1.0 Purpose

1.1 This Standard Operating Procedure (SOP) describes the correct procedure for performing Skin Prick Allergen Testing.

1.2 Skin Prick Allergen Testing is carried out to establish whether the child/young person is atopic and if the child/young person is allergic to a specific allergen.

1.3 Skin Prick Allergen Testing may be performed for various studies the primary reason being to assess contribution of allergic factors relative to the participant’s symptoms.

1.4 The risks to the participant associated with this procedure include discomfort or severe allergic reaction.

2.0 Scope
This SOP applies to the correct procedure to be followed when performing Skin Prick Allergen Testing.

3.0 Responsibilities
Only study staff appropriately trained in the procedure will be responsible for skin prick testing of participants as per section 2.8 of the ICH GCP guidelines. Skin prick allergen testing involves the use of lancets and local procedures should be followed for the safe use and disposal of needles.

4.0 Procedures
4.1 Preparation
In preparation for testing the participant should be advised to:

- Withhold antihistamines for 48 hours – antihistamines will mask any reactions.
- Avoid putting topical steroid on test area.
Skin prick testing should not proceed if the participant has:
- A history of anaphylaxis
- An extensive skin condition or where eczema is present.
- Applied topical corticosteroids to the skin of the test area
- Is uncooperative
- Had antihistamine within 48 hours of the procedure as they can produce a false negative result.
- Had tri-cyclic anti-depressant drug treatment within 2 weeks of the procedure as they can have anti-histamine properties and produce a false negative result.

4.2 Equipment:
- Lancets (1 for each allergen to be used including negative & positive solutions)
- Antigen solutions (stored in fridge between 2°C and 8°C and can be left at room temperature for 24 hours)
- Positive control (histamine) solution
- Negative control solution
- Tape with numbers corresponding to the solutions (the numbers should be at least 1.5cm apart)
- Clock or watch
- Ruler or tape measure
- Tissue or absorbent paper towel
- Sharps bin
- 1st line equipment

4.3 The procedure is explained to the participant and their parent or guardian and consent obtained.

4.4 The forearm is exposed and placed supine on a flat surface. The inner aspect of the forearm faces upward and horizontally, parallel with the floor. The arm should be kept still throughout the procedure.

4.5 The numbered tape is placed vertically on the lateral side of the inner aspect of the forearm.

4.6 One small droplet of each antigen, including the positive and negative controls is placed adjacent to the corresponding numbers on the tape. These should be around 1.5cm apart from the tape and 1.5cm apart from each other.
4.7 A lancet is used to introduce the antigen into the skin at each droplet. At each droplet, the lancet is inserted parallel to the skin until the skin can be pulled upwards. This should elicit a “tenting” effect and then a “pinging” sound is heard as the skin separates from the lancet.

4.8 The time is noted as the first skin prick is made and this process is repeated using a new lancet for each droplet. The used lancets are disposed of into the sharps bin.

4.9 When all the droplets have been pricked, the solutions are blotted off with a paper towel or tissue. Do not wipe away because this increases the risk of cross contamination between test sites.

4.10 The weals are measured when they are maximal. For the positive control this is at 10 minutes, the other weals are measured at 15 minutes.

4.11 The weals should be measured in the order the incisions were made. If the weal is not circular, the smallest and largest diameters are measured and an average is taken.

4.12 A weal of greater than 3mm is considered a positive response.

4.13 The measurements should be recorded in the CRF. These should be accurate and follow section 2.10 of the ICH GCP guidelines.

4.14 Once the measurements have been recorded, the numbered tape can be removed.

4.15 Advise to wash area and avoid scratching the weals. Positive reactions should subside within 1-2 hours.

4.16 If the participant shows any sign of anaphylaxis or severe allergic reaction at any stage during the test, the test will immediately be stopped and anaphylaxis guidelines must be followed.
5.0 Related Documents
- CRF
- Study protocol

6.0 References
- ICH/GCP Directive/guidelines
- EU Clinical Trials Directive

Approval:
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Signature:                               Date: 21/5/16