requirements, need to purchase IT equipment, are sharing research data with collaborators or want to use software which is not available in Apps anywhere you should seek advice from IS using this webform: <https://napier.unidesk.ac.uk/tas/public/ssp/content/detail/service?unid=0f0cdaa27d484c2f9e7305bf525c4294>

6.       [A list of University approved tools for managing data can be found here](https://livenapierac.sharepoint.com/:w:/r/sites/rio/RDM/_layouts/15/Doc.aspx?sourcedoc=%7Bda6c20f1-5cc8-47e4-96da-ef0aed3d4536%7D&action=edit&wdPreviousSession=235de8cf-1355-4167-aeb7-ee239f6c5f36). We are aware of some locally sourced tools being widely used, which do not have University approval for use (completed due diligence on the data governance and security), and these are not in this list.

7. The ethics committee will require evidence of the data management plan check by RDM.

***Project initiation tasks***

The [EU-General Data Protection Legislation (GDPR) and Data Protection Act 2018 (the Act)](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/default.aspx) gives individuals the right to know what information is being held about them. All researchers must adhere to data protection requirement when sharing or managing research data and must complete [a privacy impact statement](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/PrivacyImpactAssessments.aspx) (PIA) and [privacy notice](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) (PN) with the participant information and consent form to be given to participants (please use the most up to date [privacy notice](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) and privacy impact statement templates).

If using personal data then a [privacy notice](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) should be drafted to provide to participants at the time of consent. You should get the documents reviewed by [dataprotection@napier.ac.uk](mailto:dataprotection@napier.ac.uk)

Sharing personal data with an external processor requires a Data Processing Agreement (DPA), and with an external controller requires a Data Sharing Agreement (DSA). These agreements can either be standalone documents or can be included within a larger Collaboration Agreement. Please note that security and compliance checks are necessary with both DPAs and DSAs.

Once all the research governance tasks (DMP, PIA, PN) are in place and have been fully reviewed you should proceed to School ethics/integrity review.

Any further questions should be directed to [RDM@napier.ac.uk](mailto:RDM@napier.ac.uk)

Storing and Archiving Data

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It is important to adhere to University approved systems for storing all research data, regardless of whether research is funded externally or internally. Please read the Universities guidance on [storing data](https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Storing-Data.aspx) and [archiving data](https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Archiving.aspx).

The Edinburgh Napier Data Management Policy requires **research data to be retained at least 10 years after project completion** to allow time to substantiate research findings which are of potential long-term value or to support a patent. The policy also requires that funders and/or sponsors requirements are met. An increasing number of funders require data from funded projects to be archived for a minimum period after the end of the project. Funder policies may vary so please refer to the terms and conditions of your grant/award letter/contract for specific policies and requirements.

When storing and archiving it is important to have a systematic approach to **formatting, versioning and organising your data**. Recommendations can be found in in the [UK Data service guidance](https://www.ukdataservice.ac.uk/manage-data/format/recommended-formats).

Amendments

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If there are any changes to the study protocol (for example, alternative or additional research methods, sample population changes or dates of data collection) once ethical approval has been secured, the researcher will need to apply to the SHSC Ethics Committee for further ethical review.

Please make amendments via your original worktribe application on Worktribe Ethics or send the amendment form to ethics.SHSC@napier.ac.uk. Amendments to application or supporting documents are considered by the chair in the case of minor change, but applicants may be requested to submit a new application for the full review process if there are significant changes to the project and/or ethical concerns. All correspondence must use the study reference number and updated versions of the forms must state the version number and date.

In case you are not certain whether the changes you wish to make require ethical review please contact ethics.SHSC@napier.ac.uk for advice.

Research Misconduct

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If the committee is dissatisfied with the conduct of the research or the researchers, then ethical approval maybe revoked. Misconduct issues are referred through the [University's Research and Integrity Disciplinary Procedures](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/CoP%20version%203%20-%20Research%20Guidance%20Note%207.pdf).

