

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** 1572 Question  
**Date:** Monday, December 22, 2014 11:46:05 AM

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Good morning –

Based on the limited information in your email, I don't believe that the facility that performs the EKGs needs to be listed on the 1572 form.

For more information regarding the 1572 form, please see the guidance document below.

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM214282.pdf>

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA

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**From:** GYXUM/XQ  
**Sent:** Friday, December 19, 2014 3:59 PM  
**To:** OC GCP Questions  
**Subject:** 1572 Question

I was hoping that you could assist with a question that I have received from multiple client organizations.

When the only research procedure that will be performed in a hospital or outpatient facility is ECGs, does the facility need to be listed in Section 3 of the 1572?

Thank you in advance for any assistance you can offer.

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