

Bioethics Guidelines, online tool

Schedule

Planning of the • structure of the tool including • assignment of the guideline to the correct research situation • layout of the web-pages	2.5 month	Jan – mid Mar 2006
Programming	1.5 months	Mid Mar – April 2006
Launch of the tool		30 April 2006
Evaluation (using the comments and the short poll)	0.5 month	Sept 2006
Small revision	1.5 month	Sept – Oct 2006

The online version of the NuGO Bioethics Guidelines will be a web-based decision support tool that intends to help designing nutrigenomics studies that match certain ethical criteria.

Set up of the tool (first thoughts)

The tool may start with questions about the planned study, such as design of the study (e.g. observational, intervention), source population for the participants (e.g. general population, children, disabled, clinique patients), or time frames (e.g. under three years, 3 – 10, > 10 years, etc.) Based on the answers, where appropriate, the next questions will be more and more specific regarding the actual study. This way, the tool finally will lead the user to the specific guideline(s) and appropriate links, examples etc.

Example:

Are you planning to collect biological material?

- Yes
- No

If the answer is no, the bio banks part will be skipped.
If the answer is yes, the next question will be asked:

Will biological material be exchanged with partner institutions?

- Yes, partners in one or more foreign countries
- Yes, only partners in my country
- Probably
- No

If the answer is yes, the user may be asked for information on the kind of partner institution (commercial, non-commercial, etc.). The purpose here would

also be to provide the guidelines and possibly to make respective templates for sample exchange available depending on the kind of institutions that exchange samples. If no templates are available, a check list of things to take care of may also be beneficial.

Finally the appropriate set of guidelines will be displayed for the user. For example:

Storage of samples and data:

Banking of identified (nominal) samples is unacceptable, as it offers little protection for preserving privacy. Personal identifiers should therefore be removed from the sample and data collected as soon as possible. However, it would generally be essential for nutrigenomics research to potentially be able to trace individuals. This can be achieved by coding the biological material and for the code key be stored separately. Strict rules for storage and the use of the code key must be established by the data protection manager.

Access to the biobank and use of its samples and data by third parties should be subject to stipulations in form of research contracts and should also be subject to full records for future reference. Access to information or samples for genetic research should be restricted to qualified investigators and subject to institutional oversight. The curator should have the responsibility of control over the access to the collection. Funding bodies of the biobank need to determine the purpose of the collection and if it is available to both commercial ventures and academic researchers. For large genetic database, establishment of independent oversight bodies is recommended.

On the same internet page we might offer a link to an existing example and how security and quality control are guaranteed there:

Example:

<http://www.neurobiotec.net> is a French organization taking care of collections and allowing access by other researchers. On their website they have listed some standards for security, quality and ethical issues for their collections:

Security

- Clinical data are updated and validated by a neurologist and are filed in a protected room.
- Anonymity: Upon arrival at NeuroBioTec BANKS the removed biological material and the clinical data are anonymized by coding.
- The access to buildings of NeuroBioTec BANKS is strictly limited to authorized people with an access pass.
- Data processing management: The clinical and biological data related to the sample are stored on protected computers.
- The freezers: All equipment is protected using CO₂, an off-set alarm and a permanent recording of the temperatures.

Quality

- Procedures of quality assurance are recorded in a “quality handbook”.
- The tissues are systematically histologically examined by a-pathologist.

Legal and ethical context

- The activity of NeuroBioTec BANKS is ruled by the Code of the public health currently in force.

Legal principles applied:

- Exclusion of payment for the donation (art L 1211-4 CSP).
- Respect of the strict therapeutic or scientific goal of the removed material (art L 1241-1 CSP).
- For minors and people being under a legal protection measure the removal of biological material is prohibited if there is no benefice for the subject (art L 1241-2 CSP).
- Medical data confidentiality (system of coding) and rules are related to the professional secrecy. Advertisement to encourage people to give a part of their body, or product (blood, urine etc.) is prohibited (art L 1211-3 CSP).

Other supplies with links will be possible.

It is also planned to implement kind of a comment function at various stages of the decision support process so that users can give comments on things they missed or could not find etc. The comments can be used to tailor the tool after the test phase.

If you have any comment, please give it here:

When a user is about to leave the tool, the following window may pop up

This is a short evaluation poll, please answer the following questions:

Did you find what you searched for?

Yes Partly No

[If “Partly” or “No”:]

What was it what you were looking for and did not find?

...

How did you like the design of the tool?

Okay Not okay

[If “Not okay”:]

Please comment with few words what you did not like.