Terms of Enrollment

A bill of rights for clinical trial participants

August 1, 1997 By Stuart Timmons

What are your rights in an HIV clinical drug trial? Studies run by federal agencies, institutions receiving federal funds, or by any organization as part of the drug approval process, are required to follow a set of ethical regulations called the Common Rule, enforced by the U.S. Office for Protection from Research Risks (part of the National Institutes of Health) and the Food and Drug Administration (FDA). The Common Rule's core provisions mandate informed consent for all participants, avoidance of unnecessary risks to patients and independent review and supervision of each study by a local Institutional Review Board (IRB). By contrast, post-marketing trials of approved drugs run directly by pharmaceutical companies may not necessarily be required to adhere to this Rule. In either case, rules may not always be followed and abuses are a continuing problem.

Other patient protections are not so fixed. Many PWA advocates promote a right to 24-hour access to trial personnel, since a participant's regular caregivers may be helpless in the face of adverse reactions to an experimental drug. Others say researchers should inform all patients that they have the option to start or join a trial-participant support group.

More broadly, AIDS activists have fought for years to establish certain ethical principles of trial design, such as the right of participants in all sections of a study to receive the treatments considered the most current standard of care. Unfortunately, this right remains contested turf. Remember that understanding the dynamics of your own trial is crucial; a thorough discussion of the possible benefits and risks is your right -- and best protection -- as a volunteer.

A clinical trial involves medical care. In many states, hospitals and medical practices post a "Bill of Rights" for patients, which may cover additional issues. These rights are often law, and it is important for all recipients of medical care to know them.

The following principles are broadly based on international humanitarian standards regarding the rights of those participating in medical research. This list has been developed through interviews with AIDS researchers, practicing physicians, community advocates and government regulators. If you are considering participating in a study, ask about each of these points. Once in a trial, you can bring any questions or problems to the attention of the patient advocate at the trial site, the researchers coordinating the study or -- if all else fails -- the IRB for that trial. IRBs are empowered to stop a trial that doesn't do what it promised or that exposes people to harm. You may also want

to bring your complaints to the attention of AIDS community organizations or activist groups.

In the list below, items 2, 4, 5, 6 and 9 are guaranteed by federal regulations with the force of law. The others remain only ideals. They won't be rights until enough people demand them.

1. You have a right to an independent medical adviser to consult (at your own expense) about the soundness of the study's design and whether it is appropriate for your current health strategy.

2. You have the right to truly informed consent, including a signed and dated copy of the form (which you should keep), in language you can understand. This means not simply signing a release, but fully comprehending the release and the trial by asking any questions and thoroughly discussing the decision with your adviser. As one activist says, informed consent is not a signed paper, it's a thoughtful process.

3. You have a right to in-depth information about the purpose, rationale and methods of the trial. This includes obtaining a copy of the protocol (detailed plan for the trial) and all previous study data and analysis that led to it. This information may be given with reluctance if at all (in company studies, it's usually deemed "proprietary"), so be prepared to do your own sleuthing via medical libraries and the Net.

4. You have the right to know the trial's "end points," or stopping points for your role in the experiment. Depending on your health, some end points -- such as opportunistic infections or death -- may be unacceptable.

5. You have the right to be told the other treatment options -- approved and experimental -- you have for this condition and how they may be better or worse than being in the study. This right should be expanded to include sharing information -- not currently required -- on what other trials for this condition are being conducted in your area.

6. You have a right to be informed not only at the outset about side-effects found in previous studies, but also about "significant findings" discovered during the current study that may affect your health. This includes additional side-effects of the drug you're taking and benefits of treatments that could be alternatives to the one you're taking, This should be extended to cover the right to frank counseling about any side-effects you feel you may be experiencing.

7. You have a right to ask trial administrators to disclose any health dangers (such as rising viral load) that become evident to them during the trial, and to receive a prompt warning of such dangers even without your asking. Remind investigators that you have a compelling interest in receiving your own personal data.

8. You have a right to lab results within a reasonable time frame as a means of monitoring your health. Again, this information may be given reluctantly. Fight for it. Never sign away your rights to access any of your medical records, including those developed in a trial.

9. You have a right to leave the trial at any time for any reason. You may solicit informed counsel

from your own adviser, the patient advocate, the study coordinator and the IRB (contact numbers for all but your adviser should be attached to every consent form).

10. If the tested drug is found safe and effective, you have the right to know if you will be offered continued access to the treatment after the trial is over.
