



Office for the Protection of Research Subjects
Dana Farber Cancer Institute
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Notification of Activation

DFCI Legacy #: 04-153

Date: 09/16/2004

To: Marshall Posner, MD
SW D1B20

From: OPRS Office
DFCI
375 Longwood Av, L503

Title of Protocol: A Phase II Study of G3139 (Genasense) in Patients with Merkel Cell Carcinoma
Version/Number: 9/23/03
Sponsor: NCI/DCTD
IRB Review Type: Full
IRB Approval Date: 06/22/2004
Approval Effective Date: 07/19/2004
IRB Expiration Date: 06/22/2005
Activation Date: 09/16/2004

This Project was reviewed and approved by the DFCI IRB, Assurance # FWA00001121 on 07/19/2004. At that time there were several outstanding administrative requirements. The IRB has been informed that all administrative requirements have been met; therefore the Project has been activated.

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.
2. Submission in writing of any and all adverse event(s) that occur during the course of this project that are both serious and unexpected within 10 working/14 calendar days of notification of event.
3. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.
4. Informing all physicians listed on the project of changes and adverse events.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms to OPRS Office.