

**From:** Woollen, Stan - OC  
**Sent:** Friday, September 13, 2002 9:05 AM  
**To:** [Redacted]  
**Cc:** Beers Block, Patricia  
**Subject:** RE: Hi

[Redacted],

It's not clear what forms you are referring to. As far as I am aware the PI doesn't have to submit any official forms to FDA, only the applicant is required to either certify the absence of reportable interest or disclose reportable interests. These certifications or disclosures are submitted on either a form 3455 disclosure (see <http://forms.psc.gov/forms/FDA/FDA-3455.pdf>) or a form 3454 certification (see <http://forms.psc.gov/forms/FDA/fda3454.pdf>). These forms are signed by the applicant's representative not the CI. See 54.4 (a). Financial interests must be addressed for all clinical investigators as defined in 54.3(d). This would include dependent children and spouses of clinical investigators. We published a guidance on part 54 on March 20 2001. A copy is available at <http://www.fda.gov/oc/guidance/financialdis.html> I believe question 4 in the guidance answers your question about who should sign the forms. Hope this helps. [Redacted]  
Stan

-----Original Message-----

**From:** [Redacted]  
**Sent:** Friday, September 13, 2002 7:14 AM  
**To:** Woollen, Stan - OC  
**Subject:** Hi

Hi Stan:

Does anyone, other than the PI, have to sign the financial disclosure agreements? I found these forms with the PI's signature, but none for the sub investigators. Just wondering. See you next week!

[Redacted]