InSPIRES

Ingenious Science Shops to promote Participatory Innovation, Research and Equity in Science

D8.2: Final report on ethical framework and procedures

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1. Introduction

As a starting point, all project partners were informed since the beginning of the project of their corresponding national regulations as well as established institutional processes. In addition, the coordinator defined minimum overarching ethical processes to be followed throughout the entire life of the project through the elaboration of three initial deliverables, and have ensured constant training on these aspects when needed by partners. These deliverables framed and described the code of conduct for all the participating researchers. By doing so, it also reinforced the nature of InSPIRES as a Responsible Research and Innovation (RRI) project, putting ethics at the core of its practices.

Since InSPIRES partners knew from the start that the research projects they will work on were in the area of environment and health with a specific focus on vulnerable groups, we foreseen that sensitive data were going to be handled. Thus, a solid ethical framework was needed to regulate all actions and make sure all partners complied with national, European and international regulations. Considering the importance of gathering such sensitive data, a data management plan was also developed, describing how the collection, analysis, and storage of data had to occur. This plan, corresponding to Del 8.1, was approved by all consortium members during the first Steering Committee of the project.

The present report showcases the main results of a study conducted in two phases. The first phase aimed to assess the procedural aspects of ethical issues within each Science shop project (80 projects) with the goal of making quantitative assessments of the readiness level of each of the partners. We assessed how they managed the ethical committees and ethical approval reviewing process. We also assessed how they handled the data collection, processing, sharing and storage, and how they have managed sensitive data and vulnerable groups of participants.

The second phase was a qualitative assessment of specific ethical practices in science shop projects in order to identify lessons learned, challenges faced, and strategies to overcome these challenges in eight selected science shop projects implementation - one project per partner. The eight projects were selected at the end of phase one on the basis of ethical challenges faced (the most challenging projects were selected) and the type of vulnerable groups studied. Considering the importance given to ethics within the framework of the InSPIRES project and in order to ensure that all committed actions regarding ethical

aspects were respected, we conducted this deeper analysis in order to assess ethical practices in a representative sample of the consortium science shop projects.

2. Report on ethical procedures of the InSPIRES Science Shops

2.1 Objectives of the phase one of the study on ethics

The main objectives of this study were to review and control the ethical procedures followed by each partner institutions.

2.2 Methodology

We developed a simple questionnaire to collect data on existing institutional guidance and templates, data management plan and procedures, management of vulnerable participants, conventions and agreements between stakeholders to assess the preparedness of the consortium members for this final ethical audit. At the end of this first study phase, a specific question regarding ethical challenges faced during project implementation was asked in order to help them in the selection of the most challenging project in terms of identification of vulnerable human participants groups for the phase II of this study, as described in the section 3.

2.3 Data collection and analysis

After sending out the questionnaire, we noted that most science shop coordinators faced some difficulties to clearly comprehend some questions, particularly those on ethical challenges faced during projects implementation, data management policies and institutional data protection officer role. This was the case particularly for coordinators from non-medical or biomedical backgrounds who are not so familiar with strict ethical regulations. Therefore, face-to-face meetings were scheduled in order to guide these participants in their reflections and questionnaire responses. By noting such gaps in ethical literacy between partners we added questions regarding the Science shop host institution type (academic or SMEs), presence or absence of ethical and/or scientific committees and even asked if they submit

systematically research protocols to ethical committee when human sensitive data are involved. These questions were very useful to assess the Science shop environment and framework, which significantly influenced their ethical awareness and practices. All information and data gathered from each partner through the questionnaire have been manually analyzed.

2.4 Presentation of results and discussion

2.4.1 Procedural aspects

This section describes the host institution profile and ethical procedures as well as ethical committees reviewing process.

Five out of eight science shops are hosted by academic institutions/universities or public research institute. All of them have institutional ethical committees and so far only one has a registered International Reviewing Board (IRB) in the Office of Human Research Protection (OHRP) in the USA. Regarding the availability of templates, four of them have templates for informed consent and three had templates for project design and informed consent. Interestingly, two private institutions also have templates for informed consent, image/photos use even though they are not academic institutions. This is probably due to the fact that they pertain to the public network of research institutions of their country as well as to the type of research projects (health) they are involved in with hospitals.

Indeed, we observed that institutions working on health research projects involving human participants seemed to be more aware about ethical aspects and more familiar with informed consent forms and ethical committees' approvals.

One of these private research institutes (not academic) has an ethical committee with available templates as guides. They both had a good knowledge and awareness of ethical procedures and practices and are aware of sensitive data protection.

