



## Recruitment Projects

### PURPOSE

This SOP describes procedures to follow when HIC Services provides patient recruitment support for a research project and covers:

- Specifying project requirements
- Identifying and managing patient contact lists
- Validating patient lists
- Preparing and sending email or letter mailings

### SCOPE

This SOP covers the recruitment process. It is applicable to all HIC staff. This SOP is will be made available to all users and potential users of the HIC Service and will be externally visible on the public HIC website.

### PROCEDURE

#### Overview

## Specifying Project Requirement Steps

1. The recruitment mailing process is complex and requires detailed requirements gathering to ensure the correctly formatted mailing is sent to the correctly identified people. Project requirement details will be agreed and recorded within the Recruitment Project Initiation Document (PID), including:
  - Project title and summary of aims, methods and cohort.
  - A specification of how mailing targets will be identified.
  - A specification of what data HIC or the project team will be processing for the project and how the project will potentially fit within the HIC recruitment tracker system.
  - A specification of how the mailing list cohort will be validated.
  - Number of anticipated mailings:
    - Usually a recruitment target, multiplied by an anticipated response rate.
    - Can be assisted by a review of the potential target group via HIC dataset aggregates.
  - Frequency of mailings – e.g. reminder letters or different mailings to different study groups.
  - Format of mailings:
    - Letter template, with agreed and defined text, letterhead and merge fields.
    - Business Support to contact DocMail to ensure the contents of envelope, e.g. mail-merged letter, patient-information sheet, consent form, reply envelope, questionnaire, size of envelopes, colour/black & white.
    - Business Support to produce template and send to DocMail
  - A specification of whether replies will come back to HIC, e.g. questionnaires for data entry or responses for tracking through the HIC tracker.
  - A specification of what approvals will need to be obtained before HIC work can commence. Refer to HIC Services SOP 02 Data Access Approvals for information about required approvals documentation.
  - A risk assessment will be made to identify any potential use of identifiable data on forms or questionnaires and any other potential risks to data security or patient confidentiality and what mitigation will be put in place to manage these risks to an acceptable level.

## Identifying and Managing Patient Contact Lists Steps

1. The cohort selection method will be agreed with the Approved Data User and documented by a HIC Data Analyst responsible for data management, including any inclusion and exclusion criteria being used.
2. Where patient consent is to be obtained by "Opt out" methods, project-specific permission will have to be given by the HIC Governance Committee and the approval stored on the PM System.
3. Mailing cohorts identified from HIC-held Datasets will first be screened by the patient's GP practice or NHS clinic. A secure process will be followed, illustrated below, where the researcher will not see any identifiable data until the patient has given consent to being contacted by the research team.

4. Patient-identifiable data will be managed by HIC within secure NHS-network areas, including sending and receiving patient lists to/from Clinics and GP Practices and producing and sending letters to patients requesting consent to be contacted by the research project team. Researchers will only receive identifiable patient details after the patient has consented to this.
5. Lists of eligible patients may alternatively be supplied directly to HIC from an external NHS-approved source but will be checked as per the validation process below.
6. Data source-specific procedures will be agreed and documented for collaborative HIC recruitment mailing support. The procedures will include cohort validation methods and systems for confirming that appropriate governance approval has been obtained for each project being supported by the data source and requiring HIC involvement.

## Validating Patient Lists Steps

1. All cohorts created by HIC will be checked for accuracy using the following procedure, either internally by HIC Data Analysts or by an external process agreed with HIC:
  - Cohort validation will be carried out by a senior person, also familiar with the data - not the same person who created the original cohort.
  - The cohort will be checked to ensure it conforms to previously generated aggregates for the project, where available – i.e. the numbers look about right.
  - The project inclusion and exclusion criteria will be checked to ensure they were applied correctly by stepping through each condition to check individually.
2. Where cohorts are provided to HIC from external sources the "Cohort List Validation Confirmation (externally supplied cohorts)" form will be completed and provided with the supplied cohort.

## Preparing Mailing Templates Steps

1. All letter templates will be created and stored within the HIC mailing software tool to ensure a standardised approach to reduce errors, using agreed text, letterhead and merge fields for each project/ mailing batch. The template will be test-merged and quality checked by a different person against documented criteria for appearance and against documented project/ batch specifications.

2. All email templates will be created, stored and version controlled to ensure a standardised approach to reduce errors, using agreed text/images and merge fields for each project/mailing batch. The template will be test-merged and quality checked by a different person against documented criteria for appearance and against documented project/batch specifications. Once internally approved then the template will be sent to the main project contact for sign-off.

