

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Care outside of research protocol  
**Date:** Monday, August 17, 2015 6:15:23 AM

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Good morning –

There is nothing in FDA regulations that prohibits a physician from prescribing medication. Doctors/physicians would need to follow state and local laws for practicing medicine and prescribing medication.

Kind regards,

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Office of Good Clinical Practice  
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

**From:** [REDACTED]  
**Sent:** Friday, August 14, 2015 9:17 AM  
**To:** OC GCP Questions  
**Subject:** Care outside of research protocol

May a PI prescribe a drug for an infection not related to the investigative product? The guidelines indicate it is the PI's responsibility to have a procedure to handle medical and ethical issues that may arise during the trial. The subject had been given a prescription for a UTI while she scheduled a visit with her primary care physician.