

**Guidance Note
for Researchers and Evaluators
of Social Sciences and
Humanities Research**

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A. Foreword

The aim of this guidance note is to provide applicants and evaluators of Social Sciences and Humanities research projects with advice and practical guidance on dealing with the ethical aspects of Social Sciences and Humanities research. In an effort to better understand the problems associated with ethics review of social sciences and humanities projects, this document examines the main points that need to be considered in order to write a complete, accurate and robust grant application.

The document is based on discussions among twenty-eight Ethics Experts with previous experience in Ethics Screening, Review and Audit at European Commission and was chaired by Prof. Margit Sutrop and Prof. Carmen Florea. The discussion took place from September to December 2010 via the SINAPSE system and was followed by an experts' meeting in Brussels on the 8th of December 2010.

Much of the following advice is already published, and thus can be found in many books, articles and documents. However, we hope that summarizing this in one document will help both applicants and reviewers to get a quick overview of the fundamental ethical issues of Social Sciences and Humanities research.

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B. Introduction

Ethics is as an integral part of EU funded research projects

Ethics is an integral part of research: it is only by getting the ethics right that research excellence can be achieved.¹ As ethics is considered to be central to scientific integrity, the European Commission has made ethics review an integral component of research evaluation procedure. All research projects that have successfully passed the scientific evaluation are subject to an ethical evaluation.² A system of Ethics Screening has been implemented, delegated to individual Programs, Remote and Central Reviews, Follow-up and Audit, organized mainly by the Ethics Sector of DG-RTD (Directorate-General for Research and Innovation, Unit L3 – Governance and Ethics), and accompanied by increased training programs for both applicants and Commission staff.

The ethical review process at the European Commission shows that there is a lack of awareness of how one should deal with the ethical issues in Social Sciences and Humanities (SSH) research proposals. Either the applicants lack the requisite knowledge of ethics, have low awareness of how ethical principles should apply to their research, or they do not know how to demonstrate their awareness of ethical issues.

Some common reasons include:

- Failure to show any significant appreciation of the potential ethical issues of the study.
- Failure to notice that voluntary informed consent is the accepted norm of conduct for all kinds of research on human subjects; failure to give a detailed description of how the informed consent process will be implemented.
- Failure to provide appropriate documentation supporting the proposed research from the ethics and regulatory side.
- Failure to describe in detail what kind of measures of privacy and data protection will be implemented.
- Failure to assess the potential risks associated with the project and to plan measures to avoid or minimize them.

As the number of proposals in the field of Social Sciences and Humanities (SSH) is rapidly increasing and their ethical dimension is either not evident or insufficiently elaborated, there is a

¹ Ethics for Researchers. Facilitating Research Excellence in FP7 (2007). <ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-for-researchers.pdf>

² On the Ethics Review and the FP7 Ethics Framework see: ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-review-fp7-ethics-framework_en.ppt

clear need to give guidance to applicants as well as to the reviewers of SSH research projects. The aim of this note of guidance is not to teach SSH researchers how to do ethically correct science. We leave this role to the professional societies and research communities who are intensively debating the ethical issues of their specific research fields and developing their own ethical guidelines and codes of conduct.³ We are optimistic in this respect, as during the past decades there appears to be a heightened interest in the ethical considerations in the SSH research. However, ethical awareness varies considerably both among different disciplines and different national contexts.

Another problem expressed recently is that in many cases the ethical guidelines used by the ethical review boards are better suited to medical/bio-medical research than to SSH research; members of ethical review boards are unfamiliar with SSH research methods and protocols. Professional associations of SSH have expressed their concerns and pointed out that if standard rules and procedures are followed in a blanket manner on the assumption that the same ethical principles apply in the same way to all research fields, this will do more harm than good (it may heighten the risk to the participants of research instead of protecting them, and even stop socially important research).⁴ Thus, a deeper understanding of the peculiarities of the ethical considerations of SSH is needed and this should lead to improved guidance for protecting the rights and welfare of participants in various types of SSH research.

Ethical issues in SSH research involving human participants involve considerations that are as diverse as the range of disciplines and fields that constitute these sciences. The term SSH refers to the scientific study of behavioral, cultural, and social phenomena, carried out in a variety of disciplinary and interdisciplinary fields ranging from anthropology, economics, psychology, political science and sociology to archaeology, history, linguistics, literary studies and education research, among others. The methodological approaches in these sciences include surveys and questionnaires, focus groups and interviews, direct observation, physiological manipulations and recordings, standardised tests, descriptive methods, laboratory and field experiments, economic analyses, statistical modelling, ethnography, and evaluation.⁵ In some fields of SSH research, as for example in behavioural studies, minimal physical intervention (e.g. taking blood samples etc) may also take place. As today's research is becoming more and more interdisciplinary, it is impossible to

³ An extensive analysis of the ethical codes of over 250 SSH professional associations was carried out between 2001 and 2003 in the framework of the EC funded RESPECT project.

⁴ Raymond De Vries, Debra A. DeBruin, Ethics Review of Social, Behavioral, and Economic Research: Where Should We Go from Here? *Ethics&Behavior*, 14 (2004): 351-68.

⁵ Felice J. Levine, Paula R. Skedsvold, Behavioral and Social Science Research. In E. J. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, D. Wendler, *The Oxford Textbook of Clinical Research Ethics*. Oxford: Oxford University Press, 2008, pp. 336-355.

draw a strict line between SSH research and other kinds of research. Thus, the ethical considerations of SSH research are neither easy to characterize, nor can they be broken down into a single pattern that is universally applicable to the variety of research methods used in SSH while remaining globally responsive to the myriad of issues under study (ranging from daily life circumstances to those marked by various sensitivities).

