**CSU CRB Client Protocol and Consent Form Review Checklist:**

**Does the protocol contain the following elements?**

\_\_\_\_\_\_\_\_ Study rationale and background, including significance and impact.

\_\_\_\_\_\_\_\_ Animal numbers for study, including justification and power calculation.

* the statistical methods used to compare groups
* the assumptions made for the power calculations
* If this is a pilot study, how will this study guide/support future studies?

\_\_\_\_\_\_\_ Inclusion and Exclusion Criteria

\_\_\_\_\_\_\_ Estimated time in study for each enrolled patient

* How many hours at hospital?
* How many days/weeks of study?
* How long will animal stay on study, duration of follow-up?

\_\_\_\_\_\_\_ Estimated duration of study

\_\_\_\_\_\_\_ Experimental Plan:

* Trial design, procedures that will be performed including treatment protocols, blood collection, biopsies, injections, surgery, etc.
* Plan for pain management and monitoring
* Outcomes (primary and secondary endpoints), data collection, response criteria, failure criteria
* Patient monitoring for treatment or intervention responses
* Study potential risks and benefits to patient, plans to minimize study risks

\_\_\_\_\_\_\_\_Client compensation (if included in study) including compensation plan for study-related adverse events.

Does the client consent form contain the following recommended elements?

\_\_\_\_\_\_\_An explanation of the purposes of the study

\_\_\_\_\_\_\_The expected duration of the subject's participation

\_\_\_\_\_\_\_A description of the procedures to be followed

\_\_\_\_\_\_\_Identification of any procedures which are experimental

\_\_\_\_\_\_\_A description of any reasonably foreseeable risks or discomforts to the subject that are related to the study.

\_\_\_\_\_\_\_A description of any benefits to the subject or to others, which may reasonably be expected from the research

\_\_\_\_\_\_\_A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject

\_\_\_\_\_\_\_A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained

\_\_\_\_\_\_\_For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained

\_\_\_\_\_\_\_A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.

\_\_\_\_\_\_\_A statement appropriately explaining any Conflict of Interest

\_\_\_\_\_\_\_Dates and signatures

\_\_\_\_\_\_\_CSU PI contact information