



Center for Retinal and Ocular Therapy
PennCAROT



**The Center for Advanced Retinal and Ocular Therapeutics at the
University of Pennsylvania Perelman School of Medicine
&
Novartis Institutes for BioMedical Research**

are proud to announce the availability of a:

Subretinal Injection Training and Procedure Package

The collaborators wished to collaborate and leverage their complementary capabilities since Fall of 2014 in order to develop an investigator training package for performing subretinal injections consisting of:

- (i) An example of a Subretinal Injection Surgical Training Manual, a surgical training manual defining the selection criteria for identifying investigators suitable for receiving training on the Training Package and the appropriate series of animal models upon which to conduct such training, the elements of which have been independently developed by Novartis and Penn (section 2);
- (ii) An example of a Protocol for Subretinal Injections in non-human primates (NHP), the elements of which have been independently developed by Novartis and Penn (Section 3) leading to a Certification of Subretinal Injection Training Completion (Section 4);
- (iii) An example of a Human Subretinal Injection Procedure protocol (Section 5) including a Subretinal Injection Surgical Report (Section 6).
- (iv) Video recordings of subretinal injection training.

The rationale for this training is that in current retina surgical practice the closest procedure to subretinal injection of a cell or gene therapy product is the injection of thrombolytic agent (TPA) in cases of subretinal hemorrhage. Even this procedure is performed relatively rarely and the injection is performed inside an already formed subretinal bleb, in subretinal space occupied by blood. Only experience with submacular surgery (as in retinal translocation or injection of gene or cell therapy agent) in humans lends experience with injection in a subretinal space that it is not formed already. If the retina surgeon has not already acquired this experience by performing subretinal injections other than TPA in patients, it will be valuable to gain additional surgical experience by utilizing the training program provided herein before performing the first gene or cell therapy subretinal injection in a patient.

The University of Pennsylvania and the Novartis Institutes for BioMedical Research agreed and wished to make a Subretinal Injection Training and Procedure Package available to be used as an open source resource for any future training of surgeons in order to maximize safety of subretinal delivery of any compound. **This is meant to be used as a resource for those developing gene therapy studies, and not intended as a standard for surgical procedure or certification thereof.**

Organizations interested in acquiring this Subretinal Injection Training and Procedure Package can send an email request to:

jebennet@pennmedicine.upenn.edu

along with the following information:

Name:_____

Organization:_____

Date of request:_____