IMMUNE GLOBULIN QUALITY IMPROVEMENT PROJECT

DATA ENTRY USER GUIDE

ORBCON Ministry of Health IG Request Form Database

VERSION 4 DATE: SEPTEMBER 2023



Inspiring and facilitating best transfusion practices in Ontario.

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1.0 PROJECT INFORMATION

Your hospital site has volunteered to participate in this Immune Globulin (IG) Quality Improvement Project (QIP) and this document is provided to instruct hospital users on entering their IG data into the Research Electronic Data Capture (REDCap) platform. This QIP was developed in response to recommendation #3 from the Office of Auditor General of Ontario, <u>Value-for-Money Audit of Blood</u> <u>Management and Safety</u>.

Hospitals will enter required data variables for this QIP using the data found on the existing Ministry of Health (MOH) IG request forms (<u>Neurology</u> and <u>non-Neurology</u>). These IG requests could be submitted to the laboratory as paper forms, through your Laboratory Information System (LIS) via a Computerized Physician Order Entry (CPOE), or a combination of both as applicable. Data extraction from the paper forms/LIS should be straightforward - enter what you see/read, exactly as it is written or typed, into the corresponding fields in REDCap. Hospital sites that can electronically extract the IG product request from their LIS should contact ORBCoN to facilitate electronic transfer of IG information directly into REDCap.

NOTE: Your hospital site may have modified the data variables collected for IG requests if using LIS/CPOE/E-Forms. You may need to review the Ontario MOH IG paper request forms and compare them in advance to map the information collected.

2.0 REDCap BASICS

REDCap is a secure web-based platform that will be used to collect, analyze, and export hospital IG data. Ontario hospitals received a survey link to notify ORBCoN of their intent to participate in the IG QIP. Hospital site/institution information was collected to determine identify the users and how the data would be entered into REDCap. Based on information provided in the survey, user specific usernames and passwords were generated and sent to IG data entry users. The following steps provide basic information on how to get started in REDCap for participating hospital sites entering IG data using paper request forms. Sites with the ability to electronically extract IG data for LIS, ORBCoN will supply site specific information to upload data into REDCap.

Each hospital site will have a Data Access Group (DAG) assigned and users within this DAG will be able to access only records created by users within that group. Users will not have access to other DAGs unless the user has been granted access to another affiliated DAG. Users with more than one DAG will be required to use the DAG switcher, to ensure that they are entering IG information into the correct DAG. When assigned to multiple DAGs, the user will see a blue banner at the top of every project page, which will present the option to switch to another DAG.

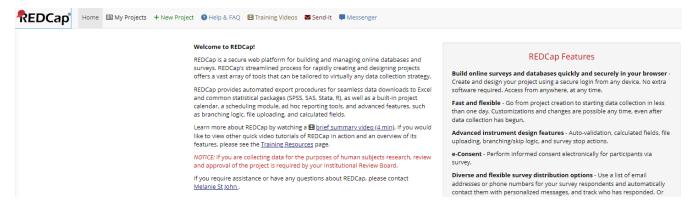
2.1 Login: https://mctr.mcmaster.ca/.

REDCap						
Log In						
Please log in with your user name and password. If you are	having trouble logging in, please contact <u>Melanie St John</u> .					
	Username:					
	Password:					
	Log In Forgot your password?					
Welcome to REDCap!						

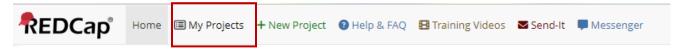
2.2 Enter your user credentials: username, and password.

- If you already have access to REDCap for another ORBCoN/TTISS project, you will use the same username and password you have already been given to access the IG QIP
- If you are a new user to REDCap, your username and password will be supplied by ORBCoN staff after the hospital site agreement to participate in the IG QIP is complete.

2.3 After login, you should be taken to the REDCap homepage or *My Projects* page.



2.4 Click on **My Projects** to be directed to the page displaying all the projects your username has been assigned to in REDCap.



2.5 Click on the project titled **ORBCoN Ministry of Health IG Request Form Database**. This will take you to the data collection home page.

REDCap	Home 🗐 My Projects	+ New Project	Help & FAQ	🖪 Training Videos	🛚 🗢 Send-It 🛛 📮 Messenger						
				Listed below are the	e REDCap projects to which you currently have	access. Click the project title t	o open the	e project	. <u>Read more</u>		
				My Projects	Collapse All		Filter	projects	s by title	×	
				Project Title			Records	Fields	Instruments	Туре	Status
				ORBCoN Ministry	of Health IG Request Form Database		313	89	1 form		۶

2.6 On the left side of your screen, you should see various links to areas within the project, including:

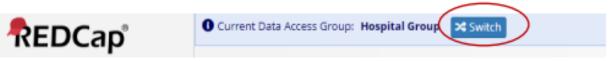
- My Projects brings you back to the overview of all REDCap projects you can access.
- **REDCap Messenger** a built-in messaging service between REDCap users.
- **Project Home** brings you to the home page of the project you're in.
- **Record Status Dashboard** shows an overview of every IG recipient entered by you (by Record ID) and the status of the form (complete/incomplete/unverified).
- Add/Edit Records add a new IG recipient record or search for an existing record.

