Subcutaneous Immunoglobulin Administration for Adult patients with Immunodeficiency UHL Guideline	University Hospitals of Leicester NHS NHS Trust **Trust Reference:C20/2020**

1. Introduction and Who Guideline applies to

1.1 This document sets out to ensure immunoglobulin is administered safely to maximise the benefits of therapy for patients with immunodeficiency, and to minimise the risks associated with administration of immunoglobulin.

1.2 This policy emphasises the administration of immunoglobulin to be given on the Medical Day case Unit (MDCU). However, this policy is transferable to the administration of immunoglobulin within UHL, under the direct care of the Clinical Immunology department.

1.3 This document highlights the tools needed to train a patient to be able to administer Subcutaneous Immunoglobulin Therapy (SCIg) independently in the patient's own home. Please note that this policy does not outline the necessary steps to train a patient to be able to self-administer Facilitated Subcutaneous Immunoglobilin Therapy (fSCIg) in the patient's own home.

1.4 This document outlines the necessary steps to administer fSCIg on the MDCU.

1.5 This policy is relevant to:

a) The immunology clinical nurse specialists and medical staff who are involved in the direct care and management of patients with antibody deficiency.

b) Medical staff and qualified nursing staff within UHL who are administering Immunoglobulin replacement therapy for in-patients (under the long term care of the clinical immunology department, UHL).

c) Staff administrating Immunoglobulin must have documented competencies in the following:

- Phlebotomy
- Aseptic Non-Touch Technique

d) Adult patients only – for SCIg administration in Paedriactrics, please contact the Paediatric day ward (LRI) or the Immunology Paediactric Specialist Nurse (LRI) on 0116 258 6711.

2. Guideline Standards and Procedures

2.1 To meet national criteria all requests must meet the standards outlined in the "Commissioning Criteria Policy for the use of therapeutic immunoglobulin (Ig) England" (2021). Following this a request form should be submitted to the immunoglobulin mailbox. If prior approval is required for the indication you must wait until the next Immunoglobulin Approval Panel (IAP), unless urgent where it should be emailed to panel members as well highlighting urgent. All cases should be approved in the local immunology MDT or by internal email discussion if urgent.

2.2 Once approval has been met continue as follows

a) Ensure that the patient has been involved in all discussions and decisions regarding their treatment and treatment options, including the risk of potential transmission of infective agents (UK PIN, 2004).

b) Ensure that the patient has received relevant information on Immunoglobulin Replacement Therapy.

Patient information can be found using the immunology patient information leaflet designed for SCIg therapy.

Further information can be found on the following accredited website:

http://www.immunodeficiencyuk.org

c) The Immunology clinical nurse specialist should support the patient with this preferred delivery method and address any questions or concerns (UK PIN, 2018).

d) Availability of Immunoglobulin is subject to a national framework due to rising costs of products. This means that Trusts receive guidance from NHS England regarding which products to prescribe. Close liaison with the dedicated pharmacy team at UHL will allow for a prescribing decision to be made regarding which Immunoglobulin products are currently available.

(NB although it is preferable for a patient to remain on a consistent product, it is occasionally necessary to change Immunoglobulin products in established patients based on product availability and NHS England recommendations).

e) The reviewing clinician (either in clinic or on the day case unit) must complete an immunoglobulin database follow-up form and send to the pharmacist responsible for managing immunoglobulin within UHL for input into the National Database.The immunoglobulin database form should be completed at every review, minimum annually.

2.3 The Immunology Team should prescribe the following:

- The agreed immunoglobulin product with the agreed route. The starting dose is usually 400mg/kg/month, but may be adjusted in individual patients, especially those with bronchiectasis (TRIAC, 2016).
- Oral Paracetamol 1g (PRN for adverse event management)
- IV Hydrocortisone 100 mg (PRN for adverse event management)
- IV Chlorphenamine 10 mg (PRN for adverse event management)

NB - the above medications are to be prescribed to give in hospital only, whilst the patient is undergoing training for SCIg or receiving fSCIg.

a) 2.4 There should be appropriate storage facilities for all Immunoglobulin products. These include a locked, temperature recorded fridge, and a locked medicine cupboard with recording facilities to monitor room temperature. Such recording should be documented and acted on as per the UHL Leicestershire Medicines Code Policy (Trust Ref. B60/2011)

2.5 Ensure that any products are stored as per manufacturer's guidelines. Ensure product is within expiry date and the liquid looks clear.

