Medical Ethics: The Belmont Report

This is the third in a series of articles about medical ethics. Our previous posts in this series included covering the basics of medical ethics and the difference between utilitarianism and deontology. Today we’ll talk about the Belmont Report and its importance in establishing modern medical ethics guidelines.

In our next post in this series, we’ll continue to explore the foundations of medical ethics by reviewing The Belmont Report, which provides us with the modern distinction between medical research and practice, and affirms the three basic ethical principles generally accepted in our culture: respect for persons, beneficence, and justice.

The 20th century saw a growing awareness of what ethical treatment of humans in research meant. In what we would now call egregious liberties taken by U.S. state and federal governments in human experiments, as well as by physician researchers in Nazi Germany, studies were conducted on people without their consent, and which caused them harm and sometimes death. The infamous Tuskegee syphilis study began in 1932, without the consent of the 600 black men in the study, and which allowed the men to go untreated for syphilis even after a cure had been discovered. The study continued for forty years, until, in 1972, it was investigated and ordered to stop by an Ad Hoc Advisory Panel commissioned by the Assistant Secretary for Health and Scientific Affairs. Reparations began after the scandal and termination of the study and on May 16th, 1977, President Clinton formally apologized to the few remaining survivors on behalf of the nation.

Partly in response to the Tuskegee study scandal and partly due to another famous scandal where medical research was conducted on prisoners of the Holmesburg prison in Philadelphia, the US government enacted the National Research Act in 1974. This law created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission was charged with codifying the basic ethical principles that
underlie the conduct of research involving human subjects and to consider the following things:

1. the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine,
2. the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects,
3. appropriate guidelines for the selection of human subjects for participation in such research, and
4. the nature and definition of informed consent in various research settings.

The Belmont Report summarizes the commission’s findings and defines the basic ethical principles that are generally accepted in our cultural tradition and are specifically relevant to human experimentation. These principles are:

**Respect for persons.** This principle is about autonomy, where an autonomous individual is capable of making decisions about their personal goals and beliefs. The tenet of respect for persons states, “Individuals should be treated as autonomous agents, and any person with diminished autonomy is entitled to protection.” In research, this means that participants of research voluntarily agree to participate and have enough information provided to them for them to make that decision reasonably. Individuals, who lack this capacity, either fully or partially, are considered vulnerable because they may not have the maturity or capacity to make an informed decision. In the case of prisoners or soldiers, they may be under the influence of subtle coercion or undue influence.

**Beneficence.** Beneficence is much more than “do no harm”. It is also requires an effort to secure an individual’s well-being by maximizing the possible benefits and minimizing the possible harm to them.

**Justice** is about fairness or about what people deserve. This principle asks the question of who should benefit from the research and who should bear its burden. It also requires consideration for in what respects people should be treated equally—what makes people equal or unequal? Four frameworks for evaluating justice are used commonly:

1. to each person an equal share,
2. to each person according to individual need,
3. to each person according to individual effort,
4. to each person according to societal contribution, and
5. to each person according to merit.
The Tuskegee experiment was a good example in our country where these three principles of ethics were not followed.

The study subjects were not informed of the experiment and did not provide voluntary and informed consent, and thus did not have autonomy under the tenet of respect for persons.

The study continued long after there was treatment for syphilis, thereby exposing the participants to undue harm and early death from the disease. There was certainly not an effort to maximize their well-being by treating their syphilis, thereby not meeting the principle of beneficence.

And last, the participants of the Tuskegee study bore the burden of the study without any expected benefit for that population. They, nor their families, benefited from the burden of the research and the disease was not only limited to a disadvantaged, black population, resulting in an injustice for these men.

Our current use of informed consent and many other clinical trial practices flow out of the ethical principles laid out in the Belmont Report.

These principles protect all people from the injustices perpetrated in the past. We must never forget our country’s infamous past every time we write, review, or obtain informed consent, and every time we conduct any aspect of a clinical trial.

Thank you for tuning into HCC’s ethics series.

The best CRAs have transferable skills

What does it mean to have transferable skills and why does it matter for a Clinical Research Associate (CRA)? We will explore these questions in our post today.
The Cambridge English Dictionary defines transferable skills as “skills used in one job or career that can also be used in another”. Google quickly provides several lists of examples of transferable skills. For example, here, here, and here.

Transferable skills fall under domains such as: interpersonal, organizational, leadership, or communication, and include specific skills like the desire to learn and improve, the ability to articulate ideas verbally or in written form, and the skills to be diplomatic in personal interactions. Sometimes called soft skills, they can be difficult to teach. They have a quality of innateness, so in this sense they can be referred to as being hard-wired in an individual. Most of the direct skills of a job can be taught, whereas the transferable skills often cannot be.