Your view should be like the following:

Project statistics display the number of records both in total and by DAG (in group).

	0	Current Data Access Group: Hospital A Switch					
Logged in as laura_hospdag Log out	c	ORBC	oN Mir	nistry o	of Health IG Requ	iest Form Database 🛛 🕫	PID 455
 My Projects REDCap Messenger Contact REDCap administrator 		A PI	roject Ho	me			
Project Home and Design	=						
 ♠ Project Home ·			_		e general dashboard info ; calendar events (Many).		with access to this project, general project
Data Collection — Hospital A	=	🖹 Pi	roject Stat	istics		\mathbf{N}	
I Record Status Dashboard		Reco	ords in pro	ject	Total: 313 / In group: 0		
- View data collection status of all records		Mos	t recent ad	tivity	09/27/2023 10:45am		
Add / Edit Records Create new records or edit/view existing ones 		Spac	ce usage fo	or docs	1.98 MB		
Show data collection instruments		1 U	pcoming	Calendar	Events (next 7 days)		
Applications			Time	Date	Description		
 Calendar Data Exports, Reports, and Stats 					No upcoming events	5	
Logging							
🗁 File Repository							
Resolve Issues							

2.7 If the user is assigned to multiple DAGs, an additional blue banner will be visible on the top of the page to allow the user to switch back and forth between the different DAGs in which they will be entering data.



2.8 Click on **Switch**, for a pop-up box with drop down option of all assigned DAGs to appear. Choose the correct DAG from the list and click **Switch**.

Exception interviewe and persons Except	REDCap
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A Add 7 Staff Records Under New York (New York) Switch Data Access Group #	
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process week rest and the second rescond rescond rest and the second rest and the seco	the fact of the second s
	Protona -
	- Data Exports, Reports, and Stats
O James Diagonal Alama Cara Diagonal Di	
Audit Data vebeco www. New Site v	udit Data
An Technologia (Contesting Contesting)	a A Subpression
Here & FAQ Switch Cancel	
a Veec Tutorian	
C. Scaggest a New Peature	Suggest a new resture

2.9 Once the selection has been made, the following pop-up will be displayed to confirm that user is in the appropriate DAG.



- 2.10 Once a record has been created, the information entered can be saved via several options so as not to lose data entered. These save options are located at the top right of the page and continually scrolls down along with the entry of data, as well as there is a separate section the very bottom of the form.
 - Save & Stay- saves work stays in current record.
 - Save & Go to Next Instance saves work and opens a new Instance for the patient.
 - Save & Exit Record saves work and exits form.
 - Save & Go to Next Record saves work and opens a new patient record.



Complete?	p Incomplete 🗸	
	Save & Exit Form Sav	e &
	– Cancel –	Save & Stay Save & Go To Next Insta
		Save & Exit Record Save & Go To Next Reco

3.0 TRACKING LOGS

3.1 PATIENT LOG

For this QIP, patient identification is <u>not</u> collected in REDCap, but hospital sites will need to ensure a patient with multiple/repeated IG requests is not duplicated. To avoid duplication, a patient tracking log has been developed (<u>Appendix 1</u>). For patient privacy reasons, this log will be maintained at the hospital site and <u>will not</u> be shared with ORBCoN or anyone outside of the hospital organization for this QIP. This log should be stored securely at your hospital site when not in use. The log is provided in both paper and excel (<u>electronic</u>) formats.

Using the REDCap generated *Record ID* for unique patient identification: Each IG recipient entered in REDCap will be automatically assigned a record number that should be kept unique to that patient.

This record number is generated based on your DAG (e.g., Mock Hospital DAG= 3285) and the assigned subsequent next sequential number. As there may be multiple MOH IG request forms for the same IG recipient, the recipient record number should be tracked, so that additional request forms can be added to that recipient record (multiple request forms for an IG recipient will be known in REDCap as *Instances*).

