Eia TASC Clinical Research Quality Management System

School/ Directorate
School of Medicine

Person Responsible
Tracy Petrie

Created
28th March, 2018

Last Review
28th March, 2018

Status
Complete

Next Review
25th March, 2019

Screening Data

What is the name/title of the policy/activity?

TASC Clinical Research Quality Management System

Describe the aim, objective and intended consequences of the policy/activity.

The Quality Management System illustrates the functional and organisational capabilities of TASC to provide services at a consistent and appropriate quality level. The Quality Management System is applied to identified activities and is supported by a set of documented procedures.

Who is responsible for the policy/activity and who implements it?

TASC Quality Assurance Manager is responsible for writing and reviewing the policy. However it is approved by the Research and Development Director and it applies to TASC staff and all clinical researchers in the University of Dundee and NHS Tayside.

Who is effected by this policy?

TASC Quality Assurance Manager is responsible for writing and reviewing the policy. However it is approved by the Research and Development Director and it applies to TASC staff and all clinical researchers in the University of Dundee and NHS Tayside. It will also benefit volunteers who participate in research programmes and ultimately the wider public.

Is there any indication that this policy is relevant to equality and the protected characteristics or that those with any of the protected characteristics will have a different experience in relation to the intended outcomes of the policy?

At first sight the policy has minimal relevance to equality, however there are matters relating to staff and participants that may have relevance and so this policy will be fully assessed.

Whilst there is little evidence at this stage of relevance to the protected characteristics, there are two areas where there may be an opportunity to promote equality of opportunity and eliminate risk. These are in relation to disability and to pregnancy and maternity.
In the first instance, the opportunity to participate in any research project may be limited to a researcher with a disability where that disability creates barriers and the individual is not given access to reasonable adjustments to allow participation.
In relation to any volunteer, again consideration of specific needs related to any disability should be taken account of where practicable.

In relation to pregnancy and maternity, research will often mean the handling of biological materials. This may at times present a risk to the unborn child or nursing mother. There is a generic risk assessment for the use of biological materials and any such risk would be identified through that process.

Recommend this EA for Full Analysis?

Yes

Comments

There is potential for some relevance to some of the protected characteristic, especially disability and pregnancy and maternity. There is no evidence at this stage to suggest issues with different experiences, however the potential remains and this EIA will take account of the steps in place to minimise that potential.

Rate this EA

Low

Impact Assessment Data

Is this policy relevant to the protected characteristic of Age?

- No

  Research may be linked to age related diseases, however in terms of this policy there is no relevance.

Is this policy relevant to the protected characteristic of Disability?

- Yes

  There is a potential for disability to result in different experiences for both staff and participants. In relation to participants it is important that their disability is taken into account in relation to the nature of the research and also to the support provided them to ensure a positive volunteer experience.
  In relation to staff it is important that anyone who has identified as having a disability and is supported by reasonable adjustments, have those adjustments in place to allow full participation in the research.
  Mechanisms to support staff with disability are in place at both the University of Dundee and at NHS Tayside.

Is this policy relevant to the protected characteristic of Gender Reassignment?

- No

  We have no evidence that the protected characteristic of gender reassignment is relevant to this policy. However we acknowledge that public opinion on gender re-assignment varies greatly and we will monitor for any change here.

Is this policy relevant to the protected characteristic of Marriage and Civil Partnership?

- No

  This is not relevant to research in the clinical context.

Is this policy relevant to the protected characteristic of Pregnancy amd Maternity?

- Yes

  There is a small risk of impact relating to the handling of biological materials. The University and NHS Tayside have generic risk assessments in place that will be carried out to identify any risk before any research is undertaken. In addition the application for the research must be passed by the Ethics Committee.

Is this policy relevant to the protected characteristic of Race?

- No

  Whilst individual projects may have a relevance to race, this policy will not and there is no evidence to support detriment related to race.

Is this policy relevant to the protected characteristic of Religion and Belief?

- No

  There is no current evidence to suggest that this is relevant or should result in different experiences.

Is this policy relevant to the protected characteristic of Sex?

- Yes

  In relation to sex, there is no current evidence of differential experiences related to this particular policy.

Is this policy relevant to the protected characteristic of Sexual Orientation?

- No

  The policy is about the quality of research standards and as such sexual orientation has no relevance to this.

Taking account of the findings so far, is there a possibility that the implementation of this policy would result in a different experience or a detriment for those with protected characteristics?

- No

  Although we have identified a potential for relevance to disability and pregnancy and maternity, that potential is very minimal and there are processes and policies in place that would reduce or remove that risk.

Based on your findings so far, what recommendations or changes (if any) would you make in relation to the policy and how it is implemented?

In relation to this policy we recognise that is some potential for impact, however that is minimal and the university and NHS have policies in place to address that potential.
As a result we find no reason to alter this policy at this point.

Our recommendations are purely in relation to monitoring for any changes in evidence to support a review of this policy.

Where you have recommended actions/changes to the policy, what are the timescales for completion of these

25-03-2019

What monitoring arrangements do you have in place to identify changes in any impact or relevance?

We have a robust auditing process and any matters relating to equality would be captured through that process. Equality considerations will be captured on the meeting agenda for TASC Clinical Research Guideline Committee. feedback through the committee will be used to inform any change to this policy.

Comments

The relevance to equality is minimal in relation to this policy. As such there are no changes to be made at this time. In order to gather any evidence of equality matters in relation to this policy, equality considerations will be an agenda item on the Committee agenda and that will inform any future changes necessary.

Organisation Sign-off Data

Having read the EIA, do you approve its findings and recommendations?

- Yes

What are your reasons for approving/not approving the EIA?

The policy in itself has little relevance to equality and at this time there is little or no evidence to suggest actual impact.

We will use the monitoring process to gather evidence where available and review the position in a year.

If you have approved the EIA, do you agree with the monitoring arrangements in place?

- Yes

The Committee meet regularly and so it is the ideal opportunity to gather information on the successes or issues arising from a research project.

Where you have not approved the monitoring process, what other steps do you require to be taken?

Not applicable

Comments

Minimal impact , no changes at this time.

Next Review Date

2019-03-25

Outstanding Actions

No outstanding actions