A SME (not academic) working on an environmental research project essentially had no ethical committee and consequently no templates since they usually do not need any ethical clearances. However, they do have a scientific "seniors" committee meeting during which they pay special attention to particular

research questions when conducting environmental projects directly linked to human participants. This committee involves some expert seniors who are familiar with ethical aspects and agree on the best approach or protocol to adapt in compliance with the EU GDPR.

2.4.2 Sensitive data management policy / strategy and data protection officer

We observed that not all partner institutions have data management policies (collection, processing/ treatment, archiving and sharing) but they all tried to follow the international recommendations and procedures in data protection and management. These policies helped project investigators in the management of their data, particularly sensitive data, and guided them when they have to adapt particular data protection concerns.

Regarding the presence of institutional data protection officer (DPO), four institutions have a DPO (one of them has an external DPO), three institutions do not have a DPO and among these two it is the ethical committee that is in charge of data management counselling.

Interestingly, one institution partner had formalized since 2020 a data management plan at institutional level that apply for all projects (became compulsory for projects). This formalization emphasizes the increased awareness and importance according to issues related to data management and had significantly influenced the setting-up of an ethical culture in the institution.

2.4.3 Use of project agreements

Regarding formal collaborative agreements (i.e. memorandum of understanding or conventions) between all stakeholders taking part of a Science shop, three Science shops had not used any agreements between partners since it was not necessary. Two other partners had used conventions, one of them only between students, supervisors and universities (academic version for student internships) and three only had used conventions including all stakeholders even with civil society organizations. Such partnership formalization seemed to significantly impact the relationship between the actors taking part of a project and how they agreed on limiting and sharing their roles and responsibilities particularly when facing barriers and challenges.

2.4.4 *Identification of vulnerable groups and informed consent forms*

Each partner identified projects involving human participants particularly those involving vulnerable groups such as minority groups (migrants), people living with neglected and stigmatized diseases, minors, people living a disease, etc.

Project principal investigators as well as science shop coordinators gave particular attention to these groups of participants and used informed consent for the majority of Science shop. However some science shops, private institutions in particular who do not have ethical committees did not use informed consent systematically. Additionally, several projects did not involve vulnerable participants and other projects did not involve human participants.

2.4.5 *Most frequent ethical challenges faced during science shop project implementation*

One of the most important challenge faced was in regards with the access and utilization of written consent for illiterate and inaccessible participants (i.e. minorities and people with neglected diseases).

Another challenge was the dissemination of the results and results ownership between academic and civil organizations included in the project.

Dealing with stigmatized diseases was also identified as a significant challenge faced since it is difficult to obtain consent from stigmatized participants.

The ethical committee's reviewing process represented also an important challenge since the ethical committee’s clearance takes a lot of time to be obtained.

Limiting and sharing responsibilities between each stakeholder in the conception and implementation of the project was also a challenge with regards to preserving equity between different partners.

In addition, ethical knowledge and literacy was limited for some actors specially from civil society members and researchers from non-health backgrounds. Low ethical literacy was also been observed among health practitioners in some projects such as nurses and technicians, and also some doctors and senior academic researchers, highlighting the importance of training on ethical aspects among all the partners.

2.4.6 *Meaning of Ethics*

Through this question partners expressed their own definition of the term ethics and several definitions have been formulated such as: integrity, morality, fairness, equity, respect, code of conduct, inclusion, care, protection, responsibility, conscious attention, equal partnership, moral compass, honesty & open communication, going beyond what is required and compulsory, quality assurance, protection of sensitive and personal data, fair participation from the beginning to the end.

In conclusion, we observed that all partners had differences in their institutional processes, due to their different institutional settings and disciplines. However, all eight partners were well aware of their national regulations and had already established institutional processes to ensure that research and innovation was conducted ethically with regards to research collaborators from civil societies.

3. Report on ethical challenges encountered in participatory research

3.1 Objective of the second phase of the study on ethics

The main objective of this second phase was to assess community-based participatory research (CBPR) ethical practices and challenges faced when implementing eight selected science shops projects. We also aimed at identifying lessons learned from science shop project strategies setted-up to overcome obstacles.

