This form is to request approval to undertake a service evaluation, evaluation, or research project at St Andrew’s Healthcare. If your project is funded by a grant from a statutory funding body, please use the **Site Participation Only** template (available upon request). Ensure all information provided is accurate and that all required documents are included (see the [Submission checklist](#checklist)). Please refer to the *Code of Practice for Conducting Research at St Andrew’s Healthcare*, ensure the information you provide is accurate and that the required documents are included.

**Applicant name:**  **Work email & mobile:**

**PROJECT TITLE:**

|  |  |  |  |  |
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| SECTION 1: OVERVIEW | | | | |
| Project category | *Please complete HRA decision tool:* [*Is my study research?*](http://www.hra-decisiontools.org.uk/research/) *and attach PDF of outcome*  ***No data is to be collected, extracted or analysed prior to project approval***  Research[[1]](#footnote-2)  Service evaluation[[2]](#footnote-3)  Evaluation[[3]](#footnote-4)  Other *(please give details)*: | | | |
| Data to be used[[4]](#footnote-5) *(select all that apply)* | New data from patients  New data from staff | | Existing patient data  Existing staff data | |
| Other – please list: | | | |
| Project sponsor[[5]](#footnote-6) |  | | | |
| Project funder |  | | | |
| Please list any other collaborators |  | | | |
| Is the project part of university-associated study? | Yes  No | If yes, has the project been approved by the university? | | Yes  No |
| *Internal applicants only:* is your line manager aware and supportive of the project? | | Yes  No |
| Project duration (months) |  | | | |
| Anticipated project dates | **From** Click to add date **To** Click to add date | | | |

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| SECTION 2: ROLES & RESPONSIBILITIES | | | |
| Role *(please add, as applicable)* | Name | Job title | Contact details *(email & tel.)* |
| Principal Investigator[[6]](#footnote-7) |  |  |  |
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| SECTION 3: ST ANDREW’S ROLE | |
| Application requirement  *(External applicants: select all that apply)* | Approval to conduct project at St Andrew’s  *\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* ***EXTERNAL APPLICATIONS ONLY:*** *St Andrew’s may be able to offer varying levels of support to external projects; however, including a St Andrew’s employee on the project is not required. Select all that apply, or contact* [*research@stah.org*](mailto:research@stah.org) *to further or inquire about other support options:*  Collaboration[[7]](#footnote-8)  Provision of clinical expertise/guidance[[8]](#footnote-9)  Support with patient/carer engagement to inform your approach  Conduct of consent process  Support with new data collection  Support with data extraction  Support with project management  Provision of specialist supervision – subject matter expertise  Advice on statistical analysis  Advice on writing up dissertations |

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| SECTION 4: PROJECT DETAIL | |
| **Aim** *(What is your overall goal? What do you hope will change because of this project?)* |  |
| **Objectives** *(How will you achieve your aim?  1-4 bullet points)* |  |
| **Introduction** *(max. 250 words)* | *Description of literature/scientific background* |
|  |
| *Identification of gap/unmet needs/reason for doing the project* |
|  |
| *Rationale for how this project will address the gap/help improve patient outcomes* |
|  |
| **Study design** *(max. 600 words)*  *Qualitative, quantitative, mixed methods etc. and brief details, including how the data will be analysed* |  |
| **STOP! Check project type** | **My project is intended to:** *(select all that apply)*  Produce recommendations for St Andrew’s  Inform/improve practice in other settings external to St Andrew’s *(this is likely research)*  Add to the knowledge base *(this is likely research)* |

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| SECTION 5: PATIENT & PUBLIC INVOLVEMENT (PPI) | | |
| Who has been involved in the planning of this project and at what level?  *(This is not being a research participant; for guidance see the* [*ladder of co-production*](https://www.thinklocalactpersonal.org.uk/_assets/COPRODUCTION/Ladder-of-coproduction.pdf)) | Patients/service user | Choose an item. |
| Carers | Choose an item. |
| Other *(give details)*: | Choose an item. |
| None *(see* ***NO Patient & Public Involvement*** *in the table below)* | |
| Please describe what you did/plan to do and explain how it will help achieve person-centred change |  | |

