Medical Warnings for Participants in Clinical Trials

A Medical Warning must be added to SI PICS for all participants in intervention studies.

This warning alerts health professionals to an individual's participation in a research trial and provides the investigator's contact details.

For departments still using paper clinical records, inserting an Alert sheet to a participant's clinical notes may also be useful. An Alert sheet template is available on the HRS website.

Medical Warnings for Intervention Studies

A Medical Warning (clinical) is a notification of crucial care information within the South Island Patient Information Care System (SI PICS).

The Principal Investigator or the Clinical Research Nurse/Coordinator (via delegated authority) must request a Medical Warning is created in SI PICS for each study participant. There is a dedicated category for patients participating in a clinical trial (*CLNTRL)*.

As part of the National Medical Warning system, Medical Warnings created in SI PICS will display in other clinical applications (e.g. Health Connect South, Mosaiq, EDIS, Medchart).

Category	**Description**	**Recommended Structure** *(max. 70 characters)*
CLNTRL	A warning that this patient is participating in a clinical trial.	<trial name>…<warning><contact phone>

Note: The start date is the day of the first study related task (usually the signing of the Consent Form).

To add or modify a Medical Warning:

1. Download the **National Medical Warnings Request Form** from Ka Tuhika Ki Te Toka: Southern Documents (MIDAS ID: 201361).
2. Complete.
3. Send to the appropriate email addresses listed on the form (note the After Hours options).
4. Check SIPICS to confirm warning appears (usually within two working days).

End of Trial

When a clinical trial warning is no longer required, use the Request Form to modify the Warning, so clinical trial participation is still recorded in the electronic health record.

Locality authorisation

To ensure awareness of the Warnings process, when relevant, Health Research South will ask for:

1. A partially filled National Medical Warnings Request form pre-filled with trial details
2. Paper Alert Sheet *(optional)*

Purpose

Warnings enable close monitoring of intervention study participants on referral or admission to hospital. This serves to maintain patient safety and study protocol adherence. For example, they allow other clinical staff to:

- Alert Principal Investigators to hospital admissions and other potential adverse events
- Request unblinding or information on study treatment
- Longer retention of clinical records

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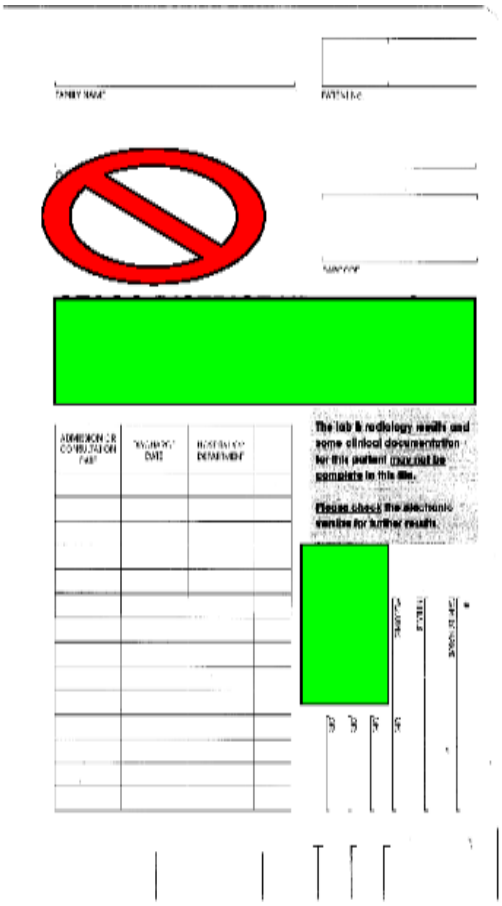
Placement of stickers on Clinical Records

Health records for clinical trial participants must often be kept longer than the legal minimum. Generally, Sponsor permission must be obtained before destruction of any relevant records. Auditors may want to review source documents and not only study files.

When a longer retention time is required, Investigators must request the medical records are not destroyed . This is done by adding a sticker to a participant's paper record.

Alert stickers and stickers detailing future destruction may be placed on the front of the Clinical Record, as long as they do not obstruct any important information on the front cover. The best placement of stickers is as noted in the green rectangles below.

The red area is used by Clinical Records staff for clerical information. Details of non-destruction dates needs to be highly visible within the limited space.



For more information:

See "Administrative Alerts and Medical Warnings Communications; part of the Go Live Packs on the SI PICS Sharepoint https://southerndhb.sharepoint.com/sites/SIPICS/