



# Varicella Zoster IgG Release Form



Subject ID: VM- \_\_\_\_\_  
(To be supplied by FFF Enterprises)

Subject Initials: \_\_\_\_\_  
First Middle Last

Please telephone FFF Enterprises at 800-843-7477 to assure an immediate response. After business hours and on weekends, please select the emergency order option.

After placing your request, please complete all pages of the downloadable release form and fax it to FFF at 951-296-2570.

### PLEASE NOTE

- This product is made available in the US under BB-IND 7201 reviewed by FDA. **IRB review is required.**
- Does your organization have a local IRB? Yes  No
- FFF requests that local IRB's waive any fees associated for their review of this study.
- Cangene has applied to FDA for cost recovery under this protocol. FDA has not determined the cost recovery amount.

### Subject Information

<b>Date of birth</b>	____ - ____ - ____ (MM) (DD) (YYYY)
<b>Gender</b>	<input type="checkbox"/> male <input type="checkbox"/> female
<b>Subject weight</b>	____ ____ LBS    lbs / 2.2 = kilograms ____ ____ KG    (required to calculate # of vials)  Dose • 125 IU/10 kg IM to a maximum dose of 625 IU (5 vials). • Minimum dose is 125 IU (one vial) for patients ≤ 10 kg.  Total number of vials required: _____

### Subject Exposure to Varicella Zoster Virus (VZV)

<b>Description of exposure</b>	
<b>Duration of exposure</b>	____ Days    ____ Hours    ____ Minutes
<b>Time since exposure</b>	____ Days    ____ Hours    ____ Minutes



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**To be eligible, the subject must belong to one of the following "at risk groups" (check all that apply):**

	Yes	No
• Child with cellular immunodeficiency or neoplastic disease or receiving immunosuppressive therapy	<input type="checkbox"/>	<input type="checkbox"/>
• Newborn of mother with VZV < 5 days before or < 2 days after delivery	<input type="checkbox"/>	<input type="checkbox"/>
• Premature infant	<input type="checkbox"/>	<input type="checkbox"/>
• Full term infant < 1 year of age	<input type="checkbox"/>	<input type="checkbox"/>
• Immunocompromised adult with no history or evidence of prior infection	<input type="checkbox"/>	<input type="checkbox"/>
• Healthy adult with no history or evidence of prior VZV infection	<input type="checkbox"/>	<input type="checkbox"/>
• Pregnant woman with no history or evidence of prior VZV infection	<input type="checkbox"/>	<input type="checkbox"/>

### Subject Exclusion Criteria

If the answer to any question below is "yes," the subject is **not eligible** to participate in this trial.

	Yes	No
1. Does subject have a known immunity to VZV, i.e. previous infection or vaccination?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does subject have medical history of IgA deficiency?	<input type="checkbox"/>	<input type="checkbox"/>
3. Does subject have a history of hypersensitivity to immune globulins?	<input type="checkbox"/>	<input type="checkbox"/>
4. Does the subject have evidence of varicella or zoster lesions prior to dosing?	<input type="checkbox"/>	<input type="checkbox"/>
5. Is the subject hypersensitive to any component of VariZIG™, its diluent or its packaging (i.e. latex stopper)?	<input type="checkbox"/>	<input type="checkbox"/>
6. Is the subject severely thrombocytopenic (platelets < 50 X 10 <sup>9</sup> /L)?	<input type="checkbox"/>	<input type="checkbox"/>

### Physician's Eligibility for Clinical Trials

If the answer to question 1 or 2 is "yes" or if the answer to question 3 is "no," the physician is **not eligible** to participate in this trial.

	Yes	No
1. Have you ever been disbarred from performing a clinical trial?	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you an employee of Cangene Corporation, or have you or your institution received a significant benefit (such as payment, proprietary interest or equity) from Cangene Corporation?	<input type="checkbox"/>	<input type="checkbox"/>
3. Are you a medical doctor currently licensed in the jurisdiction where treatment will take place and licensed to prescribe medicinal products?	<input type="checkbox"/>	<input type="checkbox"/>

**I certify that all the above information is true and accurate to the best of my knowledge.  
(Physician signature on next page)**



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\_\_\_\_\_  
Physician's Signature

Date: \_\_\_\_ - \_\_\_\_ - \_\_\_\_  
(MM) (DD) (YYYY)

\_\_\_\_\_  
Print Name of Physician

### Physician Contact Information (please print)

Hospital or medical facility name: _____ _____	Street address: _____ _____ City: _____ State: _____ Zip code: _____
Phone number (include area code):	(____) _____ - _____
Fax number (include area code):	(____) _____ - _____
Email address ( <b>important</b> ):	

### Pharmacy Contact Information

Name: _____ _____	Phone number: _____ Email address: _____ FFF account number: _____ DEA Board of Pharmacy number: _____
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### Shipping Address (if different from above)

Hospital or medical facility name: _____ _____	Street address: _____ City: _____ State: _____ Zip code: _____
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### Local IRB Contact Information

Contact name: _____
Phone number: _____
Email address: _____

### To be completed by FFF Enterprises

Is subject eligible for the study? Yes <input type="checkbox"/> No <input type="checkbox"/>	Total number of vials: _____
Release authorized by:	
_____	
Signature	
_____	Date: _____
Print Name	(MM) (DD) (YYYY)

### Notes:

- 1. This product is being provided to fill a gap in therapy in the United States.**
- 2. FDA has approved cost recovery for Varicella Zoster IgG under this protocol. When FDA approves the cost recovery amount, FFF will issue an invoice to your facility. Each facility will be responsible for submitting the cost recovery amount to FFF within 30 days of the invoice date.**
- 3. Varicella Zoster IgG may be used in only one or very few subjects at each institution. IRB review fees would significantly increase the unit cost of therapy beyond the ability of the sponsor and distributor to recover their costs. Cangene and FFF request that local IRB's waive any fees associated with their review of this study.**