Q. Can you explain what is a “short form” consent and when/how it can be used?  
A. This information can be found in the UCSD HRPP SOPP, section 3.4, Informed Consent, page 3.

Q. For HDE projects, why is a separate consent required in addition to the treatment consent from the Medical Center?  
A. The separate consent is being provided to ensure appropriate information is provided to the participant regarding the device including “A Humanitarian Device Exemption is a special FDA category for a device that can be used by a physician that is exempt from FDA effectiveness requirements and for which no comparable is available to treat [the disease or condition]. The device is intended to benefit patients in the [treatment or diagnosis] of your condition in 4,000 individuals in the United States per year. The effectiveness of this device for this use has not been demonstrated.” This information can be found in the UCSD HRPP SOPP, section 3.2, Full IRB Review, page 17.

Q. Section 3 of the IRB face page (Project Characteristics) asks for “total projected accrual for entire project” and breaks it down per location (UCSD, VA, RCHSD and other). Are these projected numbers specific to the PI or are these numbers (for other category) the projected number across all sites?  
A. The projected numbers should be for the entire project. Adding all the numbers from each category should add up to the total number of projected subjects to be enrolled in the study at all sites.

Q. I heard that as of October, the IRB will no longer be the VA’s IRB. We conduct studies at UCSD and the VA. Will I now have to go through two separate IRB processes? Will two separate consent forms be required?  
A. Initially, yes.

Q. I’d like to better understand the IRB’s latest policy in the dating of approval letters. The IRB used to use the date of initial review in approval letters and this seems to have been changed to the subsequent date of resolution. This can pose a problem for us when it passes the 3 month COG processing deadline (which did happen for an Amendment I had processed).  
A. Initial approvals and continuing review approvals are linked to the date of the IRB meeting at which the project was reviewed, assuming it did not receive a deferral. For amendment approvals, the date of approval is linked to when the approval is actually granted. This is so a study can continue to consent participants, assuming the Committee does not indicate that enrollment must stop while the amendment pending issues are resolved, and use a consent that includes the current approval date.

Q. Regarding the Moore Clause included in the Research Plan, could this requirement be added to the UCSD HRPP template for clarity? The references to requirements re: the Moore Clause are difficult to find on the HRPP site.  
A. The wording is included in the current Research Plan instructions, item 12, Informed Consent. A future version of the consent example may include this wording.

Q. My study is commercially initiated and the sponsor has prepared a national ad campaign with print ads and that have
been approved by the central IRB. Does the UCSD IRB still have to approve them since they are already IRB approved? What if the UCSD IRB does not approve them – can I still use them?
A. UCSD IRB must approve all recruitment procedures. If the recruitment material is not approved, then the material cannot be used by this site. However, typically, the recruitment material is accepted for use but the seal of approval is not provided on the material.

Q. Can recruitment materials that have been IRB approved for print (e.g. flyers) be used online (e.g. Craig’s List) without additional IRB approval?
A. Unless this recruitment procedure was previously approved by the IRB, the materials cannot be used online until IRB approval has been obtained.

Q. How should IRB approval be approached when advertising content is designed to be dynamic, for example on a website for a research program?
A. Provide a copy of the website for review as well as state any risks and risk management procedures associated with the recruitment procedures, and provide a revised Research Plan, as needed.

Q. Can social media sites like Facebook and Twitter be used as a recruitment tool? Are employees permitted to advertise study participant opportunities on their own Facebook pages?
A. If the employee is a member of the research team, this would be considered a recruitment procedure and would require approval by the IRB. Guidance regarding IRB review of clinical trial websites provided by OHRP can be found at http://www.hhs.gov/ohrp/policy/clinicaltrials.html.

Q. In completing the continuing renewal face page, section 4 requires that we list the numbers of participants enrolled who have had specific events. Should this listing be for events that happened only with the participants at our site or is it a listing for off-site events as well? Does this also include all minor AE’s that have occurred since the last continuing review (even if not related)?
A. This site only – off-site AEs would be provided separately per IRB procedures. At this time, a summary of all AEs must be provided at the time of continuing review. A summary table can be used for this as noted on the Narrative Summary of Progress to Date.

Q. When the IRB continuing renewal asks for monitoring or auditing reports, does this include internal reports from RCP or AMAS as well as external monitoring reports or audits (sponsor, FDA, etc.)?
A. Yes.