The ongoing discussions concerning ethical issues within SSH research community highlight the fact that the developmental, creative and interpretative nature of research in these fields requires particular attentiveness to ethical dilemmas and tensions.⁶ Ethical rules should not be followed or required blindly by the ethical review panels; rather one should take into account the variety of methodologies and research contexts. The researchers and evaluators should recognize the complexity of ethical decision-making in SSH research and be aware that ethical principles may frequently be in tension or contradiction with each other. These guidelines do not attempt to resolve these choices by prioritizing one principle over the others but instead, offer a framework in which individual ethical decision-making should take place.

This note of guidance does not give definitive answers but it gives examples of likely areas SSH researchers have to explore in their grant application. We hope that this will help the applicants to prepare the ethics section of the EU grant proposal and reviewers to carry out a smooth and fair ethical review of SSH projects. The document will also highlight some of the peculiarities of the ethical considerations of SSH research, outline common ethical dilemmas that are encountered in SSH research and suggest ways of dealing with them. In this sense it is intended to be both an educational tool for the research community and a stimulus for further discussions.

C. 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. To become operational these ethical principles should be translated into tools and procedures that can and should vary, depending on the field of research and sometimes even its context. These tools and procedures (such as informed consent, data protection and privacy, impact of the research results)

⁶ Mark Garner, Christine Raschka, Peter Sercombe, Sociolinguistic Minorities, Research and Social Relationships, *Journal of Multilingual and Multicultural Development*, 27 (2006): 61-78

form the basis of the ethical issues section provided in the Guide for Applicants and research proposals submitted for funding under the FP7, as well as for the ethical review process organized by the European Commission.

Six points to consider when you complete the ethical section of the application form:

Demonstrate that you are aware of the ethical issues raised by the methodology of your research and describe the suitable measures taken to appropriately address these issues.

Complete the Ethical Issues Table, which serves to identify any ethical aspects of the proposed research. You must complete this Table even if there are no ethical issues raised by your proposal. If you answer “yes” to any of the questions from the Ethical Issues Table you should provide a comprehensive discussion of how the identified issues will be addressed.

In the Ethical Annex you must discuss separately the following aspects:

- describe the ethical issues raised by the objectives of your research, its results, the potential consequences of the research outcomes and how you will address these issues effectively;
- describe the steps to be taken for the proposed research to meet the ethical standards of FP7 and the legal and ethical requirements of the country where the research will be performed;
- specify clearly where the research will be carried out and which competent authorities will be contacted to approve the study. Identify whether or not such authorities are in place and have the competencies to assess SSH research. Refer to the national and international relevant legislation and regulation and state explicitly how your research proposal would meet the ethical and legal exigencies of these documents.

If your research proposal raises highly sensitive issues (such as observation of people or research among illiterate people) it is advisable to include an independent ethics advisor or an independent ethics advisory board. In cases of major potential ethical challenges, a work package on ethics can be proposed.

You should address informed consent, data protection and privacy issues in a

comprehensive manner.

A proper assessment of potential risks (for individuals and communities/society alike), as well as a plan of minimizing potential harm should be included in the proposal.

D. Objectives and implications of SSH research. Minimizing harm, maximising benefit

The ethical review of all scientific projects starts with the question of whether the objectives of research raise any ethical questions. From the scientific point of view, every research project has to address the question of why the planned research has to be carried out, whether there is any new knowledge to be gained and whether it is worth spending the time and money to obtain it. A justification for conducting any proposed research project is a way of demonstrating that the research will offer benefits to scientific understanding, to policy and/or to practice that makes the resources spent on the proposed research worthwhile.⁷ From the ethical point of view, asking about the justification of the objectives evokes the ethical concern that social interests or the paternalistic impulses of the scientific community should not override individual interests. The contemporary debate on participants' rights and the protection of human subjects of research is grounded in Nuremberg, as a reaction to the oppressive history of eugenics and the Nazi scientists' experiments carried out in the "public interest". The respect for autonomy and the principle of informed consent have been introduced into research ethics after World War II in order to protect individual participants in research from possible harm. Since the 1990s attempts are made to balance to balance individual rights and the public interest/common good as it has been suggested by communitarian-minded critics that people's individual freedom should be limited in order to promote some kind of public good (health, scientific knowledge, or security).

It is often claimed that SSH research is less likely to involve risk for human participants than biomedical research, which has far greater potential for physical injury, harm or adverse reaction. Whereas it is true that the potential for physical harm or inconvenience is rare in SSH research, sometimes there may be potential for psychological, social, economic, or legal harm.⁸ Thus, the assessment of risks and benefits still comes into play in planning and implementing SSH research.

⁷ Ron Iphofen, *Ethical Decision-Making in Social Research. A Practical Guide*, London: Palgrave Macmillan, 2009, p. 19.

⁸ A good overview of these harms and ameliorative measures have been produced by Joan E. Sieber, a member of the Social and Behavioral Sciences Working Group on Human Research Protections. Risk and Harm. 2004. <http://www.aera.net/humansubjects/risk-harm.pdf>

In order to protect the human subjects involved in SSH research, one has to understand the differences between SSH research and biomedical research, and be able to recognize the likely risks and harms associated with such research. While in some instances, the research activity itself could produce psychological discomfort or harm, in most cases the biggest risk in SSH research relates to the disclosure of a person's identity and insufficient protection of private information which may then lead to discrimination or stigmatization.⁹ Thus, the main effort should be devoted to safeguarding subjects' privacy and the confidentiality of the data processed in SSH research. It should be kept in mind that certain groups may be more vulnerable to harm from having information they provided be linked to them (illegal immigrants, victims of home violence, prostitutes, HIV-positive employees, etc). In these cases, standard procedures for obtaining written informed consent may be harmful to the subjects instead of offering protection and therefore need to be replaced by other measures of protection.