3.2 Project design and methodology

We performed a qualitative study based on semi-directed interviews of each of the eight participating institutions. The interview guide questions were based on the four ethical pillars of CBPR. The first pillar pertains to the inclusivity of all partners within the research process. This includes the origin of the research question (How did the research question emerge?) and the co-construction of the project design and methodology. The second ethical pillar involves ethical literacy and knowledge of participants and stakeholders. It is meant to evaluate the level of familiarity and understanding from all participants and

partners involved in research pertaining to ethical principles, guidelines and recommendations. The third ethical pillar is about stigma, confidentiality, sensitive data protection, autonomy, and consent. And lastly, the fourth pillar pertains to dissemination, ownership, and benefit sharing of research results. It is intended to evaluate how the research results are publicly disseminated after completion of the project and who owns the rights to the data/results and who the information/results are shared with. All these aspects of CBPR Ethics were elaborated based on a revue of literature in the field.

Through this phase II of the study and following a qualitative descriptive case study approach, we questioned and analyzed more in depth CBPR ethical practices in the eight selected research projects included in phase I.

The sample interviewed in phase II was composed by the most challenging science shop projects including vulnerable groups as participants. These projects have been selected jointly by science shop coordinators and researchers. Vulnerable groups identified and selected are minors, women with mental disorders (some pregnant), people living with HIV, people with drug addictions, homeless persons, and people with stigmatizing diseases such as Chagas disease.

Selected projects had an academic investigator and a civil society partner. Interviews were designed for this. Both civil society and researcher partners feedback were mandatory for the interviews.

Eight interviews were conducted based on the design of semi-structured interviews lasting between 1-2 hours and were recorded after interviewees consent, fully transcribed, and coded on the qualitative data free online software, QCAmap.

The semi-structured interviews guideline was designed by the authors of this deliverable based on literature review on ethics in CBPR with focus on ethical pillars in participatory research. It was also developed to be complimentary with the Phase I questionnaire.

In total, 20 individuals were interviewed through eight semi-structured interviews, divided as such: eight project PIs and the CSO number varied from none to three representatives and the number of people in each interview varied but they were group interviews having anywhere between 1-6 members with an average of two participants per interview. For one partner, the civil society partner was not able to participate because of a language barrier, but science shop coordinators got their written translated feedback to several questions. Two partners' interviews were conducted in French and were translated and transcribed in English afterward.

3.3 Data collection and analysis

Interviews were transcribed and we used the thematic analysis methodology to analyze the data. It allowed us to highlight some pathways in ethical practices and challenges faced by partners. These responses were analyzed using inductive and deductive thematic analysis on the software, QCAmap.

3.4 Setbacks identified

There were several obstacles when collecting the phase II data. The major set-back being time constraints with scheduling people for interviews. This was a trans-continental project with teams of people in The Netherlands, Spain, Italy, Tunisia, Bolivia, Hungary, and France. There were issues with time differences, COVID-19 restrictions varying in every country and partners' agenda. There were also potential miscommunications with the interview questions being redundant; this was due to weaknesses in the question guide conception and potential language barriers of the trans-continental collaboration. Another critical challenge was that in some instances the civil society partners could not join the interviews and provided written feedback instead so interview questions had to be modified for this. Three out of the eight interviews were also conducted in French and then later transcribed to English so there is potential of some information having imperfect translations and therefore coding could have been misinterpreted. Lastly, due to time constraints and scheduling conflicts interviews had CSOs, PIs, and academic teams all being interviewed together. This could have led to biased results in the interviews and lack of complete transparency is answers because of the lack of privacy and freedom in the interviews with everyone having to answer questions in front of one another.

3.5 Presentation of results and discussion

The main results of this study showed that projects involving stakeholders from conception of the project to result dissemination had higher levels of community inclusion and participation. Also, projects involving civil society members or other civil society stakeholder groups for the enrollment of participants had lower level of stigmatization of vulnerable groups because oftentimes the third-party group was an organization that are used to work with the particular vulnerable group being studied and therefore was better suited for selection and protection of the rights of these individuals with whom they have a trusted relationship.

Recommendations to consider would be to create dissemination plans of results with the stakeholders from the beginning of the project. The dissemination of projects should include the community and all stakeholders involved and not just be shared via academic papers, usually required for academic careers, that are oftentimes not inclusive of participants belonging to vulnerable groups or community members/stakeholders.

Regarding data and results ownership, we noted that academicians tended to take power over the research process particularly on research data and results since they considered that they had the ownership on these issues regarding their familiarity with data analysis and results dissemination (international publication and academic dissemination events). However, within science shop projects involved in this study, most academic partners shared gathered data with their CSO partners but not for research results. Hence what is recommended to do in such participatory projects is that all partners have to agree from the start on the data and results ownership model and agree on the data protection approach they will use in order to share responsibilities and benefits from those data and results with ensuring the participants anonymity and sensitive data protection.

