Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

December 2012

The Roles and Functions of Ethics Advisors/Ethics Advisory Boards in EC-funded Projects

A Guidance Document Produced by a Working Group comprising:

Nicola Stingelin
Guido Van Steendam
Johannes Rath
James A Houghton
Joseph Schmucker von Koch
Ron Iphofen (coordinator)

CONTENTS

PREAMBLE

> "The dialogue between science and the rest of society has never been more important... After ten years of action at EU level to develop and promote the role of science in society, at least one thing is very clear: we can only find the right answers to the challenges we face by involving as many stakeholders as possible in the research and innovation process. Research and innovation must respond to the needs and ambitions of society, reflect its values, and be responsible."[i]

The European Research Area (ERA) was established in 2002 as part of the implementation of the Lisbon Agreement. It aims to make the EU the most competitive and dynamic knowledge economy in the world in order to: enhance quality of life; ensure the welfare of European citizens; and contribute to European competitiveness.[ii] The Commission has, in particular, proposed to restore European leadership in life sciences and biotechnology research through actions aimed at enhancing industrial competitiveness.[iii] However, these ERA goals are being pursued amidst concern that, although the public often relies upon, accepts, and even shows enthusiasm for many aspects of science, there is also a perceived uneasiness towards science. Indeed, one reason for the EC carrying out Ethics Reviews of all projects in response to what is perceived to be the demand for scrutiny of research by society. Although the products of science are important, a "growing suspicion" has been expressed about the direction chosen for scientific research, who is in control, and what their motivations are. The reasons for mistrust include the increased scope for global impacts on fundamental aspects of human biological and social life, the high level of commercial involvement in research, and the need to ensure that the fruits reach a broad population.[iv] The responses to this situation include a political and academic focus on the relationship between science and governance, ethics in research and, more practically, a focus on public participation, especially regarding the risks of scientific endeavours.[v]

Consequently, the role of Ethics Advisors (EAs) and Ethics Advisory Boards (EABs) should be seen as the EC fulfilling its obligations to help avoid public uneasiness towards science and to mitigate concerns where they exist. However, it must be made clear that EAs and EABs are acting as independent experts when they assist the Commission in meeting its duty of accountability towards EU citizens.

This document was produced by the above Working Group at the request of the Ethics Sector (DG Research and Innovation) to provide guidance on the roles and operation of EAs and EABs boards established to monitor, guide and counsel EC-funded projects. The target audience for this document includes Commission staff, advisors and members of advisory boards as well as project proposers and participating partners.

The guidance is intended to apply to all substantive fields in EC-funded projects; whether in the natural, social sciences and the humanities as well as fundamental and applied research – this includes: medicine and biomedicine, security, synthetic biology, nanotechnology, CBRNE etc. It should also apply where there are industrial and/or publicly funded bodies involved and/or commercial/market-sensitive issues apply.

Necessarily, given the nature of ethical debate, there are differences of opinion and interpretation that remain to be resolved. Nevertheless, whenever possible, consensus has been reached and action points proposed. The aim is to offer a focused and practical guidance for EAs and EABs both in FP7 and in Horizon 2020 projects.

The current document is based on wide experience of ethics review, assessment and guidance both within and beyond the European Commission. This made it possible to draw on this breadth of knowledge to address the concerns and to propose ways of progressing the advisory role in a constructive and facilitative manner. It must be stressed that ethics advice is not to be treated as a trivial matter and ethical 'errors' can have serious repercussions for projects and their impact.

(1) Definitions and Clarifications

(a) "Ethics Advisory Board" (EAB) or "Ethics Advisor" (EA) is defined in this Guidance Document as a group of ethics experts or an individual ethics expert giving advice to a researcher, research group or project consortium partners in the context of an EC-funded project. Such a provision might arise as a requirement by an EC Ethics Review Panel, might become a contractual obligation for the applicants/beneficiaries, and/or might have been proposed as a work package as part of the original research proposal and thereby become included in the Description of Work (DOW). The work of these experts should facilitate, build upon and complement existing oversight regimes by competent ethical and legal authorities.

