Important Information for Research Involving VA Patients

From Michael Davey (michael.davey@va.gov):

Many of our training programs require trainees to complete a paper and/or project during their time at the VAPORHCS. If a project involves VA patients or their data, each mentor must understand whether the related activities require any approvals (e.g., for case report reviews or human subjects research) before being initiated. This can be complicated and we are here to provide one-on-one service to assist. As early as possible, contact the Research Administration Office (at x55125 or pvamc-irb@va.gov) and we will assist you in assessing whether any approvals are required. Also, the forms section of our website (http://www.portland.va.gov/Research/piservices/rd_forms.asp#alphabetical) contains helpful information, including:

-Application for case report review

-Certification of exemption (from IRB oversight)

-QA/QI vs research checklist

A note of caution: If a trainee is here under an affiliation agreement with an outside institution, sometimes students have their project reviewed by the IRB or other entity at their home institution in order to obtain feedback and make sure the project meets the requirement of the training program. In the course of this review the outside IRB or entity may conclude the project does not require IRB or other approvals. <u>Please be advised that only the VA IRB, or IRB3 at OHSU if both institutions will be engaged in the project, or the VA Research Service (in select cases) have the legal authority to make this determination for activities involving VA patients and/or their data.</u>

Please contact our office as early as possible in the project design phase so we can assist you in determining what VA approval may be needed for your student's project and estimated timelines for such approvals. We want to work with mentors to make certain all activities conducted here have the proper approvals. Please circulate this email widely.