

Research ethics and the Way of Life programme

Research versus evaluation

The NHS National Research Ethics Service (NRES) publishes a leaflet to help professionals decide if a project is research, which normally requires review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

The leaflet can be found here:

<http://www.nres.npsa.nhs.uk/EasySiteWeb/GatewayLink.aspx?allId=355>

Briefly, the leaflet highlights that patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated outside of NRES.

The Way of Life questionnaire falls between being a service evaluation (in evaluating pilot projects) and public health surveillance (in that it seeks to look at the impacts of community interventions on public health outcomes).

Projects not managed as research:

- do not require ethical review by a NHS Research Ethics Committee;
- do not require approval from NHS R&D offices;
- may require some other form of approval from the organisation(s) undertaking or hosting the project depending on local arrangements.

In addition, where projects do not take place within the NHS this does not apply. Where the NHS is a partner in delivering a WOL project they must satisfy themselves that their own local guidelines have been adhered to. However, in those cases there is no compunction for the independent evaluators to seek NHS Ethics Committee approval.

Similar parallels can be drawn with University-based ethics approval processes; these are similarly structured for scientific research. Evaluation processes can be considered as research but they are not necessarily scientific research – community-scale projects seldom have the capacity to conduct full scientific research studies – and therefore do not generally require formal approval by an independent ethics board.

Key issues for evaluation

One of the key issues for evaluators to consider is to ensure that their evaluation is proportionate to the scale of the project, that it focuses on a small number of indicators and that it has a reasonable level of robustness in comparison to its scale of enquiry. This requires a set of methods that draw upon sound research principles, but which are adapted for use in smaller-scale situations where full scientific research is neither practical nor necessary. What we want to know when we evaluate is whether there are indications of success in what we have been doing; that is not the same as proving that a certain approach works for a range of differing circumstances. A good evaluation might draw attention to certain issues that may then warrant wider, more thorough and detailed scientific research but that is not the principal goal of evaluation.

However, that is not to say that there are no ethical issues, and the remainder of this guidance note covers the ethical issues that all projects should address as a minimum. It also outlines Hall Aitken's internal ethics processes.

About our ethical processes

All research should follow ethical guidance.

At Hall Aitken we follow Government guidance on social research, ensuring that we follow five key principles:

1. Sound application and conduct of social research methods and appropriate dissemination and utilisation of the findings
2. Participation based on valid informed consent
3. Enabling participation
4. Avoidance of personal and social harm
5. Non-disclosure of identity and personal information

As researchers we must conform to the guidelines set out by the Market Research Society and the Data Protection Act 1998. These guidelines state that:

- any data collected is only for the stated purpose.
- any personal data is held securely.
- data controllers must keep contact details up-to-date.
- any data with personal identifiers should only be held for up to 1 year.
- data held without personal identifiers can be held indefinitely.

Further, Market Research Society guidelines require that respondents should:

- understand the questions;
- be willing to answer the questions; and
- be able to answer the questions.

The responsibility is on researchers to ensure the questionnaire gathers the correct information to fulfil its purpose.

We conform to the Market Research Society guidelines and Data Protection Act 1998 by following the above guidelines and destroying personal data that is no longer needed.

Research with children

For research with children we pay particular attention to obtaining parental and child/young person consent for data gathering and for any data use. We also ensure our researchers have appropriate CRB disclosure status.

Hall Aitken internal ethical approval processes

Our ethical approval processes depend largely on the client, although in general we treat ethical checking and approval as a matter for senior management rather than through the separate ethics committee processes that large organisations such as Universities and NHS institutions employ.

Ethical issues assessment for Way of Life

Our ethical issue assessment for any research that we carry out directly as part of the Way of Life project is outlined below in figure 1.

Figure 1 Way of Life ethical issue assessment for research carried out directly by Hall Aitken

Issue		Response
Informed consent	✓	Respondents will be provided with clear information about the research. The parent/guardian of respondents will be invited to sign a research consent form document for our research. We will provide guidance for projects outlining the same.
Anonymity and confidentiality	✓	We will offer to all participants the alternative of keeping their answers confidential in part or in full.
Working with children	✓	All our team who will work face-to-face with children will hold full disclosure status and will always work in pairs (or more).
Working with vulnerable groups	✓	The respondent group is primarily children and can be particularly vulnerable. When conducting research with them we will ensure there is an experienced person available to provide support should our work with them create any distress or raise new issues.
Data protection	✓	We conform to data protection agency guidelines on use of personal data.

Ethical approvals for Way of Life self-evaluation

In the case of Way of Life we are not gathering information directly. We have supplied a recommended questionnaire that projects have tested on our behalf.

Further, we are not in control of the data gathering environment, nor how the questionnaires will be used. Therefore, it is inappropriate for us to provide any form of ethical approval.

Projects vary in their methods, but as a minimum the criteria outlined above from Market Research Society and data protection guidelines should be adhered to.

Other points for projects to note include:

- Whilst it is good practice to gain consent from children, projects should obtain parental consent for all questions asked of children.
- All projects should already have in place other appropriate protection regarding data use, suitability of staff and conduct of their own research.
- Where an outside research agency is involved we would expect the project and agency to ensure an appropriate ethical approach, founded on the five principles above.

We will be happy to assist projects in understanding the requirements of Market Research Society guidance and the implementation of their self-evaluation processes.