上海市浦东新区周浦医院伦理委员会
Ethics committee of Shanghai Pudong New District Zhoupu Hospital
审查批件
Approval Document

批件编号 **Certificate Number**	2018-C-014-M01	项目受理编号 **Item Number**	2018-C-014
审查日期 **Date**	2018-1-25	审查地点 **Address**	上海市浦东新区周园路 1500 号
审查类别 **Category**	初始审查	审查方式 **Method**	☑会议审查 Meeting Review ☐加快审查 Quick Review
研究项目名称 **Research Name**	局部注射微量 5-FU 和 TA 混合液治疗慢性局限性湿疹的临床观察及其机制研究		
项目负责人 **Sponsor**	吴赟		
研究负责单位 **Responsible Research Unit**	上海市浦东新区周浦医院（上海健康医学院附属周浦医院）		
科室 **Department**	皮肤科		
审查委员 **Review Committee**	施庆红、赵江霞、涂平安、周超、张进安、顾桂国、陈伟成、陈敏、许涛、刘中鸣、顾文昌		

审查文件（含版本号）如下：
Review Document (including version number) as follows:

初审审查申请表（科研）；任务合同书；知情同意书；

审查决定 **Review Decision**	☑ 批准 Approval ☐ 不批准 Non-approval ☐ 暂停或终止研究的决定 The decision to suspend or terminate the study
批件有效期 **Approval Date**	2019 年 1 月 25 日至 2021 年 11 月 31 日 （如试验逾期未实施，需提出延长有效期申请，过期需重新审查） （If the test is not implemented within the time limit, an application for extension of the validity period should be submitted. If the trial is implemented more than the approval date, which need to be re-examined）
持续审查频率 **Continuous review frequency**	☑是（审查频率为研究批准之日起每 12 月一次） Yes(Once a year from the date of review) ☐否 No

主任委员签名:
Signature of the committee Chairman:

伦理委员会盖章 Ethics committee seal

日期 Date: 2019年 1月25 日

地址 **Address:** 上海市浦东新区周园路 1500 号　　联系电话 **Tel:** 021-68135086

注意：

1、本伦理委员会批准的项目为涉及人体的生物医学研究，必须严格按照所批最新版本的研究方案和知情同意书开展研究，并遵循国内相关法规指南要求。

2、凡是涉及人类遗传资源出口或者按照国家规定必须经有关部门专项审批的内容，均需在项目执行前向有关部门申报并获得批准。

3、如伦理委员会审查批件时效期内不能完成所有的临床研究（包括统计分析），请于本批件失效前 1 个月提交跟踪审查。

4、对已批准的临床研究方案、知情同意书作任何修改及主要研究者更换等，应及时通知伦理委员会，重新审查，获得批准后执行。

5、如发生严重不良反应事件以及影响研究风险受益比的非预期不良事件，应及时报告本伦理委员会。

6、发现不依从/违背方案情况须及时报告伦理委员会审查。

7、暂停\提前终止临床研究，请及时通知伦理委员会。

8、完成临床研究，请提交结题报告。

1.The project, approved by the ERC, is biomedical research involving humans and must be carried out in strict accordance with the latest approved research protocols and informed consent forms, and in compliance with the requirements of relevant domestic laws and regulatory guidelines.

2.Any export related to human genetic resources or contents must be subject to the special examination and approval of the relevant departments. According to the state regulations, before the implementation of a project, it shall be reported to and approved by the relevant departments.

3.If all clinical studies (including statistical analyses) cannot be completed within the validity period of the ERC-approved approval, please submit a follow-up review one month before the approval expires.

4.If the project leader wants to modify the approved clinical study protocol, informed consent or change the principal investigator, etc., the project leader shall inform the ethics committee to review the project in a timely manner and execute the project after the approval is obtained.

5.If serious adverse events occur during the research process and adverse events beyond the expected risk to benefit ratio affect the research, the responsible person shall timely inform the ethics committee.

6.If the patient fails to comply or the implementation process violates the original plan, the responsible person shall timely inform the ethics committee for review.

7.Please inform the ethics committee of the suspension or early termination of the clinical study.

8.Please submit the final report after completing the clinical study.