_	IG Recipient Patient Tracking Log								
	REDCap	Instance	Request Date	For Hospital Use ONLY					
1	Record ID	Number	(YYYY/MM/DD)						
				Last Name	First Name	Hospital Medical Record			
						Number (MRN)			
Γ									

3.2 PHYSICIAN / PRESCRIBER LOG

Hospital sites have the option of coding their IG ordering physician/prescriber information and not entering it into REDCap. A physician/prescriber tracking log has been developed (<u>Appendix 2</u>) to assign a unique identifier to the ordering physician/prescriber. The identification code used can be any alphanumeric combination but should be different from patient identification code. The log is provided in both paper and excel (electronic) formats. Sites that choose to enter physician/prescriber information do not need to use the physician/prescriber tracking log.

Physician /	Prescriber	Contact	Information Log	

Physician / Prescriber	Physician / Prescriber		For Hospital Use ONLY	
Specialty	Identification Code	Physician / Prescriber Last Name	Physician / Prescriber First Name	Email Address / Phone #

4.0 IG REQUEST DATA ENTRY INTO REDCap

Using the MOH IG request form or information obtained from LIS, enter the IG recipient data into REDCap. This may be a <u>New Record</u> for a recipient, or a <u>New Instance</u> for a recipient already entered but has had a new request form submitted (e.g. IG recipients on maintenance / long term use).

4.1 CREATING A NEW IG RECIPIENT RECORD

A new record is created when IG is initially ordered for a patient. As per QIP protocol, sites can decide to enter retrospective data from 2018-present date. The record ID will be created for the very first request for IG.

Note: Users entering IG data with multiple DAGs <u>must ensure they are in the correct DAG</u> before they create a new record for the patient IG data they are entering or use the DAG switcher to switch to the correct DAG.

There are 3 options for entering a new IG recipient into REDCap:

4.1.1. Option One: Using Add/Edit Records

- a. Click on Add/Edit Records on the left menu bar.
- b. Then on the right of the webpage, select the green toggle button +Add new record.

REDCap		ORBCoN Ministry of Health IG	Request Form	Database	PID 455
Logged in as rebecca Log out My Projects or Control Center REDCap Messenger View project as user: rebeccatest (rebecca	ba 🗸	Add / Edit Records You may view an existing record/response by below.	selecting it from the o	drop-down lists be	elow. To create a new record/res
Project Home and Design					
Project Home · E Codebook Project status: Development		O NOTICE: This project is currently in Deproject has been moved to Production st		teal data should	I NOT be entered until the
Data Collection — Mock site 1	-				
III Record Status Dashboard		Total records: 5 / In group: 1			
Add / Edit Records - Create new records or editiview existing one Show data collection instruments Applications	-	Choose an existing Record ID	[+ Add new reco	
🛱 Calendar					
 bata Exports, Reports, and Stats File Repository Resolve Issues 		Data Search			
Help & Information	-	Choose a field to search (excludes multiple choice fields)	All fields		~
Help & FAQ Video Tutorials Suggest a New Feature Contact REDCap administrator		Search query Begin typing to search the project data, then click an item in the list to navigate to that record.			

4.1.2. Option Two: Using Record Status Dashboard

- a. Click on Record Status Dashboard on the left menu bar.
- b. Then on the right of the webpage, select the green toggle button +Add new record.

REDCap [®]	ORBCoN	Ministr	y of Health IG Request Form Database	PID 455				
Logged in as rebecca Log out My Projects or Control Center REDCap Messenger XVew project as user: [rebeccatest (rebecca ba	Displayed be for every dat	low is a tab a collection	ashboard (all records) le listing all existing records/responses and their status instrument (and if longitudinal, for every event). You					
Project Home and Design			pred buttons in the table to open a new tab/window in at record on that particular data collection instrument.	Legend for st	atus icons:			
Project Home · E Codebook Project status: Development	Please note t collection ins	hat if your truments, y	form-level user privileges are restricted for certain data you will only be able to view those instruments, and if	Incomplete Incomplete (no data saved) ? Unverified Many statuses (all same)				
Data Collection - Mark site 1		you belong to a Data Access Group, you will only be able to view records that belong to your group. Other and the second						
Record Status Dashboard .Vev data collection assus of all records .Vev data collection assus of all records .Chate new records or dottivities existing ones .Show data collection instruments			[Default dashboard] • age 1 of 1: "3285-1" through "3285-2" •	ALL (2	2) 🗸 records per page			
Applications (-	1							
Calendar Data Exports, Reports, and Stats File Repository Resolve Issues	+ Add new i	_	t status only Lock status only All status types					
Help & Information	8	Data						
Help & FAQ Video Tutorials Suggest a New Feature	Record ID 3285-1	Form						
Contact REDCap administrator	3285-2	•						

4.1.3. Option Three: After Entering a Previous Record

- a. If you are in an existing record or finishing entering a record, you can **Save & Go To Next Record.**
- b. Once the page opens, select Add new record.