There was also a lack of formalized measurement of ethical literacy of participants and stakeholders. Oftentimes, ethical literacy was assumed by the academic institution or civil society organization. This study highlighted that academic institutions had a higher level of ethical literacy as well as institutions working in the health area. In addition, civil society partners had moderate familiarity with some ethical issues particularly regarding data management policies, results dissemination and internal ethical review procedures but had a better understanding and awareness of participant anonymity and protection from stigma since they used to work with communities and vulnerable groups.

It would behoove institutions hosting participatory projects to create formalized ethical literacy measurements for stakeholders and participants in CBPR projects in order to ensure that all members of projects are fully aware of their rights.

3.6 Conclusion

As shown, ethics must be integrated throughout the research and innovation process particularly in 1) Policy development and agenda setting, choosing the appropriate targets that safeguard and foster human lives and the environment, 2) formulation of the funding call, by incorporating ethical aspects such as gender sensitivity, cultural diversity, integrity/conduct requirements, risk analysis and socio-ethical considerations and 3) project definition, implementation and evaluation that must be culturally deliberative and have open integrity. Thus, reflection should be facilitated in both project-based structures and in research and innovation organizations.

Responsible research and innovation can be expressed in many forms of methodologies and approaches, like the Science Shop model. And the development of the Science Shop concept was the main aim of the H2020 InSPIRES project, giving special attention to vulnerable groups.

These analyses have allowed us to give recommendations concerning lessons learned from InSPIRES partners experiences when implementing participatory research in respect to CBPR and RRI guidelines particularly regarding the four pillars of ethics and when working with vulnerable groups.

Phase I was a quantitative assessment of the procedural aspects, sensitive data management policies, use of conventions/agreements between different SKs/SS partners, identification of vulnerable groups and obtaining signed informed consent forms.

The second phase was an even more in-depth assessment of the challenges faced by vulnerable groups. This was done by completing a qualitative descriptive case study that focused on questioning and analyzing the ethical practices in the eight selected research projects included in phase I of the study and analyzed them based on the four ethical pillars of CBPR.

This research highlighted the importance of formalized measurements and training on ethics of participatory projects for stakeholders and participants, result dissemination plans from the beginning of the project that includes participants and the community, and clear distinctions on ownership of data and results. All of which will help to limit stigma faced by all partners in the project, create more equal power dynamics in research by breaking barriers between researchers and people being researched, and increasing impacts of results and their transformative capacity within communities.

4. Annexes

4.1 Annex 1: example of excel file for phase 1 of the study

Nº	Name of the project	A	B	C	D	F	G	H	I	J
1	[redacted]	YES	People afected by a neglected disease, they live in silent	YES	YES	NO	It was not necessary.	NO	Difficulties to have consent from all participants directly (not accessible and illitrate participants)/we get consent from community leader (community consent)	Fair participation, from the beginning to the end
3	[redacted]	YES		YES	YES	NO	It was not necessary.	NO	This project had a very good participation but the key participants received some **material incentive**, symbolic only. The ownership of the results is not clear enough	Fair participation, from the beginning to the end
4	[redacted]	YES		YES	NO	NO	The dissemination of the results of this project were not foreseen at the beginning and the non academic participants were not included in the elaboration of the audio visual materials and publications			Fair participation, from the beginning to the end
5	[redacted]	YES	People afected by a very stigmatizing disease whose consequences are not assumed by the health authorities	YES	YES	NO		NO	Also in this project participants outside the researchers were not included in the dissemination of the results, also this project was interrupetd because of the COVID pandemia. This project was posponed because of the COVID pandemia, and participants were reduced ... also the ownership of the results and the use of these is not so clear	Fair participation, from the beginning to the end
		YES		YES	YES	No		NO	this project was posponed because of the COVID pandemia, and participants were reduced ... also the ownership of the results and the use of these is not so clear	fair participation, from the beginning to the end
6	[redacted]	YES		YES	YES	NO		NO	This project is not yet finished...ethical challenges will be the same related to dissemination and use of the results , also the ownership of the results, between academic, NGO and civil organisations included in the projetc	Fair participation, from the beginning to the end

References	
A	Have this project worked with vulnerable groups? YES / NO
B	If YES to the previous question, specify what type of vulnerabilities?
C	Do you have an ethical approval/clearance provided by your ethical committee of reference to conduct the study? YES / NO
D	Have you requested and securely kept written informed consents for all participants involved in the study? YES / NO
E	If no to previous question, why?
E	Formal collaborative agreement (i.e. Memorendum of Understanding) between all SKs taking part of the SSs? YES/NO
F	1) if no to previous question, please explain why? 2) if YES, please explain if & how it was useful for the project?
G	Have you developed and formalized a data management plan and procedure for the Science Shop project? YES / NO
H	What type of ethical challenges have you encountered during SSs processes?
I	In one word, what does Ethics mean to you?

