COVID-19: Human Subjects Research

This webpage has been created to share the answers to COVID-19-related questions as pertains to the IRB and research pertaining to human subjects. It will be updated regularly.

*Updated March 17, 2020, 12 p.m. EST*

Plymouth State University Research Offices Remain Operational
The PSU Center for Research & Innovation, Office of Sponsored Programs (OSP), IRB and IACUC programs are fully functional and we expect this to continue even if the University suspends operations for contagion control purposes. Program staff will work remotely, should it become necessary.

For human subject research, highest priority is being given to all inquiries, requests, applications, and modifications related COVID-19. The IRB office is coordinating on this research [https://campus.plymouth.edu/institutional-review-board/](https://campus.plymouth.edu/institutional-review-board/).

Where to Find the Latest News
- PSU has created a [COVID-19 Information webpage](https://campus.plymouth.edu/institutional-review-board/) to share updates on PSU's response to COVID-19.
- The [Council on Governmental Relations](https://campus.plymouth.edu/institutional-review-board/) lists all federal agency policies and is updated regularly, including OMB financial policies.

In-Person Interactions with Study Participants
*Updated 3/17/20* to reflect new standards (see full announcement). In the context of rapidly evolving circumstances regarding COVID-19, and the University’s focus on social distancing and the health and well-being of the community, PSU has issued these revised standards related to human subjects-related research visits. In summary, research visits should be performed remotely (e.g., by phone, Zoom, or other means) whenever possible.

Studies involving face-to-face interaction with participants with no direct drug or device therapeutic benefit are to be postponed until further notice, effective March 17, 2020.

Participant Safety Monitoring
Some clinical studies require in-person study visits in order to conduct safety monitoring of the participants. Since PSU campus is closed to the public, researchers should plan for alternatives to in-person monitoring visits, if possible. For example, interviews could be conducted by phone or email.

These modifications to safety monitoring procedures should be approved in advance by the IRB, except when necessary to eliminate apparent hazards to a participant and there is not sufficient time to obtain IRB approval. Contact the IRB in advance psu-irb@plymouth.edu if you need to change an approved monitoring procedure to eliminate immediate possible danger.

Modifying Study Procedures to Occur Remotely
Many studies are modifying their procedures to replace in-person study visits with “remote” options for questionnaires, surveys, check-ins, screening, and consenting. Remember that these changes must be approved in advance by the IRB as a modification to the study, unless they are necessary to eliminate immediate apparent hazards to participants. If you have any questions about whether a remote option is possible or approvable (especially for consent), contact the IRB psu-irb@plymouth.edu.

Voluntary Suspension of Study Enrollment or Participation
Some studies are voluntarily halting participant enrollment or participation. This should be reported to the IRB within 5 days, using the Status Report Form. In the form, describe how any actively enrolled participants will be managed, particularly in regards to any safety monitoring/follow-up.