**NO Patient & Public Involvement**

|  |  |
| --- | --- |
| If there has been no PPI, please explain why not |  |

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| SECTION 6: DATA COLLECTION | |
| Please provide details of the Division/Wards from where data will be obtained (if known) |  |

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| --- | --- | --- | --- | --- |
| SECTION 6A: New data collection (recruitment) | | | | |
| **Participants** | **No.***[[9]](#footnote-10)* | **Eligibility**  *Give detailed inclusion/ exclusion criteria[[10]](#footnote-11)* | **Recruitment strategy**  *How will you identify/approach potential participants?* | **Method of collection**  *Give details, including time commitment for participants* |
| Patient |  |  |  |  |
| Staff |  |  |  |  |
| Carer |  |  |  |  |
| Other *(give details):* |  |  |  |  |

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| Use of technology[[11]](#footnote-12)  *(e.g. encrypted digital recorder)* |  |
| Recruitment from NHS *(e.g. staff, volunteers, patients)* | You will need to get HRA approval: [What approvals and decisions do I need? - Health Research Authority (hra.nhs.uk)](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/); this is different to ethical approval |

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| SECTION 6B: Use of existing data (extraction) | | | |
| Data subject/s | Patient  Staff | Other *(give details)*: | |
| Who is extracting the data? | Member of the direct (care) team  STAH Business Intelligence | | Person outside of direct team *(give details):* |
| Consent for access sought from the data subject? | Yes  No | If ‘no’, please explain why not | |
|  | |
| Sample size | Minimum sample size | Explain calculation | |
|  |  | |

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| --- | --- | --- |
| This table also serves as the extraction request to Business Intelligence (submitted by the Research Centre on your behalf) | | |
| Data source | Electronic health record (RiO)  Electronic medicine management system (ePMA)  Existing dataset, e.g., from previous project, audit *(please give details)*:  Other *(please give details)*: | |
| Inclusion criteria |  | |
| Exclusion criteria |  | |
| Dataset format |  | |
| Data security notes[[12]](#footnote-13) |  | |
| Variables  *(Select all that apply and give details)* | *Type* | *Details (see Appendix 2 for guidance)* |
| Demographic |  |
| Clinical |  |
| Criminal |  |
| Medication |  |
| Scale |  |
| Other |  |
| Date range for data |  | |
| Deadline for extract | Click to add date | |
| Use of raw data *(Select all that apply and give details)* | Internal use  External use | |
| Purpose | |
| Analysis for project  Patient recruitment  Project feasibility assessment  Other *(please give details):* | |

[FOR OFFICE USE ONLY]

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| Request submitted to BI | Click to add date | | |
| If person-level data is being shared externally, give details of the data sharing agreement | Agreement type:  Date signed: | | |
| Legal basis for processing undertaken by STAH | Choose an item. | Special category | Choose an item. |

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| SECTION 7: DATA MANAGEMENT | | | | | |
| Data Controller[[13]](#footnote-14) |  | | | | |
| Has Controller identified need for a DPIA?[[14]](#footnote-15) | Yes  No | If ‘Yes’, please give details |  | | |
| Required data protection agreements | N/A  Information Sharing Agreement  Data Processing Agreement | | | | |
| Data processors[[15]](#footnote-16) |  | | | | |
| Data preparation | *Who will prepare the data after it has been extracted?* | | | | |
|  | | | | |
| *Projects often involve person-level data; we consider this personal data[[16]](#footnote-17) even if deidentified, as such, it is subject to GDPR – please tick all that apply to data you will be using:* | | | | |
| Identifiable personal data  Deidentified personal data  Aggregated data | | | | |
| *What data minimisation techniques will you be using? (Please select all that apply)* | | | | |
| Pseudonymisation  De-identification | | | | |
| *Please describe the planned approach, including the details of how data minimisation techniques will be applied during dataset preparation* | | | | |
|  | | | | |
| Data analysis | *Who will be analysing the data? (Please select all that apply)* | | | | |
| Member of the care team  Member of staff who is not part of the care team  External researcher | | | | |
| Identifiability of the data | *Will the person analysing the data be able to re-identify participants from the data being used for this project? Remember to include this in* ***Section 10: Risk Assessment*** | | | | |
| Choose an item. | | | | |
| Where will the project data be stored during and after completion of the project? | | | | | |
|  | | | | | |
| Details of transportation, i.e., will the data be taken or shared outside of St Andrew’s? | | | | | |
|  | | | | | |
| Retention period & criteria *(e.g., 3 years after publication)* |  | | | Do you want Research Centre to support you with data destruction? | Yes  No |

