

 NEWS 

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ETHICA TAKES LEAD TO REGAIN PUBLIC'S TRUST IN CLINICAL RESEARCH

ethica Clinical Research Inc. recently became the first company in Canada and first CRO in the world to be officially recognized by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). With 45 organizations accredited worldwide, AAHRPP is working to protect and empower study participants with strict research standards and effective regulation.

Why all the firsts though? Why aren't more companies abiding by strict standards and being held accountable for those standards in human clinical research programs?

Although transparent clinical research seems so important, it is lacking in Canada. According to Dr. Janice Parente, president of ethica, this is because the current Canadian governance over clinical research is unclear and insufficient. "The system lacks standards, transparency, oversight, and regulation. Recent tragedies in clinical research stem from a systemic failure in research governance by Health Canada resulting in the abrogation of research participants' rights," she says. Health Canada has considered adopting accreditation for years. If they do decide to take this on, Health Canada will have to evaluate whether to adopt AAHRPP, or construct a homegrown system. Either scenario will take years. In the meantime, the public is losing trust in the industry as a whole.

This reality led ethica to pursue accreditation by AAHRPP, a process that took 18 months of hard work for the private company's 30 employees. According to Dr. Parente, the accreditation is priceless. The rewards are great; ethica is now among an elite group of researchers on the international scene reaching out to regain the public's trust. AAHRPP accreditation also fosters collaborations between accredited organizations, which means more business for ethica.

Adopting AAHRPP's standards didn't require too many changes at ethica either. Procedures were simply streamlined and tweaked because the company was already operating at a high standard. Dr. Parente admits that some companies might have to work much harder to achieve accreditation, but believes they should be willing to make that commitment. AAHRPP has 77 strict criteria to fulfill, broken down into five domains: organization, investigator (doctor), research ethics board, sponsor (drug, biotech, or natural product company), and public outreach. The most crucial criteria for ethica involved the investigator, because he or she interacts directly with the research participants. To ensure that participants' rights are protected, ethica must select doctors carefully, and thoroughly educate them on standards and processes. Doctors selected by ethica for human research programs essentially become "accredited", as do research ethics boards and other subcontractors. "Accreditation almost becomes an infection," says Dr. Parente, "with each of our subcontractors in the research process attaining the same high standards that we do".

If AAHRPP accreditation is an infection, it's a healthy one and ethica wants to spread it across Canada. Dr. Parente hopes that the industry will be encouraged by ethica's achievement and embrace AAHRPP's standards for accreditation. "Our industry has an excellent opportunity to lead the world in instituting clinical trial regulations and guidelines not borne of tragedy but simply out of a desire to protect the rights and wellbeing of clinical trial participants."

For more information about the AAHRPP, consult: <http://www.aahrpp.org>

Source: Alison Palmer

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