# Guidelines for health professionals about the benefits of genetic research in Europe

## SUMMARY OF THE BENEFITS OF PARTICIPATING IN RESEARCH:

- ***Genetic research offers the possibility of developing cures for many serious, and sometimes fatal, diseases***

- ***Research into treatments for diseases is done using biological samples donated by people affected by them***

- ***Those who participate in genetic research will help people in the future who are or will be affected by disease***

- ***It may be acceptable to offer benefits and incentives to research participants, in recognition of their investment and contribution***

- ***Genetic research cannot be done without the participation of DNA donors. Without this participation it will not be possible to develop new drugs, therapies and treatments***

### *What is 'benefit sharing'?*

Benefit sharing is the result of collaboration between those carrying out the research, and the members of the public - including patients - who enable the research to go ahead by donating biological samples.

- DNA research is carried out in order to develop treatments and cures for diseases
- Where research is successful and advances in treatments are made, 'benefit sharing' is the means by which the lives of affected communities are helped by these advances
- Those who participate in research by donating their DNA for research therefore receive a 'return on their investment', and these returns can be offered in a number of different ways

### *Why is it important?*

Genetic research has the potential to transform lives by developing new treatments that can cure or ameliorate the symptoms of inherited disorders, or prevent them from occurring at all

- Those who participate in research by donating biological samples are entitled to know about the developments and advances that may result from the research. They are also entitled to know how these developments will reach the people who need them
- It might not always be clear to potential research participants how laboratory research is turned into real improvements to health. Drug development takes time, and so there is a delay between research beginning and drugs being produced. You should inform potential research participants of this when making a decision about whether or not to donate samples
- 'Benefit sharing' helps to build good relations between researchers and those who, by donating DNA samples, enable the research to go ahead. Benefit sharing helps to ensure that research can continue to develop new treatments, and to ensure that the pace of improvements to health is maintained



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### *Benefit sharing and patient groups*

Close links between patient groups and researchers are essential in ensuring that research into curing genetic disease can continue

If a patient is considering participating in research has a genetic disorder, you may be able to direct them towards a national or international support group for the condition being researched

- Patient groups play a crucial role in facilitating communication and the transmission of benefits to those who need them and who have participated in research
- Patient groups can provide the link between the researchers, the research participants and patients affected by the disease, and ensure that the benefits returned to the research participants are fair and appropriate
- In some cases it is can be difficult to find a patient group for a specific disorder (for example in the case of rarer conditions). However, there are European organisations that you can contact in order to find out more about the disease, and what help might be available
- The European Society for Human Genetics has contact details for all the national genetics networks across Europe: https://www.eshg.org/

### *Equal distribution of benefits*

The purpose of benefit sharing is to make sure that advances made by the pharmaceutical industry in drug development are shared out between those who can benefit from them, and who may have participated in the research itself.

- Benefit sharing schemes should attempt to direct resources, health benefits, knowledge or financial support to affected communities
- Benefit sharing schemes can take a number of forms and are facilitated by a number of different agencies and bodies



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***What forms can it take?***



## Financial return

- Where people donate biological samples for research into how to treat a disorder, the research team can offer a cash incentive to the DNA donors in return for this participation

- Cash incentives may take the form of a one-off payment, though more frequently a benefit sharing scheme can be done by offering a share in the profits derived from the patenting and sale of the drugs

- As drugs are created using DNA samples donated for research, donors should therefore be entitled to share in the same financial benefits. On this basis, the company or research team developing the drug can offer the donors a financial return on a percentage basis

## Technology Transfer

- 'Technology Transfer' describes how raw scientific research, and the use of medical technology, is turned into real benefits to health

- Research into new drugs for genetic disorders is carried out using DNA samples donated by individuals participating in research

- Drugs developed as a result of this research are the outcomes of the 'technology transfer'

- Drug manufacturers carrying out the initial research may offer a subsidy on the drug to those who donated their samples, or links with patient groups and health providers facilitate opening the pathways by which the drugs can get to the people who need them

## Health promotion and training

- Benefits like these are important due to the local, national, and international inconsistencies in the provision of information across Europe about genetic diseases and treatments for them

- Investment into training and education about genetics and health could help large areas of the continent and significant numbers of people

- Investment into training and education can directly benefit patients and their communities, and can provide a base for the continuation and expansion of genetic research in the future

## Improvements to infrastructure

- Pharmaceutical companies can donate money towards specific practical improvements to health infrastructure. For example, enhancing information and IT systems, or investing in new medical equipment.

- Alternatively, a financial contribution can be offered to local healthcare providers, or community services for those affected by genetic disorders. Donations of this kind may be able to pay for disabled access to buildings, or provision for those who are hard of sight or hearing, for example

***Honesty and integrity***

It is important that benefits offered to research participants and patient communities are both deliverable and delivered. You may wish to find out the limits of any research and the possible speed of delivery of the benefits to be realised from a particular study

- Laboratory research cannot be turned immediately into new treatments, and not all research into treatments for a genetic disease will bring about a cure straight away. You should make this clear to individuals who are considering participating in research

- However, potential research participants may be willing to take part if the research body offers some commitment to ensuring that they or the affected patient community will benefit

***Legality***

The legal status of incentives, donations and returns to research participants may differ between countries

You should consider this in particular when research is being done collaboratively across national borders by several teams in different countries

Potential research participants are entitled to know how and where their data will be used, as well as the nature and extent of any benefits that may be returned to them in recognition of their involvement

If you wish to find out more about genetic research that is taking place in your country, please contact your national genetics network:
http://www.wordsandpeople.com/eurogenguide/european_societies.htm

***Access rights to outcomes of research***

In order to enable genetic research to continue and develop new improvements to health, the scientific community needs some degree of open access to the results of previous research programs

- This means that some sharing of personal genetic data donated by individuals is necessary. You should explain that this is the case to potential research participants, before they agree to provide genetic data

- Whether or not patients are happy for their DNA samples to be seen and used by other research teams is a personal matter for them. They may or may not agree to participate, but in either case, what is important from an ethical point of view is that they have been informed

- Biobanks and genetic research are supervised and externally audited, to make sure that researchers are using data appropriately. The ability of researchers to be able to continue with research in future depends on them adhering to high standards of data privacy

***NB: Disclosure of patients identity can be prevented in some cases by anonymising or encrypting data samples (for full explanation of this, see the sections on Informed Consent and Biobanking).***

***This is not carried out in all studies however as it is not appropriate for the aims of the research in every case***



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