(b) The EC perceives 'ethics' as including questions of legal and regulatory compliance as well as a branch of philosophy. It is part of a process of 'governance'. In this vein, the EC document "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research" asserts that ethics is a "key oversight mechanism" to ensure that EU funded research is not misused.[vi]

(c) The consideration of ethical issues, starting at the conceptual stage of a proposal, enhances the quality of research, increases its likely social impact, promotes research integrity, promotes a better alignment of research with social needs and expectations and, finally, supports the societal uptake of the fruits of research because high ethical standards generally merit public trust.[vii] In this spirit, the Commission aims to build a relationship between the research process and ethics that is collaborative and constructive (rather than negative and inhibitive). The challenge addressed in this document is to position EAs and

EABs so as to be part of a positive research quality assurance strategy. However, EAs and EABs must retain the courage to be unpopular in cases where significant ethics problems arise and their intervention is necessary to maintain research ethics standards. Such challenges must be equally backed by effective powers.

(d) Ethics advice can be incorporated into a project either as part of a Work Package (WP) and so contained in the original proposal, or can depend on the nomination of an EA or EAB. In some cases consultation with ethics advisors can be on a voluntary basis, in other cases consultation becomes mandatory. The specific advisory 'form' can depend upon the following factors among others:

Anticipated seriousness of potential risks
The size of the project and, therefore, the multiple issues it raises
Already existing legal and ethical oversight structures
The maturity of the proposal

Variations in form and function of EAs/EABs can directly affect the ways in which the advisor/board relates to the consortium partners and to the character and effectiveness of the relationship.

(2) Appointment/Recruitment, Expertise and Membership Criteria

(a) The size and constituency of the EAB seems vital to good working relationships and effective delivery of advice. Membership should cover a range of ethics and topic-relevant expertise and EU states involved in the Project. This is even more vital for complex projects with a variety of ethical issues at stake. The size of the EAB should allow for all members to be fully engaged and committed. Too large a group might permit too much of a 'disconnect'. The appropriateness of the members' competencies and proven expertise is essential to the effectiveness of the performance of the role – perhaps even more so when only one EA is appointed. Membership should cover expertise in law, data protection/privacy and research ethics and substantive experience in the assessment of ethics issues in the specific topic area of the project. Occasionally, also having experts without such subject-relevant expertise can be helpful – a degree of 'naivety' might allow the asking of challenging questions that subject experts might not have considered themselves. Members are often recruited based on previous work relationships with partners of the consortium. This may create concerns when it comes to the independence of the EA/EAB. In many situations, independence will be essential in providing fair ethical judgements and expertise and recruitment practice should take this into consideration.

(b) The concept and application of EABs is well established in the medical and animal welfare area and adequate expertise is usually readily available. However, in other areas of ethics (e.g. dual use, biosecurity, privacy, societal implications of research), it is often difficult to recruit adequate expertise.

(c) For projects that clearly require security clearances, it should be made clear that the members of the EAB or the EA will also need adequate clearance in order to access relevant information. This should be clarified beforehand to

ensure adequate time is given to obtain such clearances and to have a functional EA/EAB at the start of the project. (Security clearances for all EAs or EAB members might be considered given the growing number of security-related projects being funded, the multidisciplinary nature of most projects and the potential dual-use issues associated with many projects - but this does raise considerable cost implications.)

(d) Ongoing liaison between the EA/EAB and project partners might be optimized by identifying an individual from each of the partners with responsibility for communicating with the EA/EAB. It might be of some help if this individual had some expertise in research ethics, data protection and/or privacy issues – but this is by no means the only way to ensure effective liaison.

(e) There is a possibility that representatives from the partners' national data protection agencies (NDPAs) and/or any other competent ethical/legal bodies/authorities, or those with previous NDPA experience and/or other competent ethical/legal body/authority experience could become members of the EAB. This could help ensure an appropriate discourse on the specific relationship or even contrast between EAB recommendations and/or requirements and what NDPAs/competent ethical/legal bodies/authorities in specific countries require. Sharing practices at EAB level could also help NDPAs etc. learn from each other. (This is only a suggestion since there could be charges of collusion and/or conflicts of interest; so it needs to be considered fully and carefully managed if implemented.)

(f) With membership constituted in this way the EAB becomes less 'external' to the project – rather it comprises partners and 'non-partner'/independent experts who 'work together' in the best interests of the overall project.

(g) Attendance by members at as many relevant meetings as possible (whether virtual or face-to-face) continues to be important for consistency and continuity. If a member's formal attendance is limited for any reason, they should employ other means to ensure they are fully acquainted with how the project is progressing.

(h) The points raised above demonstrate the need to maintain a fine balance between the 'independence' of the EAB, any 'critical friend' function they might adopt and the achievement of productive connections with the partners. Even if WPs include ethics review as part of the project structure, the means for sustaining this independence of operation is essential. The following proposed methods of operation are aimed at ensuring this 'balance' is maintained.

