

# Purchasing and Storage of Study Medications

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## Amendment History

Version	Date	Author/s	Amendment Details
2	14/09/2017	Gudrun Wells	Reviewed

## Purpose:

To outline the appropriate protocol for the purchasing, storage, destruction and recording of medications used by the Behavioural and Situational Research Group (BSRG) as part of approved research studies.

## Responsibility:

It is the responsibility of the Chief Investigator (CI) to ensure that this protocol is in line with current University of Tasmania policy and relevant legislation. The CI is responsible for delegating and training staff in how to purchase and store medications (as recorded in the Delegation Log and Training Log).

## Scope:

This protocol outlines how smoking cessation medications—e.g. varenicline, bupropion and nicotine replacement therapies—should be purchased, stored and documented for use in BSRG studies, and how they are to be destroyed when no longer required. This includes both unregulated medications, and ones that have been designated as Schedule 4 by the Poisons Standard 2015.

## Materials:

- Study medications and their packaging or Safety Data Sheets
- Poisons record book (held in BSRG lab and MS1)

### Procedure:

Smoking cessation medications that are commonly utilised by BSRG fall into two categories: Scheduled Poisons as defined by the Poisons Standard 2015 (varenicline and bupropion) and unregulated medications (e.g. nicotine patches). There are different regulations for how medications from these two categories can be purchased and stored. The storage specifications for each drug should be based on ICH recommendations.

### Schedule 4 Poisons

These medications (e.g. varenicline and bupropion) must be purchased through the Division of Pharmacy Laboratory Manager using a University of Tasmania credit card or purchase order, or Royal Hobart Hospital Pharmacy requisition order, as per permit No. R6/150514 under Regulation 6 of the Poisons Regulations 2008 and the Poisons Act 1971. They must be stored in a secure area that is only accessible to study staff (e.g. in a locked cabinet inside a University office). Additionally, per the Division of Pharmacy's licensing requirements, these medications can only be stored in areas of the University that are designated as being part of the Division of Pharmacy or, in offsite studies, approved in writing by the Associate Head of the Division of Pharmacy.

Specifics for how medications are stored are to be found on the product packaging or Safety Data Sheet, and the specifications for each type of medication should be checked with each batch purchased.

The receipt, usage and disposal (e.g. when it is out of date) of medicines must be recorded in the S2, 3 and 4 Poisons register held in the BSRG lab.

### Unregulated Medications

Unregulated items (such as nicotine patches) may be purchased as required by study staff. Purchasing large amounts of a particular medication may be restricted for individuals by retailers, in which case they should be purchased through the Division of Pharmacy Laboratory Manager using a University of Tasmania credit card or purchase order.

There are no storage restrictions with unregulated medications, however due to their high cost it is advisable to store them in a secure area as for the S4 Poisons. Their use does not need to be documented, except as required for study purchasing, accounting or ethics (see note above about recording dispensation).

### Registering medication receipt, dispensing and destruction

For all medication used in BSRG studies the dispensation must be recorded in a GCP-compliant manner. This includes the tracking of the following information:

- Date supplied
- Quantity and batch or lot number supplied
- Who supplied the medication
- Medication type and quantity dispensed to each participant at each visit
- Batch number and quantity of medication to be destroyed.

## Standard Operating Procedure

All medications that have passed their use-by date, or are otherwise no longer required for the study, are to be logged and then given to the Pharmacy Laboratory Manager for destruction.

### **References:**

The Poisons Standard July 2015: <http://www.tga.gov.au/publication/poisons-standard-susmp#electronic>