Q. Can you explain what types of subject complaints should be included in the Continuing Review?
A. All.

Q. Do all protocol violations/deviations have to be reported to the IRB? What is the time line to report?
A. Both major and minor violations/deviations must be reported. Major violations/deviations typically impact subject safety or substantially alter risks to participants including those considered to be UPRs and must be reported within 10 working days. Minor violations/deviations typically do not have impact on subject safety or substantially alter risks to subjects such as failure to perform a study visit/study labs within the required time frame, that, in the opinion of the PI, does not substantially affect subject safety or data integrity; over enrollment; missing lab results; and study procedure conducted out of sequence should be reported at the time of continuing review.

Q. Can you please clarify the classifications of AEs, the time line to submit them to the IRB and if AEs that occur at other sites need to be submitted to the IRB?
A. This information can be found in the HRPP Fact sheet, Reporting Unanticipated
Problems Involving Risks to Participants or Others (UPR) to the IRB, which is available on the HRPP website at https://irb.ucsd.edu/Factsheet_UPR_120208.pdf.

Q. If I am a member of the PI's research team and have nothing to do with his/her clinical practice, am I allowed to review his/her clinical subjects charts for potential inclusion into a study?
A. If the procedure is specifically outlined in the Research Plan and has been approved by the IRB.

Q. For NIH studies, the coordinating center wants all of the participating sites to use their HIPAA. Are we required to use the HIPAA form on the IRB website?
A. If the study is collecting information at UCSD, then the UC systemwide HIPAA authorization must be used.

Q. Can I start screening patients before the IRB approves the project? What about pre-screening, i.e., chart reviews and/or reviewing the clinic schedule?
A. No. No procedures associated with the study may be done without IRB approval.

Q. Please discuss the views of the HRPP regarding PII (personally identifiable information) in regards to study devices with GPS time-stamped, latitude and longitude coordinates.
A. As with any subject information collected by the study, procedures for protecting subject privacy and confidentially and risks associated with this collection must be described in the Research Plan and the consent form.

Q. My approved consent form is in English and I want to enroll a subject that only speaks Spanish, but I do not have an IRB approved Spanish consent form. Can I use a UCSD translator or a family member to translate the English consent form?
A. No. As noted in SOPP, section 3.4, Informed Consent, pages 7 and 8, “If it is likely that the study will enroll individuals who cannot read or speak English, then Research Plan must describe the procedures that will be used to obtain consent from these subjects including the use of documents translated into the subject’s primary language, the use of a qualified translator, and how it will be ensured that continued, qualified interpretive services to the participant will be provided. Individuals unable to speak English may not be excluded from participating in a study without scientific justification. The subject must be given an approved translation of the consent form and the Experimental Subject's Bill of Rights in their native language to sign. Unless the researchers are fluent in the subject’s language, a qualified translator must be included in the consent process and then sign his or her name at the end of the approved translated consent form. A relative who speaks English does not qualify as an official translator.”

Q. If a subject signs an adolescent assent form at age 15 and is still in the study when they become an adult at age 18, do they have to sign an adult consent form? Is the same true for a child who signed a child assent form and turned 13 during the study, i.e., sign an adolescent assent?
A. Yes.

Q. I am enrolling pediatric subjects and the IRB approved one parent signature on the parental permission form. For families where the parents are not married or are divorced, how do I know which parent has authority to sign?
A. Ask.

Q. What would the IRB consider to be a valid reason for “unreasonably available” in regards to obtaining permission from both parents, in accordance with 45 CFR 46.408, when research is determined to be approvable under 45 CFR 46.406 (research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject’s disorder or condition).
A. The federal regulations provide no definition of unreasonably available. The PI must make this determination. Due diligence to obtain the consent would be required.

Q. I want to enroll a child who is in foster care. What are the requirements?
A. You would need to ensure the parent permission(s) was/were signed by the guardian(s) of the child.

Q. In a pediatric study comparing an IND with a placebo arm, will the IRB automatically find that the study falls under 45 CFR 46.406 or would the additional monitoring and clinic visits required as part of the study be considered in the IRB’s determination?
A. All study procedures associated with such a study would be considered in the IRB’s determination.

Q. Could the IRB provide clarification as to what, legally, we are or are not supposed to do in terms of reporting to the parent or guardian regarding a positive pregnancy test in a female < 18 years of age as part of screening or participation in a research project.
A. The parent consent and adolescent assent examples include wording regarding what is to be reported. Additional information can be found at http://www.californiateenhealth.org/wp-content/uploads/2011/06/toolkit-cri-Web.pdf

Q. How are studies prioritized for review at monthly scheduled D (Pediatric) committee meetings (some of my studies have been bumped once or even twice)?
A. A number of factors may affect the timing of review of submissions including the type of application, the quality of the application, the number of submissions, available IRB member expertise, and HRPP staffing levels.