Frequently Asked Questions

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**When do I need to apply for ethical approval my research?**

***All*** *research involving human participants, their tissue and/or data****must*** *be subject to research ethics review by the relevant school ethics committee.*

**Does an evaluation project involving focus groups, interviews and/or surveys require ethical review?**

*Evaluations seek to systematically assess a particular service or policy. Evaluation projects involving human participants that have specified questions, use recognised research methods do require ethical review.*

**Do I need ethical review for projects that use on-line resources, secondary-datasets, auto-ethnographical and/or public engagement approaches?**

*Studies may require ethical review to ensure that participants are giving informed consent, the data being collected is non-identifiable, that there are adequate safeguards where appropriate, and that data storage meets current GDPR/Data Protection regulations.*

**What kinds of ethical issues arise in relation to evaluation studies/research?**

*The following ethical issues to consider include: recruitment and selection of participants; procedures for seeking informed consent; anonymisation of data; confidentiality; risks to participants and/or researchers; data protection, storage and management; data sharing and archiving; and data disposal.*

**What type of studies do not require ethical approval?**

*Some projects involving information freely available and the data is not identifiable to individuals (e.g. published journal articles, systematic reviews), and the analysis of open sourced datasets with permissions from researchers, where the data have been checked as properly anonymised and informed consent was obtained at the time of original data collection to address the question of the study. If you are unsure if the data is properly anonymised it is recommended that you contact University Governance for advice.*

**Do I need to get ethical approval prior to submitting a funding application?**

*Before applying for a research grant, you should always check the terms and conditions applied by research funders to check if ethical approval is a condition required prior to funding. However, most funders make ethical approval a condition once the award is offered, therefore you should submit the worktribe prefunding “checklist” not a full ethics application.*

**Does my study need to include a research protocol?**

*It is good practice to include a research protocol, which should include the details of your study. There are templates available from* HRA at <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/> that includes protocol templates for qualitative and CTIMP studies and NIHR templates for clinical protocols at <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/protocol/>.

**My project will recruit NHS patients, do I need to inform the school ethics committee?**

*University sponsorship review using the worktribe online system is required for* ***all*** *projects that require NHS REC review.**Applicants will need to apply to an* NHS *REC for approval via the online* [*Integrated Research Application System (IRAS).*](https://www.myresearchproject.org.uk/)

**My project will involves research NHS staff and/or premises, do I need ethical approval from the school ethics committee?**

*You will need to obtain* SHSC *ethics approval for your research in addition to permissions from the relevant NHS Research and Development office before access staff or use NHS premises. Please contact the NHS Research and Development office for advice if there is a requirement to use the online* [*Integrated Research Application System (IRAS).*](https://www.myresearchproject.org.uk/)

**My research includes vulnerable patients that lack capacity to consent, what ethical approval do I need?**

*Applications under the Adults with Incapacity Act relating to research including those outside the NHS will be accepted for review by NHS Research Ethics Committees.* [*Scotland A Research Ethics Committee*](https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/scotland-research-ethics-committee/) *who can provide ethical opinions for the purposes specified in section 51 of the Adults with Incapacity (Scotland) Act 2000.*

**What permissions are required to access University staff and students as participants?**

*If staff or students within the SHSC are the participants, then you must obtain permission from the Dean of School (to access staff) and Programme/Module Leaders (to access students). If staff/students from more than one school are involved in the project, then permission must be obtained to recruit from each of the schools involved and the application sent to the* [*University Research Integrity Committee*](https://staff.napier.ac.uk/services/research-innovation-office/Pages/Research-Integrity.aspx) *(URIC) who will provide Cross University Ethics Review (please contact the URIC clerk for further information).*

