

Certification and Agreement of Research Study For posting on the SPD website

The following document must be on file in the SPD office prior to posting the research study on the SPD website.

I/We certify:

- the product/medication involved in the research study outlined below has been approved by the institutional review board;
- the manufacturer of the drug to be studied supports the research study.

I/We agree to release the SPD from any and all litigation that may occur with regard to the research study.

The research study is described as follows: _____

Name/Title of the Principal Investigator: _____

Name of Study: _____

Sponsor: _____

Institution: _____

Name/Title of person completing this form: _____

Address: _____

Telephone: (____) _____

Fax: (____) _____

Signed: _____ Date: _____

Date when patient recruitment will no longer be necessary: _____

Sample Website Posting

This is an example of a possible research study outlined in the format that we will be using for posting on the SPD website. Please adhere to the format as much as possible.

Description of Study:

- Safety and efficacy of topical pimecrolimus for atopic dermatitis

Skin Condition:

- Mild to moderate atopic dermatitis

Major Criteria:

- Minimum 10% of total body surface area involved
- Male or female
- 2 months to 18 years of age

Reasons Why You May Not Qualify:

- Previous use of pimecrolimus or tacrolimus
- Active cutaneous infection

Study Specifics:

- 1 year open-labeled treatment with monthly study visits
- Study enrollment ends December 2001
- Compensation?

If you are interested in being involved in this research study or interested in receiving more information, please contact:

_____ (Primary Investigator)

Or _____ (Nursing Coordinator)

Phone: _____

Or E-mail: _____

Location of Study and Hours of Contact if applicable.: _____