(3) Establishing Working Practices

(a) Working practices should be formally agreed and clarified from the outset. A 'division of labour' between the EAB members and applied to specific project deliverables according to members' expertise can increase the efficiency of operations. An EAB Chairperson should be elected from the membership and

may speak on their behalf. To avoid confusing flows of information it should be clearly outlined in a Memorandum of Understanding (MOU) how the interaction between the consortium and the Ethics Advisory Board takes place and the mandate of the EAB (e.g. advice on approval requirements, risk benefit assessments, guidance on specific ethical questions, reporting obligations, guidance concerning the relevant legal framework and regulatory requirements in the countries where the research takes place) should be clearly defined. The MOU should be negotiated between the Chair of the EAB and the Consortium Management if not already contained in the DOW.

(b) Ethical issues can become quite formidable or can be capable of being addressed in a straightforward way – largely dependent on the primary substantive focus of the project. In all cases 'proportionality' is of the utmost importance. EA/EAB practice should be proportionate to the topic in hand. The format and frequency of meetings should reflect this proportionality, as should the reporting function. Project partners should be invited to meetings in case specific questions need to be addressed.

(c) Securing the 'best interests' of the general public and civil society is one of the main goals. EAs/EABs exist to offer guidance, advice, monitoring and recommendations for future work. Boards and advisors should operate according to the mandate outlined in the MOU at the beginning of the project – neither dominating the work nor obstructing it unnecessarily. They should be facilitative. However, there are times when EAs/EABs will and must be able to apply mandatory or regulatory powers.

(d) Funding must be adequate to the task. Clarity over fees and expenses is vital. The workload in complicated projects can be very high and may require the commitment of several full days per year. The commitment can be substantially higher if the DOW links the advisory work to specific research and/or networking activities. Advisors may have to gain some level of familiarity with the technical aspects of a consortium's work and the research field in general, as well as gaining fuller understanding of how the consortium plans to operate. To have a real impact, they may have to be part of the management structure. To ensure that adequate expertise can be recruited and the task is treated in a professional manner, compensation for the work should be foreseen in the project application. To avoid conflicts of interests and compromising its independence as a result of financial interests, the compensation budget should not be linked to any specific outcome of the ethical assessments. Since members are acting in an advisory capacity, it is hard to fully anticipate the budget in advance since the need to address unanticipated issues might occur. This suggests that some room for manoeuvre within the budget is needed. There must also be clarity over who and what is to be paid for and what activities are "voluntary" in order to ensure members are treated equitably.

(e) Although face-to-face meetings are advantageous in solving complicated issues, it is often not feasible to convene all members together at a certain place and time due to time and financial constraints. Alternatives might be e-mail conversation or videoconferences or one-off site visits. Nevertheless, face-to-face

meetings should take place as often as possible to ensure active discussions between the members of the EAB and also with the researchers involved in the project.

(f) The individual members of the EAB should cooperate to work out consensus-based recommendations. In cases where no consensus can be reached, it is recommended that the EAB provide a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.

(g) All meetings of the EAB should be based on an agreed agenda to ensure efficient decision-making. Relevant documents should be circulated beforehand to allow for adequate preparation. Meetings should be co-ordinated by the Chairperson and a report should be prepared for each meeting and communicated to the project management.

(4) Nature of Advisory Role – Practice 'culture', Powers and Managing Relationships

(a) The EA/EAB must maintain an overview of operations throughout a project, helping with preparation in terms of thinking ahead about possible problems and how they can be addressed. Any sense of static, 'tick-box' approvals must be avoided. EAs/EABs are resources for advice and guidance when ethical dilemmas arise during a project. EABs with oversight functions will usually check compliance with ethical standards within the relevant research fields. Independence and freedom of any conflict of interests are requirements for the participation in these EABs.

(b) If there is an additional Advisory Board (AB) with oversight of the project – with an EC Project Officer attending – then the EA/EAB Chair should be *ex officio* a member of the AB. If there is no AB, the Chair of the EAB should be allowed to actively participate in Consortium meetings. Ideally, the EAB must be fully integrated into the management structure, should attend Kick-Off and Plenary Meetings, participate in all significant technical group meetings, review all Annual Reports and papers for publication and help in preparing authorizations and approvals and monitor all the authorizations, approvals and licences etc. This active engagement facilitates ongoing liaison between the various agents and groups and helps ensure thorough knowledge of overall project activities and better acceptance and integration of the EAB into the consortium activities.