		Click the down arrow button to view more save options.	Total records: 6 / In group: 2	
Hospital MAK Code * mut provide value Form Status	es case	The option chosen for this button will become its default for you next time in this	Incomplete Records (2)	select record 🗸
Complete?	Complete? Inc projet	project.	Complete Records (0)	select record 💌
		ancel - Save & Stay Save & Go To Next Instance Save & Go To Next Record Save & Go To Next Record		Add new record

4.1.4. Once the new record has been created, a *Record ID* will automatically be generated for that IG recipient. The first four digits reflect your DAG group ID followed by the next sequential record number. Document this number on your Patient Tracking Log (<u>Appendix 1</u>) and complete the *Hospital Use Only* section with the remainder of patient information.

📰 IG Online Data Collection Form

Adding new	Record ID 3285-1 . (Instance #1)		
Record ID			3285-1	
ORBCoN Ministry of Health IG Request Form Database			atabase	

4.1.5. Continue to Entering Form Demographics to enter required information for QIP.

4.2 CREATING A NEW INSTANCE

A new instance will occur when an IG recipient has had multiple MOH IG request forms submitted. This scenario is likely when a patient is on maintenance/long term IG therapy. You will have to refer to your patient log to determine if you have entered information for your IG recipient previously or not, to determine if it's a new record or a new instance. For example, if you have 3 forms for one patient you will have 3 instances entered in REDCap for one *Record ID*. Therefore, each additional order/form will be an instance for that IG recipient in the data capture system.

There are 3 options for entering a new instance for an IG recipient into REDCap:

4.2.1. Option One: Using Add / Edit Record

- a. If an existing record has already been created and you would like to enter another form, select the Add /Edit Records.
- b. Choose your existing IG recipient *Record ID* from the drop-down menu.
- c. Once record home page displays, select + Add new.

Data Collectio	n	Total records: 311	
_	itatus Dashboard	Choose an existing Record ID	select record 🗸
🔓 Add / Ed	it Records w records or edit/view existing ones		select record 1
Record ID	<u>Select other recor</u>	<u>d</u>	2 3 3285-1
IG Online D Form (2)	Data Collection		
1	۲		
2	0		
	+ Add new		

4.2.2. Option Two: Multiple Orders for Same Record ID

a. If you are entering multiple MOH IG request forms for the same patient continuously from the first form/instance, choose **Save & Go To Next Instance** at the top right side or at end of the data entry form (e.g., this option can be chosen if back entering multiple forms/requests since the project allows for patient records back to the year 2018).

	Click the down arrow button to view more save options.
Hospital MAK Code * must provide value Form Status Complete?	The option chosen for this button will become its default for you next time in this
	Inc project.
	- Cancel - Save & Stoy Save & Go To Next Instance
	Save & Exit Record Save & Go To Next Record

4.2.3. Option Three: Record Status Dashboard

- a. Click on Record Status Dashboard.
- b. Find existing IG recipient Record ID number.
- c. Click on + symbol to enter a new instance for existing patient.



4.1.6. Once new instance is created, continue to enter request Form Demographics.

📕 IG Online Data Collection Form

Current instance: 🔘 2 🤝		
Editing existing Record ID 3285-1. (Instance #2)		
Record ID	3285-1	
ORBCoN Ministry of Health IG Request Form Database		

4.3 ENTERING IG DATA INTO REDCap FORM

IG request data is entered for both new records and new instances. If at any time the wrong information was selected, you can choose the opposite radio button or select the reset option at the far-right side of the form. All demographics with an asterisk * indicate that the variable/field is mandatory on the form and must have data entered to successfully move forward.

4.3.1. Form Demographics

- a. **Hospital site (where form is received):** Select your hospital site by one of the following methods:
 - Using the drop-down arrow select your hospital name; or
 - Start to type the hospital name until your site name appears to be selected; or
 - Enter the 'first letter' of the hospital name repeatedly until your site name appears to be selected.

- b. Form type: Select either the form type by clicking on the appropriate radio button:
 - Neurology
 - Non-Neurology

Note: Choosing the appropriate form type will determine the IG indications available further down in the form demographics. If your site uses a modified / adapted form for LIS, you may need to determine if the indication/diagnosis of the patient fits under Neurology or Non-Neurology form type.