A CRA’s role involves interacting with a variety of people, at different job levels and institutions, and can involve difficult conversations requiring the ability to develop rapport with many different types of people. CRAs are expected to work well in a team at the same time as being able to work independently. They are expected to be problem-solvers, using creativity to identify solutions, while at the same time adhering to the guidelines and regulations that drive much of our industry.

Much of what a CRA does on a daily basis involves an intricate lattice of direct experience and transferable skills, making them an extremely valuable gift to bring to any employer.

Here at HCC, we look for people who have key transferable skills, like perceiving nonverbal messages and managing conflict, among many others. While direct experience is important, we feel that identifying and leveraging the transferable skillsets of our staff has allowed us to build a team that can reach both deep and broad. A team that can fill the necessary gaps in a clinical project. Ultimately, a team that can effectively problem solve to
achieve high quality results, consistently.
If you are interested in sharing your transferable proficiencies with HCC, please contact us at the link below.

Hart Clinical Consultants Contact page

Hart Health Hints: January is National Blood Donor Month

Did you know that every two seconds someone in the U.S. needs blood? Or that less than 10% of the population eligible to donate blood does so annually?

Although researchers keep trying, it is still not possible to manufacture artificial blood, making blood donations a necessity to supply patients with lifesaving blood products.

The American Red Cross (ARC), which supplies 40% of the nation’s blood supply, sponsors National Blood Donor Month every January, and this year is no exception. The mission of the ARC this month is to raise awareness about the need for blood donations and to encourage people to donate. Criteria for eligibility can be found here or here. Even if you’re not eligible to donate your blood, consider volunteering with a blood bank to help with blood drives, donating to your local blood bank, or recruiting an eligible donor.
Donating whole blood only takes about an hour

Donating by apheresis takes about two hours, but individual blood components can be separated out of your blood, with the remaining put back in. So, plasma, platelets, or red blood cells can be extracted from your blood individually and the other components are left in your blood.

There is even a mobile app to help speed up the process. One, called simply, Blood, can help you schedule and track your donations, and even allows you to earn rewards from participating retailers. Another app, called RapidPass, allows you to save time donating by starting the donation process at home. There is a wide range of free Red Cross apps including information to help you in case of an emergency. To find first aid, pet first aid, and disaster information, go here.

So this January, consider doing something to help save one of the millions of patients who need blood every year. Think about National Blood Donor Month and commit to doing one small thing: make a donation of your blood, your time, or some cash. Make a family day of it. After all, it may be a family member, a friend, or you that needs a blood transfusion one of these days.

From all of us here at HCC, have a wonderful January, and stay warm!

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Essential documents Deep Dive: The clinical protocol and amendments

Hart’s Good Clinical Practice glossary
Welcome back to the Hart GCP knowledge series. We have been reviewing essential documents, and we looked specifically at the Investigator brochure in our last glossary post. In today’s post, we will dive a bit deeper into what is required for a clinical study protocol.

The guideline defines a protocol as “a document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents. Throughout the ICH GCP Guidance, the term protocol refers to protocol and protocol amendments”. The definition for a protocol amendment is, “a written description of a change(s) to or formal clarification of a protocol.”

Protocol and its amendments are the map to a clinical study. These documents lay out the plan for the study and for continent plans if things don’t go according to plan. They form the blueprint for each study’s conduct for the sponsor, sites, IRB/EC, and regulatory agencies to gauge the scientific merit and likelihood of successful execution for each study.

Section 6 of the guideline provides the minimum information that should be included in a clinical protocol and suggests options for its layout. Site-specific information, pre-clinical background information, or other required information may be contained is separate documents that are referenced within the study protocol. These may include documents such as the investigator brochure, statistical analysis plan, monitoring plan, financial contract, or insurance, etc.
For details on the preparation of a study protocol and amendments, please see the E6 guideline, here. Generally, a protocol (or its reference documents) should include the following:

- General information
- Background information
- Details about the objectives and purpose of the trial
- Trial design details
- Selection and withdrawal of study participants
- Treatment of study participants
- Assessment of efficacy
- Assessment of safety
- Statistics
- Assurance of direct access to source data and documents for monitoring, audits, IRB/EC review, etc.
- Quality control and quality assurance
- Financing and insurance
- Publication policy
- Supplements

The protocol should have an area for the primary investigator’s signature, which asserts that the trial will be conducted in compliance with the protocol, good clinical practices, and all applicable regulatory requirements. All protocol amendments should include revision numbers, dates, and the primary investigator’s signature.

Thank you for reading HCC’s glossary series! Next time we will continue to examine key essential documents by looking at advertisements used during a trial.