2.6 Clinical Guidance for the 1st SCIg infusion and subsequent infusions

On the first Subcutaneous (SC) infusion on the MDCU (INGID, 2019):

a) Record base line observations – blood pressure, heart rate, respiratory rate, oxygen saturations and temperature - to assess for an active infection.

b) Assess if the patient has a current infection, or is producing green/discoloured sputum. If so obtain a sputum sample for culture and sensitivity.

c) If the patient has an active infection, antibiotics should be given as per antibiotic guidelines and postpone the infusion for 48 hours, or until the patients' symptoms have started to improve. The clinical team should be informed and a decision made to whether the patient requires a medical review, either by his/her GP, the Immunology Team or the on-call medical registrar.

d) The Consultant Immunologist, Immunology Trainee (Registrar) or Immunology Clinical Nurse Specialist needs to obtain informed consent. Here the benefits/ risks and possible adverse reactions are discussed, if not already done in the Outpatient clinic.

e) Gain consent to collect bloods prior to the first infusion for:

- Hepatitis C by PCR (Polymerase chain reaction) Hepatitis B surface antigen

- LFTs
- U&E
- Immunoglobulins
- Serum Save
- FBC

f) Commence the 'Immunoglobulin Record Sheet' (Appendix 1).

2.7 Prior to future SC infusions on the MDCU (INGID, 2019):

NB It is thought that the patient will attend a minimum of 6 hospital based SCIg infusions.

a) Assess for any active infections.

b) Assess for any symptoms of infection since the last infusion.

c) Assess for any adverse reactions to the last infusion.

d) Assess for any new medications that the patient has been prescribed.

e) Assess that the immunoglobulin product is prescribed correctly.

f) Consider pre-medication to prevent any adverse reactions.

g) Patient to record the relvant sections priot to their infusion on their infusion record (Appendix 2).

2.8. **Administration of SCIg on the Medical Day Case Unit**

a) Ensure the patient has a printed wrist band in place stating their **Name, Date of Birth** and their **Hospital Number** prior to commencing the infusion. Red printed wrist bands should be used if a known allergy is present. The information on the wrist band should be checked with the patient before the wrist band is placed on.

b) Ensure that all equipment is present:

- SCIg product
- PPE
- Alcohol swabs
- 20mls Syringes (amount subject to dose/volume required)
- Microspore tape
- Gauze
- SC Infusion pumps (x2)
- Sterile field
- 24g winged needles (amount subject to dose/volume required)
- Green hypodermic safety needles (amount subject to dose/volume required)
- Sharps bin
- Infusion record
- Clock (at home only)
- Telephone (at home only)
- Non-occlusive dressing (amount subject to the amount of injection sites)

NB: Whilst training in hospital ensure that all emergency medications are readily available and in date.

c) It is expected that the CNS will administer the 1st SCIg infusion. The process below should be followed by the CNS but also adopted by the patient when they are independently trained:

- Check that you have enough of the correct immunoglobulin product and that the solution is clear and not cloudy
- Check the expiry date on the immunoglobulin product has not passed and record the batch numbers on the infusion record