- c. Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG): Select the product that is being requested by the physician for the IG recipient:
 - IVIG
 - SCIG

Hospital site (where form is received):		
✓	0	
Form type:	M	
O Neurology		
O Non-Neurology		reset
Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) O IVIG O SCIG		reset

- 4.3.2. Patient Demographic Information
 - a. **Age Category:** Will need to be extrapolated from DOB information provided in top right corner of MOH IG request form or pulled from LIS. In REDCap, categorize patient into the following:
 - Adult (defined as greater or equal to 18 years old)
 - Pediatric (defined as less than (<) 18 years old)
 - Neonate (defined as less than (<) 4 months old)
 - b. **Sex**: MOH IG request forms use the term 'Gender', however the intent of the form when written was to collect *biological sex* of the recipient. Please note dose calculator is based on *biological sex*.
 - Male
 - Female
 - c. **Patient Location:** Categorize your institution location (e.g., 4W Reception Area) into one of the following categories:
 - Inpatient
 - Outpatient (clinic)
 - Outpatient (home infusion)
 - Outpatient (not specified)
 - Emergency Department

See Appendix 1 IG Recipient Patient Tracking Log	
Please ensure that the patient is coded with the Record ID to be used for multiple order forms	
Age Category: O Adult O Pediatric < 18 yrs O Neonate < 4 months	rese
Sex: O Male O Female	rese
Please note the form uses the term Gender; however, the intent is to collect the sex of the paitent	Tese
	iod)
Patient Location: O Inpatient O Outpatient (Clinic) O Outpatient (Home Infusion) O Outpatient (not specific Emergency Department	ied) C

4.3.3. Section A: Physician/Prescriber and Hospital Information

- a. **Date Requested:** Format (YYYY/MM/DD) Enter as supplied on MOH IG request form. If the date is not supplied on form, or LIS request submitted, use the date that the request was received in the Transfusion Medicine Laboratory.
- b. **Date Required:** Format (YYYY/MM/DD) Enter as supplied on MOH IG request form or LIS submitted request.
- c. **Physician/Prescriber Contact Information Code:** To be used if hospital site is choosing to code physician/prescriber information. Code entered should match the code used on the Physician/Prescriber Contact Information Log (<u>Appendix 2</u>). Each physician/prescriber should only have one code associated with them on the physician/prescriber log and used for all IG recipient entries.

If your hospital site is providing physician/prescriber contact information, the following information would be entered into REDCap:

- Name of ordering/treating physician/prescriber
- Physician/prescriber phone number
- Physician/prescriber email address
- d. **Physician/Prescriber Specialty:** Using the down arrow, select the appropriate specialty for the ordering/treating physician/prescriber. The following specialties are listed:
 - Neurology
 - Immunology
 - Hematology
 - Dermatology
 - Infectious Disease
 - Transplant
 - Rheumatology
 - Emergency Medicine
 - Internal Medicine
 - Other (if selected, an additional data collection field will appear to enter other specialty)
 - No Information
 - Unknown

- e. Is the Patient being seen by Neurologist/Neuromuscular Specialist: Radio buttons only appear when *Neurology* is selected under physician/prescriber specialty data collection field and neurology form type. If radio buttons available, choose either:
 - Yes
 - No
- f. **Hospital where the patient will receive IG:** This might be referred to as where the product is being picked up; some multi-site hospital laboratories may have a centralized location for IG requests to be receive, but product is issued for infusion at another site. Select your hospital site by any of the following methods:
 - Using the drop-down arrow select your hospital name; or
 - Start to type the hospital name until your site name appears to be selected; or
 - Enter the 'first letter' of the hospital name repeatedly until your site name appears to be selected.

Depending on the product type (IVIG or SCIG) selected either of the two questions will be shown:

- g. If IVIG is selected, Will this IVIG be infused at another hospital?
 - Yes
 - No
- h. If SCIG is selected, Will this SCIG be picked up at another hospital?
 - Yes
 - No

SECTION A: Physician/Prescriber & Hospital Information	
* Date Requested (YYYY/MM/DD)	
Date Required (YYYY/MM/DD)	
See Appendix 2 Physician/Prescriber Contact Information Lo	g
Physician/Prescriber contact information code:	
If you are providing contact information for the Physician/Prescriber please enter the in	formation below:
Name of Ordering/Treating Physician/Prescriber	
Physician/Prescriber's Contact Phone Number:	
Physician/Prescriber's Email:	
* Physician/Prescriber Specialty:	
	E M
Other Specialty if applicable:	
Is the patient being seen by a Neurologist/Neuromuscular Specialist	
Hospital where patient will receive IG	
✓	
Will this IVIG be infused at another hospital?	
Will this SCIG be picked up at another hospital?	