In preparing the ethics section, researchers should provide an assessment of risks, stating explicitly what kinds of harm might occur, the actual likelihood of subjects actually incurring such harm, and the available methods of ameliorating it. According to the UK Economic and Social Research Council,¹⁰ the following research would normally be considered as entailing more than minimal risk: research involving potentially vulnerable groups and people unable to consent; research involving sensitive topics and which might induce psychological stress, anxiety or humiliation; research involving deception; research where the safety of the researcher may be in question; research involving respondents through the Internet, in particular where visual images are used, and where sensitive issues are discussed or where participants and other individuals may be identifiable in the visual images used or generated.

It would be also important to distinguish between risks related to the research subjects, groups and the society as well as to the researchers themselves. Whereas there are many situations where SSH research can be said to be analogous to the biomedical research model, where research also often involves investigating the circumstances of vulnerable groups, there are many kinds of social research where the model of the powerful well-informed researcher and the vulnerable research subject does not apply. On the contrary, the balance of power and knowledge may be reversed. Examples might include research involving interviews with high-ranking political figures carried out by political scientists or research involving interviews with senior managers in transnational

⁹ Felice J. Levine, Paula R. Skedsvold, "Behavioral and Social Science Research". In E. J. Emanuel, C. Grady, R. A. Crouch, R. K. Lie, F. G. Miller, D. Wendler, *The Oxford Textbook of Clinical Research Ethics*. Oxford: Oxford University Press, 2008, pp. 336-355.

¹⁰ Economic and Social Research Council (ESRC) Framework for Research Ethics (UK, 2010). (http://www.esrc.ac.uk/images/Framework_for_Research_Ethics_tcm8-4586.pdf)

corporations carried out within the fields of business or organisational studies. Extending to such powerful figures the right to withhold or withdraw consent (which is clearly appropriate for vulnerable and ill-informed research subjects) can leave SSH researchers seriously disadvantaged, without even the most basic rights to make enquiries by other social groups, such as investigative journalists, or even ordinary citizens who might confront such figures at public meetings.

Even more importantly, there are many situations of social research where the personal interests of individual research subjects may be subordinated to more general social and collective interests. Examples of this involve the research into criminal behaviour, such as drug-dealing, human trafficking, child abuse or more mundane crimes such as tax avoidance or benefit fraud. In such cases any attempt to obtain informed consent in advance will of course seriously compromise the value of research. Even when a research topic does not involve activities that are formally defined as criminal, it may involve investigation of anti-social activities (such as playground bullying, binge drinking, xenophobic name-calling, football hooliganism, insensitive treatment of the handicapped, etc.) in situations where the research cannot be effective if the research subjects are formally notified in advance of the topic of the research, asked to sign consent forms, etc.

Thus, it is important not to apply the ethical principles (e.g. respect for autonomy and informed consent) in a blanket manner on the assumption that all research subjects are vulnerable. There is therefore a need for informed professional ethical judgement on how SSH research should be carried out in which the risks and benefits of participation in the research to individuals are carefully balanced against the risks and benefits to society as a whole.

Outline the anticipated benefits of conducting the research.

Describe the research findings which will help deliver better services, add value, change policy/practice or offer improved value for money.

Explain whether (and if so, how) the research will be of direct benefit to the site/organisation/community in which it is being conducted.

Explain the feasibility of implementing any findings.

Outline any harm that might occur, the actual likelihood of subjects actually incurring such harm, and the available methods of ameliorating the harm.

How will unforeseen or adverse events in the course of research be managed? (e.g. do you have procedures to deal with any disclosures from vulnerable participants, do you have procedures to deal with disclosures of criminal behaviour?)

Useful links to consider potential risks in SSH research:

http://www.esrc.ac.uk/images/Framework_for_Research_Ethics_tcm8-4586.pdf

<http://www.aera.net/humansubjects/risk-harm.pdf>

[See Project Risk Assessment Matrix in](#) Ron Iphofen. *Ethical Decision-Making in Social Research. A Practical Guide*. London: Palgrave Macmillan, 2009.

E. Methodology and research ethics in SSH

SSH research poses specific ethical issues in terms of **methodology**. This derives primarily from the research methods employed (for example quantitative, qualitative and observational studies). Research methods in social sciences and humanities are dynamic, progressive and developmental, therefore unforeseen risks at the beginning of a research could arise during the course of a study. It is recommended that researchers in SSH take a more systematic approach to risk assessment. The risk-based assessment should clearly consider not only individuals, but also give equal

consideration to society-based risks.

Particular emphasis should be placed on issues of data protection and privacy, the process of obtaining Informed Consent, stigmatization and discrimination. These aspects are highly relevant from an ethical perspective because research in SSH is often carried out over long periods of time and outside institutional settings; it focuses on time limited events, public behaviour, and contentious/stigmatized behaviour. It is within this context and along these lines that applicants should consider their proposed methodology carefully and in great detail. Given that SSH research involves very different degrees of interactions/intrusions with/on the research participants the ethical review of such proposals would be facilitated if these aspects are considered appropriately.

Of special importance are the ethical issues raised in qualitative research, the process of which is characterized by dynamic and evolving analytical approaches, as in ethnography, discourse analysis or oral history. During such studies, researchers act in a variety of social contexts and over long period of time. It is therefore difficult to anticipate at the beginning of the study all ethical issues that could arise; some of them become evident only in the course of research.

