UNIT FOR RESPONSIBLE CONDUCT IN RESEARCH (URCR)

Guidelines on Incidental findings policy

Preamble

Incidental findings policy as an ethical issue is addressed in the Commission's guidance entitled "how to complete your ethics self-assessment". The Commission has published these guidelines in order to help all Horizon Europe 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 (such as, confidentiality and communication to research participants).

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 ethics self-assessment checklist is considered essential.

DEFINITION

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, incidental findings can be defined as:

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- "test results that are outside the original purpose for which the test or procedure was conducted"
- "observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose or variables of the study or medical problems discovered in the course of a research/clinical trial which were not related to the topic of research"
- "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"

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.

Ethical concerns raised by incidental findings

- 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?

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The main steps of the risk assessment:

1. Identify incidental findings: can researchers anticipate them?

2. Recognise and list incidental findings;

3. Manage incidental findings by categorising and evaluating them;

4. Communicate them to research participants: who should be responsible for communicating them?

5. Design a follow-up policy

The importance of informed consent

Participants must be given a detailed informed consent form written in a language and in terms they can fully understand. In the consent form, researchers should:

• 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:

a. inform potential research participants in the informed consent process and forms that 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;

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

GUIDING QUESTIONAIRE FOR RESEARCHERS

- 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 resources 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) (*SPHINX Self Assessment Risk Questionnaire*)

Important Remark:

"Despite these general considerations about providing feedback to participants on "incidental findings" resulting from clinical research, such feedback is not without ethical questioning. On the one hand, the risk-benefit balance must be assessed and, on the other hand, participants' autonomy should always be respected . It is therefore important to define the concrete context of the "incidental finding" which should be communicated to participants. "

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(CEIC Recommendation for the management of "Incidental Findings" in the context of Clinical Research and in particular in Clinical Trials (CE) – available on https://www.ceic.pt/documentos-orientadores)

References

SPHINX Consortium, 2019, Incidental Findings Policy:

https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e5c7c9a499&appId=PPGMS

The law of Incidental Findings in Human Subjects Research – Establishing Researchers' Duties

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2581517/

US Presidential Commission for the Study of Bioethical Issues For Researchers: Incidental and Secondary Findings

https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Researcher%20Primer%20Incidental%20Findings%2010.30.16.pdf

Elinne M Bunnik et al, BMC Medical Ethics. Ethical framework for the detection, management and communication of incidental findings in imaging studies, building on an interview study of researchers' practices and perspectives. Available on: https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-017-0168-y

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