“Sponsored research” is defined as research funded by external entities through a grant or contract that involves a specified statement of work (e.g., the research proposal) with a related transfer of value to the sponsor. Sponsored research includes, but is not limited to, clinical trials involving investigational drugs, devices or biologics and federally-funded studies (e.g., studies funded by NIH, NSF, DOE, etc.).

For sponsored research at UH, protection of research participants are addressed by the following:

1. Including in their standard contract a provision that the sponsor acknowledges and understands that the UH HRPP is applicable to all human participant research. See: myGRANT Institutional Questions form
2. Requiring the inclusion of such a provision in any proposed contract that does not already include this language in their standard contract template
3. Including in the cover letter accepting and acknowledging the grant an equivalent statement regarding the human research protection program in grants to UH.
4. At proposal stage, the Principal Investigator (PI) is required to identify whether the proposed project involves human research via UH’s internal system, myGRANT. The proposal is routed via myGRANT from the PI to the unit’s Fiscal Administrator, Chair/ Director, then the Office of Research Services (ORS). ORS is responsible for institutional approval of sponsored research proposals.
5. Before acceptance of an externally-funded award, the PI is required to provide ORS with documentation of IRB approval.

Additionally, the IRB will review the proposed consent form and reject any provision that requires a participant to waive or appear to waive any legal rights (i.e., exculpatory language).

215.2 Provision Addressing Medical Care for Participants

University of Hawaii

For UH sponsored research, medical care for participants is addressed by:

- Including in its standard contract template a provision that the sponsor will reimburse UH for reasonable and customary costs incurred for treatment of an injury to the subject if it is determined that an adverse event was reasonably related to the administration of the study drug/ device/ biologic. (See ORS’ CTA Guide SOPP 301.1)
- Included in the cover letter accepting and acknowledging the grant an equivalent statement regarding the human research protection program in grants to UH.
• Including the language of any such provision in the consent form.
• Including a statement in the consent form that participants do not waive any liability rights for personal injury by signing the consent form.