Another area of ethical concern pertains to the observational research that is central to much socio-psychological research. Observational approaches can vary (focused, participant, invasive/intrusive, visible, covert/overt; recorded rigorously using audio/visual methods or hand written notes compiled after the event). Researchers should ask themselves several questions concerning the research setting (e.g., is it public or private?), the behaviour under scrutiny (in a public or private setting), the way data is collected (recorded or not), and whether or not the protection of participants is ensured. For example, in the case of participatory observation it is advisable that the researcher have the skill and experience to ensure that there is nothing about their personal attributes that offends or intimidates the subjects.¹¹ When employing observational approaches in their study, researchers should devise a risk-management plan in case “sometimes does go wrong” in order to minimize/avoid the harm that might be inflicted on those observed. It has been observed that an ethical situationism tailored to the specific contexts and the development of study during the various phases of research could help researchers deal with the ethical issues encountered.¹² In this type of research, which usually includes fieldwork, the way relationships between researchers and research participant are established and how these develop during the course of the study must all be given equal consideration.

¹¹ Iphofen, Kraye, and Robinson, *Reviewing and Reading Social Care Research: From Ideas to Findings*, Bangor University, 2009, pp. 211-221.

¹² Rachel Hurdley, *In the Picture or Off the Wall? Ethical Regulation, Research Habitus, and Unpeopled Ethnography*, *Qualitative Inquiry*, 16 (2010): 517-28

All research proposals employing deception in research should give a strong justification for the use of this research method, demonstrating that there are no undisclosed risks (that are more than minimal), and including an assessment of the impact of the study. Researchers undertake an enormous responsibility when using deception with respect to the potential risks incurred by participants. In case deception is used, retrospective informed consent should be obtained and participants must be debriefed. Deception requires strong justification and appropriate assessment of the impact and the risk incurred both researchers and participants.¹³

F. Participating in SSH research

Human participation in SSH research is not obligatory and should be given proper justification. Whenever initiating a study in this field, researchers should consider the following: inclusion of adults, of children, of vulnerable groups (such as prisoners, immigrants, people with decreased mental capacity etc.). Applicants must justify the inclusion of these individuals/groups according to the main research objectives of the proposal. Special consideration should be given to vulnerable populations. Adopting a protective guardianship concerning the participation of members of such groups may not always be the best way to go. Depending on the nature of this involvement and the implications of the research results for the wellbeing of these individuals and the communities they belong to, appropriate measures should be in place in order to deal with the ethical concerns raised by the participation of such people. Participatory research is one such measure. When illiterate people are approached in order to obtain their participation in the research, it is often advisable to assess whether obtaining their consent in an ongoing and collaborative manner would ensure an ethical treatment of such participation.

On the other hand, there seem to be many cases of research – e.g. studies of behaviour in public places or the use of social media – where practices of obtaining consent are not truly relevant: therefore researchers should devise strategies of dealing with the ethical issues in accordance with the research questions, the status of existing knowledge / state-of-the-art and the availability of existing qualitative or quantitative data.

Researchers must recognize the right of the participants to withdraw from the investigation whenever and for whatever reason they wish. In all such circumstances researchers must examine their own actions to assess whether they have contributed to the decision to withdraw and whether a change of approach might persuade the participants to re-engage.

¹³ For example, Respect Code of ethics (www.respectproject.org/code) suggests that deception should be used only when there is no other ethically sound way of collecting accurate and appropriate data.

However, these are not the only ethical dilemmas that arise during this recruitment stage. Political or legal sensitivities, issues of coercion and/or undue influence should also be considered by the researchers. It should also be remembered that sometimes research in social sciences and humanities is dominated by different degrees of interactions and status between the researchers and the research participant (as for example when interviewing political leaders when conducting a study on political sciences).

Researchers in SSH such as archaeologists, historians, or art historians should also take into account the ethical aspects involved in the study of human remains. Attention has been called to the way public display of human remains might affect local communities and the preservation of cultural heritage. Ideas of protecting posthumous interests and the vital importance of ancestral human remains and sites where such remains are kept have surfaced in the debates of the last decades and found their way into various codes of ethics and international documents.¹⁴

Selecting, Recruiting, Retaining and Releasing Participants

Are you planning primary research or secondary research? Specify which research methods you are planning to use.

Who will be the research participants?

What are the inclusion and exclusion criteria?

How, where, and by whom will participants be identified, approached and recruited?

Are research participants selected equitably? Will any unequal relationships exist between anyone involved in the recruitment and the potential participants?

Is there a need for participants to be de-briefed? By whom?

Can participants opt out?

Researchers must consider the ethical implications not only for those participating in their research,

¹⁴ T. M. Wilkinson, Last Rights: the Ethics of Research on the Dead, *Journal of Applied Philosophy*, 19 (2002): 31-41. Useful guidance on how to deal with human remains can also be found in the Codes of Ethics adopted at the World Archaeological Congress, 1990, in The Vermillion Accord on Human Remains adopted in 1989 and the Tanaki Makauran Accord on the Display of Human remains and Sacred Objects adopted in 2006.

but also for the research team. Conflicts of interest and integrity of the researcher (freedom of the researcher, responsibility of the researcher, the possibility of pressure from some political groups or government to have access to certain results-- for example in sociology) should also be considered. Scientific integrity and proper conduct are essential for individual researchers and must also prevail in the functioning of the research teams. Research misconduct refers to falsification of results, fabrication of data and plagiarism; this has been identified as an ethical issue in the context of EU funded research and integrated into the EU's ethics oversight (screening, reviewing and auditing).¹⁵ Other moral, ethical and legal aspects worth considering are those concerning participation of students, the relationship among the members of the research team and the scientific responsibility towards research colleagues. The results of a focus group discussion conducted to identify specific ethical issues in the humanities revealed that because of the social and interactional nature of this type of research, interpersonal relationships are of high importance. On the one hand there is the responsibility to remain objective when assessing research results, but given the inherent subjectivity of these results (such as in performing arts or musicology), researchers are confronted with other ethical tensions. Similarly, supervisors of students should try to balance the need for guidance and mentorship with the necessity to allow students to freely develop their own research interests. Ethical tensions concern issues of intellectual property, protection of the sources of information and of the data obtained.¹⁶