(c) It is important that the EA/EAB keeps up regular contact with any partner bearing WP responsibilities for ethics-related actions and that both know what actions the other is taking and planning. This should ensure consistency and help avoid any unnecessary duplication of effort. It is highly recommended that principal link to the consortium be established between the Chairman of the EAB and Project Coordinator. This is also important for ensuring consistency of advice and avoiding confusion – as controversial issues might need discussion among all members of the EAB prior to the formulation of clear advice.

(d) Clarity in all communications coming from the EA/EAB is essential. Advice offered must be understandable by the partners so that appropriate actions can be taken – it must be pragmatic/workable. Direct communications between advisors and partners is vital.

(e) In EU member states EABs might need to have specific powers to put a hold on the project on ethical grounds and/or to call for an Ethics Audit by the European Commission. These powers should apply without any restriction with respect to non-EU countries. The funding contract can give power to the EA/EAB to come up with binding judgments (as a contractual obligation). Such requirements should be clearly outlined in the funding contract/DOW and incorporated in the MOU established at the beginning of the project. In such situations, it is of paramount importance to ensure the selection of fully independent experts that are free of any conflict of interest and that the EAB is given full access to all necessary information.

(f) Grant Agreements often indicate that beneficiaries shall comply with all applicable EU/national legislation, and any relevant future legislation and the requirements of FP7 specific programs. However, the local standards (on which the necessary approvals, e.g. from RECs, are based) can be less onerous or less appropriate than the best practice standards set by the EC for applications in FP7 funded projects. The role of EA/EAB would be in such instances to ensure that appropriate EU standards are met, with an additional role to play in research carried out outside Europe to ensure that it complies with EU standards. Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006, concerning the Seventh Framework Programme, does make mandatory statements for all research funded by the EC.

(g) In cases where the role of the EAB is closely linked to a technical deliverable (e.g. participation in the development of "Privacy by Design" concepts), it might be worthwhile considering the use of individual work packages and integration of ethics experts as project partners as part of the working structure that ensures easier integration of the expertise in the daily research. Similarly, where ethics is integrated and part of the research work packages including project partners familiar with the legal and ethical requirements might serve the project better than an independent EA or EAB. The work package construction usually allows a better integration into the daily research and management structure of the project and sometimes does not require independence. Ensuring independence and avoiding conflicts of interests in a situation where the ethics work is so closely linked to a successful project output requires special attention. Nonetheless, to ensure independent judgement in highly sensitive research, the establishment of an EAB should be considered in addition. All functions and responsibilities of the EAB must be properly addressed. This requires a clear description of the tasks in the DOW and an appropriate management structure.

(h) Provision for indemnity insurance has to be considered. Recent liability claims and even criminal charges for wrong advice have made public headlines

and it is unclear what the legal status of the EAB is. This should be clarified, and adequate safeguards, such as indemnity insurance, implemented.

(i) The work of EABs can produce judgements that may conflict with project goals. Therefore, much higher emphasis must be given to ensuring independence and limiting conflicts of interest in such circumstances.

(j) In addition 'conflicts of personalities' can impede effective ethical practice, so the operational mechanisms must be such that personality 'clashes' can be overridden. In all cases a culture of mutual respect and understanding of the other's position should be cultivated.

(k) Transparency and critical detachment are important components of ethical oversight. Being open and clear about decision, actions to take and the rationales behind them is good practice. All other project groups (partners and advisors) should be encouraged to raise issues with the EA/EAB knowing they are to be treated with discretion.

(l) In summary, the EA/EAB should do whatever is necessary to diligently monitor the aims, objectives, methodology and implications of the research to ensure that it conforms to the highest ethical standards and ensures that the researchers, the Commission and the general public are not exposed, by the work of the project, to activities that would be considered to be ethically unacceptable. As research activity is dynamic and evolves along unpredicted pathways advisors must be prepared to tackle new issues and concerns as they arise and the ethical perspective will need to be modified throughout the lifetime of the project.

(m) Ethics advisors should include independent summaries of discussions and issues arising in formal meetings in their regular reports. Suggestions for items to include in reports are in attached Appendix 2.

(5) Identifying Appropriate Ethical Principles and Criteria to Apply

(a) Ethics needs to permeate all parts of the project 'culture' to be effective. In the interests of raising and maintaining ethical awareness, all aspects of the project's activities require the maintenance of an ethical perspective. A sound ethics policy requires transparency and balance. Evidently some risks of harm for any project can be anticipated, but by no means all.

