CANGENE

Varicella Zoster IgG Release Form

FFF enterprises
Helping Healthcare Care®

Subject ID: VM-__ __ __ __ __ (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 IRBs 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	__ __-__ __-__ __ __ __ (M M D D Y Y Y Y)
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)
(VariZIG administration must be within 10 days of exposure to VZV)

Description of exposure	
Date of first exposure to person infected with VZV	__ __-__ __-__ __ __ __ (M M D D Y Y Y Y)
Time since exposure	__ __ DAYS __ __ HOURS __ __ MINUTES
Date of appearance of lesions on mother (for babies with in-utero exposure only)	__ __-__ __-__ __ __ __ (M M D D Y Y Y Y) ☐ Not applicable

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INCLUSION CRITERIA

VariZIG administration must be <u>within 10 days of exposure to VZV</u>

Is the Subject any of the following at risk patients?
Check all that apply:

	Yes	No
• Immunocompromised child with no history or evidence of prior infection	☐	☐
• 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	☐	☐

EXLUSION CRITERIA

If the **answer to any question** below is **"yes,"** the subject is **not eligible** to participate in this trial.
Time since exposure cannot exceed 10 days.

	Yes	No
1. Does subject have a known immunity to VZV, i.e. previous infection or vaccination? (vaccination = 2 doses of varicella vaccine)?	☐	☐
2. Does subject have a history of hypersensitivity to blood or blood products including IV or IM human immunoglobulin preparations?	☐	☐
3. Is the subject hypersensitive to any component of VariZIG™, its diluent or its packaging (i.e. Varicella-Zoster Immune Globulin (Human), sodium chloride, sodium phosphate, glycine, polysorbate 80, latex stopper)?	☐	☐
4. Does the subject have a history of selective immunoglobulin A (IgA) deficiency?	☐	☐
5. Does the subject have evidence of varicella or zoster lesions prior to dosing?	☐	☐
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: __ __-__ __-__ __ __ __ M M D D Y Y Y Y

_____ 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 **(required)**:	

Research Coordinator Contact Information (please print)

Name: _____ _____	Phone number: (_____)_____-_____ Fax Number: (_____)_____-_____ Email address: _____

Pharmacy Contact Information

Name: _____ _____ _____	Phone number: (_____)_____-_____ Fax Number: (_____)_____-_____ Email address: _____ FFF account number: _____ DEA Board of Pharmacy number: _____

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Shipping Address (if different from physician contact information)

Hospital or medical facility name:	Street address: _____
_____	City: _____
_____	State: _____ Zip code: _____

Local IRB Contact Information

Contact name: _____

Phone number: (_____)_____-_____

Email address: _____

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 IRBs waive any fees associated with their review of this study.**