The research team should pay attention to the following aspects:

- scientific integrity and academic freedom must govern the functioning of the research team
- scientific responsibility is at the core of any research enterprise
- involvement of students in research experiments is subject to same ethical requirements as the other research participants
- refer to the European Charter for Researchers, The Code of Conduct for the Recruitment of Researchers and the relevant professional codes

Useful link: http://europa.eu.int/comm/research/rtdinfo/index_en.html

¹⁵ Johannes Rath, A Comprehensive Strategy on How to Minimize Research Misconduct and the Potential Misuse of Research in EU Funded Research, 2010. (http://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf)

¹⁶ Cheryl K. Stenmark & Alison L. Antes & Laura E. Martin & Zhanna Bagdasarov & James F. Johnson & Lynn D. Devenport & Michael D. Mumford, Ethics in the Humanities: Findings from Focus Groups, *Journal of Academic Ethics*, (published online November 2010, Springer)

G. Obtaining informed consent

Informed consent: this is the most critical part in SSH research and a very detailed informed consent is a crucial requirement in SSH research. Although informed consent procedures are primarily derived from a human biomedical research model, there are nevertheless important aspects that SSH researchers must take into account. For example, the power relationship between the investigator and research participants, the vulnerability of the population under study, the impact of the research results on individuals and communities, with particular emphasis placed on avoiding stigmatization and discrimination. All relevant aspects from this list should be given thorough consideration in research protocols.

The process of obtaining Informed Consent (IC) is neither easy, nor is it necessarily time limited. SSH researchers must pay close attention to the way research participants are approached. In many cases consent is obtained from family or community leaders only to approach individuals, but this should not substitute an individually obtained consent. In case of people not able to consent (e.g. children), parents/legal representatives consent and children`s assent are necessary. Many times, particularly when research consists of fieldwork, obtaining informed consent might not be a one-time event, but should rather be regarded as an ongoing process, which might evolve differently from what was anticipated before beginning research.

When seeking to obtain individual, written consent from research participants, researchers should take into account the cultural and ethical norms of the population(s) under study. In case a written consent does not respond to the ethical norms of those studied, the applicant must provide alternative ways of obtaining consent (such as recording the oral consent, the presence of witnesses, all procedures used must be documented). In case of participants who for any reason are not fully capable of understanding and expressing their will, the IC should be replaced by other robust protective measures. Sometimes the collection of written informed consent may bring participants under danger as their anonymity will no longer be guaranteed.

In case of observational studies, reasonable IC should be obtained from all participants, and approval from the gatekeepers before the beginning of the study; if individuals cannot be identified, then individual consent might be sought after the study is finished. Depending on the nature of the study, observation of people in a completely public environment might not require consent, but researchers have to demonstrate that their study would in no way alter the usual behaviour of those under scrutiny and that their privacy would be respected.

As has been detailed above, deception raises complex ethical issues, particularly because it impacts

the informed consent process, one of the most important safeguarding mechanisms for participation in research. The applicants should clearly describe the exact content of the “modified truth” or the “misleading information” that is going to be used, whilst at the same time specifying that these deviations from the truth will not impose any short or long term hazard for the participating subject. By the end of the study, researchers should undertake the obligation to reveal to the participants the misleading information that was used during their involvement in the protocol and explain to them the necessity of its use. Clear justification is needed for the use of deception; ideally participants should be informed afterwards about the deception and why it was deployed. It is better to provide less information on any informed consent form rather than providing misleading information on this form.

In SSH research it can be permissible or even encouraged that consent be renegotiated should the inquiry move in unanticipated new directions. The methodological limitations on gaining “fully informed” consent would have to be made clear at the outset.

While it is not essential to submit the informed consent documents to the European Commission in your grant application, you need to demonstrate a good understanding of the issues in your ethics section. Ideally, you can include a sample informed consent document and Information Sheet which contains information about who will be the researchers, sources of the funding, aims/purpose of the study, how subjects will be selected and recruited, research procedures, risks/discomfort anticipated, who will benefit from the study, how findings will be disseminated (incl. feedback to the participants), steps taken to protect the privacy and confidentiality of the data.

In the process of obtaining informed consent you should keep in mind the following questions:

Will the voluntary informed consent be sought?

How will consent be gained and/or recorded and by whom?

How will the competence of participants to give informed consent be determined?

What information will participants be given about the research? Does the information sheet contain all the information participants need?

Will the participants be informed that participation is voluntary, that consent can be refused, and that withdrawal is possible at any time?

If the study is being undertaken in a developing country, where written consent is not common practice, detail what practices you will apply to obtain informed consent (e.g. with witnesses, following local customs, having it video or audio recorded etc).

Are there any reasons for not seeking consent?

Is there any need for incomplete disclosure? Would some form of deception be used? Would this harm the research participants, the researchers and/or society in general in any way?

If your research changes, how will consent be renegotiated?

As the process of obtaining Informed Consent is complex and since it is considered one of the most important safeguarding mechanisms in research, the sections of the Ethical Issues Table also refer to children and vulnerable adults. If you are involving children in your research you should devise appropriate strategies of informing them about their participation (for example by using audio or video materials, posters, flyers, suitable to their age and understanding). Children who are capable of forming their own views should be granted the right to express their views freely in all matters affecting them, commensurate with their age and maturity.

In the case of participants whose age, intellectual capability or other vulnerable circumstance may limit the extent to which they can be expected to understand and agree voluntarily to undertake their role, researchers must also seek the collaboration and approval of those who act in guardianship (e.g. parents) or as 'responsible others'.