(b) One way of maintaining ethics awareness is to establish a set of 'core values' or 'principles' to be signed up to by all partners. Additionally an ethics checklist to act as an aide memoire and modified to apply specifically to the project in hand can be a focus for ethical practice. Application of the checklist can highlight misunderstandings of terminology and conceptual problems associated with the rationales that lie behind conventional ethical principles. A basis for core values and principles relevant to FP7 is outlined in N 1982/2006/EC, ("fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union"); this together with applicable legal

provisions, codes of conduct and guidance documents provided by the European Commission should form a base for the work of any EAB. The EAs/EABs should ensure, to the best of their ability, that the consortia adhere to the Fundamental Rights Declaration of the European Union.

(c) Clarification of remit in terms of appropriate ethical issues should be carried out at the start of the whole process. They should clearly justify making any recommendations and requirement for an EA/EAB. The EA/EAB should ensure that both ethics screening reports and ethics review reports (ERRs), when they exist, are fully available to partners, that they are acted upon and, as far as is possible, there is consistency of advice and practice across all ethics experts. The partners' actions are consistent with their responses to the Ethics Issues Table contained in the original proposal. Any subsequent amendments should be reported and explained to the EA/EAB. In some cases, the DOW might introduce specific criteria e.g. lawfulness in the context of Special Clause 15/1 or further requirements usually derived from the Ethics Review. It is an important function of the EAB to ensure compliance with the requirements outlined in the DOW, e.g. by providing reports as Ethics Deliverables. Where differences of opinion, judgment and/or interpretation exist within the EAB, these should be explained to partners to assist in their application to practice.

(6) Liaison with other relevant EC-projects/EC- information 'resources'

(a) EAs/EABs should be aware of, and able to liaise with, other relevant EC-funded projects. Many EC-funded projects have faced and continue to face very similar ethical issues. It should be possible for each new project to learn from them. A range of factors inhibits open cross-fertilisation and interaction between projects. These include intellectual property rights, security and confidentiality. But unless such 'obstacles' are overcome there is likely to be considerable duplication of effort, which is wasteful of resources and impedes the building of foundational work that could enable more rapid and widespread ethical awareness.

(b) EU projects that have established 'codes of conduct' could provide the basis for similar ethics progress elsewhere. One example is the code of conduct for responsible nanosciences and nanotechnologies research: http://ec.europa.eu/nanotechnology/pdf/nanocode-rec_pe0894c_en.pdf
Another is the RESPECT project code for socioeconomic research http://www.respectproject.org/code/
Another excellent model for large scale EC collaborative project that could inform practice is the ETICA Project (completed May 2011):
http://www.etica-project.eu/
The 'official' status of such codes can very greatly – the main point is to be aware of foundational advice they contain and perhaps view them as 'helpful tools'.

(c) Any liaison activities between EABs directly related to project actions should be discussed and agreed with the project management in advance, to ensure that no confidential, project-specific information is exchanged between competing research consortia. This could be contained in a confidentiality

agreement. An exception should be included in any such agreement for the option to report ethical misconducts directly to the European Commission, to ensure adequate and timely information of the funding institution.

(7) Principle of Ensuring Consistency in Practices and Policy

(a) This section is directly linked to sections 4 and 5 above and will affect section 7 below. It is not particularly helpful if different advisors and different groups are applying advice in different ways. The core of this 'principle' requires effective communication between advisors, a repository of knowledge on 'best practice' (what has been shown to work and what doesn't) and clarity over legal and regulatory compliancy, EC-required principles and norms, and wider ethics reflections and analysis. An online community for advisors and occasional face-to-face conferences might help in securing consistency in practice and enable contributions to policy development.

(b) The societal implications of any EC-funded projects might be considered to be relevant to ethics oversight. EAs/EABs might be tasked with including some assessment of societal implications and/or risks as part of their duties.

(c) Ethics advice should incorporate the assurance that EU/national laws are complied with, as well as international 'soft laws,' and widely accepted ethics codes and guidelines. This position is reflected in the statement that "…research activities supported by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union. The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account."[viii] One of the greatest challenges is to ensure that all advice given is underpinned and justified by an EU appropriate document. What is required is a list of all normative documents that EA/EABs should refer to in order that their work has legitimacy and is coherent across the board. *[Some suggested sources of legal and ethical guidance are indicated in Appendix III.)*

(d) Reflection on the experiences and outcomes of the project, in terms of meeting ethics requirements, should be compiled and subsequent reports summarizing the lessons learned delivered to the Commission. Some degree of flexibility is of benefit when thinking through both ethical and societal impact issues. The combination of partner ethics, independent expertise and the potential to draw upon a breadth of experience across an EAB allows for a balance of 'interests' and could help ensure that no 'vested interests' dominate.