- Make sure the syringe driver is fully functional
- Wash and dry your hands correctly and thoroughly
- Cover the dry work surface with a sterile drape
- Open all ancillary items onto the steriole field to promote ascepsis
- Once the dust caps have been removed, clean the top of the rubber bung on the IG product with an alcohol wipe and let it dry
- Draw up the required amount of immunoglobulin into each 20mls syringe. TIP – draw into the syringe around 5-10mls of air, which you then add to the vial, to help with the drawing up procress
- Use a new green safety needle with each vial of immunoglobulin
- Remove needles and dispose of it into a sharps container
- Make sure there are no air bubbles in the syringe
- Attach a 24g winged butterfly needle by its port to each 20mls syringe
- Prime the butterfly tubing by gently pushing the plunger on the syringe until the immunoglobulin reaches the tip of the actual needle
- Make sure the correct amount of immunoglobulin is in the syringe after priming
- Choose a suitable site for the infusion. Suitable sites include the lower abdomen and the thighs. Be mindful of any open wounds, previous scar tissue, or stretch marks
- Raise the surface of the skin by gently pinching the area where you want to insert the needle
- Insert one of the butterfly needles into the skin at approximately a 45° angle to the surface, with the bevelled edge downwards
- Secure the needle with a sterile dressing
- Check for any back flow of blood into the tubing of your winged needle. Do this by drawing back the syringe plunger gently. If no blood is seen in the line, then the needle is sited correctly. If blood is seen the needle may be sited in a vein. **DO NOT** continue if blood is seen. Remove the butterfly needle and re-site using a new needle, as per above
- Load the syringe in the infusion pump
- Commence the infusion at the desirable rate
- Document onto the infusion the infusion record the following:
- Write the date on which the infusion is given.
- Describe the sites where the butterfly needle was inserted.
    - e.g. 2 in L side of abdomen, 1 in R thigh.
- Write down the number of mls given at each site.
    - e.g. 10mls in 3 sites on abdomen and 15mls in site on thigh.
- Write down the total dose given.

- e.g. 45mls (3 sites at 15mls)

- Write down the rate you have set the syringe driver at, in ml/hour
  - e.g. 20ml/hr
- Please note the infusion rates will differ, depending on what infusion pump is used.
- At the end of the infusion, the syringe should be removed from the syringe driver and the butterfly needle should be removed along with the syringe and discarded into a sharps bin
- Clean the infusion pumps as per local protocol

d) Give the patient the SCIg information pack – found in the SCIg folder on the shared immunology drive, titled 'Training programme for the Home infusion of Subcutaneous Immunoglobulin'.

e) Provide education behind the theory of SCIg administration at home. Follow the teaching plan – found in the SCIg folder on the shared immunology drive, titled 'Training programme for the Home infusion of Subcutaneous Immunoglobulin'.

2.9 Administration as an inpatient

a) Ensure the patient has a printed wrist band in place stating their Name, Date of Birth and their Hospital Number prior to commencing the infusion. Red printed wrist bands should be used if a known allergy is present. The information on the wrist band should be checked with the patient before the wrist band is placed on.

b) Check the patient understands his/her condition. Check for the patient for his/her understanding of SCIg, to ensure verbal consent for treatment has been obtained.

c) Ensure contact telephone numbers for the immunology team are available.

d) Assess for signs of an active infection. Document on the SCIG infusion record. Such signs of an infection could be:

- A temperature of 37.5ºC or above.
- A productive cough or discoloured sputum production.
- A CRP above 20 mgs/l.

If an infection appears to be present inform the immunology nursing team and postpone the infusion until the infection has been treated with antibiotics for at least 48 hours, and the above signs of infection have resolved.

Ask the patient if they had any adverse reactions to the last infusion.

e) Assess that the immunoglobulin product is prescribed correctly.

f) Ensure that hand washing and asepsis is performed adequately as per hospital policy.

g) Ensure the SCIg product is at room temperature.

h) Make sure emergency drugs (e.g. adrenaline) and emergency equipment are available and in working order.

i) Ensure that all equipment is present:

- SCIg product
- PPE
- Alcohol swabs
- 20mls Syringes (amount subject to dose/volume required)
- Microspore tape
- Gauze

- SC Infusion pumps (x2)
- Sterile field
- 24g winged needles (amount subject to dose/volume required)
- Green hypodermic safety needles (amount subject to dose/volume required)
- Sharps bin
- Infusion record
- Clock (at home only)
- Telephone (at home only)
- Non-occlusive dressing (amount subject to the amount of injection sites)

2.10 To administer SCIg, follow the steps found in section 2.8 c)

a) Record all batch numbers of the SCIg product given in the medical notes

b) Ask the patient to report any pain, redness or swelling that occurs at the needle site during the infusion.

c) At the end of the infusion record any adverse reactions and treatment in the medical and/or nursing notes.