If participants may experience distress or discomfort in the research process you should take necessary steps to reduce the sense of intrusion and take care of the participants well-being (e.g., when interviewing on the topic of the death of close relatives, or an experience of violence, a psychologist should be provided for support).

Children and vulnerable adults

Will any vulnerable subjects be recruited, (e.g. children, people with disabilities, elderly, pregnant women, prisoners, armed services personnel, immigrants etc.)?

If you are using vulnerable subjects justify this and explain exactly what procedures will

be undertaken.

Justify how many subjects will be used in your study and give inclusion and exclusion criteria.

Specify exactly what information you will collect and what you will do with it.

Specify how informed consent/assent will be obtained.

State any expected harm and benefit to the vulnerable subjects.

If you use vulnerable adults with reduced capacity to consent (e.g. elderly patients in a residential home with advanced Alzheimer's), particular attention should be given to how informed consent will be obtained, and support provided, if necessary.

Children should be facilitated to give fully informed consent.

Ensure that the best interests of the child will be your primary consideration.

Ensure that researchers and any collaborators or research assistants and students under their supervision comply with legal requirements in relation to working with children or vulnerable young people and adults.

Special attention should be paid when making photos, audio and video recordings and other communication materials that depict vulnerable populations, (e.g. children) produced in the research projects.

Useful link concerning child protection and safeguarding policy www.ahgtm.ac.uk

H. Protecting personal data and privacy

Researchers must consider protection of personal data, but also data that refer to/is or has been obtained from various settings (such as cultural heritage, public space, video and audio recordings, mapping etc.). There are three different categories to which data protection refer: the users, the providers and the environment. All these different aspects must be taken into account when devising mechanisms for data protection in the course of research (including publication of findings and dissemination to the general public). There is an internationally recognized and globally accepted standard (such as [ISO/IEC 27001:2005](http://www.iso.org/iso/standards/catalogue_tc/list_standards.html?csnumber=7200)) that can be used by SSH researchers.

It is not always possible to anticipate the ways in which data obtained will be used, therefore

informing research participants at the beginning of the study about the uses of the data they provide will not always be sufficient to safeguard their interests and to protect them; ongoing communication with them is therefore highly recommended.¹⁷ Researchers in social sciences and humanities must consider the ethical implications of this aspect.

There are different understandings of privacy in different cultural contexts. Privacy is a contested concept: it is the right to be left alone, but it can also be something positioned at the interface between private life and public life. It entails a dynamic relationship between private persons in different situations and different degrees of interaction. It is crucial to respect the privacy of research participants, but in SSH research there are other relevant rights' holders the researchers should consider. It is therefore important to detail the purpose of the research according to the different understandings and legal definitions of privacy.¹⁸ For example in "covert research," researchers should take into account the meanings of public and private in the contexts they are studying. Covert observation should only proceed if researchers can demonstrate clear benefits of the research, when no other research approach seems possible and when it is reasonably certain that no one will be harmed or suffer as a result of the observation.

Researchers must ensure that data is kept securely and that the form of any publication, including publication on the Internet, neither directly nor indirectly leads to a breach of agreed confidentiality and anonymity. In some rare cases there may be a need to override agreements on confidentiality and anonymity (e.g. if maintaining confidentiality agreements facilitates continuation of illegal behaviour which has come to light in the course of the research). In such circumstances the researchers must carefully consider making disclosure to the appropriate authorities. Insofar as it does not undermine disclosure, researchers must appraise the participants or their guardians or responsible others of their intentions and reasons for disclosure.

¹⁷ Pamela Innes, Ethical Problems in Archival Research: Beyond Accessibility, *Language and Communication*, 30 (2010): 198-203

¹⁸ For the legal definition of this concept see The Universal Declaration of Human Rights Article 12 and Article 8 of the European Convention on Human Rights.

Maintaining Privacy and Confidentiality

What type of data will be collected? Justify if any personal data will be collected. State that only relevant data will be collected and this will not be more than what is needed for the research study.

Describe in detail all data protection measures, providing evidence that the confidentiality of the participants will be ensured according to the relevant EU standards (see e.g. EU Directive 95/46/EC).

Have you considered anonymity and confidentiality? Clarify whether the data will be anonymised (link to the data will be destroyed) or coded (the data will be reversible). Explain how you will ensure data protection and how any link to the research participants will be handled if not fully anonymised.

If the data will not be anonymised, explain why you cannot anonymise the data (e.g. you need to recontact the participants or do follow-up in case of long-term study). If the data will be coded, describe the coding system, and who will have access to the code. Confirm that it cannot be tracked back to individuals unless essential for the study.

How will you store your collected data? Explain how and where the data will be stored and for how long?

How will data be disposed of and after how long? Explain what will happen with the data after the completion of the research.

If using secondary data, does the consent from the primary data cover further analysis? If not, explain how new consent will be obtained for the reuse of the data.

Explain if any information could lead to stigmatization, depending on how it is collected.

Useful document: Caroline Gans-Combe, Data Protection and Privacy Ethical Guidelines

http://cordis.europa.eu/fp7/ethics_en.html (click on Privacy in the Ethics checklist)

I. Research in non EU-Countries (Developing Countries)

Non-EU countries, especially developing countries (DCs) represent a very wide and constantly changing, variety of situations. Many of the ethical issues that are specific to these countries originate from the potential vulnerability of local stakeholders

Some overall considerations apply to all research projects in DCs:

1. The research must be responsive to the needs of the country where it is carried out (e.g. the study must have value for the welfare of the intended participants, their community, and/or their country). This issue is of critical relevance for emerging and developing countries.
2. Sensitivity must be shown to local conditions. Explain how your research proposal fits into local customs and practices.
3. It is also important to indicate how the results of your research can be applied in the developing country.
4. Ideally your application will also be able to show that you are helping build local capacities by conducting research in developing countries and by bringing something extra to the community.
5. If appropriate, state that you are planning to discuss in advance the planned research and dissemination of the results with relevant parties in the developing society.
6. The research needs to adhere to FP7 ethics requirements and the research must abide by relevant local and international laws and guidelines.
7. As for doing research in non-EU countries, you also need the approval of the host countries which will judge the ethical acceptability of the research in accord with the customs and traditions of the society concerned.

