FACT SHEET

What’s New in the Updated Version of
the Biomed Standard Facesheets

The Biomed Standard Facesheets have been revised to provide additional information requested by IRB Chairs and members, HRPP staff and our collaborators including OHRP, FDA, VA, and the University of California, Office of the President.

The changes to the updated Facesheets include the following:

1. Section 3
   a) Addition of “Yes/No” boxes to indicate whether the study is closed to accrual.
   b) Addition of boxes to indicate the number of participants accrued thus far at UCSD, VASD, RCHSD, and non-UCSD/VASD/RCHSD facilities.
   c) Addition of boxes to indicate projected participant accrual for the entire project at UCSD, VASD, RCHSD and non-UCSD/VASD/RCHSD facilities.
   d) Additional box to provide VA R&D APP number should “Yes” box for “Involves VA resources/services such as medical records, funds, staff, patients” be checked.
   e) Additional box to provide BUA number should “Yes” box for “Involves gene therapy, recombinant DNA and/or gene transfer” be checked.

2. Section 4
   a) Addition of “Yes/No” boxes to indicate whether the project will use VASD Investigational Drug Service.

3. Section 8
   a) Addition of wording regarding what the PI is certifying by signing the Facesheets.
   b) Addition of wording regarding what the Department Chair and VA Service Chief are assuring by signing the Facesheets.