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| SECTION 8: RESOURCES | |
| FINANCE & EQUIPMENT | *Details (Include your plans for resourcing additional requirements)* |
| Will there be additional project costs to the Division or to St Andrew’s?[[17]](#footnote-18) |  |
| Additional equipment required |  |
| Other |  |

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| SECTION 9: RISK ASSESSMENT | | |
| Are there any anticipated risks associated with this project? *(E.g., concerns about recruitment; resource or time constraints)* | | |
| Description of risk | Mitigation[[18]](#footnote-19) | Contingency[[19]](#footnote-20) |
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| SECTION 10: ETHICS | |
| *Research directly involving patients will often require review by a Research Ethics Committee (REC) – this may or may not need to be an NHS REC, depending on various criteria. Please work through the following to help you get to the correct outcome.* | |
| 1. For research only, please complete: [*Do I need NHS REC approval?*](http://www.hra-decisiontools.org.uk/ethics/) Is **NHS** **REC** review required? | Yes   No  N/A |
| If yes, please give details of submission; if no, proceed to 2) |  |
| 1. For research not requiring NHS REC approval, please identify the correct ethics requirements using the [ethics flow diagram](https://sahcorp.sharepoint.com/sites/Research/Shared%20Documents/Forms/AllItems.aspx?id=%2Fsites%2FResearch%2FShared%20Documents%2Fresources%2Fprocess%5Fflowcharts%2Fethics%5Fapproval%5Fresearch%2Epdf&parent=%2Fsites%2FResearch%2FShared%20Documents%2Fresources%2Fprocess%5Fflowcharts) | University REC  Independent REC  N/A |
| 1. For all other projects, plus research identified as not requiring REC approval only, please complete [*Appendix 1*](#_Appendix_1:_Ethics) – is **further ethical consideration** required? | Yes   No |
| If yes, please give details or contact the Research Centre for further guidance |  |

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| SECTION 11: SCHEDULE (complete or attach separate chart) | | |
| Example project activities | Estimated dates & timeframe | Action owner  *Name/Organisation* |
| Design & planning |  |  |
| Ethics approval |  |  |
| Recruitment |  |  |
| Data collection |  |  |
| Data analysis |  |  |
| Preliminary results |  |  |
| Final results |  |  |
| CPD presentation (midpoint) |  |  |
| Draft report |  |  |

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| SECTION 12: OUTPUTS & IMPACT | | | |
| Example project activities | Estimated dates & timeframe | Dissemination plan  *(E.g., how will you share/implement findings to deliver patient benefit?)* | |
| Final report (required) |  |  | |
| Thesis/dissertation |  |  | |
| Guidance/procedure |  |  | |
| Intervention/change in practice[[20]](#footnote-21) |  |  | |
| Recommendations |  |  | |
| Poster/conf presentation |  |  | |
| Publication |  |  | |
| Other |  |  | |
| **STOP! Check project type** | Do you intend to publish findings in an academic journal?  *If you selected ‘Yes’, but classified your project as a service development/evaluation, please see the recommended disclaimer in the Code of Practice for Conducting Research at St Andrew’s Healthcare* | | Yes  No |

**Delivery assessment**

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| All completed projects are subject to a delivery assessment against the proposed outputs; please advise when you anticipate your project will be ready for this to be undertaken | Click to add date |
| We assume delivery of the final report marks project completion. If this is not the case, please advise which output/activity represents the end of your project. |  |

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| SECTION 13: DIVISIONAL SUPPORT | |
| Evidence of St Andrew’s support   * *Have you liaised with anyone at St Andrew’s?* * *Evidence of interest?* |  |
| Please list any other staff who have been consulted in the development of this project (For example, Research Centre or Centre for Developmental and Complex Trauma for trauma-informed care/moral injury projects) |  |

