

HEALTH-NCP-NET
Ethics training on 7 March 2011
by Anne Demoisy

RHIZOME Consulting s.a.
anne.demoisy@skynet.be

How to fill in your Ethics section in an
EU proposal : Strong points for an
evaluation.

The Ethics review

- Is conducted by a panel of experts having different background and nationality in order to ensure a proper coverage of the fields assessed.
- Relies on precise criteria listed within the ethical issues table.

See the guidance for applicants in the ethics section on http://cordis.europa.eu/fp7/ethics_en.html

The Ethics review(2)

- The ethics requirements will become contractual obligations.
- The respect of the ethics requirements will be monitored by the Project Officer during project life.
- The Project Officer can call some experts to conduct a project audit during the project life.

HOW TO FILL IN YOUR ETHICS SECTION (SECTION 4 ON THE FORM)

Fill the ethical issues table with references

	Research on Animals	YES	PAGES
	Does the proposed research involve research on animals?	x	p52-56
	Are those animals genetically-modified laboratory animals?	x	WP6
	Are those animals genetically-modified farm animals?		
*	Are those animals non-human primates?		
	Are those animals cloned farm animals?		

Don't be afraid to tick an issue within the ethical issues table

- Ticking no issue does not prevent an Ethics Review to be conducted.
- Ticking an issue and providing relevant justification increases our confidence in your understanding of the issues at stake.

Describe who has the responsibility to manage the ethical issues

- An internal /external ethical advisor,
- An Ethics Advisory Board,
- Each workpackage leader,
- The workpackage leader of the a specific workpackage dedicated to Ethics.

Give a timeframe and list the deliverables

- Is a continuous monitoring needed?
- Are there mandatory approvals to provide prior to the start of the project/experiments?
- Do you plan some ethical deliverables?
- Is there an Ethics section included in the periodic reports ?
- Is there a specific workpackage dedicated to Ethics ?

Present your procedures for managing the ethical issues

FOR EXPERIMENTS WITH HUMAN BEINGS

- how informant consent is collected,
- the participants exclusion criteria (if any),
- the insurance coverage,
- incidental findings ,...

FOR ANIMALS EXPERIMENTATION

- how the 3Rs are applied,
- The animals number and justification for use,
- their housing conditions,
- the humane endpoints,...

Present your procedures for managing the ethical issues (2)

FOR DATA COLLECTION

- which data are collected and if they are private,
- the data protection measures (covering anonymisation, retention period,...).

FOR the NON EUROPEAN Countries

- the benefit sharing.

Include only the relevant references

- Recent EU legislation.
- Animals licences.
- Existing ethical approvals.
- Draft Informed Consent Forms.
- Names of projects showing synergies.

QUESTIONS ?