A topical combination of rapamycin and tacrolimus for the treatment of angiofibroma due to tuberous sclerosis complex (TSC): a pilot study of nine japanese patients with TSC of different disease severity.

15) *Arch Dermato*l in press
A novel application of topical rapamycin formulation, an inhibitor of mTOR, for patients with hypomelanotic macules in tuberous sclerosis complex

16) *British Journasl of Dermatology* 165: 1365-2133, 2011
Treatment of Facial Angiofibromas with Topical Application of Oral Rapamycin Solution (1 mg/mL) in Two Patients with Tuberous Sclerosis

［担当医師保管用］

同　意　文　書

私は、「**薬事申請を目指した結節性硬化症に伴う顔面血管線維腫に対する安全性の高い外用剤の開発のための臨床試験**」に参加するに当たり、以下の内容について説明を受け、十分に理解した上で、自らの自由意思により本治験に参加することに同意します。

（説明事項）

1．治験とは？
2．あなたの病気（結節性硬化症）について
3．治験の目的
4．治験の方法
5．この治験に参加いただく前に確認したいこと
6．予測される患者さんの利益と生じるおそれのある不利益について
7．結節性硬化症に対する治療法について
8．治験に関する新たな情報について
9．健康被害が発生した場合について
10．治験への参加とその撤回について
11．治験を中止する場合について
12．プライバシーの保護について
13．治験の費用について
14．守っていただきたいこと
15．担当医師への連絡

患者さん署名欄

患者さん氏名：＿＿＿＿＿＿＿＿＿＿

同意日：平成　　年　　月　　日

また、生検検査についても説明を受け、十分理解した上で、自らの自由意思により生検検査に同意します。

患者さん氏名：＿＿＿＿＿＿＿＿＿＿

同意日：平成　　年　　月　　日

代諾者署名欄

代諾者氏名：＿＿＿＿＿＿＿＿＿＿（患者さんとの続柄：＿＿＿＿＿＿＿＿）

同意日：平成　　年　　月　　日

患者さん本人が署名できない理由：＿＿＿＿＿＿＿＿＿＿

（生検検査への同意）

代諾者氏名：＿＿＿＿＿＿＿＿＿＿（患者さんとの続柄：＿＿＿＿＿＿＿＿）

同意日：平成　　年　　月　　日

患者さん本人が署名できない理由：＿＿＿＿＿＿＿＿＿＿

担当医師署名欄

担当医師氏名　：＿＿＿＿＿＿＿＿＿＿

説明日：平成　　年　　月　　日

説明補助者署名欄

治験協力者氏名：＿＿＿＿＿＿＿＿＿＿

説明日：平成　　年　　月　　日

II. 研究成果の刊行に関する一覧表

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