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| SECTION 14: DECLARATIONS | |
| Applicant  I agree to all the Terms (Appendix 3). *By checking this box, you are acknowledging that approval is subject to a satisfactory review.*19  I confirm that all individuals associated with this project have read and understood their responsibilities as set out in the [Code](https://www.stah.org/assets/Uploads/Research-Policy-v1.1-Mar-23.pdf) of Practice for Conducting Research at St Andrew’s Healthcare*.*19  Name (printed):  Signature x | Academic Supervisor *(student applications only)*  I confirm my support for the project and agree to all the Terms (Appendix 3) and roles & responsibilities (Section 3), on behalf of my Research Organisation.19  Name (printed):  Signature x |
| Project Supervisor/Chief Investigator *(non-student applications)*   I agree to provide the necessary supervision required to ensure the delivery of a high-quality project.19  I agree to all the Terms (Appendix 3) and roles & responsibilities (Section 3), on behalf of your Research Organisation.19  Name (printed):  Signature x | Clinical Director/Executive Medical Director (EMD) *(internal applications)*[[21]](#footnote-22)   I confirm my support [[22]](#footnote-23) for this project (including subject of study and any participant recruitment) within my division/the Charity; I understand that my support does not guarantee final approval by the Service Evaluation and Research Review Committee.  Name (printed):  Signature[[23]](#footnote-24) x |

**SUBMISSION CHECKLIST**

Once completed, please email this form to [research@stah.org](mailto:research@stah.org) and attach all that apply:

Output from HRA decision tools (Is my study research? and Do I need NHS REC approval?)

External sponsor confirmation (on sponsor organisation’s headed paper; can be a scan attached to an email)

Participant information sheets and consent forms – these should be dated and version controlled; the consent form should reference the version number of the information sheet

Research Ethics Committee approval (we advise you to seek project approval before applying for ethical review)

Any documents demonstrating support from the service where you intend to conduct the study

Data collection forms and/or interview questions/topic guide

Applicant’s CV and supervisor’s CV (student projects only)

Costing and justification of resources for projects seeking or applying for additional funding from St Andrew’s (internal & collaboration projects only)

External peer review (only required for projects seeking an additional investment of ≥£5,000 from St Andrew’s)

Research Passport Application[[24]](#footnote-25) (external applicants only)

## Appendix 1: Ethics screening questions

For use with service evaluation, evaluation and research projects that do not require REC approval

|  |  |
| --- | --- |
| Does the proposed project have any of the following ethical issues that need consideration before starting?[[25]](#footnote-26) | |
| Infringe on any patient rights?  Yes  No  Patients recruited without consent?  Yes  No  Risk breaching any patient’s confidentiality or privacy?  Yes  No  Place a burden on a patient beyond those of his or her routine care?  Yes  No  Involve any clinically significant departure from usual clinical care?  Yes  No | Involve a potential conflict of obligation to patients, for example, a trade-off between quality and cost?  Yes  No  Involve the use of any untested clinical or systems interventions?  Yes  No  Allocate any interventions differently among groups of patients or staff?  Yes  No  Could the findings have implications for a specific patient’s immediate care?  Yes  No |
| *If the answer to any of the above questions is yes, the project should have ethical consideration* | |
| We aim for projects at St Andrew’s to provide benefit to patients or improve patient care – is that true for this project?  Yes  No | |
| *If the answer to this question is no, the project should have further ethical/strategic consideration* | |

**Infringing patient rights** — Review any activity that limits or restricts patients’ rights to make choices about their healthcare, such as restricting access to evidence-based practice.

**Risk breaching confidentiality or privacy** — Review any of the following situations: collecting or disclosing data that could be used to identify any patient; using such small sample sizes that individual patients can be identified; or having someone collect data who does not normally have access to patients’ information or records.

**Placing a burden on a patient beyond those of his or her routine care** — Review the following types of activities: A patient is required to spend additional time for data collection, provide samples not essential for care or attend extra clinic or home visits; a vulnerable person is required to participate directly; or a patient is asked to answer more than a minimal number of factually based questions or to provide sensitive information.

