

Heer Health Clinic Announces Heer System for Patient-Centric Clinical Studies

By Norman M. Goldfarb

Dr. Seldon Heer, Medical Director and Principal Investigator at the Heer Health Clinic, today announced what he terms the "Heer System" for patient-centric clinical studies. According to Dr. Heer, "The clinical research enterprise has barely even started taking half-hearted measures to implement the new concept of patient-centric studies. It's time for a research site to take leadership," says Dr. Heer, "and we don't take half measures."

"The current approach to clinical research involves fitting square pegs — patients — into round holes — studies," said Dr. Heer. "We have a different approach. Our study concierges work with each patient to find exactly the right study. If we are not already conducting that study, we are usually pre-initiated and can start it up within 48 hours. Of course, the courier needs time to deliver the study drug. Even if the study materials are staged locally, IRB approval can delay everything for hours. We have been very pleasantly surprised with the support we are getting from study sponsors. If we can't find a suitable study, we work with the study sponsor and the patient to design a compassionate use study, but initiation can take as long as four days, not counting weekends."

Informed consent has become more and more problematic over the years, as studies become more complex and consent forms longer. "Our patients like our system of engaging an independent physician to advise the patient during the consent process," says Dr. Heer. "We like it too, since it keeps us honest. The trick is finding a physician who has the same medical condition. The good news is that sometimes the physician enrolls, too. We used to retain an independent attorney for the patients as well, but boy can they talk."

Transparency is currently the central focus of patient-centric studies. "That's why I'm available 24/7 and so is our biostatistician, says Dr. Heer. "Most studies are blinded, but almost all sponsors have now adopted the ISO code, 'unblind123', for accessing the randomization database. Surprisingly, most research sites don't know that any respectable pharma will give research sites real-time access to the online study database. Of course, there are forms to fill out, but those are online too."

Dr. Heer also announced the opening of his new waiting room. "Given the huge, huge contribution that clinical trial subjects make to society, it's unconscionable to make them wait for a study visit to start. Instead, our study nurses wait in the room for the *patients* to arrive." The clinic's former waiting room has been converted into a study lounge, where participants can relax during breaks. Artisanal juices, holistic teas, and organic tapas are available. The lounge coordinators are certified in Laotian massage, Nepalese acupressure, and Bhutanese aromatherapy. "We expect afternoon study visits to be especially popular, since the bar opens at 4:00 p.m.," says Dr. Heer. "At the end of the day, it's all about the patient."

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