



# Standard Operating Procedure (SOP) 001

## Guidance on the use of the Investigator Site File

### Scope

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To describe the use and maintenance of the Investigator Site File (ISF) for the PICNIC Feasibility Study.

### Purpose of the ISF

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- In order for a research study to be run in accordance with the International Conference on Harmonisation Good Clinical Practice guidelines (ICH-GCP), there are certain essential documents that must be compiled and retained at the site.
  - Essential documents are those that enable evaluation of the conduct of the study and the quality of the data produced. These documents demonstrate compliance of the investigator(s), site research staff (where delegated), Sponsor and Study Management Group with the standards of ICH-GCP.

### Use of the ISF at your site

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- The ISF will be provided by the ICNARC Clinical Trials Unit (CTU) prior to patient recruitment.
  - The responsibility for the care and maintenance of the ISF rests with the site Principal Investigator (PI) or delegated members of the site research staff (see SOP 002\_Delegation of study duties).
  - All essential documentation relating to the study must be retained locally in the ISF.
  - The ISF should be kept in a secure but accessible location (available to site research staff).
  - If an essential document is not filed per the ISF checklist, a file note should be inserted clearly detailing the location of the document (electronic or hard file) and why it does not appear in the ISF (a file note template is provided in Section 9: Quality Assurance, of the ISF).

## Maintaining an ISF

- All essential documents relating to ICH-GCP and Research Governance must be filed together.
- All superseded documents must be filed in the relevant sections of the ISF in chronological order (by version number and date).
- All study related updates, information and correspondence should be placed in Section 13: Correspondence / Information, of the ISF in a timely manner.
- The ISF should be made available to the ICNARC CTU and the Sponsor on request.
- Once the study has finished, the PI (or delegate) is responsible for ensuring that the ISF, containing all essential documents, is stored securely. Where appropriate, documents should be clearly cross-referenced using a file note.
- The ISF must be securely stored for at least five years, in line with Sponsor requirements, after the completion of the study.

### Documents to be kept up-to-date in the ISF

The table below shows the documents that are required to be kept up to date, and the relevant timescale of updating them:

Document to be updated	How often to update
<b>Trial Specific Standard Operating Procedures (SOPs)</b> (Section 3)	Any updated versions of SOPs sent by ICNARC CTU should be filed, with previous versions marked as superseded.
<b>Study protocol</b> (Section 4)	Any updated versions of the study protocol sent by ICNARC CTU should be filed with previous versions marked as superseded.
<b>Documents for participants</b> (Section 5)	Any updated versions of patient information sheets, consent forms and questionnaires should be filed with previous versions marked as superseded.
<b>Signed consent forms</b> (Section 6)	All consent forms must be completed, signed and filed in chronological order.
<b>Screening and Enrolment log</b> (Section 6)	<p>This is a working document and must be updated whenever a patient has been screened for the study.</p> <p>A patient is considered enrolled once they have been allocated a study number.</p> <p><b><i>Email to the ICNARC CTU when requested: <a href="mailto:picnic@icnarc.org">picnic@icnarc.org</a></i></b></p>

Document to be updated	How often to update
<b>Patient Study Number lists</b> (Section 6)	These are working documents for the Ecology Surveillance weeks and PICnIC Period One and Two. They must be used whenever a patient has been entered to provide the study number.
<b>Case Report Forms (CRFs)</b> (Section 8)	Any updated versions of the CRFs sent by ICNARC CTU should be filed with previous versions marked as superseded.  All individual SAE reporting forms should be uploaded to Macro within 24 hours of the site becoming aware and ICNARC should be informed via <a href="mailto:picnic@icnarc.org">picnic@icnarc.org</a> . Do not send a copy via email. (Please see SOP 009 Safety Monitoring for further details)
<b>Site approvals</b> (Section 11)	Site approvals for any amendments made during the course of the study should be added to the ISF.
<b>Delegation log / Research Staff Contacts Form</b> (Section 12)	These are working documents and must be updated whenever there is a change to the delegated study duties and authorised by the PI.  <b>Email ICNARC CTU when updated:</b> <a href="mailto:picnic@icnarc.org">picnic@icnarc.org</a>
<b>CVs/GCP training</b> (Section 12)	All CVs must be signed and dated, and updated every two years.  All GCP training certificates need to be up-to-date (updated every two years).
<b>Correspondence</b> (Section 13)	Any important correspondence with ICNARC should be kept up to date and filed in the ISF.

*The ISF is a working file and will act as a reference to the conduct of the study.* It provides a single place for all records to be kept, ensuring all necessary documents are being filed securely.

These are working documents and must be updated whenever there is a change to the delegated study duties and authorised by the PI. **Email to the ICNARC CTU when updated:**  
[picnic@icnarc.org](mailto:picnic@icnarc.org)