2.11 On completion of infusions on the MDCU

a) Following on from the 1st infusion only - the patient should stay on the ward for a further observation period of 60 minutes.

b) Patients should be given post infusion advice (verbal or written) for any adverse delayed reactions.

c) The patient should be given contact numbers of the Clinical Nurse Specialists for any advice needed for the possibility of delayed reactions – 0116 258 6711 (LRI).

d) The patient should be given the next date for their SCIg.

2.12 Administration of fSCIg (HyQvia)

a) HyQvia is supplied as a pack containing:

One glass vial of recombinant human hyaluronidase

One glass vial of human normal immunoglobulin 10%.

Store in a refrigerator (2°C to 8°C). Do not freeze

b) The recombinant human hyaluronidase of HyQvia contains small amounts (4.03 mg per ml) of sodium. This may have to be considered for patients who are on a controlled sodium diet.

The recombinant human hyaluronidase is a clear and colourless solution.

The human normal immunoglobulin 10% is a clear and colourless or pale yellow solution.

c) All patients receiving fSCIg should sign consent prior to commencing therapy. Consent differences with traditional SCIg infusion. Please ensure patients are aware of the long term effects of hyaluronidase.

d) **Standard operating procedure for ramp up phase.**

One quarter of the prescribed dose at 1 week intervals. This will be increased step-wise to larger doses at 3- to 4-week intervals with the next infusions.

Patient should stay 1 hour post infusions 1, 2 and 3 during ramp up phase and for the first infusion following a full dose to monitor for adverse reaction.

e) Before preparing the infusion allow vials to reach room temperature. This may take up to 60 minutes.

f) Assess patient's condition (infection, temperature, etc). Check baseline obs on first infusion or if clinical indicated. any symptoms of infection, for example an increased

coughing, you are producing larger amounts of sputum than normal and/or it is discoloured, or you have a temperature of **37.5°** or more, you **MUST** delay the infusion .

g) Monitor for adverse reactions closely before increasing the rate of infusions.

h) Don't increase the infusion if patient doesn't feel well, and closely observe.

i) Do not infuse HyQvia into or around an infected or red swollen area on skin because it may cause the infection to spread

j) Use infusion technique and regime tailored to unique needs:

k) Consider higher infusion volume per site leading to fewer sites, fewer needles and longer infusion intervals.

Pumps – up to 600 mmHg pressure required or use of high flow needles if you are not using a high pressured pump.

l) Stop infusion immediately for any sign of adverse reaction

m) If patient has been unwell with an infection **DO NOT** administer infusion until patient has had prescribed antibiotics for a minimum of 48 hours.

2.13 **Equipment needed for subcutaneous immunoglobulin**

Immunoglobulin product	Sterile drape
Sharps bin	Sterile dressings
Alcohol gel	Gauze swabs
Clean towel	Pump
Documentation	Butterfly needles (24 gauge)
Pen	Green needles
Alcohol swabs	10/20 ml Syringes

a) Check that you have enough of the correct immunoglobulin product.

b) Check the expiry date on the immunoglobulin product has not passed and record the batch numbers on the infusion record.

c) Collect all items for your infusion. Items include: dual vial unit(s) of HyQvia, infusion supplies (subcutaneous needle set, solution container (bag or syringe), sterile clear bandage and tape, pump tubing, transfer devices, syringes, gauze and tape), sharps container, pump, and treatment logbook and other supplies as needed'.

d) Wash and dry your hands correctly and thoroughly.

