|  |
| --- |
| Related image**Guidance on Service Evaluation** Policy No. P2021-219Effective Date: October 2020Last Revised: October 2020.Review Interval: 3 yearsReview Date: October 2023Approval Body: University Research Ethics & Governance sub-committee. |
| **Policy Owner**: REIS**Policy Author**: Dr Sherrill Snelgrove/Angela Smith/Anjana Choudhuri |

 ***(P2021-219)***

The following is the Swansea University guidance for Ethical Review of Service Evaluation**.** It is primarily for Swansea University staff and students who intend conducting a service evaluation. The information provided draws on, and is supported by

<https://arc-w.nihr.ac.uk/training-and-capacity-building/evaluation-best-practice-and-guidelines/>

<https://www.hqip.org.uk/wp-content/uploads/2017/02/guide-to-managing-ethical-issues-in-quality-improvement-or-clinical-audit-projects.pdf>

<https://www.weahsn.net/wp-content/uploads/Best-practice-in-the-ethics-and-governance-of-service-evaluation.pdf>

**Defining Service evaluation, Audit and Research**

Service evaluation may be defined as “A study in which the systematic collection and analysis of data is used to judge the quality or worth of a service or intervention, providing evidence that can be used to improve it”

(<https://arc-w.nihr.ac.uk/Wordpress/wp-content/uploads/2020/02/Full-guidelines-for-Best-Practice-in-the-Ethics-and-Governance-of-Service-Evaluation-Final02.pdf>)

In comparison, audits are commonly viewed as measuring a service against set standards or criteria not requiring ethical approval. Audits usually involve analysing existing data with results disseminated locally.

Research may be defined as “the attempt to derive generalizable or transferable new knowledge to answer clearly defined questions with scientifically sound research methods. This excludes audits of practice and service evaluations (UKPFH&SCR 2017). Research usually, but not always, requires ethical approval <https://www.swansea.ac.uk/media/P1415-956-Research-Integrity>

**Service Evaluation**

A service evaluation is part of quality Improvement (QI) and is crucial to ensuring those who use a particular service (patients/clients/ students) get the best care or service. It can be used for new or existing services to evaluate effectiveness, safety, efficacy, experience. It may be used for innovation to support the evidence base for commissioning or service development 1. Ultimately it is an activity which aims to improve service, bring about positive change in a particular setting.

Examples of a service evaluation

The following list is not exhaustible. These examples are provided by<https://arc-w.nihr.ac.uk/Wordpress/wp-content/uploads/2020/02/Full-guidelines-for-Best-Practice-in-the-Ethics-and-Governance-of-Service-Evaluation-Final02.pdf>

* Aims to judge a service's effectiveness or efficiency through systematic assessment of its aims, objectives, activities, outputs, outcomes and costs.
* Asks questions such as - "has this service been a success?" or "how satisfied are patients /clients with the service being provided?"
* Are often specific to a department or clinical area.
* Never involves allocating service users randomly to different treatment groups.
* May also be used to compare the effectiveness or efficiency of a new practice/service (where supported by evidence) with an existing one - however this would be for the purpose of local comparison, i.e. not with a view to derive generalizable or transferrable results (which would be research).
* Whilst benchmarking may be used to compare services, the evaluation will not involve measurement against agreed standards (which would be clinical audit).
* Generates evidence of effectiveness of a service which may lead to service redesign.

**Service Evaluations and Ethical Review**

It is commonly thought that service evaluations do not involve ethical review. Although service evaluations and audits fall outside the Research Ethics System, ethical issues may be embedded in a project with possible risk of psychological or physical harm to participants and therefore should have ethical review or oversight depending on the project evaluators themselves, academic supervisors and/or REC Chairs.

**Role of the University**

It is the role of the University to ensure that there are processes, or forms of approval, in place to ensure that ethical protection is afforded to participants in any research or evaluation study. While service evaluations may not require full ethical review, all service evaluations should be screened for potential ethical consideration by the evaluators themselves, and if necessary reviewed by a third party to identify and address ethical issues and risks, and monitored throughout the evaluation process. This need not be an external body such as NHS Research Ethics Committee or a full University committee review but could be an ethical overview conducted by Peers, Faculty, School or College REC Chair, designated committee or Research or Clinical Director against an agreed checklist assessing risk, ethical issues and governance arrangements (see below).

