EMDR Europe Research & Development Ethics Policy and Application Documentation

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Section 1: Scope of this Policy

1.1 Initial context: In order to maintain the highest standards of integrity with regards to EMDR Therapy/ Adaptive Information Processing (AIP) Research and Development adherence to good ethical practice is essential. This Policy sets out the principles and procedures for carrying out EMDR Therapy and related subject research.

1.2 For the purpose of this policy the following terms of used:

- **Research**: original investigation leading to the creation of knowledge replication of an investigation for the purposes of developing the researcher.
- **Researcher:** any member of the EMDR Europe community wishing to conduct research that is not connected with a European Academic Institution.

1.3 It is important that all EMDR Europe research is conducted with the highest standards of integrity. All researchers are expected to consider the ethical implications of their research and to submit their research for ethical review as appropriate.

1.4 The following research activities, however, are particularly likely to raise ethical issues:

- the participation (active or passive) of people in activities such as interviews, questionnaires, focus groups, testing, experiments or observations research that utilizes personal data from the living or the recently deceased
- children or vulnerable adults
- collection of DNA, cells, tissues or other samples from humans or animals
- testing or observation of animals
- human remains or burial sites

1.5 This policy sets out the principles for ethical research and the procedures for ethical review. It is expected that this policy will be read in conjunction with the relevant subject-specific and professional codes and guidance on ethics and research conduct as well as taking into account all relevant legislation.

1.6 This policy will be reviewed by EMDR Europe Executive Committee on an annual basis.

Section 2: Ethical Principles

2.1 EMDR Europe's stance on ethical issues is underpinned by the following key principles:

- Research must be justified
- Informed consent must be given by participants
- Participation in research must be voluntary
- Confidentiality must be ensured
- Participants and the researcher(s) should not come to any harm during the research

2.2 Justified Researchers should be able to demonstrate that the research they undertake is worthwhile and necessary and contributes to the development of EMDR Therapy as a psychotherapeutic discipline.

2.3 Researchers should be able to show that the study will add new knowledge and not simply replicate research that already exists. The value of the new knowledge gained should outweigh the potential disruption and inconvenience caused to those involved in the research.

2.4 Informed consent: Those involved in research whether as participants or researchers should be informed of the nature and purpose of the research, and any potential benefits, risks, obligations or inconvenience associated with the research before they choose to participate. It is therefore normal practice to provide an information sheet or similar to potential participants that sets out the details of the research in a form accessible to the non-expert and in a format appropriate to them.

2.5 Wherever possible, and proportional to the nature of the research, evidence of consent (either written consent, or oral consent witnessed by another) should be obtained and retained as appropriate. Participants should be informed that they are free to withdraw this consent at any time without adverse consequences, and that any data provided by them will be destroyed should they request it.

2.6 Where consent is being sought to collect sensitive personal data explicit consent must be given by the participant to collect this data. Sensitive personal data is defined in the European Union Protection of Personnel Data (2012) as personal data consisting of information relating to:

a. the racial or ethnic origin of the data subject
b. his/her political opinions
c. his/her religious beliefs or other beliefs of a similar nature
d. whether he/she is a member of a trade union
e. his/her physical or mental health or condition
f. his/her sexual life
g. the commission or alleged commission by him/her of any offence
h. proceedings for any offence committed or alleged to have been committed by him/her, the disposal of such proceedings or the sentence of any court in such proceedings

2.7 Particular care is needed in gaining consent from vulnerable groups, such as:

i. Children
ii. Persons lacking mental capacity

iii. Persons whose first language is not indigenous

2.8 For research involving children, researchers should seek to gain the consent or perhaps more appropriately the assent of the child in keeping with Article 12 of the United Nations Convention on the Rights of the Child which states that 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. The consent of the child's parent/legal guardian should normally also be obtained when this is feasible.

2.9 For research involving persons lacking mental capacity, researchers, in keeping with the European Union Agency for Fundamental Rights (2013) of Legal capacity of persons with intellectual disabilities and persons with mental health problems, should: assume a person to have capacity to consent unless it is established that he/she lacks capacity not treat a person as unable to make a decision unless all practicable steps to help him/her to do so have been taken without success not treat a person as unable to make a decision merely because they make an unwise decision

2.10 When access to participants is controlled by a 'gatekeeper'[1] , researchers should adhere to the principle of gaining informed consent/assent from the participants themselves, whilst respecting the legitimate interests of the gatekeeper.

2.11 In the case of research in educational settings, the researcher must consider carefully the need to gain parental consent for participation in addition to that of the child. The school acts in loco parentis but it must not be assumed that this always negates the need to ask parents to consent to their child's participation. This will particularly be the case where the research is of a sensitive nature or where the research requires children to undertake activities beyond those normally asked of them.

2.12 There may be some types of research design (e.g. deception studies or covert research) that require the research to be undertaken without informed consent. Such design should be carefully considered and fully justified with procedures put in place to provide post research full debrief and/or granting of post hoc consent.

2.13 Voluntary Participation: As well as being informed, consent should also be freely given. Researchers should ensure that participants are taking part in the research voluntarily, that they do not feel pressured or obliged to participate, and are not subject to coercion.

2.14 Researchers should be aware that where there is a power relationship between the researcher (or representative of the researcher, e.g. a gatekeeper) and the participant - such as between a clinician/ patient; educator/ student; doctor/ patient – a person may feel compelled to participate. In these circumstances, a researcher should endeavour to find ways of ensuring voluntary participation, e.g. by using a neutral intermediary to gain consent.

[1] Gatekeepers are those who have the power and authority to grant the researcher access to a group of (normally vulnerable) participants, for example: a head-teacher or a care home manager would be considered as 'gatekeepers'.

