Committee for Public Relations and Ethical Issues of the
German Society of Human Genetics

Statement on Postnatal Predictive Genetic Diagnosis

I. In predictive genetic diagnosis, a healthy individual is tested for genes that predispose to
disease in later life. For diseases that can be prevented or treated, these tests can be an
important help for the individual with decisions about possible preventive or therapeutic
measures. For diseases that cannot be prevented nor treated, predictive genetic diagnosis
of persons concerned that they or their children are at risk of becoming affected, opens
up new options for life and family planning. Therefore, for ethical reasons predictive
genetic diagnosis should not be withheld from concerned individuals. However, its
application raises numerous problems that must be carefully approached and regulated,
taking the following into consideration:

1. Comprehensive information must be offered to all concerned persons, and
counselling about alternative options must be guaranteed.
2. Voluntary utilization and with it the right not to be informed must be guaranteed.
3. Explanations and counselling about available tests must be nondirective.
4. Predictive genetic diagnosis may be performed only for persons of legal age.
   Exceptions are for disorders for which preventive or therapeutic measures could
   be initiated in childhood.
5. The property of the sample and the right to utilize the test results must be clearly
   regulated. At the same time legal data protection concerns in all their
   ramifications must be duly considered. The right of third parties to inquire about
   whether such exams were carried out or about the results must be excluded.
6. Predictive genetic diagnosis must not become a routine investigation. When
developing guidelines, the expectations of the affected should be extensively
considered as was done internationally and exemplarily for Huntington disease.
   In particular, a prolonged period for the subject to reflect whether he/she wants a
diagnostic test should be required, and the subject must be able to withdraw
permission at any time. A corresponding statement of the Berufsverbandes
Medizinische Genetik e.V. [Professional Association of Medical Genetics] refers
to the application of this type of diagnosis in medical practice.
II. During predictive genetic diagnosis, data are produced that can be considered the core of an individual’s private domain and that therefore hold the danger of discrimination against and marginalization of affected persons. This danger is to be counteracted by offering individual investigations, by educating the public, by legal regulations, e.g. the Richtlinien der Bundesärztekammer [Guidelines of the Federal Medical Council] and procedural methods and embodiment of procedures in the Berufsordnung für Ärzte [Professional Regulations for Physicians], and by legal regulation of the insurance business and occupational medicine.

III. Since manifold problems are foreseeable, predictive genetic diagnosis should be introduced only within the framework of a scientifically accompanying pilot project.

IV. Due to their limited personnel and equipment and in spite of professional competence, human genetics institutes and genetic counselling facilities presently are able in only a limited way to guarantee that predictive genetic diagnosis is carried out within the required framework. However, attempts should be made to establish this type of diagnosis, including the required counselling, at qualified nonprofit institutions.