FACT SHEET

What’s New in the Updated Version of
the Biomedical Application Research Plan

1. New items
   a) Item 5, Lay Language Summary or Synopsis
      1. Request for description of study using non-technical terms.

   b) Item 16, Privacy and Confidentiality Considerations Including Data Access and Management
      1. Request for description of procedures to address participant privacy and participant and study data/specimens confidentiality.

   c) Item 29, Other Approvals/Regulated Materials
      1. Request for PI to ensure other UCSD review committees have reviewed and approved/authorized the study or are currently reviewing the study.

2. Consolidated items
   a) Previous items 21, Industry-Sponsored or Collaborating Studies, and 22, Other Funding Support for This Study, now item 23, Funding Support For This Study
      1. Only one item to request information regarding funding support.
         a) Request for copy of grant proposal should the study be support by a grant.

3. Items with major changes
   a) Item 8, Preliminary Studies/Progress Report
      1. Request for preliminary data to justify performing the proposed study.

   b) Item 9, Research Design and Methods
      1. Request for specific information regarding studies associated with the administration of drugs and use of devices and whether the study has a “formal” designation and associated with randomization, blinding, multicenter, database for future use, video/audio recording, questionnaires/surveys.
      2. Request for a “discrete” paragraph that clearly outlines which procedures are standard of care and which are experimental/study-related.
      3. Request for specific information regarding study visits, timelines, and participant time commitment.
      4. Request for description of procedures if UCSD or VASD or RCHSD is a coordinating center or prime grant holder.
c) Item 10, *Human Subjects*
   1. Information noting that once a participant signs the consent/assent, the participant is considered enrolled in the study.
   2. Request for specific information regarding vulnerable populations.
   3. Request for justification should certain individuals be excluded from enrolling in the study.
   4. Request for justification of involvement of non-Veterans in VA research.

d) Item 11, *Recruitment*
   1. Request for information regarding procedures for recruiting vulnerable participants.
   2. Request for information needed to request waiver of consent/authorization for recruitment purposes.

e) Item 12, *Informed Consent*
   1. Request for description of the process associated with obtaining consent/assent/permission/authorization.
   2. Request for description of specific procedures associated with enrolling non-English speaking participants.
   3. Description of procedures regarding placement of consent/assent at the UCSD Medical Center.
   4. Request for copy of HIPAA authorization.
   5. Description of information needed to receive waiver of consent, waiver of documented consent and waiver of individual HIPAA authorization.

f) Item 13, *Alternatives to Study Participation*
   1. Request for information regarding alternatives to participation for all studies.

g) Item 14, *Potential Risks*
   1. Request for information should the participant be restricted from receiving standard treatments and inclusion of risk of loss of confidentiality.

h) Item 15, *Risk Management and Adequacy of Resources*
   1. Request for specific examples of procedures to minimize risks including procedures involving less risk, taking advantage of clinical procedures, special monitoring, supportive interventions, etc.
   2. Request for a discussion of the resources in place to assure protection and welfare of participants including adequate time for the researchers to conduct and complete the study and number of trained study staff.
   3. Request for description of procedures to address vulnerable populations including those that are economically or educationally disadvantaged, mentally disabled, or students (undergraduate, graduate, and medical students) and employees of UCSD, VASD, and RCHSD (administrative, clerical, nursing, lab technicians, post-doctoral fellows and house staff).
i) Item 19, Expense to Participant
   1. Request for specific description of which procedures/drugs that will be billed to
      the participant or the participant’s insurer and which will not.
   2. Wording regarding billing cancer studies under California Clinical Trial Law.

j) Item 20, Compensation for Participation
   1. Wording regarding compensation for class credit.
   2. Wording regarding compensation for research conducted at the VA.

k) Item 21, Privileges/Certifications and Licenses and Research Team Responsibilities
   1. Request for information to clearly indicate by which entity each member of the
      research team is appointed/employed and the funding support for each member.
   2. Information noting that all key personnel must have completed CITI training.

l) Item 25, Investigational Drug Fact Sheet and IND/IDE Holder
   1. Request for information regarding how the investigational drug will be handled.
   2. Request for submission of Investigator’s Brochure for drugs and copy of relevant
      reports and determination letter from FDA for investigational device.
   3. Request for submission of package insert of drug if approved for use as proposed
      on study by FDA.
   4. Request for description of who holds IND/IDE.

m) Item 28, Supplemental Instruction for Cancer-Related Studies
   1. Wording regarding billing under California Clinical Trial Law.

n) Item 30, Procedures for Surrogate Consent and/or Decisional Capacity Assessment
   1. VA information regarding research involving individuals with impaired decision-
      making capacity.

4. Items with minor or no changes
   a) Item 1, Project Title
   b) Item 2, Principal Investigator
   c) Item 3, Facilities
   d) Item 4, Estimated Duration of the Study
   e) Item 6, Specific Aims
   f) Item 7, Background and Significance
   g) Item 17, Potential Benefits
   h) Item 18, Risk/Benefit Ratio
   i) Item 22, Bibliography
   j) Item 24, Biological Materials Transfer Agreement
   k) Item 26, Impact on Staff
   l) Item 27, Conflict of Interest