4.3.4. Section B: Request Type

- a. **Initial Request or Renewal Request:** Select radio button *Yes* for the appropriate request type (only 1 request type per instance to be chosen):
 - Initial request
 - Renewal request

SECTION B: Request Type NOTE: Only select Initial request or Renewal request not both Ores reset Initial request: Maximum 6 month approval Ores Renewal request: A reassessment should be done to confirm IG treatment continues to be effective and that minimum effective dose is being applied. Maximum 12 month approval

- 4.3.5. Section C: Clinical Indication
 - a. Indication: Use the down arrow, type the indication or type the first letter of indication repeatedly, selecting the appropriate indication as documented on MOH IG request form or LIS request. The indications available for selection are:
 - Acquired hemophilia
 - Acquired red cell aplasia
 - Acquired von Willebrand's disease (AvWD)
 - Acute disseminated encephalomyelitis (ADEM)
 - Allogeneic bone marrow or stem cell transplantation
 - Autoimmune hemolytic anemia (AIHA)
 - Autoimmune neutropenia
 - Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
 - Fetal/Neonatal Alloimmune Thrombocytopenia (F/NAIT)
 - Guillain-Barré Syndrome (GBS) including Miller Fisher Syndrome and other variants
 - Hematopoietic Stem Cell Transplant in primary immunodeficiencies
 - Hemolytic Disease of the Fetus and Newborn (HDFN)
 - Hemolytic transfusion reaction (HTR)
 - Hemolytic transfusion reaction in sickle cell disease (HTRSCD)
 - Idiopathic Inflammatory Myopathy (IIM) Includes Dermatomyositis and Polymyositis
 - Immune Thrombocytopenia (ITP) Adult
 - Immune Thrombocytopenia (ITP) Pediatric
 - Invasive Group A streptococcal fasciitis with associated toxic shock
 - Juvenile Idiopathic Inflammatory Myopathy (J-IIM) (previously Juvenile Dermatomyositis)
 - Kawasaki Disease (KD)
 - Kidney transplant from living donor to whom the patient is sensitized
 - Lambert-Eaton Myasthenic Syndrome (LEMS)
 - Multifocal Motor Neuropathy (MMN)
 - Myasthenia Gravis (MG)
 - N-methyl-D-aspartate (NMDA) encephalitis
 - Pediatric Autoimmune Neuropsychiatric Disorders Associated with Streptococcal Infections (PANDAS)
 - Pemphigus Vulgaris (PV) and Variants
 - Peri-transplant (heart, lung, kidney, pancreas)
 - Post-transfusion Purpura
 - Post-transplant (Solid Organ Transplant)
 - Pre-transplant (Heart)
 - Primary Immune Deficiency (PID)
 - Rasmussen's encephalitis
 - Secondary Immune Deficiency (SID)
 - Staphylococcal Toxic Shock
 - Stiff Person's syndrome
 - Toxic epidermal necrolysis (TEN)/Stevens-Johnson Syndrome (SJS)
 - Virus associated hemophagocytic syndrome (VAHS)
 - Other

- Missing Data Codes:
 - No Information (NI)
 - Unknown (UNK)

If "Other" is selected from the indication list, an appropriate data collection field will appear to enter other indication.

SECTION C: Clinical Indication Clinical indication for use Refer to Ontario IG Management Utilization Guidelines for additional indication where IG may be appropriate.

Indication (please select from the drop down)	Other	
If applicable request is for another indication please specify		

4.3.6. Other Treatment Information

- a. Has the patient used other therapies to treat this condition: If this information is provided on the MOH IG request for or is known, please indicate the number of lines of treatment used previously to treat this condition. By selecting the appropriate numbered radio button corresponding to the number of treatments previously used, appropriate number data table will become available to enter the following information:
 - Treatment (name/description)
 - Dose (if applicable)
 - Duration of treatment
 - What was the outcome? Select the appropriate outcome:
 - No Response
 - \circ Contraindications
 - \circ Intolerance
- b. **Other Comments:** includes notes regarding response to IG therapy or any other pertinent comments.

Other Treatment Information	Other	Treatn	nent In	forma	tion
------------------------------------	-------	--------	---------	-------	------

Has the patient used other therapies to treat this condition.

Please indicate the number of lines of treatments:
1 02 03 04 05

If Yes, specify other treatments below

Treatment	Dose (if applicable)	Duration of treatment	What was the outcome?			
Expand	Expand	Expand	O No Response O Contraindications O Intolerance reset			
Other Comments (include notes regarding response to IG therapy						
			Expand			

4.3.7. Section D: Dosage Information

If MOH IG request form includes more than one dose type, another instance will need to be entered for the second dosing information (e.g., Initial induction dose and maintenance dose indicated on one form received).

a. Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG): The response entered at the beginning of the form will display. This serves as a review to make sure the right product was selected. If you need to correct it, you will need to go to the beginning and review the information previously entered.

Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) 🖲 IVIG OSCIG Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) IVIG

OR

Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) 🛛 IVIG 🔘 SCIG Intravenous Immune Globulin (IVIG) or Subcutaneous Immune Globulin (SCIG) SCIG

- b. Patient Weight (Kg): Enter the patient weight in the unit kilogram (Kg).
- c. **Patient Height (cm):** Enter the patient height in the unit centimeter(cm).

reset

- d. **BMI (calculated field by REDCap):** The patient's weight and height will be used to automatically calculate the *Body Mass Index (BMI)*.
- e. Dose: Indicate the dose type from the options:
 - Single (one time) dose
 - Induction dose
 - Maintenance dose

Patient Weight	(Kg)
Patient Height	(cm)
BMI (pre calculated field)	View equation Dose must be adjusted
for BMI greater than or equal to 30	

- f. If you select **Single (one time Dose)** or **Induction Dose** for IVIG use, the following fields will be active:
 - Dose in g/Kg (please enter number to one decimal place)
 - Total dose (g)
 - Divided over '<u>x</u>' days.
 - Options include 1-7
 - Missing Data Codes:
 - No Information (NI)
 - Unknown (UNK)

Dose: Single (one time) Dose O Induction Dose O Maintenance Dose	
	reset
Dose in g/Kg (please enter number to one decimal place	
Total dose (g):	
Divided over	
	θ
	M
days	
Frequency Every weeks	
For a duration of	

- g. If Maintenance Dose is selected, the following will be active:
 - Dose in g/Kg (please enter number to one decimal place)
 - Total dose (g)
 - Divided over '<u>x</u>' days.
 - Options include 1-7
 - Missing Data Codes:
 - No information
 - Unknown
 - Frequency Every '____x___' weeks.
 - Options include 1-6
 - Missing Data Codes:

- No information
- Unknown
- For a duration of (e.g., number of treatments or number of months) Note: Displays for any dose selected.
 - Options include 1, 2, 3, 6, 12
 - Missing Data Codes:
 - No information
 - Unknown

Dose: O Single (one time) Dose O Induction Dose 💿 Maintenance Dose	
	reset
Dose in g/Kg (please enter number to one decimal place	
Total dose (g):	
Divided over	
	H P M
days	
Frequency Every	
✓	⊕ 🖓
weeks	
For a duration of	
	θ
	P M

- h. Was the dose calculator used? Select one of the options:
 - Yes
 - No
 - Unknown
- i. **If no, why was it not used:** If you select *No* or *unknown* the comment box will open for you to enter any information on why the dose calculator was not used.

/as the dose calculator used? ⊃ _{Yes} ● No	
O Unknown	
	reset
No, why was it not used	
	Expand

4.3.8. Laboratory Testing Results

- a. If laboratory testing results are provided on the MOH IG request for or are readily available in LIS, the following testing results are available for entering:
 - IgG level
 - Platelet count
 - Other, specify the test name and result.

Date of associated test can be entered using the format YYYY-MM-DD.

Laboratory Testing Results (as documented on form)

If applicable, enter the approriate test results

Date (YYYY-MM-DD)

4.3.9. Dose Calculator

Based on the pre-set variables entered in the form from the MOH IG request form/LIS request, the dose calculator will show the calculations to determine the dose. An example of the blank dose calculator and what it might look like once your form information has been enter is shown below:

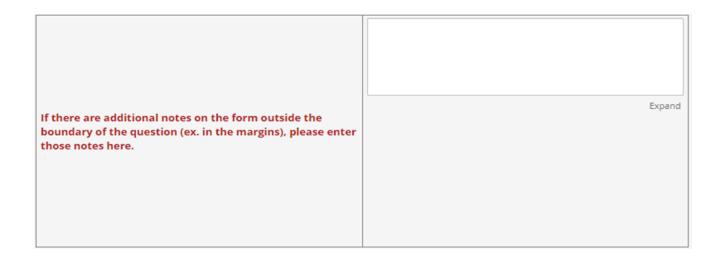
Adjusted Dose (BMI >30) [linke	d to dose calculator]			Dosing Calculation steps	If Male	If Female	
Dosing Calculation steps	If Male	If Female		3.78		View equation	
Ideal Body Weight (male) = 50.0 kg + 2.3 kg (each inch > 5 feet) Ideal Body Weight (female) = 45.5 kg + 2.3 kg (each inch >				Ideal Body Weight (male) = 50.0 kg + 2.3 kg (each inch > 5 feet) Ideal Body Weight (female) = 45.5 kg + 2.3 kg (each inch > 5		54.2 View equati	n
5 Adjusted Dosing Weight (kg) Used when patients body weight is greater than the ideal body weight				Adjusted Dosing Weight (kg) Used when patients body weight is greater than the ideal body weight		66.9 View equation	m
Dosing Weight To be used in the dose calculator				Dosing Weight To be used in the dose calculator		66.9 View equati	n
Dose (gram/kg)			View equation	Dose (gram/kg)			View equation
5552 (S. MILLIN, 18)							
IVIG Dose Calculator				IVIG Dose Calculator	View equation	View equati	n
IVIG Dose Round to Nearest 5g (to be validated)			View equation	IVIG Dose Round to Nearest 5g (to be validated)			View equation
If an Adult < 152.4 cm				If an Adult < 152.4 cm			

