D1.6 Incidental Findings Policy

WP1– Project Management

Version: 1.00

SPHINX

A Universal Cyber Security Toolkit for Health-Care Industry

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Document information

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Executive Summary

This deliverable report examines the issue of incidental findings during research carried out under the SPHINX project. The obligation to address the possibility of discovering incidental findings and describe in advance the procedure that shall be followed in such case acting both proactively (for instance acquiring consent forms by the participants), as well as following such findings (confidentiality, communication to research participants etc.) is both an ethical requirement and a formal obligation identified by the European Commission in all research that involves human participants. To this end, this report first identifies the issues related to incidental findings in research, developing the basic elements of a relevant policy, and then applies these findings onto the SPHINX project circumstances. The report concludes that, as unlikely as it is to incur incidental findings during the SPHINX project, partners are encouraged to perform a self risk assessment that could be used as guidance in view of competently addressing any relevant matter that may occur.

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1 Incidental findings in research

1.1 EU funding and incidental findings policy

Incidental findings policy as an ethic issue is addressed in the Commission's guidance entitled "how to complete your ethics self-assessment".[1] The Commission has published these guidelines in order to help all Horizon 2020 programme applicants to get their proposal ethics-ready" for EU funding. Incidental findings policy is included in the ethics issues checklist published by the European Commission and in particular in its section 2 (humans). It is therefore concluded that this ethical obligation applies to research that involves human participants. If this is the case, namely a human subject research, the procedures that will be implemented in the event of unexpected incidental findings should be clearly stated (namely whether the participants have the right to know or not to know about such findings). In other words, researchers have an obligation to address the possibility of discovering incidental findings and describing in advance the procedure that shall be followed in such case acting both proactively (for instance acquiring consent forms by the participants), as well as following such findings (confidentiality, communication to research participants etc.).

If one considers the ethical implications such findings may raise for researches and at the same time what implications their disclosure to participants may present, it becomes apparent that incidental findings present a range of ethical, legal, and practical challenges, for both their recipients, as well as the researchers who encounter them. Therefore, their inclusion in the ethic self-assessment checklist is considered essential. In order however to better understand these implications and their possible consequences in the context of research conduct, a definition should be included in this report.

1.2 Definition of incidental findings

The notion of incidental findings originated in medical and genetic research. In this context all existing definitions of incidental findings have a medical focus/orientation. For instance, a definition defines incidental findings as:

> *"test results that are outside the original purpose for which the test or procedure was conducted or*
>
> *incidental findings are observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose or variables of the study or*
>
> *the medical problems discovered in the course of a research/clinical trial which were not related to the topic of research or*
>
> *a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study"*

A practical example, in order to better understand what incidental findings are, involves for instance a medical study where the researcher comes across an unexpected abnormal finding, such as a brain tumor on a research neuroimaging scan of a volunteer.

[1] http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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The Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) has issued a report for researchers under the title incidental and secondary findings. According to this report incidental findings can be either "anticipatable" or "unanticipatable."

An **anticipatable** incidental finding is one that is known to be associated with a test or procedure. Anticipatable incidental findings need not be common or even likely to occur—their defining characteristic is that the possibility of finding them is known.

Unanticipatable incidental findings include findings that could not have been anticipated given the current state of scientific knowledge. Researchers cannot plan for these types of findings specifically. However, they can consider in advance what they might do if a particular kind of unexpected finding arises, for example, one that could be actionable or lifesaving.

1.3 Ethical concerns raised by incidental findings

The main ethical concern when incidental findings in research occur is whether or not these findings should be disclosed to research participants. Some of the questions the researches ought to have answered in advance before commencing their research are:

- How should a finding of potential clinical significance be handled in the research setting?

- Should it be communicated to the research subject or not?

- Who shall be responsible to evaluate potential risks and benefits of such disclosure and ultimately take the final decision of whether to communicate such findings or not?

- Should participant welfare be protected and privacy be safeguarded?

- What duties belong to basic research scientists who do not have medical training?

- Whose responsibility is it to communicate the finding to a subject, to follow up, and to treat if needed?

The answers to these questions bring to the surface further ethical concerns when incidental findings in research may raise. In more detail, possible implications these findings may have on participants should be taken into serious consideration: for example, will research subjects be ready to face the shock and anxiety that may be triggered by unwelcome and potentially bad news, can they afford the costs associated with follow-up, but most importantly do they want such findings to be communicated to them in the first place?

As far as researchers are concerned the main ethical concern that needs to be addressed is: are researchers ethically obligated to share such information with study participants and, if yes, are they qualified to do so? This obligation derives from the broader researcher duty of beneficence to secure participants' well-being by maximizing benefits and minimizing harms. In other words, researchers have an ethical duty to plan for incidental findings to the best possible extent.

1.4 The role of incidental findings risk assessment

Given the constantly increasing number of people working in research today, the advanced medical technologies used and the number of people participating in research, the possibility of incidental findings is becoming increasingly common.

The best way to minimise the risks of incidental findings in research which may potentially entail for both researchers and participants, is the performance of a sound risk assessment.

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The first step that needs to be undertaken when conducting a risk assessment is identifying incidental findings. The researchers should evaluate in advance the possibility of discovering incidental findings in their research, as well as the extent of such possibility. Once they identify the possibility of discovering incidental findings, they should recognise and list such findings first by stating if they are anticipated or anticipatable. The possibility of findings that could not be predicted at all, if existing, should also be taken into consideration. Management of incidental findings should be an important part of the risk assessment. Researchers at this stage should be able to categorise the findings and evaluate their magnitude and the significance and potential implications they may have to research participants, seeking expert consultation, if needed. This will affect the next step of the risk assessment, that is communication policy. Specifically, what are the incidental findings should be communicated. How shall these findings be communicated? Who is the person responsible to communicate them to research subjects? The final step of the risk assessment is designing a clear policy outlining what follow-up assistance will be provided. To this effect, the implementation of an appropriate plan for the incorporation of outside expertise to evaluate incidental findings and/or apply the best return and communication policy of such findings to their recipients, could prove very useful.