e) Open HyQvia dual vial unit(s). Remove blue protective caps to expose the vial stoppers. Prepare to transfer the recombinant human hyaluronidase component of HyQvia by wiping each vial stopper with an alcohol swab, if directed, and allow to air dry (at least 30 seconds).

f) Prepare recombinant human hyaluronidase vial (HY) by removing the smaller sterile syringe from package and attach to a non-vented spike

g) Pull back on the plunger; fill the smaller syringe with air equal to the amount of recombinant human hyaluronidase in the HY vial(s).

h) Remove the cap of needle/non-vented transfer device. Insert the tip of the needle/non-vented transfer device into the centre of the vial stopper and push straight downward. Push the air into the vial. Withdraw the full contents of the recombinant human hyaluronidase into the syringe.

i) **If possible, combine all of the recombinant human hyaluronidase needed for the entire dose of IgG into the same syringe**. Point the syringe tip up and remove any air bubbles by pointing the syringe tip up and gently tapping the syringe with your finger. Slowly and carefully push the plunger to remove any remaining air.

j) **Prepare the needle set with the recombinant human hyaluronidase**

Attach the syringe filled with recombinant human hyaluronidase to the needle set Push the plunger of smaller syringe to remove the air and fill the needle set up to the needle wings with the recombinant human hyaluronidase

k) **Prepare human normal immunoglobulin 10% vial.** Prepare to transfer the immunoglobulin 10% component of HyQvia by wiping each vial stopper with an alcohol swab, if directed, and allow to air dry (at least 30 seconds).

The human normal immunoglobulin 10% of HyQvia may be infused either by pooling from the vials either into larger syringe; or directly from the IG vial.

l) Insert the spike of the vented pump tubing or spike and venting needle into human normal immunoglobulin 10% vial(s). Fill the administration pump tubing and set aside until the recombinant human hyaluronidase has been administered. If more than one vial is required for a full dose, spike subsequent vials after the first vial has been fully administered.

m) **Prepare the infusion site.** Choose an infusion site(s) in either the middle to upper abdomen or thigh. Select sites on the opposite sides of the body to infuse in two sites for doses above 600 ml. **Avoid bony areas, visible blood vessels, scars and any areas of inflammation or infection.** Rotate infusion sites by choosing opposite sides of the body between future infusions.

n) Clean the infusion site(s) with an alcohol swab. Allow to dry (at least 30 seconds).

o) **Inserting the needle** Remove the needle cover. Insert needle completely to the wings of the needle with a rapid motion straight into the skin at a 90-degree angle. Wings of needle should lay flat on the skin. Secure needle in place with sterile tape.

p) **Administer the recombinant human hyaluronidase infusion first:**

Slowly push the plunger of the smaller syringe with the recombinant human hyaluronidase at an initial rate per infusion site to approximately 1 to 2 ml per minute and increase as tolerated.

q) **Administer the human normal immunoglobulin 10%:**

After infusing all of the content of the smaller syringe (recombinant human hyaluronidase), remove the syringe from the hub of the needle set.

Attach the pump tubing or, the larger syringe containing human normal immunoglobulin 10% to the needle set.

r) **Administer the human normal immunoglobulin 10% with a pump at the rates as per the attached protocol (dependant on ramp up phase dosage /maintenance dosage) – see Appendix 4 – this is based on a dosage of 20gs.**

s) Post infusion preperation

- Remove needle set.
- Remove the needle set by loosening the dressing on all edges.
- Pull the needle wings straight up and out whislt gently pressing a small piece of gauze over the needle site and cover with a protective dressing.
- Throw away the needle(s) into the sharps container.
- Dispose of the sharps
- Complete paperwork (appendix 4).