- 4.3.10. Section E: Transfusion Medicine Only
 - a. Dose Verified: Select Yes if dose was verified by technologist.
 - b. Dose adjusted to: Enter the adjusted dose.
 - c. **Adjusted by:** Enter the appropriate information; your site may code this information, or you could enter the role of the person making this decision (MLT, TM Physician).
 - d. **Confirmed with ordering physician:** Select *Yes* if dose was confirmed with ordering physician/prescriber.
 - e. **Date confirmed (YYYY-MM-DD):** Enter the date the dose was confirmed with ordering physician/prescriber.
 - f. **Transfusion Medicine Medical Director/Designate Approval (request status**): Select using the down arrow:
 - Approved as ordered
 - Denied
 - Adjusted dose approved
 - No information
 - Unknown
 - g. Signature of approving Physician/Prescriber (please type name if allowed by your institution: This information can be coded as per the Physician/Prescriber Tracking Log (<u>Appendix 2</u>).

SECTION E: For Transfusion Medicine Use Only		
Dose Verified O Yes		reset
		, coct
Dose adusted to:		
Adjusted by:		
Confirmed with ording physician/prescriber OYes		reset
Date confirmed (YYYY-MM-DD)		
Transfusion Medicine Medical Director/Designate Approval (request status)	(H)	
	M	
Date Approved/Denied (YYYY-MM-DD)		
Signature of approving Physician/Prescriber (please type name if allowed by your instituti	on)	

4.3.11. Additional Notes/Information

If there are additional explanatory notes on the form outside of the standard questions on the MOH IG request form (e.g., in the margins), please enter those notes here.



4.4 FORM STATUS

To save the data information entered in the form and come back to it at another time to finish entering the data, the **Save & Exit** option can be used to create the record. The *Form Status* in this situation can be left as **Incomplete**. On the *Record Status Dashboard*, the coloured radio button will stay **Red**.

The Form Status must be changed to **Complete** by using the down arrow, once all the data has been

entered to change the coloured radio button on the *Record Status Dashboard* to **Green**. • Changing the record to complete does not affect the option to add additional instances in the future.

Form Status	
Complete?	G Incomplete V
	Save & Exit Form Save &
	– Cancel –

4.5 OTHER IMPORTANT INFORMATION

IMPORTANT: For privacy purposes, do <u>NOT</u> enter any of the following data into REDCap (there should not be any fields in REDCap to enter this data into) – patient name, date of birth, or OHIP number.

If information from the MOH paper form is missing in any text field in REDCap, please type/enter *NI* into the REDCap field to indicate that the paper form was blank. If information from the MOH form is missing in a drop-down field in REDCap, please choose the option
 Missing Code – No Information. If information from the MOH form is provided, but it cannot be deciphered or interpreted, please choose the option Missing Code – Unknown.

- For Treating/Ordering Physician and Physician Phone fields, do not pull this information from the hospital derived patient information sticker. The Most Responsible Physician (MRP) and Family Physician (FP) from the sticker may not be the same as the treating/ordering physician for the IG request and shouldn't infer that they're the same. Enter the information that is typed/written into the corresponding fields on the paper form. If the fields are blank, enter them as null.
- Ensure you are recording any additional notes from the paper forms at the bottom of the REDCap forms in the **Additional Notes / Information** section.

5.0 Acknowledgements

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6.0 Appendices

Appendix 1: Patient Tracking Log. (electronic version)

Appendix 2: Physician / Prescriber Information Log. (electronic version)

6.1 Appendix 1: Patient Tracking Log

IG Recipient Patient Tracking Log

REDCap	REDCap Instance Request Da Record ID Number (YYYY/MM/I	Request Date	For Hospital Use ONLY		
		(YYYY/MM/DD)	Last Name	First Name	Hospital Medical Record Number (MRN)

6.2 Appendix 2: Physician / Prescriber Information Log

Physician / Prescriber Contact Information Log

Physician / Prescriber	Physician / Prescriber Identification Code	For Hospital Use ONLY				
Specialty		Physician / Prescriber Last Name	Physician / Prescriber First Name	Email Address / Phone #		