**Why is it not recommended to use emails to recruit the participants?**

*Recruitment of participants should avoid coercion and the method of recruitment should be clear within the application. Recruitment using emails directly from the researchers within the university is not permitted unless sent via a gatekeeper with relevant permissions to comply with the* [*ENU Electronic Information Security Policy*](https://staff.napier.ac.uk/services/cit/Documents/Security/Information%20Security%20User%20PolicyV2.0.pdf) *and* [*EU-General Data Protection Legislation (GDPR) and Data Protection Act 2018 (the Act).*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/default.aspx)

**Can I include inducements to recruit to the study?**

P*articipants should be free from coercion and should not feel pressured in a study. Inducements (other than reimbursement for expenses) should be avoided as per the* [*University Code of Practice for Research Integrity*](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf)*.*

**Why do I need an Independent Advisor for my project?**

*An Independent Advisor for your study should be identified within the application and on relevant supporting documents such as the participant information sheet. The independent advisor should be someone who knows about the project, but is not directly involved in the study, and should be aware the* [*University Code of Practice for Research Integrity*](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf)*. Please note that the Independent Advisor does not comment on complaints about the research, which must be* referred through the [University's Research and Integrity Disciplinary Procedures](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/CoP%20version%203%20-%20Research%20Guidance%20Note%207.pdf).

**Is there a template for the Participant information and consent forms?**

For participant information and consent forms we recommend that you use the HRA templates[*: http://www.hra-decisiontools.org.uk/consent/*](http://www.hra-decisiontools.org.uk/consent/)

**Can I use freely available Survey tools to collect data?**

*As data may be stored on a cloud often out with the UK there are risks in security when using survey utilities available on the internet that may not comply with the University Code for Data Protection. Therefore, only survey tools approved by the* [*University Research Integrity Committee*](http://staff.napier.ac.uk/services/research-innovation-office/Pages/Research-Integrity.aspx) *are recommended. A* [*list of University approved tools can be found here*](https://livenapierac.sharepoint.com/:w:/r/sites/rio/RDM/_layouts/15/Doc.aspx?sourcedoc=%7Bda6c20f1-5cc8-47e4-96da-ef0aed3d4536%7D&action=edit&wdPreviousSession=235de8cf-1355-4167-aeb7-ee239f6c5f36)

**How do I get access to the University Approved Survey Online tool?**

*Ethical review is required prior to access to the* [*NOVI Survey Online tool*](https://my.napier.ac.uk/IT/YourITServices/Pages/NoviSurvey.aspx)*. Novi Survey is a web-based survey application facilitate the gathering and analysis of data from different audiences, both on and off campus. However, the university also supports* [*Microsoft Forms*](https://staff.napier.ac.uk/services/cit/O365/Pages/Office-365.aspx)*.*

**Does the online survey require to include consent?**

*The online survey should ask participants for consent and include all relevant questions at the start of the questionnaire and a reminder at the end of the survey. Participants must be given information, including participant information and privacy notice. Information on the ways to withdraw from the study, along with information on when it may no longer be possible for their data to be removed should be clear in the consent section, for example, after submitting an anonymous online survey response their data cannot be removed.*

**Do I have to obtain written consent from participants?**

*Consent must be given freely and voluntarily and under no circumstances should coercion or indirect pressure be used to obtain a person’s consent to participate in research. Wherever possible, and bearing in mind the nature of the research activity, an individual’s consent should be obtained, this is usually in writing - see the* [*University Code of Practice for Research Integrity*](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf)*.*

*The HRA sets out the legal and ethical requirements for seeking and documenting consent using electronic methods at* [*https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/*](https://www.hra.nhs.uk/planning-and-improving-research/best-practice/informing-participants-and-seeking-consent/)*. This statement is aligned with the existing* [*HRA online guidance for consent and participant information*](http://www.hra-decisiontools.org.uk/consent/)*.*

**Does my study need a Privacy Notice?**

*A* [*Privacy Notice*](https://staff.napier.ac.uk/services/research-innovation-office/research-governance/Pages/research-privacy-notices.aspx) *is required for all research projects including the processing of personal data. The* [*privacy notice*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) *should be drafted so that it is understandable to participants and should be given at the time of consent either as a document accompanying the participant information sheet and consent form or a link to the relevant Privacy Notice site. You should get the documents reviewed by*[*dataprotection@napier.ac.uk*](mailto:dataprotection@napier.ac.uk)