Q. The IRB SOPP recommends documenting the consent process. What type of note/documentation is necessary?
A. As noted in SOPP, section 3.4, Informed Consent, “For intervention studies, it is recommended as a best practice that a progress note documenting the informed consent process be placed in the subject’s medical record and signed by the investigator. At a minimum, the progress note should include the name of the study, the person consenting the subject, a statement that the study was explained to the subject or the subject’s representative, a statement that the subject or representative appeared capable of understanding, and a statement that the subject was given the opportunity to ask questions, and documentation that consent was obtained before any subject procedures were performed. Unless specifically waived by the IRB, VA research studies must document the informed consent process by a ‘Research/Informed Consent’ progress note…."

Q. If pictures are going to be taken of subjects for research purposes, does a separate photo consent need to be signed by the subject if the disclosure of taking the pictures is covered in the main consent? Is there a photo consent template?
A. For UCSD studies, there is no separate form. The VA does have a separate form.

Q. Does a participant need to be re-consented when there is a renewal of the project and new date stamp consent (if no changes were made)?
A. Re-consenting a subject should take place when additional information has been obtained that may affect the subject’s willingness to continue enrollment in the study.

Q. In conducting an internal review of one of our studies, we found that there were issues with the consent forms, for example, some were not signed by the person obtaining the consent, dates were missing (from both the person obtaining consent and the subject), the coordinator dated the consent for the subject, etc. Do these issues need to be reported to the IRB? What is the time line to report?
A. As noted previously, both major and minor violations/deviations must be reported to the IRB. Major violations/deviations typically impact subject safety or substantially alter risks to participants including those considered to be UPRs and must be reported within 10 working days. Minor violations/deviations typically do not have impact on subject safety or substantially alter risks to subjects such as failure to perform a study visit/study labs within the required time frame, that, in the opinion of the PI, does not substantially affect subject safety or data integrity; over enrollment; missing lab results; and study procedure conducted out of sequence should be reported at the time of continuing review.

Q. In the consent form, we have given an opt-out clause for certain protocol required procedures. The protocol doesn’t indicate that an opt-out is available. Is this ok?
A. No. All procedures must be included in the Research Plan for review and approval by the IRB. If such procedures were done, this would be considered a protocol deviation/violation, and depending on the circumstances, could be considered a Major deviation/violation.

Q. Is it ok for me to write the subjects name or use a registration label on the consent form line that indicates “write subject name here”? The subject or LAR will still sign and date the consent.
A. Yes. Unless the Research Plan specifically describes that the subject will write his/her name on that line.

Q. If the line on the consent says “Printed Name (Subject)” and is above a line that says “Signature (Subject)” does this denote that the subject should be the person both printing and signing their name?
A. No. Unless the consent process described in the Research Plan and consent wording specifically state that the subject will print and sign, only the signature line would require the subject’s signature.

Q. Is it ok for the study team to date the consent for the subject?
A. No. As noted in the SOPP, section 3.4, Informed Consent, page 2, “The IRB requires documentation of informed consent by use of a written consent form approved by the IRB that is signed and dated by the subject or the subject's legally authorized representative.”

Q. My study approval has lapsed and is re-opened under a new IRB#. During the lapse, we continued to see subjects for regular study visits (not for safety). Is the data obtained during this time usable? What activities can be done during the lapse? With the renewal, my project now has a new consent form. Do the subjects still on trial need to re-sign the consent?
A. If procedures were done during the lapse, this must be reported to the IRB. Typically, this information would be not be usable as it was collected when no IRB approval was in place. During a lapse of approval, no study procedures may be done unless it is determined to be in the best interests of the already enrolled subjects to continue participating in the research. However, there is no lapse in a study if the continuing review has been reviewed by the IRB before the date of expiration and the IRB has put no restrictions on the pending approval such as enrollment cannot be done. Re-consenting of a subject is not required after continuing review approval has been granted. Note: Re-consenting of subjects should be done any time additional information has been obtained that may affect the subject’s willingness to continue participating in the study.

Q. Is there a way to remove uploaded documents (once they have been uploaded), in cases where the uploader inadvertently uploads an incorrect document to the UCSD HRPP website?
A. No. A cover letter must be uploaded that specifically states what documents were incorrectly uploaded and state that you wish to have those documents withdrawn from review.