From: OC GCP Questions
To: [redacted]
Subject: Request for short interview on the topic of using death row prisoners for medical research
Date: Thursday, December 03, 2015 11:45:58 AM

Good morning –

We are a small office and most of my colleagues are out of the office this week attending a meeting and we generally do not give interviews. I can offer you the following information, which was presented to inquirers in the past regarding human subject research on prisoners. Please be aware FDA regulations do not specifically address prisoners but the Common Rule (45 CFR 46) does.

You may be confusing the regulations of the Department of Health and Human Services (DHHS – Common Rule) with FDA's regulations. To clarify, FDA regulates clinical investigations involving investigational drugs or biologics under 21 CFR 50, 56, and 312. [You can access our regulations by visiting FDA's Good Clinical Practice webpage: www.fda.gov/oc/gcp/ ; click on "Good Clinical Practice/Clinical Trials Regulations" in the center column.]

The regulation that you cited (45 CFR 46) is DHHS' codification of the "Common Rule," and is enforced by DHHS' Office for Human Research Protections (OHRP). The "Common Rule," so called because in 1991, DHHS and 14 other Federal agencies adopted a common Federal policy for the protection of human subjects participating in research, established requirements for human subject protection and informed consent, and ethical review of studies that are funded or sponsored by federal agencies. 45 CFR 46 includes "Subpart C--Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects." You can find the DHHS regulations on OHRP's website (www.hhs.gov/ohrp/). That office has also issued guidance about this issue (Office for Human Research Protections (OHRP) | HHS.gov) which may be of interest to you.

At the time the Common Rule was adopted, FDA amended its regulations to ensure that they were harmonized with the Common Rule to the extent possible, given FDA's unique statutory responsibilities under the Federal Food, Drug, and Cosmetic Act and the fact that FDA is a regulatory agency that does not fund or support much research. While FDA's regulations do not prohibit using prisoners in clinical trials, FDA does not have any specific regulations pertaining solely to studies involving prisoners (on death row or not on death row). However, prisoners are considered a "vulnerable" category of subjects (see 21 CFR 56.107(a)). If an IRB regularly reviews research that involves a vulnerable category of subjects, then the IRB must give consideration to including "one or more individuals who are knowledgeable about and experienced in working with those subjects."

In case you are interested in additional historical information about the prisoner issue, I've pasted in a brief chronology of FDA's prisoner regulations below, that includes Federal Register notice citations.

Each time Congress enacts a law affecting products regulated by FDA, the agency develops rules to implement the law. FDA takes various steps to develop these rules, including publishing a variety of documents in the Federal Register announcing FDA's interest in formulating, amending or repealing a rule, and offering the public the opportunity to comment on the agency's proposal. The Federal Register notice explains the legal issues and basis for the proposal, and provides information about how interested persons can submit written data, views, or arguments on the proposal. Any comments that are submitted are addressed in subsequent publications that are part of the agency's decision-making process.

The "preamble" to each of these Federal Register notices includes all of the printed information immediately preceding the codified regulation. The preamble provides information about the regulation such as why the regulation is being proposed, FDA's interpretation of the meaning and impact of the proposed regulation, and in those cases where the agency has solicited public comment, the agency's review and commentary on those comments . The preamble can also include an environmental impact assessment, an analysis of the cost impact, comments related to the Paperwork Reduction Act, and the

effective date of the implementation or revocation (as the case may be) of the regulation.

Here is the chronology of FDA's prisoner regulations:

1/14/1977 (42 FR 3076): The National Commission concludes that the prison environment is inherently coercive, diminishing the capacity of prisoners to give informed consent to participation in biomedical and behavioral research and recommends limitations on the types of research conducted on prisoners.

1/5/1978 (43 FR 1050): The Department proposes regulations adopting the National Commission's findings and implementing its recommendations and concluded that FDA should consider whether to apply the recommendations to research within FDA's jurisdiction.

5/5/1978 (43 FR 19417): FDA proposes to adopt regulations to provide protection for prisoners involved in research activities that fall within the agency's jurisdiction (21 CFR Part 50 Subpart C).

11/16/1978 (43 FR 53652): The Department adopts the final rule on the use of prisoners in research.

5/30/1980 (45 FR 36386): FDA adopts the final rule on the use of prisoners in research and announces effective date of 6/1/1981.

7/29/1980 - Fante and the Upjohn Company v. Department of Health and Human Services, et al., Civil Action No. 80-72778): Suit is brought in the United States District Court for the Eastern District of Michigan to have FDA's regulations declared invalid, arguing that the regulations would effectively ban all research on prisoners.

3/27/1981 (46 FR 18951): FDA delays the effective date and announces that unless the District Court declares the regulations to be invalid, the final rule will become effective 5 months from the date of the District Court's final judgment on the merits of the suit.

7/7/1981 (46 FR 35085): FDA stays the effective date and announces that it will in the near future re-propose the regulations at which time it will provide for public comment on the re-proposal.

12/18/81 (46 FR 61666): FDA re-proposes Subpart C, amended to allow research on prisoners if the sponsor can establish that the recommendations of the National Commission were met.

1/25/1996 (61 FR 2192): FDA proposes to revoke certain regulations that are obsolete or no longer necessary, including 21 CFR Part 50 Subpart C.

7/23/1997 (62 FR 39439): FDA announces the final rule revoking Subpart C.

You can contact OHRP directly at:

Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

Toll-Free Telephone within the United States: (866) 447-4777
Telephone: (240) 453-6900
Fax: (240) 453-6909
E-mail: OHRP@hhs.gov

Please the NIH link below that might be of interest to you.

Research Involving Prisoners - Research Involving Human Subjects

I hope this information is helpful.

Kind regards,

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

From: [redacted]
Sent: Thursday, December 03, 2015 12:47 AM
To: OC GCP Questions
Subject: Request for short interview on the topic of using death row prisoners for medical research

Dear Sir/Madam,

My name is [redacted], a senior studying Biochemistry at the [redacted] . As part of a course I am currently taking, my teammates and I are interested in investigating the controversial issue of the use of prison inmates, specifically criminals on death row, as subjects for medical research. If it is not too much trouble, could you please forward this email to someone who works in the FDA who has expertise regarding good clinical practices (GCP) or medical research involving human subjects who would be willing to share his or her opinion on the topic in a short interview?

In our hypothetical scenario, criminals sentenced to death would be given the option of living, but as a subject for medical research. Certain guidelines and regulations would still apply, but essentially, the person consents to becoming a human guinea pig in order to further medical research. If you could be so kind as to spare us about 30 minutes of your time, we would like to ask what you think about this scenario - the ethical issues behind it, whether it would be viable or even permissible, the kinds of guidelines that should be in place if this were to take place, etc.

Our professor, [redacted], assigned us to interview experts on our chosen topic in order to get information straight from the source. We would very much appreciate it if you could share some of your knowledge and opinions with us.

If you are available for an interview, either by phone or webcam (Skype, Google Hangout, etc), please let me know. [Redacted] is available if you need to confirm any details before making a decision. You can choose to give your opinions anonymously if you so desire. [redacted] just wishes that we actually speak to professionals in order to get experience interviewing experts to gather information for a research topic. If you you have any questions, please do not hesitate to email me at [redacted]

Thank you for your time and I hope to hear from you soon.

Sincerely,

[redacted]