**Involving any clinically significant departure from usual clinical care** — Review an activity that varies from accepted current clinical practice or that causes any disruption in the clinician-patient relationship.

**Involving a potential conflict of obligation to patients** — Review any activity that considers a trade-off between cost and quality for individual patients or a group of patients.

**Involving the use of any untested clinical or systems intervention** — Consider the risk patients could face if an activity involves implementing a new practice that is not already established.

**Allocating any interventions differently among groups of patients or staff** — Review if different groups of patients are to be assigned to interventions or treatments or patients are to be recruited to participate in an activity.

**Providing no direct benefit to patients or patient care** — Review any activity that does not directly benefit the patients participating to ensure that the risk to patients is acceptable.

Appendix 2

|  |  |
| --- | --- |
| **Data category** | **Example variables**  Please provide further details for each variable, including type of variable (see examples below), timeframe (e.g. violent incidents between Mar - May), follow up (e.g. every 3 months, 6 months).  This is not an exhaustive list of variables within the electronic systems at St Andrew’s; please liaise with Research & Innovation if you need advice. |
| Demographic | Age (e.g. at admission, at time of data extraction), gender, education, ethnicity, language |
| Clinical | Section of the Mental Health Act (1983), date of admission/discharge, discharge location, primary diagnosis (ICD-10 codes), comorbidities, IPUs, re-admissions, length of stay, enhanced support/restrictive practice |
| Criminal | Index offence, date of index offence |
| Medication | Type of medication (any medication, antidepressant, antipsychotic, rapid tranquillisation), date of prescription/administration, dosage, frequency of administration, time reference, follow ups |
| Scale | HCR20, HoNOS, ReQoL, START, SASBA, APOM, OAS,  Other; complete questionnaire/single item, , date of assessment, follow ups |
| Other | Violence, type/severity of violence, date of incidents, time reference, follow ups |

These terms describe the limited basis on which St Andrew’s Healthcare (**Charity**) shall make its data (**Charity Data**) available to you.

APPENDIX 3: ST ANDREW’S HEALTHCARE RESEARCH DATA USE TERMS

1. Access to the Charity and the Charity Data is given to you for your non-commercial use and only for the research purposes agreed with the Charity in the application form The Charity Data must not be used for any commercial purpose.
2. You will receive de-identified Charity Data and will not attempt to deconstruct or establish identity of any persons nor attempt to link the Charity Data to any other data.
3. You shall not distribute, grant access to, sub-licence or transfer the Charity Data to any other person or organisation, nor publish it on the internet or any other public forum. You will keep the Charity Data in a secure location.
4. You will ensure appropriate ethics approval has been obtained before conducting any research using the supplied Charity Data and will provide evidence of such to the Charity, upon request.
5. You will respond promptly to any requests from the Charity regarding your use of the Charity Data.
6. You acknowledge that no intellectual property or ownership rights are being transferred to you by the access granted and agree not to claim (directly or indirectly) any intellectual property or ownership rights in the Charity Data.
7. No warranties are given and no responsibility or liability is or will be accepted by the Charity in relation to or as to the accuracy, availability or completeness of the Charity Data. All Charity Data is provided “as is” and “as available”. The Charity Data may be updated or amended by the Charity from time to time (without notice).
8. You shall not remove or alter any copyright or other notice contained on or within any Charity Data.
9. You must acknowledge the Charity in any papers or publications which use Charity Data.
10. The Charity shall automatically be considered an official collaborator on any studies and the appropriate staff should be represented in the contributors’ line of any research papers. This should be done using the CRediT taxonomy (<https://casrai.org/credit>).
11. Copies of all publications, either as peer-reviewed papers, abstracts or posters, should be submitted to the Charity within one month of publication or presentation. Students should also share their thesis/dissertation on completion of their studies.
12. Save as provided in paragraphs 8 and 9, you must not use the Charity’s name or logo without the Charity’s prior written consent. You must not use the Charity Data in any way which is (or may be) detrimental to the Charity or which may bring the Charity into disrepute.
13. The Charity may immediately terminate your access to the Charity Data if you fail to comply with any of these terms.
14. On termination of this arrangement, or completion of the research (if sooner), you will return all Charity Data to the Charity and confirm (in writing) that you have done so.
15. Any manipulations of the data or secondary data generated should also be returned to the Charity and the Charity may subsequently distribute this to third parties in a similar form to primary data. It shall remain the property of the Charity.
16. These terms supersede any previous agreements in relation to the Charity Data.
17. The Charity may amend these terms at any time, such amendments to be effective 30 days after publication. If you do not agree to such amendments, you must stop using the Charity Data immediately.
18. If any of these terms is or becomes invalid, illegal or unenforceable, it shall be deemed modified to the minimum extent necessary to make it valid, legal and enforceable.
19. A waiver of any right or remedy under these terms or law is only effective if given in writing. No failure or delay to exercise any right or remedy shall constitute a waiver of that or any other right or remedy.
20. These terms (and your access to and use of the Charity Data) are subject to English law and the exclusive jurisdiction of the English Courts.