2.14 Management of Adverse Events to SCIg and fSCIg

a) Reactions are unlikely once the patient is established on immunoglobulin. If they do occur, it is usually due to the patient having an underlying infection or the infusion rate being given too fast.

b) Common 'post infusion' symptoms that are reported can be flu-like symptoms and tiredness for up to 24 hours post infusion.

c) It is advisable that patients keep paracetamol and oral antihistamine at home in case of any delayed mild reactions.

d) Refer to Appendix 3 for the management of adverse reactions to Ig.

e) If the patient has a moderate or severe adverse reaction, this should be reported to the clinical immunology team. The patient may require a change of product.

f) Present at PID MDT in the 'patients with clinical issues' section.

g) Complete a DATIX form.

2.15 **Process for patient monitoring**

a) Documentation

Each batch number used for a patient should be recorded on the infusion record by affixing the 'peel off label' from the bottle of immunoglobulin product. There should be one label per bottle.

The expiry date of the immunoglobulin product should also be written on the infusion record, adjacent to the respective 'peel off label'.

Each infusion event should be signed by the person carrying out the assessment.

b) **Monitoring of patients blood tests**
Bloods should be taken with verbal consent being obtained from the patient. The following bloods are required at the following intervals:

- Immunoglobulin – 12 weekly
- Us & Es – 12 weekly
- LFT's – 12 weekly
- FBC – 12 weekly
- Serum Save – annually

c) Trough IgG levels for IVIG patients should be as follows, although it may vary according to clinical status;

- Approx 7.0g/L for patients without bronchiectasis
- Approx 8.0g/L for patients with bronchiectasis

Levels may be higher in some patients including those specific antibody deficiency and IgG subclass deficiency.

d) SCIg patients will be followed up every 6 months within the Outpatient clinics- under the code REG1J.

e) Monitoring of patient's respiratory status:

Primary immune deficiency patients may develop respiratory conditions such as bronchiectasis or interstitial lung disease. Their respiratory status should be monitored on a regular basis:

- Spirometry annually
- Full pulmonary function tests every 2 years
- CT thorax as clinically required

3. Education and Training

None

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Patient satisfaction	Patient satisfaction survey	Immunology CNS team	Annually	This will be reported in Monthly Immunology MDT meetings.
Postive clinical outcome	Clinical reviews	Immunology service	6 Monthly	This will be reported in Monday afternoon SCIG clinic meetings

5. Supporting References

UHL IV Administration (Trust Ref B25/2010)

UHL Personal Protective Equipment at work Policy (PPE) (Trust Ref B9/2004)

UHL Infection Prevention & Control Policies (available via INsite Documents)

UHL Patient Identification Band Policy (B43/2007)

Immunodeficiency UK (2021) Patient information re: treatment options

http://www.immunodeficiencyuk.org

Immunodeficiency UK (2021) Immunoglobulin therapy

http://www.immunodeficiencyuk.org/static/media/up/PIDUKIgtherapy.pdf

University Hospitals of Leicester Insite (2019) Injectable Medicines Guide

http://medusa.wales.nhs.uk/LocalSelect.asp

UK PIN (2018) Immunoglobulin Product Choice for Patients with Primary Immunodeficiency

http://www.ukpin.org.uk/docs/default-source/default-document-library/ukpin-position-statement/ukpin-position-statement.pdf?sfvrsn=3928c8b4_8

UHL Aseptic Non-Touch Technique (2021)

http://insitetogether.xuhl-tr.nhs.uk/pag/pagdocuments/Aseptic%20Non%20Touch%20Technique%20UHL%20Guideline.pdf

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INGID (2019) European Nursing Guidelines for Immunoglobulin Administration, UK version p22-26

https://ingid.org/wp-content/uploads/2016/07/European-Nursing-Guidelines-Immunoglobulin-Administration.pdf

TRIAC (2019) The Compendium of Immunology, Edition 2

https://docs.google.com/document/d/1xAhDBRIBQ6l25rIeupl-PsZA2LHR52UFMdbeseuSN7k/edit

6. Key Words

SCIg - Subcutaneous Immunoglobulin

Home therapy

Medical Day Case Unit – Ward 1 Leicester General Hospital (MDCU)