The main steps of the risk assessment could be summarised to the following:

1. Identify incidental findings;
2. Recognise and list incidental findings;
3. Manage incidental findings by categorising and evaluating them;
4. Communicate them to research participants;
5. Design a follow-up policy.

1.5 The importance of informed consent

Informed consent is absolutely necessary in order to conduct research in an ethical and lawful manner. The European Commission in the same document mentioned above “Horizon 2020 Programme Guidance How to complete your ethics self-assessment” provides some useful guidelines to participants in research on how to acquire a right and adequate informed consent from the research participants. In more detail:

Participants must be given an informed consent form and detailed information sheets that:

- are written in a language and in terms they can fully understand;
- describe the aims, methods and implications of the research, the nature of the participation and any benefits, risks or discomfort that might ensue;
- explicitly state that participation is voluntary and that anyone has the right to refuse to participate and to withdraw their participation, samples or data at any time — without any consequences;
- state how biological samples and data will be collected, protected during the project and either destroyed or reused subsequently;
- state what procedures will be implemented in the event of unexpected or incidental findings (in particular, whether the participants have the right to know, or not to know, about any such findings).

Incidental findings therefore need to be taken into consideration when researchers design their consent forms. More specifically, researchers should inform potential research participants in the informed consent process and forms that:

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a. incidental findings may be found;

b. describe to them the anticipated incidental findings that may arise;

c. inform them of the process by which incidental findings will be evaluated;

d. inform them of the circumstances under which they will be communicated to them, as well as of the disclosing process;

e. indicate how participants might opt out of receiving certain findings;

f. most importantly, researchers should acquire the participants' written and clear consent that they wish such findings, if any, to be notified to them.

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2 The SPHINX project: Project description and other parameters to be taken into account. Could incidental findings occur during the SPHINX research?

2.1 Project's description

SPHINX aims to introduce a universal cyber security toolkit that will enhance the cyber protection of Health IT Ecosystem and ensure the patient data privacy and integrity. The SHPINX toolkit will be easily adapted or embedded on existing, medical, clinical or health available infrastructures. In the context of the project, SPHINX's cyber-security ecosystem shall be validated and evaluated against performance, effectiveness and usability indicators at three different countries (Romania, Portugal and Greece). Hospitals, health care providers and device manufacturers participating in the project's pilots will deploy and evaluate the solution at business as usual and emergency situations across various use case scenarios.

Project's description indicates that any research findings generated during the project's life shall focus on cybersecurity in the health sector. In particular, vulnerabilities of the Health IT Ecosystem to cyber threats, existing cybersecurity solutions already used and ways to better protect the Health IT Ecosystem against such threats, are some of the issues that shall be examined and evaluated during the project's progress.

2.2 Likelihood of incidental findings in SHPINX

Given the project's description, it is unlikely that any incidental findings will occur throughout its duration. More specifically, as mentioned in the first part of this report, incidental findings focus on medical/health information that may accidentally or incidentally arise when conducting research. However, SPHINX research findings focus on cybersecurity threats, vulnerabilities of health infrastructures and cyber solutions and have therefore no medical/clinical orientation. In addition to that no human subjects are expected to participate in the SPHINX research.

There is a possibility that medical data will be processed during the SPHINX project, but this is another parameter that shall be dealt with separately and does not fall within the scope of this report (instead, see D2.2). In any case, possible processing of personal data and more particularly, health data, shall occur only incidentally, during the process of identifying cyber threats and testing the hospitals infrastructures mostly during WP7 activities. As a result, no further processing of such data will be performed by the SPHINX researchers that could possibly lead to the discovery of incidental findings.

Consequently, if the definition of incidental findings is taken into consideration, as well as the project's description, there is low probability that incidental findings shall be discovered during the SPHINX project.

2.3 How could the SPHINX project comply with the obligation regarding incidental findings?

In the previous sections, it was demonstrated that the scenario of discovering incidental findings during the SPHINX research has low probability to occur. However, following the Commission's guidelines regarding ethical compliance, it is recommended that a self-risk assessment is performed in the context of SPHINX concerning

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this subject matter. The questionnaire that follows could be used as a guidance by SPHINX in order to minimise any chance of incidental findings occurrence, even though not anticipated.

QUESTIONAIRE	YES	NO	PROBABILITY OF OCCURENCE (%)
Does your research involve human participants?			
Will clinical or other tests be performed on human subjects during the research?			
Do you expect the discovery of any incidental findings?			
In the event of discovery of incidental findings do you have the recourses and experts to classify and evaluate them?			
In the event of discovery of incidental findings do you have a management plan available?			
In the event of discovery of incidental findings do you have a communication/ disclosure policy available?			
Have you provided for the right person (physician or other individuals with scientific training) qualified to communicate such findings to the subjects concerned, if this is required?			
Have you included information regarding incidental findings (including consent for disclosure of such findings) in the consent forms you acquire from the data subjects? (applicable in cases where there are human participants)			

Table 1: SPHINX Self Assessment Risk Questionnaire

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3 Conclusions

This deliverable report has highlighted the definition of incidental findings onto research context, and has also brought forward the basic elements of a relevant policy. However, after juxtaposition between these and the SPHINX project description it has been established that there exists substantially low probability that any incidental findings shall occur to any project partner during project execution. Notwithstanding these findings, a methodology to deal with any such event is being recommended to all project partners, by means of applying a self risk assessment in the form of a questionnaire to be performed at an early project execution stage.

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