CANGENE

Varicella Zoster IgG Release Form

FFF enterprises
Helping Healthcare Care®

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.
- The FDA has approved cost recovery for Varicella Zoster IgG under this protocol at $128.34 per 125 IU vial.

Subject Information

Date of birth	__ __ - __ __ - __ __ __ __ (MM) (DD) (YYYY)
Gender	☐ male ☐ female
Subject weight	__ __ __ 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)

Description of exposure	
Duration of exposure	__ __ Days __ __ Hours __ __ Minutes
Time since exposure	__ __ 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	☐	☐
• Newborn of mother with VZV < 5 days before or < 2 days after delivery	☐	☐
• Premature infant	☐	☐
• Full term infant < 1 year of age	☐	☐
• Immunocompromised adult with no history or evidence of prior infection	☐	☐
• Healthy adult with no history or evidence of prior VZV infection	☐	☐
• Pregnant woman with no history or evidence of prior VZV infection	☐	☐

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?	☐	☐
2. Does subject have medical history of IgA deficiency?	☐	☐
3. Does subject have a history of hypersensitivity to immune globulins?	☐	☐
4. Does the subject have evidence of varicella or zoster lesions prior to dosing?	☐	☐
5. Is the subject hypersensitive to any component of VariZIG™, its diluent or its packaging (i.e. latex stopper)?	☐	☐
6. Is the subject severely thrombocytopenic (platelets < 50 X 10^9/L)?	☐	☐

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?	☐	☐
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?	☐	☐
3. Are you a medical doctor currently licensed in the jurisdiction where treatment will take place and licensed to prescribe medicinal products?	☐	☐

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 **(important)**:	

Pharmacy Contact Information

Name: _____ _____	Phone number: _____ Email address: _____ FFF account number: _____ DEA Board of Pharmacy number: _____

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 ☐ No ☐

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 at $128.34 per 125 IU vial. 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.**