

PVDOMICS STUDY

Statement of Understanding of Policy Concerning Publications and Presentations

To assure that all professionals involved with the PVDOMICS Study know and understand the policies of the PVDOMICS Study regarding publications and presentations, and to preclude the possibilities of misunderstandings after initiation of the Study, each professional member will be given a copy of the Manual of Operations Section 11 detailing these policies and will be asked to sign this form attesting to his/her acceptance of these policies, which are summarized below.

I. Material Covered by These Policies

All material to be presented at meetings or submitted for publication or dissemination by individuals associated with the PVDOMICS Study and dealing with any aspect of the PVDOMICS Study must receive prior review and approval by the Publications and Ancillary Studies (PAS) Committee with the following exception:

Material prepared for publicity purposes within the recruitment region of a PVDOMICS Clinical Center, or presented orally or as handouts or posters to professional audiences solely for the purposes of informing the profession of the PVDOMICS Study and its objectives, need not be reviewed by the PAS Committee. Material for dissemination does need to be reviewed and approved by the PAS Committee. Such material must be limited to a background discussion of the issue involved and a description of the PVDOMICS Study organization, objectives, and entrance criteria, and to results of the Study that have previously been presented to a scientific body or published in a scientific journal. It must not include discussion of any previously unrepresented or unpublished PVDOMICS Study outcomes or results, and must not itself result in publication of an abstract or other citable professional reference.

II. Assignment of Writing Committees for Publications

The PAS Committee will solicit volunteers for each writing committee for abstracts and publications and make a recommendation on the writing committee and topic to the PVDOMICS Steering Committee Chair. The PVDOMICS PAS Chair will decide on the final composition and topic of the committee. All interested individuals will be given a chance to request appointment to the various writing committees, but the final appointments will be determined by the Chair of the PAS Committee.

III. Authorship

The PVDOMICS policies specify the authorship for each of the four different classes of publication or abstract (See Section 11.6 of the Manual of Operations). These policies are binding and must be followed in all publications derived from the PVDOMICS Study.

IV. Review of Abstracts

All abstracts must be reviewed and approved by the PAS Committee before being submitted (See Section 11.11 of the Manual of Operations). These abstracts must be delivered to the reviewers at least seven (7) days before the submission deadline to permit time for this review. Abstracts not approved in this fashion will be withdrawn by the PVDOMICS Study.

V. Review of Materials for Presentations

Approval for submission of an abstract does not automatically grant approval of the material ultimately to be presented. This material must also be submitted for review and approval by members of the PAS Committee at least seven (7) days prior to the scheduled oral or poster presentation.

VI. Review of Papers

All materials for which there is no explicit deadline, and all full papers that may result in a citable scientific reference, whether or not there is a deadline for submission, must be submitted to the Chair of the PAS Committee for formal review by the entire Committee (see Section 11.12 in the Manual of Operations). If there is a deadline for submission of a formal paper, it is the responsibility of the submitter to be certain that it is submitted to the Chair of the PAS Committee at least 30 days prior to the deadline, to permit such review.

VII. Certification by PVDOMICS Study Investigators

This is to certify that I have read the above statement of policies of the PVDOMICS Study with regard to publications and presentations, understand it, and agree to abide by it in matters of all publications and presentations derived from the PVDOMICS Study.

(Signature)

(Date)

(Print or Type Name and Institution)