(8) Sustainability – developing and sharing enduring principles and practices.

There is a need for clear archives both for EU projects and related work located in specific nations within and outside the EU. A resource centre and even an information centre with a degree of autonomy to allow it to offer independent advice and networking.

CONCLUSION

This document is intended to draw some initial observations and recommendations. The Working Group is seeking to establish some guidance for best practice and ground rules that outline what the Group believes should be the framework of operation of the ethics advisor and/or advisory board. There is still a great deal to be done and it is proposed that these suggestions are taken further and aired more fully with all stakeholder representatives.

In certain respects, the role of EA/EAB can be seen as the EC fulfilling obligations that arise from the funding of emerging, innovative (often weakly governed) research to ensure that the most appropriate standards are applied and met, whilst admitting that some standards that develop in a complex innovative environment can only be provisional best practices. Meeting the challenge of making the EU the most competitive and dynamic knowledge economy in the world requires that innovative research be funded, but it is precisely such research that may pose the most complex ethical challenges.

Nevertheless, it is hoped that proposers take into account the views expressed here so that proposals do not merely pay lip service to the advisory function, but recognize how seriously it is to be taken throughout the life of a project. Any attempt to simply use the EA/EAB to satisfy the Commission concerns while ensuring that Advisors do not inhibit or interfere with the main direction of the research is to be strongly resisted. An Ethics Advisor must not simply become a symbolic cipher without any effective power to influence the direction of the research activities or the methodology that will be used. The advisory role is a proactive one. The cultivation of mutual understanding between advisors and partners can see differences resolved through diplomacy and clear communications. Problems can be forestalled through cooperative endeavour and a culture of collaborative working.

There is no doubt that serving as an Ethics Advisor on a major project is a very challenging and demanding job and requires a great deal of dedication, experience, commitment and enthusiasm. It is essential to master the details of the research, keep up-to-date with the latest developments in the field whilst at the same time keeping pace with developments in the ethical opinions and legislation. It also requires the patience to win over what may initially be a critical group of researchers, enthuse them with the concept of ethical probity and demonstrate that the Advisor has something positive to contribute to the project. It should be clear from the foregoing that the Working Group sees it as imperative that the forms and functions of EAs/EABs are strengthened in recognition of the vital service performed by ethics assessment, the public protections it affords and the checks and balances on the massive investment of public funds. When seeking to formulate good practices in the area of ethics the uncertainty that often surrounds emerging, innovative science that may give rise to further aspects of ethics uncertainty. It is thus suggested that a strong focus should be on developing procedures for deciding what should be done, applying the principles of participation, procedural justice, responsible stewardship, accountability, transparency, effectiveness, and coherence.

APPENDIX I: QUICK REFERENCE LIST OF "DO'S" and "DON'TS" WHEN APPOINTING AND WORKING WITH AN ETHICS ADVISOR OR ETHICS ADVISORY BOARD.

Recruitment/Appointment/Establishing Tasks of EA/EABs (See section 2):

	Do's	***Don'ts***
Expertise	Select advisors on the basis of their known competence	Select on basis of prior knowledge alone and/or their known compliance.
Range	Cover the range of skills relevant to the project	Merely look for 'breadth' of coverage
Complementarity	Ensure the advisors' skills match project needs and fit with each other	Neglect to examine CVs to determine skills
Adequacy	Check for relevant experience	Assume all ethics advisors have same skills
Independency, Conflict of Interest	Recruit independent professional experts	Ask your best friend for a favour or recruit your EAB from the project partners or their home institutions
Security clearances	Define clearly for whom and from whom security clearances are needed and request such clearances in advance	Wait until project starts to think about security clearances
Confidentiality agreements	Clarify what can be 'shared' outside the project and allow for direct interactions with EC representatives	Assume advisors know what can be shared
Handling of confidential information	Provide clear guidance on what constitutes project confidential information or security sensitive information and provide adequate platforms for sharing such information	Assume advisors know how to handle project confidential agreements
Indemnity insurance	Check what insurance can be/has been provided	Assume liability cover is unnecessary

Relationship to Consortium (section 3):

