CLINICAL RESEARCH - PARTICIPANT REIMBURSEMENTS

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- The purpose of this procedure is to outline the process for the reimbursement of out of pocket or other expenses incurred by clinical research participants during their involvement in clinical research.
- The procedure must be followed by all personnel involved in the process of reimbursement of out of pocket or other expenses.

CHANGE SUMMARY

- Document due for mandatory review.
- Read Acknowledgement and Related Documents sections updated.

READ ACKNOWLEDGEMENT

- Read/Acknowledge Only – Personnel involved in the process of reimbursement of out of pocket expenses incurred by clinical research participants during their involvement in clinical research.

Approved by:	SCHN Policy, Procedure and Guideline Committee	
Date Effective:	1st September 2021	**Review Period**: 3 years
Team Leader:	Clinical Research Manager	**Area/Dept**: Kids Research

Date of Publishing: 17 August 2021 11:41 AM Date of Printing: 17 August 2021

Purpose/Scope

The purpose is to outline the procedure for the reimbursement of out of pocket or other expenses incurred by clinical research participants during their involvement in clinical research.

This procedure must be followed by all personnel involved in the conduct of clinical research involving the reimbursement of clinical research participants.

Background

In line with the National Statement on Ethical Conduct in Human Research[1] Section 2.2.10 and 2.2.1, it is expected that participants involved in clinical research will be reimbursed for reasonable out-of-pocket or other expenses.

This may include travel, parking, meals, time and accommodation for the participant (child or young person) and an accompanying parent/legal guardian, as applicable for a given clinical research study.

Procedure

- Any intent to provide reimbursements for out of pocket or other expenses must be disclosed in the Participant Information Sheet and Consent Form(s), and will be subject to review and approval by the responsible Human Research Ethics Committee (HREC) and Research Governance Office (RGO);
- The Participant Information Sheet and Consent Form(s) must clearly state if receipts are to be kept to enable a claim of any reimbursement;
- It is generally not appropriate for participants' out of pocket or other expenses related to participation in clinical research to be claimed via the 'Isolated Patients Travel and Accommodation Assistance Scheme' (IPTAAS) (Section 4.3.6);
- The details of any participant reimbursement including the nature of reimbursement(s), maximum amounts, any requirements for the provision of supporting documentation and prior approvals, must be detailed in the Agreement(s) between SCHN and the Sponsor (or Delegate);
- Responsibilities for reviewing, approving and/or issuing participant reimbursements (including any use of any third-party vendors on behalf of the Sponsor), must be clearly outlined in Agreement(s) with the Sponsor or Delegate;
- Ground travel may be undertaken via public transport, private vehicle or taxi;
- Private motor vehicle usage will be reimbursed according to mileage, in line with the rates specified by 'C2021-03 – Meal, Travelling and Other Allowances', as amended from time to time, unless otherwise agreed with the Sponsor or Delegate;

- Where expenses or out of pocket costs exceed the maximum amount stipulated in the Agreement(s) with the Sponsor, approval (if required) is to be requested on a case-by-case basis, prior to the expense being incurred (where feasible);
- If SCHN is responsible for the reimbursement of out of pocket or other expenses, the reimbursement will be issued via electronic funds transfer to the participants nominated account, unless another arrangement has been approved by the responsible HREC and RGO;
- Reimbursements should not be processed prior to the expense being incurred i.e. paid up front, unless prior approval has been obtained by the responsible HREC and RGO, or if special circumstances warrant upfront payment (e.g. to avoid undue financial hardship);
- Clinical research participants will be encouraged to promptly request any claims for processing;
- If the Sponsor or Delegate is responsible for issuing participant reimbursement directly, any supporting documentation such as receipts provided must be de-identified by clinical research personnel prior to provision to the Sponsor or Delegate;
- Clinical research personnel will ensure that adequate records of reimbursements, including any approvals and supporting documentation (e.g. receipts) are maintained as part of the Investigator Site File.

Abbreviations and Definitions

HREC	Human Research Ethics Committee
IPTASS	Isolated Patients Travel and Accommodation Assistance Scheme
NSW	New South Wales
PD	Policy Directive
RGO	Research Governance Office
SCHN	Sydney Children's Hospitals Network
TC	Treasury Circular

Related Documents

1. National Statement on Ethical Conduct in Human Research (2007) - Updated 2018 - https://www.nhmrc.gov.au/guidelines-publications/e72
2. NSW Health PD2019_039 - Isolated Patients Travel and Accommodation Assistance Scheme (IPTAAS) Policy - https://www1.health.nsw.gov.au/pds/Pages/doc.aspx?dn=PD2019_039
3. SCHN Policy – Clinical Research [DRAFT]
4. SCHN Policy 2013-9000 - Isolated Patients Travel and Accommodation Assistance Scheme Framework - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4824
5. SCHN Procedure 2019-145 – Clinical Research - Record Keeping - http://webapps.schn.health.nsw.gov.au/epolicy/policy/4661
6. C2021-03 Meal, Travelling and Other Allowances for 2020-21- https://arp.nsw.gov.au/c2021-03-meal-travelling-and-other-allowances-for-2020-21/