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Human Research Protection Programs, Inc.®

Guidance on HRPP Response to COVID-19

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AAHRPP recognizes the significant effects the response to coronavirus and COVID-19 is having on researchers, IRB members, and everyone involved in HRPPs. We recognize the fluidity of the situation, and offer the following with the recognition that as time goes on things may necessitate as-yet uncontemplated further responses by organizations and AAHRPP, so please watch this space. The recommendations below draw upon creative and innovative practices of a number of accredited organizations, as well as federal agency guidance.

As always, AAHRPP and accredited organizations share the philosophy that:

- The protection of participants is paramount.
- AAHRPP Standards are flexible, and we believe there are no conflicts between AAHRPP requirements and measures organizations may take to increase social distancing, or other actions to protect the health and well-being of participants and everyone involved in research.

Changes to research procedures

Because of the rapidly evolving response to COVID-19, researchers may need to make immediate changes to research to eliminate hazards to the participant, prior to notifying the IRB or obtaining IRB approval. Researchers should take all necessary steps to protect participants and others, including research staff, and then notify the IRB of changes made to research. A key principle during this challenging time is transparent, ongoing communication between researchers and the IRB.

Examples of measures that sponsors, organizations, and researchers are taking to reduce hazards include:

- Reducing the number of study visits.
- Conducting virtual study visits via phone or video (such as Skype or Zoom).
- Limiting in-person study visits to those needed for participant safety or that occur along with clinical care.
- Replacing protocol-mandated visits to healthcare facilities with home visits or telemedicine.
- Use of alternate locations for assessment and safety monitoring, such as having blood draws or imaging occur at remote or commercial laboratories or imaging facilities.
- Shipping investigational products to research participants directly instead of having participants come to a healthcare facility to pick them up.

AAHRPP's Standards recognize the need to make changes to protect participants from apparent immediate hazards prior to notifying the IRB or obtaining IRB approval. (See Element II.2.E.(a)(xx)(C) on page 140 of the Evaluation Instrument).

AAHRPP Standards are consistent with regulations. For example, FDA regulations require that IRBs:

> (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. 21 CFR 56.108(a)(4).

DHHS and agencies that follow the Common Rule require that organizations have written procedures for:

> Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject. (45 CFR 46.108(3)(iii))

IRB review of changes

AAHRPP Standards, and regulations, require that researchers promptly notify the IRB, and require that the IRB review the changes to ensure the changes are consistent with participants' continued welfare. (See Element II.2.E.(a)(xx)(C) on page 140 of the Evaluation Instrument). AAHRPP Standards are flexible, and allow organizations to approach this in different ways:

- Notification does not need to occur through a formal protocol amendment.
- To allow researchers to focus on the response to COVID-19 and caring for participants, IRBs should consider accepting notifications via email, memos, or letters that describe the changes made to the research.
- Organizations may also want to consider implementing a special form in their online IRB systems, or changing the existing form researchers fill out to amend or modify research.
- Organizations should also bear in mind that many changes made to increase social distancing do not involve greater than minimal risk and may be approved through an expedited procedure.

Reporting Changes to the IRB

AAHRPP Standards do not define how soon researchers must report to the IRB, but only require researchers to report "promptly". Some organizational policies, developed outside the context of a public health emergency, may require "immediate" reporting, or reporting within 24 or 48 hours. Organizations should consider revising policies to allow reporting periods that allow researchers the time to focus on making the changes necessary to protect participants. For example, instead of a 24-hour reporting period, policies might be revised to require 5-day reporting.

In addition to changes to specific studies, some organizations have also mandated organization-wide changes to all research, or research of a certain type. Examples include:

- Postponing all studies involving face-to-face interaction with participants with no direct drug or device therapeutic benefit.
- Stopping new recruitment or enrollment of participants, except for certain drug or device studies where the potential benefits to participants may outweigh the risks posed by the research.
- Canceling gatherings of people involving research activities such as focus groups, and research-related activities such as community advisory boards and support groups for study participants.

IRBs should keep in mind that these types of mandates to pause research, whether imposed by the organization, or by funding agencies, are not the same as IRB-initiated suspensions and terminations. As such, they do not require the IRB report to the FDA or OHRP under 21 CFR 56.113 and 45 CFR 56.108(4)(ii).

Consent and communication about changes to research to research participants

AAHRPP Standards are flexible in how researchers notify participants of changes to research. IRBs do not need to require a formal consent document revision, or require that participants sign a revised consent document. Instead, IRBs can allow researchers to notify participants by phone or video conference or other mechanism. However, researchers should consult with sponsors about sponsor requirements for participant notifications and documentation.

Changes that may be mandated by the health system, such as COVID-19 screening procedures to allow entry into the facility, are not considered changes to the research and do not require a revision of the consent document.

Single IRB review

When organizations rely upon external IRBs, they should contact the external IRB for instructions on reporting.

Monitoring and Auditing

Monitoring and auditing of research studies should be conducted remotely for the time being whenever possible.

Reporting to AAHRPP

AAHRPP annual reporting requirements ask organizations to report catastrophic changes or events that have impacted their HRPP and human subjects research. Organizations do not need to report changes to respond to the current situation regarding COVID-19 to AAHRPP. In the annual report an organization may simply answer as it would have in the pre-COVID-19 environment - that is, with information about changes or events unique to their organization that occurred outside and distinct from the organization's response to the current public health emergency.

Additional Resources

AAHRPP encourages accredited organizations that are in the process of developing policies to draw from existing work of other accredited organizations:

These suggestions are consistent with FDA's guidance on the conduct of clinical trials during the COVID-19 public health emergency, and include measures being taken by a number of other organizations, in addition to federal agency guidance.

As a service to the research community, we wish to serve as an informal clearinghouse of policies and approaches that our accredited organizations are taking. If you would like to share with us a link for public posting (as below) of your organization's policies for managing human research during this public health emergency, we would invite you to do so.

FDA Guidance:

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic

Advarra Inc.

https://www.advarra.com/about-advarra/news/impact-of-coronavirus-outbreak-on-protocols-under-advarra-irb-review/

Columbia University

https://research.columbia.edu/covid-19-novel-coronavirus-frequently-asked-questions-relating-research#/text-14577

Drexel University

https://drexel.edu/research/resources/coronavirus-preparedness-information/research-projects-involving-human-subjects-contingency-planning/

Prime Review Board LLC

https://primereviewboard.com/content/prime-covid-19-update

The Johns Hopkins University

https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/index.html

University of California Los Angeles

https://ohrpp.research.ucla.edu/

University of Iowa

https://research.uiowa.edu/covid-19-information-researchers

University of Michigan

https://research.umich.edu/covid-19

University of Utah

https://research.utah.edu/coronavirus/index.php

WIRB-Copernicus Group

https://www.wcgclinical.com/events/webinar-clinical-trials-in-the-era-of-covid-19-the-changes-you-need-to-make-now/

and:

https://www.wcgclinical.com/events/webinar-covid-19-preparedness-information-from-the-experts/