	Do's	Don'ts
Memorandum of Understanding	Agree terms of working relationship	Believe that it works anyway
Points of contact	Work through project management/coordinator	Fail to formalize liaison arrangements
Participation in Consortium Meetings	Be involved from planning proposals through the project at all stages to completion	Sideline advisors
Independence v. integration	Invite partner representatives in EABs meetings if necessary	Compromise independence

Within EAB (section 4):

	Do's	Don'ts
Nominate a Chairperson	Elect the Chair from the EAB members	Accept an appointee from the consortium
Decision making procedure	Clarify decision making within EAB	Be vague about decisions to be taken
Meetings protocol	Set agenda and record decisions and actions	Allow meetings to be informal 'conversations'

EA/EAB Powers:

	Do's	Don'ts
Oversight	Maintain vigilance over the whole project	Assume all recommendations will be followed
Contractual approval obligations	Be clear about what is allowed and be willing to apply contractual powers if necessary	Approve if full information is not given. Hesitate to act due to 'personal' concerns
Guidance	Be clear and precise about actions to be implemented	Leave room for doubt
Whistleblowing clause	Encourage disclosure of problems	Accept complaints at face value
Budgetary control	Ensure adequate finances for whole project	Devalue the work of ethics advice

External relationships (obligation and responsibilities) (sections 6 & 7):

	Do's	***Don'ts***
European Commission	Ensure contractual ethics obligations are met	Fail to use Commission expertise
National Data Protection Agencies, Radiation safety authorities, Biosafety Authorities, RECs with legal authority (e.g. animal welfare, clinical trials)	Ensure compliance with local requirements	Forget to ascertain 'proper' authority
Institutional RECs with 'local' jurisdiction	Find out the limits to jurisdiction, obtain and implement their advice	Upset or ignore local institutional RECs

APPENDIX II: REPORTING TEMPLATE FOR EAs/EABs

Reporting Guidance

EAs/EABs should develop:
(a) a Program of Work lasting for the duration of the project that includes reporting deadlines;
(b) procedures for conducting its work that apply the principles of appropriate participation, procedural justice, responsible stewardship, accountability, transparency, effectiveness, and coherence.

The Program should define and shape reporting; the stated procedures should guide the decision making process and be reflected in all Reports.

EAs/EABs should recall that the reports and advice offered be pragmatic/workable, clearly explained and justified (with reference to the principles, criteria, approached being applied, and the sources of this guidance), and be understandable by the partners so that appropriate actions can be taken.

The EA /EAB should aim to give consensus-based recommendations. In cases where no consensus can be reached, it is recommended that the EAB provide a transparent overview on its discussion to the project management, detailing why no definitive advice was possible.

REPORT ITEM HEADINGS

Number of Report **Date of Report**

Date(s) of actions referred to

Author of Report

Report Title:
Subtitle: with reference to Deliverables, Item in Work Programme, Task, Issue to Hand

Target Audience

Minutes of/notes from any previous meeting

In Attendance at Meetings and/or Contributors to Report

Actions Completed (by whom)

Decisions taken

Information given

Next Steps

Actions on whom

Next meeting (date and place)

APPENDIX III: POTENTIAL SOURCES OF LEGAL AND ETHICS GUIDANCE (Non-exhaustive list)

1. Council Decision 2006/973/EC) concerning the specific programme 'People' implementing the Seventh Framework Programme of the European Community

"Ethical aspects

During the implementation of this specific programme and in the research activities arising from it, fundamental ethical principles are to be respected. These include, inter alia, the principles reflected in the Charter of Fundamental Rights of the EU, including the following: protection of human dignity and human life, protection of personal data and privacy, as well as animals and the environment in accordance with Community law and the latest versions of relevant international conventions, guidelines and codes of conduct, e.g.

a. *the Helsinki Declaration,*
b. *the Convention of the Council of Europe on Human Rights and Bio-medicine signed in Oviedo on 4 April 1997 and its Additional Protocols, the UN Convention on the Rights of the Child,*
c. *the Universal Declaration on the human genome and human rights adopted by UNESCO,*
d. *UN Biological and Toxin Weapons Convention (BTWC),*
e. *International Treaty on Plant Genetic Resources for Food and Agriculture,*
f. *relevant World Health Organisation (WHO) resolutions."*

2. Decision 1982/2006/EC of the European Parliament and of the Council (Recital 30 and Article 6)

Research activities supported by the Seventh Framework Programme should respect fundamental ethical principles, including those reflected in the

