The facilities in which clinical research is conducted obviously vary enormously with circumstances. High quality research which has far reaching consequences can be performed in some of the poorest countries in the world using the most basic facilities. Conversely, research of inferior quality is sometimes performed in teaching hospitals and purpose-built contract research organisations in the West. Nevertheless, it is common sense that failure to be adequately equipped to meet the requirements of conducting a specific study in humans will have a negative impact on the quality of data obtained and is likely to compromise the safety of the subjects. The Association of the British Pharmaceutical Industry (ABPI) has therefore issued guidelines on minimum standards for facilities for the conduct of studies in non-patient volunteers and, in our view, these standards are applicable to most clinical research that is conducted on inpatients as well. While these guidelines are not legally binding there are certainly medico-legal implications for clinicians conducting research in conditions which do not meet the requirements and everyone involved in such activities should be familiar with them. It should also be recognised that, if the results of the study are submitted to a regulatory authority such as the Food and Drug Administration (FDA) in the USA, the data are quite likely to be unacceptable simply because of inadequate compliance with Good Clinical Practice (see Chapter 11). It therefore behoves every clinical researcher to be sure that the facilities in which he conducts research are adequate. What follows is not intended to substitute for the ABPI guidelines but summarises and briefly discusses the standards that should be met.

Ideally, the building in which clinical research is conducted on healthy volunteers or patients should be designed for this purpose. It is extremely difficult to carry out complex procedures.
and intensive blood sampling on a general hospital ward. If such a facility is not available the accommodation should be modified so that subjects are comfortable and staff can conduct the research in a safe and proficient manner. Consideration should be given to the fact that study subjects are entitled to privacy and that confidentiality is a requirement of Good Clinical Practice; therefore the general public should not have access to the Unit.

If not situated in a hospital, the facility should have easy access for an ambulance and be within a few minutes drive of a hospital capable of handling emergencies. Corridors and doorways should be sufficiently wide to allow passage of a bed or stretcher. It should be appreciated that even if a clinical study is being conducted in a medical school or hospital building, access to emergency staff and facilities is not guaranteed. A little back room at the top of a flight of stairs is not an appropriate location for this sort of activity.

The ward area should be separate from those where subjects and staff eat or prepare meals so that there is no chance of contaminating food with biological specimens. Its layout must be such that staff can monitor the well being of all subjects easily. Single rooms with subjects hidden behind closed doors or curtains are not compatible with close observation at all times. There should be adequate space for medical and nursing staff to administer the study out of ear shot but at close proximity to the subjects. Even if it is not intended for a study to be residential, the facilities should provide for an overnight stay for subjects and staff in the event of a subject feeling unwell or not being fit for discharge at the end of the study day.

Biological samples should be handled and stored in a separate, designated room which meets the requirements of Health and Safety standards and Good Clinical Practice. Toilet facilities should be adequate taking into account that subjects may be required to provide accurately timed urine or faecal specimens and collections. There should be a secure cupboard for storage of drugs at room temperature and a secure refrigerator designated exclusively for storage of drugs which must be stored under these conditions. Appropriate arrangements must be made for the additional security required for storage and accountability of controlled drugs. There should be adequate arrangements with the local pharmacy for formulation, storage and dispensing of drugs. If it is absolutely necessary to prepare formulations in the Unit, this should be done in a clean area or room designated for the purpose.