### **Preparing Other Mailing Document Steps**

1. Care will be taken to closely follow agreed mailing requirements for each batch, including preparing and collating the correctly specified contents. In addition to the mail-merged letter, any of the following may also be included in each envelope:
  - Patient information sheet (PIS)
  - Consent reply slip
  - Study brochure
  - Questionnaire, potentially also with merged study identifiers
  - Reply envelope

The details of any additional documents will be specified for each project/batch in the project PID.

### **Merging Template with Mailing Cohort Steps**

1. The HIC mailing software tool will auto-match, using unique identifiers, the template to the cohort list and carry out the merge.
2. DocMail will provide the batch count of printed materials and to confirm the number of errors and will be recorded on the quality control documentation.

### **Quality Checking the Letter Mailing Batch Steps**

1. Following the documented project/batch specifications, the mailing is checked by a senior member of the Business Support team for:
  - Mail-merge accuracy, e.g. correct batch number, header doc, footer ID codes, signature format.
  - Other documents included, as specified
  - Batch count of the packed mailing to be provided by DocMail and recorded on the quality control documentation.
  - Appearance quality criteria of the completed mail-set
  - Batch counts from the HIC Mailing Software, printed resources and packed envelopes will be confirmed and recorded on the quality check document.
2. The details of the mailing quality check are documented for each batch.

### **Sending Mailing Batch Steps**

1. Once the letter mailing has been checked and ready for sending it is logged by a member of Business Support Team in the Transfer of Custody log before sending to DocMail.
2. Once the email template has been checked and ready for sending the batch dates/times for sending are added to the records. Any issues with sending (e.g. invalid email address) are logged against the record and reviewed by Recruitment Manager.

### **Letter Responses Steps**

1. Letter responses will be returned to the Business Support Team through the HIC freepost address, if required for the study. These responses (positive and negative) will be recorded on the HIC Recruitment Tracker with only positive responses transferring to the research team.

## **APPLICABLE REFERENCES**

- Recruitment Project Initiation Document (PID)
- HIC Recruitment Mailing QC Checks doc
- [Data Security](#)
- [Data Access Approvals](#)
- Staff Confidentiality Agreement

- [Legal and Governance Policy](#)
- [For Definitions see ISMS Glossary](#)
- SOP Appendix C – Roles and Contact Details

## DOCUMENT CONTROLS

Process Manager		Point of Contact	
Keith Milburn		<a href="mailto:hicbusiness-support@dundee.ac.uk">hicbusiness-support@dundee.ac.uk</a>	
Version Number	Effective Date	Edited By	Edition Details
1.0	01/01/15	Duncan Heather (HIC Governance Manager)	New SOP
2.0	01/01/16	Duncan Heather (HIC Governance Manager)	Added reference to External Cohort Validation form in 5.4.1.2
2.1	01/05/18	Keith Milburn (ADP Manager)	Added reference to email contact alongside existing letter contacts
3.0	08/11/18	Duncan Heather (HIC Governance Manager)	Updated to reflect new Staff Confidentiality Agreement
4.0	10/06/2019	Claire Jones (ADP & Data Entry Manager)	Updated to include batch count confirmation between batch requirements, printed resources and packed mailing
	24/02/2020	Tracey Stewart (Data Entry Team Leader)	Updated cover sheet with new approval process information
5.0	25/06/2020	Adrian Clatworthy (Business Support Co-ordinator)	Updated to reflect third party mailing vendor DocMail and updated process flows
5.0	18/01/22	Duncan Heather	Reviewed, no changes made

5.1	19/02/23	Bruce Miller	Moved SOP from SharePoint to Confluence
<b>Last Review Date</b>	<b>Trigger</b> <ul style="list-style-type: none"> <li>• Annual Review</li> <li>• Internal Audit (conducted by TASC annually) has identified opportunities for improvement (OFI) or nonconformities (NC)</li> <li>• External Audit has identified OFI or NC</li> <li>• Significant Event has highlighted OFI</li> <li>• Client Complaint has highlighted OFI</li> <li>• HIC All Staff (individuals of) have identified OFI</li> </ul>		
18/01/22	Annual Review		
<b>Approved by the HIC Ops Group Date</b>			<b>Approved by the HIC Exec Date</b>
4 <sup>th</sup> May 2020			12 <sup>th</sup> May 2020

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