- *Charter of Fundamental Rights of the European Union.*
- *The opinions of the European Group on Ethics in Science and New Technologies are and will be taken into account. Research activities should also take into account the Protocol on the Protection and Welfare of Animals and reduce the use of animals in research and testing, with a view ultimately to replacing animal use.*

*The European Charter of Fundamental Rights_*

- *Art. 3: Right to the integrity of the person;*
- *Art. 8: Protection of personal data*

3. 2012, Directorate-General for Research and Innovation, Ethical and Regulatory Challenges to Science and Research Policy at the Global Level

Recommendation 11: Following the Millennium Development Goal approach, the European Commission should work to engage all relevant sectors of society in contributing to the aspiration of benefit sharing.
Recommendation 12: The European Commission should collaborate with the WHO to devise a comprehensive benefit sharing framework relevant to future access to human biological resources as well as global public health.

4. The European Charter for Researchers The Code of Conduct for the Recruitment

of Researchers, European Community 2005

Research freedom, ethical principles: researchers should adhere to the recognised ethical practices and fundamental ethical principles appropriate to their discipline(s) as well as to ethical standards as documented in the different national, sectoral or institutional codes of ethics; professional responsibility; professional attitude; contractual and legal obligations; accountability (researchers need to be aware that they are accountable towards their employers, funders or other related public or private bodies as well as, on more ethical grounds, towards society as a whole. in particular, researchers funded by public funds are also accountable for the efficient use of taxpayers' money); good practice in research (researchers should at all times adopt safe working practices); dissemination, exploitation of results, public engagement ("researchers should ensure that their research activities are made known to society at large in such a way that they can be understood by non-specialists, thereby improving the public's understanding of science. Direct engagement with the public will help researchers to better understand public interest in priorities for science and technology and also the public's concerns.")

5. Guidance Note for Researchers and Evaluators of Social Sciences and Humanities Research 2010.

"Underlying ethical principles
Avoidance of exploitation, just distribution of benefits and burden, beneficence, respect for persons, respect for human dignity, scientific validity, social value, the rights and interests of research participants are overarching ethical principles of any scientific research. From the stage of research design to the dissemination of research outcomes these principles should be taken into account when identifying and dealing with the ethical issues raised by a particular research."

6. Principles of European research ethics (Power point presentation, European Commission DGRI Ethics)

Ethics principles:
- *The principle of respect for human dignity*
- *The principle of utility*
- *The principle of precaution*
- *The principle of justice*

7. 2010 EC European Textbook on Ethics in Research

8. European Commission, "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research"

9. FP7 Guidance For Applicants, Informed Consent. European Commission

10. FP7 Guidance For Applicants, Ethics in research and international cooperation",. European Commission

11. Commission Decision (2001/497/EC) of 5 June 2001 on standard contractual clauses for the transfer of personal data to third countries

12. Introduction to IP rules in FP7 Projects (http://www.iprhelpdesk.eu/, 2011)

13. EU Data Protection Directive

14. Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes

15. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. OJ L 121, 1.5.2001

16. Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data OJ 23 November 1995 No L. 281 pp. 0031-0050

17. Council for International Organizations of Medical Sciences (CIOMS) ISBN 92 9036 075 5
http://www.cioms.ch/frame_guidelines_nov_2002.htm

---

[i] Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science Message delivered at the conference «Science in Dialogue - Towards a European Model for Responsible Research and Innovation» Odense, Denmark, 23-25 April 2012

[ii] Commission of the European Communities, Communication from the Commission: Competitive European Regions Through Research and Innovation, 2007. A contribution to more growth and more and better jobs {SEC(2007)1045}

[iii] 4.9.2001 COM(2001) 454 final Communication From The Commission Towards A Strategic Vision Of Life Sciences And Biotechnology: Consultation Document

[iv] European Textbook on Ethics in Research, Directorate-General for Research Science, Economy and Society, 2010

[v] Ibid.

[vi] European Commission, "A comprehensive strategy on how to minimize research misconduct and the potential misuse of research in EU funded research". The report is addressed towards The EU Commission; EU Ethics Screeners, Reviewers and Auditors, and Research project applicants.

[vii] European Commission, „*Ethics for Researchers* – Facilitating Research Excellence in FP7," Luxembourg: Office for Official Publications of the European Community, 2007, Göran Hermerén, President of the European Group on Ethics (EGE).

[viii] Decision No 1982/2006/EC Of The European Parliament And Of The Council
of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)