UNIVERSITY of ALASKA

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COVID-19 Guidance on Human Subjects Research

1 message

George Kamberov <gkamberov@alaska.edu> Mon, Mar 23, 2020 at 10:33 PM
To: researchers@lists.uaa.alaska.edu, uaa_faculty_dl@lists.uaa.alaska.edu
Bcc: jaredmond@alaska.edu

Dear Researcher:
The UAA IRB and the Office of Research Integrity and Compliance would like to update you on some parameters that will affect the way you conduct Human Subjects Research and plan for studies in the near future. The primary considerations are Federal CDC guidelines for social distancing and UAA restrictions on conducting research on campus.
With these considerations in mind we would like to communicate the following guidelines regarding approved projects.

1) Active Data Collection Phase
If you believe that an aspect of an approved protocol has the potential to expose participants to the novel coronavirus (COVID-19), and therefore could increase risk and have negative health outcomes from participation, we ask that you immediately take action to reduce risk and eliminate immediate hazards even if this means deviating from your approved protocol. You must then advise the IRB within no more than 5 business days of this deviation. Your notification to the IRB must explain the need for the protocol deviation and describe the specific form it has taken.

Thus, if your approved protocol involves in-person interactions:

- You may modify your procedures to continue your research and remotely interact with subjects using telephone or internet means. When this is done to eliminate apparent immediate hazards to subjects, no prior approval is required, but a protocol deviation report must be submitted within five business days.
- If you cannot modify your research to eliminate in-person contact, you must put your research on hold. Pausing research does not require an IRB amendment or other notification. When you intend to resume your research, you must notify the IRB and discuss possible modifications based on emergent conditions.

Note: This COVID-19 advisement is consistent with existing federal regulations:
Each IRB shall … (a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects. 45 CFR 46.108(a)(4).

2) Data Management
Research projects typically involve the storage of identifiable private human subject data. Some of these data may be very sensitive and the inadvertent disclosure of those data could harm participants. Thus, federal guidelines require IRB protocols specify procedures for data management including data storage, data security, secure transmission of data between research sites and or between members of the research team. Given requirements on working from home, many UAA researchers may now be unable to use and share data under the procedures set out in their approved IRB Proposal form, section 11 or elsewhere. Given the specific provisions of your approved protocol, a researcher may or may not be able to remove sensitive data from their UAA Office or Lab Facilities for use in their alternate research work area. Any Modification Requests to store, access, or share human subject data differently from the approved protocol must be submitted in advance of making those changes. The IRB will review these modification requests as quickly as possible. In the unfortunate event that a researcher has deviated from their approved data management protocol as a response to changing work conditions at UAA, they should advise the IRB/ORIC of this protocol deviation within 5 business days. These changes will be reviewed to ensure compliance with 45 CFR 46.111(a)(7).

3) Protocols Currently Under Review (or which will be submitted soon for review)
Researchers may have a protocol under review at this time. Some protocols specify face to face interactions in the process of recruitment, data collection, or debriefing. Researchers are advised that such interaction will fall under increased scrutiny. Researchers may be advised to consider alternate methods to avoid or minimize face to face contact. Consent forms may need to include mention of risk of COVID 19 exposure. If you anticipate a Full IRB Review of your project, please note that the IRB is conducting full board reviews via Zoom teleconferencing for the foreseeable future. Like most areas of the University, the UAA IRB and Office of Research Integrity and Compliance are doing their best to respond to the rapidly changing conditions associated with the developing pandemic. We hope that we can continue to serve you well and that you are able to manage to conduct your research in some fashion in these trying times.

Best regards,
----George

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