From: OC GCP Questions
To: [redacted]
Subject: enrolling prisoners
Date: Friday, August 29, 2014 12:49:42 PM

Good afternoon --

FDA does not have specific regulations that pertain to research involving prisoners, nor prohibitions against their participation in research. However, it is well accepted that some subjects (generally referred to as "vulnerable subjects") may need additional safeguards to adequately assure and protect their rights, safety, and welfare. The sponsor and the IRB would need to be informed. Special consideration should be taken into account as to how the subject (prisoner) will be able to make scheduled follow-up visits per protocol. Additionally the subject (prisoner) should not be influenced or coerced in to participating in the study.

For IRB review the full text of the regulation can be found at (21 CFR 56.107(a)) -- "If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experience in working with those subjects."

While FDA does not have a specific guidance that addresses prisoner involvement in research, the Office of Human Research Protections (OHRP) does. If the research is conducted or supported by the Department of Health and Human Services (HHS), or conducted in an institution that has assured HHS that it will review all research in accordance with the "Common Rule," then the research would be subject to 45 CFR 46, including Subpart C--"Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects." Although these additional protections may not be applicable to a particular research study, they are a good model to follow. Please see the link below.
Office for Human Research Protections (OHRP) | HHS.gov

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Friday, August 29, 2014 7:33 AM
To: OC GCP Questions
Subject: enrolling prisoners

Hi,
My question is : can you enroll a prisoner to a treatment based clinical trial. Pt. has stage IV lung cancer and would like to participate in a clinical trial. He will be incarcerated for 1 year.

Thank you,

[redacted]