**Does my study need a data management plan (DMP)?**

*All researchers must complete the appropriate* [*Data Management Plan*](https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Data-Management-Plan.aspx) *using the templates for funded projects or non-funded/student projects, this should be completed and checked early and reviewed by Research Data Management (RDM) prior to submission to the ethics committee. You should include evidence that the DMP has been reviewed and agreed by RMD with your application.*

**Where do I find information of data management and storage?**

*Confidentiality, anonymity, data handling and storage should adhere to the* [*University Code of Practice for Research Integrity*](https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf)*,* [*ENU Data Management Policy*](https://staff.napier.ac.uk/services/research-innovation-office/Documents/Research%20Data%20Management%20Policy.pdf) *and* [*EU-General Data Protection Legislation (GDPR) and Data Protection Act 2018 (the Act)*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/default.aspx)*.*

*It is the responsibility of the researcher to make it clear how the participants’ identity will be stored and protected throughout the lifetime of the project and once the research is finished as per the* [*Data Storing Policy*](https://staff.napier.ac.uk/services/research-innovation-office/research-data/Pages/Storing-Data.aspx)*.*

**Where can I find information on whether my research is covered by insurance and indemnity?**

*It is important to check that your research is not exempt from normal* [*University insurance and indemnity*](https://staff.napier.ac.uk/services/finance/Pages/InsuranceCertificates.aspx)*. In some cases, for example research involving clinical trials or undertaken overseas, researchers may be asked to provide further evidence from insurers that they have sufficient University coverage*

**Do I need to submit an Oath of Confidentiality with my application?**

*All students conducting research at Edinburgh Napier University which involves processing personal data must sign an* [*Oath of Confidentiality*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/Pages/ProcessingDataforResearch.aspx) *in relation to personal data to which they will have access in the course of their studies.  This form should be submitted with their application and will retained by the area in which the research is being conducted for the period end of studies with the University plus 6 years.*

**Do I need to encrypt my research data?**

*Data that includes personal or sensitive data****,*** *including digital recorded interview and video data are subject to the* [*EU-General Data Protection Legislation (GDPR) and Data Protection Act 2018 (the Act)*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/default.aspx)*. Therefore, all researchers must ensure the security of the data, for example by using an encrypted device.*

**What should I do if data needs to transferred outside of the University secure servers?**

*Please seek advice from the SHSC ethics if you need to store data or transfer data outside the ENU secure servers as you may need a Data Sharing Agreement, please see the Data Protection Code of Practice at* [*https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/default.aspx*](https://staff.napier.ac.uk/services/governance-compliance/governance/DataProtection/CodeofPractice/Pages/default.aspx)*.*

**Can Audio transcription be undertaken by an external company?**

*It is considered safer if the transcription is undertaken by researchers on a University computer, which is password protected. If transcription is undertaken by a transcription service, it can only be one which has been approved by the University under the terms of a data processing agreement issued by the University as data controller. The university has a data-sharing agreement in place with external company called 1st Class Secretarial Services. This organisation to ensure that all data is kept secure, you can view their Privacy Statement here*[*https://www.1stclass.uk.com/privacy\_statement\_01052018.pdf*](https://www.1stclass.uk.com/privacy_statement_01052018.pdf)

***Where do I find the Lone Working Policy?***

*The* [*lone working policy*](https://staff.napier.ac.uk/services/governance-compliance/healthandsafety/policies/Documents/Lone-Working-Procedure-Social-Researchers-v1.0.pdf) *highlights the potential risks to researchers working away from the campus or supervisor. It is important that researchers are aware of potential risks and have safety procedures in place. Please complete the health and safety risk assessment form found on the* [*SHSC Research & Integrity Website*](https://www.napier.ac.uk/research-and-innovation/research-search/school-research/school-of-health-and-social-care/research-ethics-shsc) *if your project involves lone working or risk to participants/researchers .*

