

ICO Newsletter

ICO or CT-RMG? Research or trial? It's all in the details

Industry-funded projects involving human subjects may fall into a gray area between clinical research and clinical trials. Agreements for trials are handled by CT-RMG; ICO is responsible for clinical research contracts. When a project is not obviously fish or fowl, CT-RMG and ICO confer to determine the appropriate office for contract negotiation and administration.

CT-RMG and ICO consider the following factors when deciding which party will handle the agreement:

- location of activities (campus or the hospital)
- sponsorship (investigator- or sponsor-initiated)
- intended use of results (for publication or supporting a regulatory submission)
- level of risk (potential for adverse events)
- IP ownership
- payment structure (by milestones or subject enrollment)

Trial and research agreements have many common terms, but there are key differences, driven in large part by differing objectives. A trial agreement will often include subject injury terms, which address liability in case of an adverse event (a harmful or undesired effect of the trial), and related reporting obligations. Generally, Stanford doesn't assume any liability for research activities and results. Trial results can be expressly intended for regulatory submissions; a research project may allow for such use of results, but not as the project's primary objective. As for intellectual property, Stanford retains ownership of inventions arising from research. In a trial, the sponsor will likely expect to own inventions arising under the sponsor's protocol. Finally, to comply with federal regulations, clinical trials are registered at www.clinicaltrials.gov. No such registration is required for research projects.

To expedite the CT-RMG/ICO review and contracting process, an investigator with a project that has both trial and research aspects should contact early either ICO or CT-RMG and request a preliminary review. That review requires the project work statement, budget and applicable IRB protocol(s).

Contact information for CT-RMG is located at:

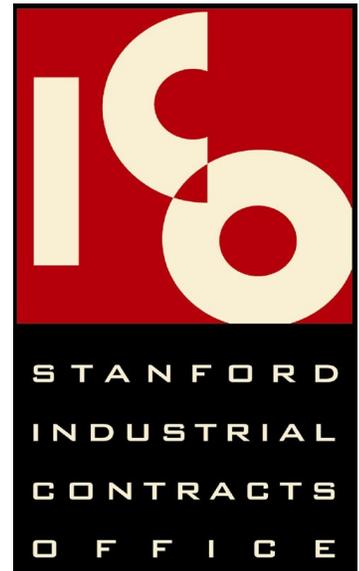
<http://med.stanford.edu/rmg/rpmmaster.html#CTCO>

ICO officers can be contacted at the addresses to the right.

Keep the shutdown in mind (and don't blame Congress)

Researchers anticipating funding from an industrial partner before year end should keep the Stanford winter shutdown in mind. All Stanford administrative offices, including ICO, are closed from December 20th, 2013 until January 6th, 2014. Normally, the last two weeks before the shutdown are hectic at ICO, and projects can get stalled if not submitted sufficiently early. Also, while some sponsors require an invoice before year end, Stanford accounts receivable may not be able to issue invoices for agreements signed in the last two weeks before the shutdown.

To be removed from ICO's mailing list, send an email to ico@stanford.edu



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