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) **William Coltman** **Immunology Specialist Nurse**	**Executive Lead** **Dr Shanti Mahabir** **Immunology Consultant**
Details of Changes made during review: **1.3 Addition of fSCIG** **1.4 Addition of fSCIG** **2.1 Addition of the commissioning criteria policy for the use of therapeutic IG (2021)** **2.2 b) Update to immunodeficiencyuk.org web address** **2.2 e) Ammendment to eligibility of who can complete a database request form** **2.12 Addition of fSCIG** **5.0 Update to immunodeficiencyuk.org web address** **5.0 Addition of TRIAC compendium (2019)** **Appendix 4 Addition of fSCIg 'ramp up phase' infusion rate**	

Appendix 1
Immunoglobulin Record Sheet

Product……………………………….

Weight (kg) ……………………..

Care plan review date………………..

Affix Addressograph label here

DATE		**Comments**	
Infection	Yes/No	Cough ☐ Diarrhoea ☐ Headache ☐ Joint Pains ☐ Nasal discharge ☐ Sinus ache ☐ Sore Throat ☐ Wheeze ☐ Other……………………………………	
Treatment		Yes/No	
Adverse effects		Yes/No	
Cannula site			
Blood samples		Ig's ☐ LFT's ☐ CRP ☐ GGT ☐ Other ☐ ………………………………………………………	
Batch Numbers		**Signature**	
		NAME	

DATE		**Comments**	
Infection	Yes/No	Cough ☐ Diarrhoea ☐ Headache ☐ Joint Pains ☐ Nasal discharge ☐ Sinus ache ☐ Sore Throat ☐ Wheeze ☐ Other……………………………………	
Treatment		Yes/No	
Adverse effects		Yes/No	
Cannula site			
Blood samples		Ig's ☐ LFT's ☐ CRP ☐ GGT ☐ Other ☐ ………………………………………………………	
Batch Numbers		**Signature**	
		NAME	

DATE		**Comments**	
Infection	Yes/No	Cough ☐ Diarrhoea ☐ Headache ☐ Joint Pains ☐ Nasal discharge ☐ Sinus ache ☐ Sore Throat ☐ Wheeze ☐ Other……………………………………	
Treatment		Yes/No	
Adverse effects		Yes/No	
Cannula site			
Blood samples		Ig's ☐ LFT's ☐ CRP ☐ GGT ☐ Other ☐ ………………………………………………………	
Batch Numbers		**Signature**	
		NAME	

Appendix 2
SCIg Infusion record

	DATE OF BIRTH	**Unit Number**
NHS NUMBER	**Product**	**Weight (Kg)**

Infusion Date	**Sites Used**	**Dose per Site**	**Total Dose**	**Rate mls/hour**	**Batch Numbers**	**Blood Sample Taken?**	**Length of Infusion**	**Adverse Reactions or Problems?**	**Signature**
Have you had any of the following symptoms of infection in the previous week please tick the box: Cough ☐ Diarrhoea ☐ Joint pain ☐ Headache ☐ Nasal discharge ☐ Sinus ache ☐ Sore throat ☐ Wheeze ☐ Shortness of breath ☐						***Name, dose and the start and finish dates of any treatment taken***			
Have you had any of the following symptoms of infection in the previous week please tick the box: Cough ☐ Diarrhoea ☐ Joint pain ☐ Headache ☐ Nasal discharge ☐ Sinus ache ☐ Sore throat ☐ Wheeze ☐ Shortness of breath ☐						***Name, dose and the start and finish dates of any treatment taken***			
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Have you had any of the following symptoms of infection in the previous week please tick the box: Cough ☐ Diarrhoea ☐ Joint pain ☐ Headache ☐ Nasal discharge ☐ Sinus ache ☐ Sore throat ☐ Wheeze ☐ Shortness of breath ☐						***Name, dose and the start and finish dates of any treatment taken***			

Appendix 3
Adverse reaction checklist

ADVERSE REACTIONS

Mild Reactions

These symptoms include:

Itching	Shivering
Muscle aches	Nausea
Flushing	Anxiety
Mild headache	Light headedness/dizziness

- Take the analgesia and/or antihistamine you have been prescribed for such reactions. **DO NOT** take paracetamol if you have already taken a medication containing paracetamol in the past 4 hours or if you have had the equivalent of 8 paracetamol tablets in the last 24 hours.
- The symptoms should gradually pass. Wait half an hour and restart the infusion at its minimum rate. Gradually and carefully increase the infusion rate.

