Purpose:
The purpose of this SOP is to outline the procedure for the collection and storage of urine samples during the course of a study.

Responsibility:
Chief Investigator(s) is responsible for delegating and training study staff (as recorded in Delegation and Training Logs). Appropriately trained persons are responsible for receiving and storing urine samples from study participants.

All persons receiving urine samples must be experienced and trained in the procedure and deemed by the Chief Investigator(s) as proficient prior to undertaking the procedure independently.

Scope:
This Standard Operating Procedure applies to the reception of urine samples in the laboratory by staff that have been trained and are competent in the reception procedure.

Materials:
- 50mL specimen containers
- 15mL specimen vials (2 per sample)
- Permanent markers
- Biohazard waste bags
- Gloves, lab coat, safety glasses
- 70% EtOH spray, handwash, cleaning materials
Standard Operating Procedure

- Fume / biohazard hood availability
- If away from BSRG lab, you will also need an esky and ice pack
- Urine sample tracking sheet is required to record the urine samples with study name, study group, subject number, study visit, date of collection, sample number and volume.

Procedure:

Safety precautions

1. All study staff must be inducted into the safe operating procedures to use the wet lab, and a building induction must be undertaken before receiving urine. The lab manager must ensure that all study staff comply with UTAS regulations regarding working with human biosamples including, but not limited to, being vaccinated against Tuberculosis and Hepatitis B.
2. Wear lab coat, gloves, eye protection and face mask at all times in the wet lab.
3. Turn on the safety hood air filtration system and light.
4. Decant the sample as outlined below.
5. Dispose of the urine sample specimen containers and used vials/gloves/face mask into biohazard waste bags (double bagged) with each bag tied.
6. Wipe down the biosafety cabinet and fume cupboard benches with 70% ethanol, and dispose of the clean-up materials into the double bagged biohazard waste (point 5 above).
7. Give the biohazard waste disposal bags to the Technical staff for appropriate disposal.

Sample collection procedures

1. Prior to the appointment, write the study name, study visit number, subject ID number and date of sample on the side of the specimen container with permanent marker; also write the subject ID number, study name and study visit number on the lid for easy identification.
2. Prepare specimen vials with subject ID number and study visit number on the lid, then on the side write subject ID number, study name, date and sample number, e.g. 1/2 or 2/2. The number of vials and volume sampled from each urine specimen will depend on the specific study protocol. If the subject has not provided enough urine, collect as many vials as possible.
3. Give the subject the specimen container. Have the subject collect a mid-stream urine sample in the specimen container in the nearest bathroom and show them where they can place the sample in the study lab fridge (4 °C, not in the freezer) on their return from the bathroom. If sample collection occurs away from the BSRG lab, have the subject place the specimen container in the travel esky (foam box) in the interview room. You will need to bring it back to the BSRG lab in the travel esky to decant and store. Make sure the esky has a freezer bag to keep the specimen cool, and make sure they are transferred into a fridge within 2-3 hours.
4. Samples can only be stored in the fridge for a maximum of 48hrs before being decanted and stored in the freezer.
5. Decant the samples in a fume hood following protocol set out in wet lab induction, and as per relevant Safety Manual (for the BSRG lab, this is the
Chemistry Building Safety Manual). Check to make sure the specimen container matches the vials. Decant the specimen into the two vials leaving at least a 1cm gap at the top, secure the lids tightly and place them in the vial holder. Note: Do not completely fill the vial, leave at least 1 cm gap at the top in case it expands when frozen. If there is a spill follow Safety Procedures outlined above.

6. Place the used specimen container and any other used materials in the biohazard waste bag provided.
7. Place the vials to the freezer (-20 °C) in the BSRG lab.
8. At regular intervals the urine samples should be transferred to the locked chest freezer. The only people with access to the chest freezer will be authorized study personal and the laboratory manager. Urine samples will be stored for 5 years, or until no longer necessary.

References: