



IRB Modification Information

1. Change the location of data storage. It will no longer be Dartmouth College. The new location is:

**Statistical Analysis Center, Department of Biostatistics
Mailman School of Public Health, Columbia University
722 W168th St, Room 611
New York, NY 10032
212-342-2000
<http://www.sac-cu.org/>**

For any other part of the IRB that references Dartmouth College, you can change mentions of “Dartmouth College” to “**Columbia University**” and change “Clinical Trials Center” to “**Statistical Analysis Center**”.

If required, security measures in place at the SAC may be described as follows:

“The Statistical Analysis Center (SAC) in the Department of Biostatistics in Columbia University’s Mailman School of Public Health has computer resources in two locations: in their offices in the Department of Biostatistics on the campus of Columbia University Medical Center, and in a secure computer co-location facility in downtown Manhattan. The co-location facility, New York Internet Company (NYI), provides a high-security, high-uptime data infrastructure, including multiple-redundant power supply and internet access. In addition, SAC servers hosted at NYI are protected by a both hardware and software firewalls and continual process monitoring. NYI provides 24x 7x365 on-site staff for routine issues, and the SAC has an ongoing maintenance contract with Technology Campus Inc., to provide advanced technical assistance when needed. All servers hosted at NYI are regularly backed up to both tape and hard-drive, and copies are taken off-site.

The computers on the CUMC campus reside behind the campus firewall, and employ software firewalls as well. These computers are backed up daily to removable hard drives, which are regularly stored off-site. All databases are encrypted at rest, and access is solely via authenticated logins by specifically authorized users. Web sites and other internet-based communications run on Internet Information Services v.8. All web-based communication is encrypted using 256-bit encryption certificates.

Data systems have been certified by Columbia University Medical Center IT as secure for the storage of both research and patient care data. As part of this certification, the systems are audited regularly for security and regulatory compliance. Certification is based on HiTrust standards (<https://hitrustalliance.net/benefits-hitrust-certification/>).

2. Update the number of participating institutions to 60, as of April 2020.
3. Change the data points that are collected. Remove what is currently listed. Reference the new document titled, “**PSRC New Variables Collected – April 2020**” for data points to be collected. You can attach this document to your modification submission.



4. If previously included, remove any attached examples of the Dartmouth web-based interface. Reference the new document titled, "**PSRC Database Screenshot Examples – April 2020**" which you can attach to your modification.

If you have any questions, please contact Juan Boriosi (Chair, Research Committee) at jboriosi@pediatrics.wisc.edu