



# Bulletin & Update

#5 April 2012

## COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

*The Committee for the Protection of Human Subjects (CPHS) periodically releases issues of the Bulletin & Update to inform researchers and others regarding important changes in CPHS procedures as well as state and national issues of importance for human subject protection in research. Copies of the Bulletin & Update will be distributed via e-mail to researchers and other interested stakeholders as well as being posted on the CPHS Website*

*([www.oshpd.ca.gov/Boards/CPHS/bulletins.html](http://www.oshpd.ca.gov/Boards/CPHS/bulletins.html)).*

**The purpose of this bulletin is to announce some major changes in the Committee for the Protection of Human Subjects' (CPHS) submission and approval process.**

**W**e are pleased to announce that CPHS is transitioning to a new Web-based protocol application system, the California Protocol Electronic Communication and Tracking System, CalPROTECTS, as of April 9, 2012. This is a momentous shift in our business practices for our end users. These users include researchers, who are submitting protocols, the CPHS members (reviewers), who approve projects, the CPHS staff who screen and track protocols and the staff from other state departments who require CPHS approval prior to releasing data for research purposes. This bulletin will describe and explain several aspects of the new system.

Another major protocol addition included in CalPROTECTS involves extensive additions to the Data Security Requirements in the Protocol Information sections 8-10. CPHS has developed these requirements, in consultation with state data security staff, to more adequately ensure the data security and privacy of research data, as required in federal and state legislation and regulations. These sections may take additional time for investigators to complete.

### **CalPROTECTS**

Due to the implementation of CalPROTECTS, the Instructions for Researchers <http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf> on the CPHS Website ([www.oshpd.ca.gov/boards/cphs](http://www.oshpd.ca.gov/boards/cphs)) have been revised to reflect those changes. Please read them thoroughly prior to submitting your electronic protocol. Note that the eProtocol, which is referenced in the heading of this system, is interchangeable with CalPROTECTS.

The only requirement for accessing CalPROTECTS is access to the Internet. It is important to note that you will not be able to complete any of the application until the Principal Investigator, the Responsible Official and any other staff working on the application are registered in the system. The Responsible Official must be an administrative superior to the principal investigator (e.g., department or division administrator or manager, laboratory chief, another person with administrative authority above the level of the principal investigator). To register staff, go to: <https://cphs.keyusa.net/>. Please follow the instructions in the Researchers' User Guide ([www.oshpd.ca.gov/boards/cphs/UserGuides/User-Manual.pdf](http://www.oshpd.ca.gov/boards/cphs/UserGuides/User-Manual.pdf)), which provide screen shots and a detailed description of how to

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use the system. This guide has not been fully developed so please contact CPHS staff ([cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov) or 916-326-3660) if you have questions about the submission processes that are not explained in the User Guide instructions. It is advised that when a project is due for renewal all research staff who will be using this system for protocol submissions or approval register as early as possible.

Since this is the first year of CalPROTECTS, all projects being submitted will be considered new to the system. Please send the latest approved version of all of the current documents (e.g., latest approved protocol, consent forms, CVs, checklist for vulnerable populations and bill of rights) in the Attachments section of CalPROTECTS. If the form is not currently being used in the project, it is not required to be submitted. If you have amendments only, formerly referred to as revisions only, or amendments with a continuing or annual renewal to your study, include a copy of your last approved protocol with tracked changes of the amendments in the Attachment section, so reviewers can identify where changes had been made. Clean copies of the protocol changes are not required but the online protocol must be entered in the CalPROTECTS format with all of the changes already accepted.