**How to determine whether the project is service evaluation, audit or research?**

Service Evaluations do not ordinarily require full Swansea University or NHS ethics scrutiny. It is therefore crucial that researchers are clear about whether their project is research, service evaluation or audit. The difference between Research, Service Evaluation and Audit can be slight. If there is uncertainty about whether the study is a service evaluation, research or audit then researchers should seek advice from their College/School/Faculty Research Ethics Chair or consult ‘The Health Research Authority (HRA)’ which provides a tool for those working in an NHS to help decide whether or not a study is research, evaluation or audit. ([http://www.wales.nhs.uk/sites3/Documents/952/RES\_Defining\_Research\_Sept\_2013.pdf](https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.wales.nhs.uk%2Fsites3%2FDocuments%2F952%2FRES_Defining_Research_Sept_2013.pdf&data=02%7C01%7CA.Choudhuri%40Swansea.ac.uk%7C773984cc2f8644d6a36808d86b81e525%7Cbbcab52e9fbe43d6a2f39f66c43df268%7C0%7C0%7C637377552923447011&sdata=tX7uJTgOv%2BznK2HyxM0wdy0uxkEZuoGDYIequaN%2Fbqo%3D&reserved=0)

**NHS projects**: Projects in the National Health Service (NHS) normally has a separate process of evaluation. In Swansea, the ***Joint Study Review Committee* (JSRC);** Swansea Bay University Health Board is responsible for reviewing and evaluating whether a project is an audit or service evaluation and should therefore be consulted by those intending to submit to NHS REC but unsure whether their project is research.

<https://sbuhb.nhs.wales/hospitals/a-z-hospital-services/research-and-development/sponsor-information/>

There is no service evaluation department at Swansea University. If service evaluations are undertaken as a stand-alone project or as part of an audit or as preparatory work for a grant application and you are unsure whether you require independent ethics oversight, then please consult your College/School or Faculty Research Ethics Chair. If you are a student or postgraduate, then your supervisor should provide the necessary support. For NHS applications please consult resgov@swansea.ac.uk

**Are the appropriate skills, knowledge and information available to conduct a service evaluation?**

Those conducting service evaluations should make a judgement about whether they or the evaluator are suitably qualified to conduct the evaluation with the population under study. For example, taking account of issues such as independence, political interest and conflict of interest. They should also decide on whether they require any of the following:

* a professional registration,
* a Disclosure and Barring Service (DBS) checks,
* a research passport or
* suitable references.

**What kinds of Ethical Risks may be encountered? How can I monitor them?**

The kinds of ethical issues that arise in research may also arise in service evaluations:

* Recruitment and selection of participants
* Procedures for seeking consent
* Anonymization of data
* Confidentiality
* Risk to participants
* Data protection
* Data storage and data management
* Data sharing and archiving
* Data disposal
* Conflicts of interests

**When does an evaluation study require ethics review or oversight?**

Evaluators should conform to their own professional or Institutional guidelines to assess whether a service evaluation needs ethical consideration

If in doubt, researchers should consult the College/School/Faculty Research Ethics Committee Chairs. In the case of student projects, Academic Supervisors should make the final decision on whether or not to ask Research Ethics Committee Chairs for ethical oversight or whether to undertake the ethical review themselves.

The following questions have been adapted from the HQIP (Healthcare Quality Improvement Partnership <https://www.hqip.org.uk/> who propose the following questions to screen for possible ethics questions in service evaluations:

If the answer to any of these questions is **yes** then the study will need ethical oversight/ consideration

|  |  |  |
| --- | --- | --- |
| **Does the evaluation** | **Yes** | **No** |
| Infringe on individuals’ rights? |  |  |
| Risk breaching patient /client confidentiality or privacy? |  |  |
| Place any extra burden on the individual beyond usual care or activity  |  |  |
| Involve any significant departure from usual clinical care or service |  |  |
| Allocate any interventions differently among groups of service users? |  |  |
| Involve a potential conflict of obligation, for example, a trade-off between quality and cost, to patients, clients, staff |  |  |
| Involve the use of any untested clinical or systems intervention |  |  |
| Provide no direct benefit to care of patients, service users, or their care or improving the service |  |  |
| Is there risk to physical, psychological, emotional, social or financial risk |  |  |
| Are there any conflicts of interest(E.g. a Manager conducting an evaluation who may have a conflict of interest) |  |  |
| Seek out data or human tissue not usually collected  |  |  |

**When does a project not require Ethical Approval?**

**(**If in doubt, please consult your Research Ethics Committee Chair. In the case of student projects, Academic Supervisors would make the final decision on whether or not to consult the Research Ethics Committee Chair for ethical oversight):

* If there is a firm **no** to all the above questions.
* If the evaluation uses existing personal data in a way which complies with the University’s Data Protection policy then no ethics is required <https://www.swansea.ac.uk/about-us/compliance/data-protection/>
* If the Data is completely anonymous;
* If the use of the data does not cause substantial distress or damage;
* If the data collected is to be used for evaluations of educational modules that does not collect personal data and is used to enhance curriculum development;
* If it involves routine audit and evaluation, within the established management procedures of the organisation;
* If the data collected is to be used for evaluation of teaching methods already within University processes. E.g. figures for grades, attendance, module evaluation and engagement etc. for which students would not normally be approached to provide for further consent;
* If the data collected is for the development and evaluation of teaching materials that does not embody original research.