1. Where a new intervention or change to treatment is being introduced as part of the project protocol, this will be considered research [↑](#footnote-ref-2)
2. May include the collection of pre and post data to assess a new/change to a service (introduced independently of the project) [↑](#footnote-ref-3)
3. May include the collection of pre and post data to assess a new/change to a non-service element (introduced independently of the project) [↑](#footnote-ref-4)
4. This includes secondary analysis of data previously collected for a specific project or purpose, for example, the use of existing clinical data [↑](#footnote-ref-5)
5. The organisation responsible for the conduct of the project; usually the Data Controller [↑](#footnote-ref-6)
6. Required as a minimum; however, all team members should be listed [↑](#footnote-ref-7)
7. An equal partnership; joint participation in research design and decision making; expectations of joint authorship and data ownership [↑](#footnote-ref-8)
8. Provision of focussed clinical expertise; authorship as appropriate and agreed [↑](#footnote-ref-9)
9. How many participants do you need? [↑](#footnote-ref-10)
10. Be specific: specificity contributes to the clarity, validity, reproducibility, ethical compliance, and overall quality of the project [↑](#footnote-ref-11)
11. Remember to consider contraband lists if you are collecting data on a ward [↑](#footnote-ref-12)
12. Information about how it should be sent to the requestor, password requirement on file, details of data minimisation wanted [↑](#footnote-ref-13)
13. Usually the sponsor. There may be more than one controller. [↑](#footnote-ref-14)
14. Data Protection Impact Assessment: this is the responsibility of the Data Controller [↑](#footnote-ref-15)
15. List all the data processors involved, for example, Business Intelligence Team, the researcher [↑](#footnote-ref-16)
16. [What is personal data? | ICO](https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/key-definitions/what-is-personal-data/) [↑](#footnote-ref-17)
17. If yes, please attach your costing information (internal & collaborative projects only) [↑](#footnote-ref-18)
18. Mitigation = steps you have taken to reduce the likelihood of the risk happening [↑](#footnote-ref-19)
19. Contingency = steps you will take if the risk happens [↑](#footnote-ref-20)
20. Meaningful co-production is required in the project planning; patient representation is expected in the data collection [↑](#footnote-ref-21)
21. The EMD delegates this role to the Head of Research & Development for projects that do not involve the Research Centre [↑](#footnote-ref-22)
22. Support can also be indicated via covering email, please copy and paste statements into your email [↑](#footnote-ref-23)
23. Delete as appropriate; EMD signature is required for multiple-division studies, with Divisions invited to take part via CDs once project is approved [↑](#footnote-ref-24)
24. External researchers: Your Research Passport application form can either be submitted along with this project application form OR after the project has received St Andrew’s approval. Please note: whilst the most time-efficient approach is to submit the Research Passport application with your project application, doing so does not guarantee project approval. [↑](#footnote-ref-25)
25. The screening questions have been adapted from: [guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf (hqip.org.uk)](https://www.hqip.org.uk/wp-content/uploads/2017/02/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf) [↑](#footnote-ref-26)