Useful document on how to do research in developing countries can be found at:

ftp://ftp.cordis.europa.eu/pub/fp7/docs/developing-countries_en.pdf

J. Ethical review process. Ethical approvals

Applicants should identify the relevant national/local legislation and guidelines concerning data protection and human participation in research. They should also mention whether local ethical committees are in place and whether or not ethical approval is required in the country where the research will be carried out. In case such committees do not exist, the applicant should refer to the ethical principles that would govern the proposed research and the relevant international legislation and regulation to be followed (such as the European Charter for Researchers, The European Charter of Fundamental Rights etc.)

In some but not all countries there are special ethics committees for dealing with SSH research projects. If EC requires ethical approval of the local/national ethics committee, this may cause a situation where SSH projects will be examined by ethics committees set up for assessing projects in biomedical research. Their competence may not allow giving a fair judgment of the ethical aspects of SSH projects. On the other hand, the clear requirement to obtain the approval also for SSH projects may speed up the process of establishing the ethical committees for research in SSH.

Given the developmental nature of SSH research prior approval is not always the best solution. Particularly qualitative research may need “flexible protocols”, where the research is adapted according to a stepwise approach, depending on interim findings from focus groups, surveys, questionnaires etc. Such projects could be approved, but only if the researchers define limits of the flexibility and describe how they will handle new problems as they occur, such as privacy or exploitation. Interim reporting on a regular basis or as /when ethical challenges emerge is a normal requirement. The applicants could also be required to establish ethical boards to oversee the conduct of the study, including interim results, subject attrition, unanticipated events, etc. before changes are made to the approved protocol. This might not be possible in traditional ethnographic studies but may be applicable to community-based research. In research projects involving observational approaches, observation schedules should be drafted. They must be clearly structured to allow for easy data recording-issues of anonymity and confidentiality: links between sources of data and individual cases must be anonymised immediately and known only to those permitted. When deception is used, the Ethics Review Board should thoroughly examine the potential of any hazardous consequences for the subjects and in case of a negative conclusion, grant permission for this particular manipulation. It is advisable that applicants include ongoing ethical monitoring in the management section of the project.

Local ethics committees and authorizations of competent bodies

Specify if your research already has been given ethical approval at the local or national level. If so, it will aid your application to submit a copy of this approval in your application. If not, specify which Ethics Committee is most appropriate for your research. Have you considered the time you need to gain ethics approval?

In case of multinational research, ethical approvals for the planned research should be obtained from the ethical committee of the country of the researcher as well as from the committees where the research (or parts of the research) will be

performed.

Have you considered what legislation your project will need to abide by?

How will the ethics aspects of the project be monitored throughout its course?

If the research methodology, techniques or protocols that will be used within the project will raise complex sensitive ethical issues, it is advisable to appoint an expert in ethics or an independent ethics advisory board, or in case of major potential ethical challenges, include a work package on ethics.

Useful link for the Ethics Review and the FP7 Ethics Framework at http://cordis.europa.eu/fp7/ethics_en.html#ethics_cl

K. Recommendations

As a result of online discussions among the experts involved in the ethical review system set up by the European Commission, the 8th December 2010 workshop devoted to the ethical issues in SSH and the opinions formulated by external experts, the following list of recommendations emerged:

1. In what concerns The Ethical Review Boards:

- the composition of the ethical review boards should be interdisciplinary, thus ensuring that the peculiarities of SSH research would benefit of appropriate consideration during the review process.

- As effective local/national structures have been put in place for the ethical review of biomedical projects, the imperative is to outline similar procedures for projects in SSH area

national or regional ethical committees to assess and approve SSH research projects should be established

- the ethical review boards should check whether or not legal and ethical obligations were considered by the applicants

- EC should initiate training courses for national/local ethical review committees

- Competent authorities in each countries should be encouraged to adopt a uniform assessment. Networking among ethical committees could significantly contribute to the development of such uniform assessment.

2. In what concerns The Ethical Issues Table:

- it should be modified so as to more fully reflect the daily research questions encountered in SSH

research

- it should be devised as follows: clinical/non clinical research; impact of the research results (psychologically, socially etc.); the use of data in public domain; research involving indigenous population; observing people, internal ethical review system in your institution; vulnerable population (in terms of legal and/or economic status, age, gender, etc.), data protection and privacy, informed consent process, discrimination and stigmatization, dual use/misuse, misconduct, research activities in developing countries or countries with emerging economies
- two separate questions should be introduced: genetic information and personal data; and quantitative/qualitative data;
- methodology and management of ethical issues
- this relevant checklist should be put on the website; it should be responsive and adaptable; the same checklist should be used by the applicants and the reviewers

In what concerns The Guide for Applicants:

- it would be desirable to have an ethical checklist included in Part A of the proposal and in Part B the ethical issues being integrated into the state-of-the art discussion, methodology, management of the project, risk contingency plan and dissemination
 - it should be highlighted in the application forms that in order for an application to be considered complete and eligible, the applicant must provide details on the ethical issues raised by his/her proposal
 - it should include guidance notes on addressing ethical issues in SSH research
- guidelines should be addressed to both policy makers and national/local authorities
- the applicants are encouraged to follow the terms of national or disciplinary-specific ethical codes in the conduct of their research (for example RESPECT Code of Practice)

