

**TITLE:** Processes for ITCC Sponsor, National Coordinating Centre (NCC) and participating site selection for ITCC academic – sponsored trial

**VERSION:** 1.0

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**SUPERSEDES:**  
Version of NOV-2015

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**REVIEWERS:**  
Members of the ITCC Sponsor Institutions Committee

**REASON FOR CHANGE**  
Need to have a clearer procedure, easier and understandable for all the ITCC members (Sponsor Institutions Committee, NCC, sites)

**IMPLEMENTATION PLAN :**  
Following approval by the ITCC Sponsor Institutions Committee, the SOP will be disseminated to all ITCC sites.

## PURPOSE :

The purpose of this SOP is to have a clear process to confirm the Sponsor for an academic-ITCC clinical trial and to select the NCCs and sites to run the trial.

## SCOPE:

This SOP is applicable for the ITCC Sponsors, NCCs and the selected sites.

## PROCEDURE

- 1) A Lead investigator proposes a trial.
- 2) This trial is presented to the CTC, which can add comment and suggest revisions before ITCC approval of the trial given.
- 3) The CTC allocates a number to the trial on behalf of the ITCC (ITCC-XXX) and notifies the Sponsor Institutions Committee
- 4) If Sponsor known, the Sponsor Institutions Committee sends a letter of approval to the sponsor. If Sponsor is not known, it will be proposed by the Sponsor Institutions Committee
- 5) The Sponsor sends an expression of interest to NCCs to notify them that there is an ongoing trial.
- 6) The Sponsor can now choose the National Co-ordinating Centres (NCC) to conduct the trial, among the 11+6 ITCC NCCs (11 additional NCCs and 6 single-site countries).

If the national site selected is not an ITCC NCC:

- Sponsor must request for an exception and justify its choice; ITCC NCCs have to explain why they can't conduct the trial; the selected center has to demonstrate expertise in acting as NCC.
- The Sponsor Institutions Committee, the Sponsor and the selected center may need to have an extraordinary TC to discuss the proposal.
- If the proposal is approved, the selected center is considered NCC for this trial ONLY.

If the proposal is not approved, the center is not accepted for the trial, further discussion and feedback is possible with the potential for subsequent approval as NCC

- 7) The selected NCCs can now suggest to the Sponsor the national ITCC sites to participate in the trial. NCCs and/or Sponsor can follow their own /national processes for site selection, for example by utilising a circulation of "Expression of Interest" on behalf of the Sponsor (sent from the ITCC secretariat).
- 8) The Sponsor agrees the final selection of suggested sites in agreement with the relevant NCC.


- 9) The Sponsor will have access to information regarding the national processes for site selection.

DEFINITIONS:

RELATED RESOURCES:

Flow diagram / Logigramme

## AUTHORISATION

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EDITORIAL AMENDMENTS:			
Editorial amendments #	Reason for update	Person making update	Date of amendment

FULL REVIEWS			CHECK BOX IF NOT APPLICABLE <input type="checkbox"/>
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