Projects that are going to be considered by the full committee must also be submitted in 14 hard copies to CPHS by the deadline for that meeting. The deadlines for each meeting may be found on the CPHS Website at: [www.oshpd.ca.gov/General\\_Info/Public\\_Meetings.html#CPHS](http://www.oshpd.ca.gov/General_Info/Public_Meetings.html#CPHS). Projects that require full committee include:

- New projects with human subject contact, such as administering a survey or collecting specimens
- Projects with major amendments (revisions), such as adding a new intervention that requires new consent and survey forms
- All projects that are considered greater than minimal risk

There are some forms that will still need to be submitted along with new projects, continuing renewals and amendments (revisions). The required forms are explained in the new Instructions for Researchers [www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf](http://www.oshpd.ca.gov/Boards/CPHS/InstructionsforResearchers.pdf). The forms, which may be found at: [www.oshpd.ca.gov/Boards/CPHS/forms.html](http://www.oshpd.ca.gov/Boards/CPHS/forms.html) include:

- Checklist for Research Involving Children
- Checklist for Research Involving Neonates
- Checklist for Research Involving Pregnant Women and Fetuses
- Checklist for Research Involving Prisoners
- Continuing Periodic Review Form – Data Only
- Continuing Periodic Review Form – Human Subjects Contact
- Annual Report Form for Information Practices Act
- Death Data Only Revisions, Completed or Withdrawn Checklist
- Amendments (Revisions) Only Request Form
- California's Confidential Vital Statistics Death Data Files
- Report of Adverse Event/Unanticipated Problem
- Departmental Initial Review Letter for CA Information Practices Act
- Participant's Bill of Rights for Medical Research (English and Spanish)
- Participant's Bill of Rights for Non-Medical Research (English and Spanish)

Many of these forms will be incorporated into CalPROTECTS at a future date.

During the first year, vulnerable population checklists (children, pregnant women and fetuses, and prisoners) must be submitted (if applicable) for continuing renewals, amendments and new projects. For continuing renewals, the Continuing

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Periodic Review Forms for Common Rule projects and the Annual Report for the Information Practices Act studies must be completed and attached. The reason for this requirement is that the questions asked on these forms have not yet been incorporated into CalPROTECTS. The bill of rights forms have been moved from the Instructions for Researchers to the Forms tab.

Two new forms have been developed and should be used for new projects only:

- Informed Consent Form
- Informed Assent Form

Completed and Withdrawn projects will not be submitted in CalPROTECTS for the first year of implementation. Hard copies of these requests must still be submitted to CPHS, along with a cover letter that indicates how the data will be returned or destroyed. The reason for this is that we did not want to require researchers to enter the project protocol into CalPROTECTS just to complete or withdraw it.

If you are having difficulty using CalPROTECTS, please make sure you have read the Instructions and User Guide. If you are still having problems, call the CPHS main line, 916-326-3660 or e-mail, [cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov).

CalPROTECTS is definitely a work in progress and we appreciate your feedback on the system. Please e-mail any comments to [cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov). We understand from other institutional review boards, who have converted to online submissions, that the first year is very difficult, but the researchers loved it the second year once their documents were in the system. The researchers also liked the ability to track the progress of their projects online.

### **New Data Security Requirements in CPHS Protocol**

Please note that the Data Security Requirements section of the Protocol Information has been greatly enhanced and may take longer to complete. If you cannot meet specific requirements, provide a rationale or an alternate way to meet the requirement. A letter from your chief information officer or other staff in your organization who is responsible for assuring data security and privacy is requested. CPHS does not have a template at this time for that letter, so please ensure the language indicates that your organization is meeting the CPHS data security requirements. The policy is reflected in the questions posed in this section. A link to this new policy will be placed on the CPHS Website.

CPHS must assure the federal and state governments that all measures are taken to secure the personally identifiable data (PID) being released for research purposes. PID is defined by CPHS as any data containing one or more of the 18 Health Insurance Portability and Accountability Act (HIPAA) identifiers (<http://oshpd.ca.gov/boards/CPHS/HIPAAIdentifiers>). "Personal information" is also defined in the California Information Practices Act (IPA), Civil Code, Section 1798.3, as any information that identifies or describes an individual.

### **Summary**

These are two ambitious tasks that CPHS is implementing. They will improve the CPHS approval process and lead to more secure data in the studies submitted for CPHS approval. They are both works in progress and we appreciate your patience and feedback. Please submit feedback in an e-mail to [cphs-mail@oshpd.ca.gov](mailto:cphs-mail@oshpd.ca.gov) or call 916-326-3660.