In what concerns the Raising Awareness Process:

- development of promotional material for SSH researchers
- specific/standardized educational training programmes through the National Contact Points (NCPs)
- training for commission staff on handling ethical issues in SSH research
- supporting documents for SSH researchers should be available on the Cordis website, but also be presented at the information days (at national and EU level)

- case studies reflecting the experience of the present FP7 funded projects should be presented in training workshops and online
- EU Member States should be encouraged to introduce legal regulation of the use of data about identifiable individuals for the purpose of research, including bodies to supervise and enforce the regulation, if such regulations do not already exist
- professional bodies should be involved through the National Contact Points to participate actively in the training programmes and workshops
- the coordinators of current FP7 projects could be requested to comment on their experience (obtaining ethical approvals, including ethics in their research strategy, experience of ethical audit etc.). This experience could be used as best practice/case studies to be included in the training programmes
- include links in the CORDIS “Find a Document” list, relevant DG websites, national research references, sectoral research associations
- printed materials: applicant guides, good practices and flyers to distribute at events

L. Reading materials and links

Supporting documents for preparing the Ethical Issues Section of your grant application

One of the key EU web pages to review is Sinapse <http://europa.eu/sinapse/sinapse/>. This has all the latest documents related to research on humans as well as guidelines for researchers.

Getting through Ethics Review http://cordis.europa.eu/fp7/ethics_en.html

The EU gets tough on ethics. <ftp://ftp.cordis.europa.eu/pub/fp7/docs/technology-ireland.pdf>

Ethics Review and the FP7 Ethics Framework ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-review-fp7-ethics-framework_en.ppt

Ethics for Researchers. Facilitating Research Excellence in FP7 (2007).
<ftp://ftp.cordis.europa.eu/pub/fp7/docs/ethics-for-researchers.pdf>

Integrating Ethics in EU Research. <ftp://ftp.cordis.europa.eu/pub/fp7/docs/integrating-ethics.pdf>

A Comprehensive Strategy of how to minimize research misconduct and the potential misuse of research in EU funded research ftp://ftp.cordis.europa.eu/pub/fp7/docs/misconduct-misuse_en.pdf

Charter of Fundamental Rights of the European Union (2000)

http://www.europarl.europa.eu/charter/default_en.htm

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

(2005). <http://ec.europa.eu/euraxess/index.cfm/rights/index>

Professional guidelines and codes of conduct

A list of the most well-known codes of ethics of international professional associations in social research, collected in the framework of the EU-funded RESPECT project is available at:

<http://www.respectproject.org/ethics/412ethics.pdf>

Academy of Criminal Justice Science. *Code of Ethics* (2000).

http://www.acjs.org/pubs/167_671_2922.cfm

American Anthropological Association. *Code of Ethics* (1998).

<http://www.aaanet.org/committees/ethics/ethicscode.pdf>

American Association for the Advancement of Science. *Ethical and Legal Aspects of Human Subjects Research on the Internet* (1999).

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American Association for Public Opinion Research. *Code of Professional Ethics and Practice*

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American Educational Research Association. *Ethical Standards of the American Educational Research Association* (2000).

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The American Political Science Association. *A Guide to Professional Ethics in Political Science.*

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The American Psychological Association. *Ethical Principles of Psychologists and Code of Conduct*

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American Sociological Association. *Code of Ethics and Policies and Procedures of the ASA*

Committee on Professional Ethics (1999). <http://www.asanet.org/about/ethics.cfm>

- Association of Internet Researchers. *Ethical Decision-Making and Internet Research* (2002).
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- Association of Social Anthropologists of the UK and Commonwealth. *Ethical Guidelines for Good Research Practice* (1999). <http://www.nomadit.net/asatest/ethics/guidelines.htm>
- Australian Government, National Health and Medical Research Council, Australian Research Council, and Australian Vice-Chancellors' Committee. *National Statement on Ethical Conduct in Human Research* (2007).
http://www.nhmrc.gov.au/_files_nhmrc/file/publications/synopses/e72-jul09.pdf
- Australian Market and Social Research Society (AMSRS). *Code of Professional Behaviour*
http://www.mrsa.com.au/files/Code_of_Professional_Behaviour.pdf
- British Educational Research Association (BERA). *Revised Ethical Guidelines for Educational Research* (2004). <http://www.bera.ac.uk/files/guidelines/ethical1.pdf>
- British Society of Criminology. *Code of Ethics for Researchers in the field of Criminology* (2006).
<http://www.britisocrim.org/codeofethics.htm>
- British Sociological Association. *Statement of Ethical Practice for the British Sociological Association* (2002). <http://www.britisoc.co.uk/equality/Statement+Ethical+Practice.htm>
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- Council on Social Work Education. *National Statement on Research Integrity in Social Work* (2006). <http://www.cswe.org/cms/17157.aspx>
- Economic and Social Research Council (ESRC, UK). *Framework for Research Ethics* (2010).
http://www.esrc.ac.uk/_images/Framework_for_Research_Ethics_tcm8-4586.pdf
- ESOMAR. *Tape and Video Recording and Client Observation of Interviews and Group Discussions* (1996).
http://www.esomar.org/uploads/pdf/ESOMAR_Codes&Guidelines_TapeAndVideoResearc

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The Ethics Committee of the British Psychological Society. *Code of Ethics and Conduct*. (2009).
http://www.ucl.ac.uk/educationalpsychology/resources/BPS%20Code_of_Ethics_Conduct.pdf

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UK Research Integrity Office. *Code of Practice for Research* (2009).

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UNICEF Evaluation Office. *Children Participating in Research, Monitoring And Evaluation*

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