4.2 Annex 2: semi-structured interview guideline for phase 2 of the study

Interview Guideline for Semi-Structured Interviews on Ethical Practices in SS projects: On Behalf of InSPIRES Consortium Experience

Introductory questions:

1. What is the overall goal of this project and how did the research question emerge?
1. What ethical issues were anticipated in this project?
2. What ethical challenges did you not account for?
3. How did these identified aspects influence the reconsideration of the project design?
4. What is your strategy to self-reflect on the project risk-benefit for community and society analysis?

Pillar 1: Inclusivity in the research process and building trust

2. Who are the stakeholders in this project and how did you develop your relationship with them?
3. How was the research (academic) team identified?
4. How are you sharing responsibility with the stakeholders of this project?
5. Who is the project leader, academic researcher, CSO partner? or two equal ?
6. Has this leadership role definition generated any tension within the team? If yes, how have these tensions been resolved?
7. Have CSOs members had any role or commitment in the project conception, results analyses or implantation?
8. Have you conceived a "convention" describing the conceptual model of partnership/ collaboration with them? Was it useful to clarify roles and responsibilities?
9. How has the study methodology/approach been designed? Has it been designed by researchers alone or in co-reflection with all the partners?
10. How did you gather, contact, and enroll the participants of this study?

11. How did you involve your partners in this research, reflection, and decision making? What method did you use to involve them (workshops, brainstorm meetings, etc)? Do you think this was successful? Why or why not? What would you have done differently?
12. Have partners and/or participants opinions been taken into consideration? If not, please explain why?
13. How useful were their opinions or suggestions for the design and implementation of the project?

Pillar 2: Research topic knowledge and ethical literacy

1. What ethical challenges did you identify prior to the start of this project?
2. Did community representatives and CSO partners have a good understanding/knowledge of the study topic as well as ethical issues? How did you evaluate that?
3. How would you assess the ethical literacy of the stakeholders and participants of this project?
4. Are you familiar with Ethical principles, codes of conduct, institutional research ethics guidance and research governance frameworks developed by research councils and funders?
5. How did you try to make researchers and other partners of your team adhere to rigour, responsibility and respect of the ethical practices?
6. Are you familiar with specific ethical guidance for executing Science shops, community-led research or participatory research?
7. According to you (PIs and CSOs), what are the ethical principles that should not be lacking in science shop projects or similar research?

Pillar 3: Stigma, confidentiality, sensitive data protection, and consent autonomy

1. Have you made an informed consent for participants to the researcher? If yes, have you involved CSOs partners in its conception?
2. What kind of confidentiality agreement did you use? Did this type of vulnerable group need a special type of confidentiality agreement?
3. Have you opted for an individual or communal (leader), oral or written consent form? How have you negotiated your option?
4. Who was the person in charge of community (participants) for informed consent obtaining (academic researcher, CSOs representative or doctor)?
5. Have you clearly informed participants of the way they will participate in the research (which kind of samples collected and questions asked)?
6. What data management system are you using for this project? Describe your experience and familiarity with it.
7. What ethical issues did participants face in the project?
8. How did you identify members of this vulnerable group?
9. Which measures have you taken in order to preserve them from stigma?
10. Which challenges have you faced to obtain their consent (or representative consent) ? Was there any resistance to consent?

Pillar 4: Dissemination, ownership, and benefit sharing of research results

1. How do you reflect on the studied community/societal impact and outcome of the project results?
2. Have you agreed with all SKs on who has the ownership of the results/data?
3. Is the ownership shared equally between all the SKs?
4. How do you plan to disseminate your results?
5. How are you going to include stakeholders and participants in this process?
6. Does the dissemination methodology you are using being decided with stakeholders and participants? If no, why not? If yes, why?
7. Have the research results been clearly (in an understandable way) shared with all the SKs including the studied community?
8. If yes, how was the dissemination approach conceived or planned?
9. What was the main impact/outcomes of results dissemination within the community?

Concluding questions:

1. Learning from the experience of working with these ethical issues, what are your reflections on what ethical strategies worked and what did not?
2. What could have been done differently?
3. What recommendations might be made to other similar project?