Moderate Reactions

These symptoms include:

Itchy, raised rash	Mild wheezing
Chest tightness/pain	
Worsening or reoccurring mild reaction symptoms	

- If you notice any of these symptoms **STOP** the infusion **immediately**. The symptoms should pass.
- **Contact** your GP **immediately**. This is important so any further treatment can be prescribed.
- You should also take any analgesia and/or antihistamine you have been prescribed for such reactions.
- If the symptoms pass, wait half an hour and restart the infusion at its minimum rate. Gradually and carefully increase the infusion rate as before.
- If you are still experiencing problems, **STOP** the infusion and contact your GP again.

Severe Reactions

These symptoms include:

Tightness of the throat	Sensation of pressure in the chest
Severe dizziness or fainting	Severe headache and shaking
Severe difficulty breathing/wheezing	Moderate symptoms becoming worse.
Collapse	

- **STOP** the infusion **immediately**.
- **Call an ambulance, 999**.
- Keep the bottles of immunoglobulin you have used, as these may need to be examined.
- Remember to complete the adverse reaction section of the infusion record when you can and report the reaction to the Specialist Immunology Nurse as soon as possible.
- Remember to fill out the RCN Adverse Reaction form as well.

Appendix 4
Protocol for fSCIg ramp up phase (based on a dose of 20g as an example)

Protocol for ramp up phase –step wise approach to infusions

FIRST WEEK Hyqvia 5gms (50mls) Total length of infusion ≥2hrs 15min Keep 1hour for visual obs and monitoring	Rate (mls/hr)	Volume (VTBI)	Time	Total Voloume Infused (mls)
	5	1.33	15mins	0
	10	2.6	15mins	1.33
	20	5.2	15mins	2.6
	40	10.4	15mins	5.2
	80	20.8	15mins	10.4
	TOTAL 19.53 (grams mls or time?)			
	80mls/hr to infuse the remaining volume			

SECOND WEEK Hyqvia 10gms (100mls) Total length of infusion ≥ 2hrs 15min Keep 1hour for visual obs and monitoring	Rate (mls/hr)	Volume (VTBI)	Time	Total Voloume Infused (mls)
	5	1.33	15mins	0
	10	2.6	15mins	1.33
	20	5.2	15mins	2.6
	40	10.4	15mins	5.2
	80	20.8	15mins	10.4
	TOTAL 19.53			
	80mls/hr to infuse the remaining volume			

THIRD INFUSION Hyqvia 15gms (150mls) Total length of infusion ≥ 2hrs15min Keep 1hour for visual obs and monitoring	Rate (mls/hr)	Volume (VTBI)	Time	Total Voloume Infused (mls)
	5	1.33	15mins	0
	10	2.6	15mins	1.33
	20	5.2	15mins	2.6
	40	10.4	15mins	5.2
	80	20.8	15mins	10.4
	TOTAL 19.53			
	80mls/hr to infuse the remaining volume			

One week off then proceed to 4th infusion (maximum dose)

This is also the maintenance dosing schedule

Fourth INFUSION Maintenance infusion Hyqvia 20gms (200mls) Total length of infusion ≥ 3hrs Keep 1hour for visual obs and monitoring	Rate (mls/hr)	Volume (VTBI)	Time	Total Voloume Infused (mls)
	10	2.6	15mins	0
	20	5.2	15mins	2.6
	40	10.4	15mins	5.2
	80	20.8	15mins	10.4
	100	26.0	15mins	20.8
	TOTAL 39.0			
	100mls/hr to infuse the remaining volume			