**From:** OC GCP Questions
**To:** [redacted]
**Subject:** FDA Guidance on requirements for electronic temperature data loggers
**Date:** Monday, April 16, 2018 6:26:00 AM
**Attachments:** [redacted]

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Good morning –

I had to send your email to the Center for Drugs (CDER), Office of Medical Policy (OMP). Please see their response below.

Here is our cleared response:

The data flow process for capturing, transmitting, and recording the temperature measurement and the database where the measurement will be maintained and archived would fall under the scope of part 11. Please note that Part 11 regulations do not address the sensitivity and specificity of the electronic temperature monitor to measure the temperature.

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:** [redacted]
**Sent:** Friday, April 13, 2018 9:49 AM
**To:** OC GCP Questions <gcpquestions@fda.hhs.gov>
**Subject:** FDA Guidance on requirements for electronic temperature data loggers used to monitor the temperature of Investigational Medicinal Products while stored at the clinical investigational sites

Dear Madam, dear Sir,

More and more clinical investigational sites are using electronic temperature data loggers to monitor the temperature of Investigational Medicinal Products. Do these devices fall under the requirements of 21CFR Part 11 regulation?

Any information which could be provided will be most appreciated.

Sincerely,