**Where do I find the forms related to Health and Safety and Adverse events?**

*It is sometimes possible that participants will be adversely affected by issues raised by the research. This could be emotional, psychological, physical, social or economic. It is therefore important to consider all possible causes distress and possible reactions and how these may be mitigated by completing the health and safety risk assessment form found on the* [*SHSC Research & Integrity Website*](https://www.napier.ac.uk/research-and-innovation/research-search/school-research/school-of-health-and-social-care/research-ethics-shsc)*.*

**My study is a clinical trial, how do I report procedures for Adverse Events?**

*Adverse Event and other safety event identification, recording and reporting procedures must comply with the requirements of* [*Good Clinical Practice (GCP)*](https://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice)*. Copies of the University Adverse Event and Urgent Safety Measures Standard Operating Procedures, which describes the process for identifying, recording and reporting adverse events can be found at* [*Research Policies and Guidance*](https://staff.napier.ac.uk/services/research-innovation-office/policies/Pages/Research-policies.aspx)*.*

Useful Weblinks and Contacts

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**Please submit your ethics checklist to** [**ethics.shsc@napier.ac.uk**](mailto:ethics.shsc@napier.ac.uk)

**Useful Weblinks:**

* University Code of Practice for Research Integrity 2018 <https://staff.napier.ac.uk/services/research-innovation-office/policies/Documents/2018%2009%2018%20-%20%20CoP%20version%203.pdf>
* Health Research Authority (UK wide) [www.hra.nhs.uk](http://www.hra.nhs.uk)
* Health Research Authority Consent and Participant Information Guidance
  + Adults <http://www.hra-decisiontools.org.uk/consent/principles-ALC-Scotland.html>
  + Children/young persons <http://www.hra-decisiontools.org.uk/consent/principles-children.html>
  + GDPR <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/>
* GMC Good practice in research and consent to research <https://www.gmc-uk.org/-/media/documents/good-practice-in-research-and-consent-to-research_pdf-58834843.pdf>
* IRAS [https://www.myresearchproject.org.uk](https://www.myresearchproject.org.uk/)
* ACCORD: [www.accord.ed.ac.uk](http://www.accord.ed.ac.uk)
* R&D approvals: <https://www.accord.scot/research-access/approvals>
* Caldicott Guardian: <https://www.accord.scot/research-access/go-study-mangement>
* [ISD Scotland and electronic](https://www.accord.scot/research-access/go-study-mangement) Data Research and Innovation Service (eDRIS) <https://www.isdscotland.org/Products-and-Services/eDRIS/>
* Public Benefit and Privacy Panel (PBPP) for Health and Social Care (PBPP): <https://www.informationgovernance.scot.nhs.uk/pbpphsc/>
* Adults with Incapacity (Scotland) Act 2000 Code of Practice re research <https://www2.gov.scot/Publications/2010/10/20153801/4>
* Mental Welfare Commission for Scotland Consent to Treatment <https://www.mwcscot.org.uk/sites/default/files/2019-06/consent_to_treatment_2018.pdf>

**The following Research Governance Frameworks include:**

* [Chief Scientist Office (CSO) Research Governance Framework](https://www2.gov.scot/Topics/Research/by-topic/health-community-care/chief-scientist-office/6864/6933)
* [Department of Health (DH) Research Governance Framework for Health and Social Care](https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition)
* [Governance Arrangement for Research Ethics Committees (GAfREC)](http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/)
* [UK Research Integrity Office (RIO)](http://ukrio.org/publications/code-of-practice-for-research/)
* [Universities UK’s Concordat to Support Research Integrity](https://www.universitiesuk.ac.uk/Pages/home.aspx).
* [HRA Research Governance Frameworks for Health and Social Care (UK)](http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/)