

SOP number	50.019	Version	2.0
Title	Independent Stakeholder Assessment		

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SOP category	NHS GG&C General			
Staff category				
Staff Category	R	A	C	I
R&I Quality Manager		X		
All Clinical Research & Innovation Staff				X

1. Scope

This procedure applies to all staff within Clinical Research & Innovation and Investigators of R&I approved studies.

2. Purpose

The purpose of this SOP is to describe the steps that can be taken when carrying out an Independent Stakeholder Assessment, this can cover any number of different actions, documents, tools or activities which require a review from a number of different sources and expertise and require evidence of the review that has taken place.

3. Procedures

When an Independent Stakeholder Assessment is required to be conducted, this SOP along with Form 50.019A can be followed. Alternative methods of documenting reviews can also be utilised, for example the functionality present in Q-Pulse for the review of SOPs.

The purpose of the Independent Stakeholder Assessment is to demonstrate evidence of due diligence being taken when implementing Actions, Processes or the release of new tools. The Research and Innovation Department is made up of wide range of individuals and roles, each with their own areas of interest and expertise. It is vital that full advantage is taken of this collective of expertise to ensure steps taken are always fit for purpose.

When an item is to come under review, it is the responsibility of the Assessment Owner to initiate the Independent Stakeholder Assessment. The Assessment Owner will be the individual who has the overall responsibility for the preparation, implementation or acceptance of the end deliverable. This can take a number of different forms, one example of this would be in the preparation of a new or updated SOP. In this instance the Assessment Owner will be the individual who prepares the SOP, they will be tasked with collecting the input of a representative for all areas impacted by the SOP. This can be achieved by downloading Form 50.019A and following the instructions within and those detailed in GUI 50.019A to elicit the input of a relevant group of stakeholders.

3.1. Selecting Reviewers

A key step to completing an effective Independent Stakeholder Assessment is to select appropriate reviewers. Consideration must be given to the item under review to establish an appropriate selection of stakeholders, a good place to start is to identify any individual or group who are required to complete an action as part of the normal operation of the item under review.

For example, if an SOP is being developed in which the Monitors have an action to complete or process to follow it is important to get input from the Monitoring Team. Similarly if it is a member of Pharmacy, PV or Systems etc.

It is always good practice to ask for input from Governance and Quality as they will have the experience of most of the issues previously encountered and can provide helpful guidance from past issues on how to avoid them.

It is useful to ask for a range of input, where possible, always ask for the feedback of individuals who implement the process and have first-hand experience of the activity. They will be able to identify issues relating to the practicalities of its use.

If the process, tool or action is likely to have an impact on the ways of working for the organisation it is a good idea to get input from Senior Management so that the impact can be properly considered.

3.2. Conducting Review

When conducting the review, it is good practice for the Assessment Owner to engage with the reviewers in advance to give some background and get feedback on their availability to carry out a review.

The individual reviewers should be aware of the timescales involved and aim to supply their input within this timescale, this is a key opportunity for them to have their input considered as it is likely to be of impact to them going forward.

Returned reviews should always be given an appropriate level of consideration by the Assessment Owner, it is good practice for them to engage with the reviewers and discuss solutions to any observations they have raised. The value in the Independent Stakeholder Assessment is when a consensus is reached on the appropriate solution. Ultimately, the ownership of the item under review will remain the same and the final decision will remain with them. If a mutual agreement cannot be achieved, it is within the remit of the owner to decide the way ahead. This should be seen as the final resort and all efforts should be made to reach a mutual agreement.

If reviews have not been returned by the agreed date, if it is feasible and time allows, the Assessment Owner should contact the individual and try to agree a new time for the completed review to be returned. In the event that a completed review is not returned, the original form sent to the individual must be recorded to show that no feedback has been received. This enables evidence to be shown that the correct stakeholders have been engaged.

3.3. Evidencing Review

It must be possible to evidence that the review has taken place, to this end, the completed forms must be saved and remain available to be retrieved at a future date. It is important that these forms are stored in the correct locations and also, sufficiently classified so that they can be retrieved. This will act as the evidence that the appropriate skill sets have been deployed when implementing new Processes, Actions or Tools. Depending on what is being reviewed, there may be more than one location for the Independent Stakeholder Assessment Forms to be stored, if the review is relevant to a specific trial it may need to be stored in the Trial Master File for example. However, all Independent Stakeholder Assessments should be stored in Q-Pulse as a master copy, this can be achieved by the Assessment Owner sending the Completed Forms to the Research and Innovation Quality Manager who will arrange for them to be uploaded and provide a reference number when this is complete.

4. Referenced documents

- Form 50.019A – Independent Stakeholder Assessment Form
- GUI 50.019A – Independent Stakeholder Assessment Guidance

5. Related documents

- N/A

6. Document history

Version	Date	Description
1.0	2/10/2020	First Release
2.0	09/06/2023	Migration to updated template, minor change to applicability to make optional.

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