2.15 Researchers should also be aware that the use of incentives to encourage participation may be viewed as coercion if such incentives are any more than a token. For example, giving those who complete a questionnaire access to a free prize draw will not normally be seen as coercive. On the other hand, paying individuals more than reasonable expenses to take part in an interview would normally be seen as coercive.

Section 3: Confidentiality

3.1 Except where explicit written consent is obtained to the contrary, researchers should protect the confidentiality and anonymity of all human participants and their data relating to them at all times.

3.2 Researchers should be aware of the risks to anonymity, confidentiality, privacy and security posed by the data they collect and store, and take measures to prevent accidental breaches of confidentiality. The collection, storage, use and disclosure of data must comply with the European Union Protection of Personnel Data (2012).

3.3 It is important to note that the duty of confidentiality is not absolute in law and may, in exceptional circumstances, be over-ridden by more compelling duties, such as the duty to protect individuals from harm.

Section 4: Avoidance of Harm

4.1 Researchers should seek to minimize the risk of harm to any individual (the participants, the researcher him/herself, other researchers) or organisations arising from the research.

4.2 Harm is broadly conceived to include physical injury and psychological distress (beyond that encountered in daily life), but also negative impacts on economic or social standing.

4.3 Researchers should assess potential risks prior to the commencement of a project and accordingly make adjustments to the project design and make provisions to provide help and support for any individual who suffers harm.

4.4 Most fundamentally, researchers must always ensure that participants and other researchers are fully aware of any potential risk of harm. This will enable the individual to make their own risk assessment before choosing to participate and, if fully informed, the individual is best placed to make this judgment.

Section 5: Ethical Review Procedures

5.1 The submission for ethical approval should first include an Ethics Checklist. The checklist is designed to highlight significant ethical issues with the research and the researcher should always answer the questions honestly, taking into account the ethical principles outlined in Section 2 of this document.

5.2 When a researcher answers 'no' to all questions, the research is not normally subject to any further review.

5.3 When a researcher answers 'yes' to one or more questions in the checklist the research proposal must then be submitted for full ethical review.

5.4 In both cases, the completed checklist is signed by the researcher and submitted to the EMDR Europe Ethics Committee for full ethical review.

5.5 The exception to this is where the researcher has answered yes to question 18 (NHS or other Academic Institution involvement). In this case the research will need to be approved through the appropriate NHS ethics processes or the relevant academic institution. The researcher should submit to these processes and not complete the Application for Ethical Approval.

5.6 The EMDR Europe Ethics Committee will review applications and contact the researcher with the outcome normally within 8 weeks.

5.7 There are three possible outcomes:

1. The application is approved without any changes needed

2. The application is approved subject to revisions being made to the satisfaction of the EMDR Europe Ethics Committee

3. The application is not approved

5.8 If a researcher wishes to deviate from the approved research at any time, he/she should discuss this with the EMDR Europe Ethics Committee. The researcher may have to resubmit the application for ethical approval

5.9 Any researcher who fails to comply with ethical review procedures will be subject to investigation under the Procedures for Misconduct as stipulated by EMDR Europe

Section 6: Responsibilities of the EMDR Europe Ethics Committee

6.1 It is the responsibility of the EMDR Europe Ethics Committee:

i. To promulgate good conduct in research and professional practice within the remit and responsibility of EMDR Europe
ii. To act in an advisory capacity to the EMDR Europe Executive and EMDR Europe Board on ethical and research governance matters
iii. To keep the EMDR Europe policies and guidelines on ethics and research governance under review
iv. To ensure mechanisms are in place to monitor the conduct of research that has been granted approval
v. To formulate EMDR Europe responses to national and international developments relating to ethical and research governance issues

Section 7: Collaborative Research

7.1 Where research is undertaken with another Higher Education Institutions (HEI), it is best practice that only the ethics committee of the lead researcher's/principal investigator's HEI will undertake a full ethical review of the research, with the HEI(s) of any co-investigator(s) being kept fully informed of the process and outcome.

7.2 Where research is undertaken with an organisation outside the Higher Education sector that has its own ethical approval system, the same principle of avoiding duplication of full ethical review should be maintained.

Application for EMDR Europe Ethical Approval

To be completed by EMDR researchers proposing to undertake ANY research involving humans centred upon EMDR Therapy/ Adaptive Information Processing (AIP) [that is research with living human beings; human beings who have died (cadavers, human remains and body parts); embryos and foetuses, human tissue, DNA and bodily fluids; data and records relating to humans; human burial sites] or animals.

Section A: Researcher and Project Details

Lead Researcher:	
Other researcher(s):	
Email:	
Institution/Department/ Faculty/ Organisation:	
Status of lead researcher:	
Project Title:	
Project funding:	

Section B: Checklist

		Yes	No
1.	Does your proposed research involve the collection of data from living humans?	☐	☐
2.	Does your proposed research require access to secondary data or documentary material of a sensitive or confidential nature from other organisations?	☐	☐
3.	Does your proposed research involve the use of data or documentary material which (a) is not anonymised **and** (b) is of a sensitive or confidential nature **and** (c) relates to the living or recently deceased?	☐	☐
4.	Does your proposed research involve participants who are particularly vulnerable or unable to give informed consent?	☐	☐
5.	Will your proposed research require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited?	☐	☐
6.	Will financial inducements be offered to participants in your proposed research beyond reasonable expenses and/or compensation for time?	☐	☐
7.	Will your proposed research involve collection of data relating to sensitive topics?	☐	☐
8.	Is pain or discomfort likely to result from your proposed research?	☐	☐
9.	Could your proposed research induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?	☐	☐
10.	Will it be necessary for participants to take part in your proposed research without their knowledge and consent at the time?	☐	☐
11.	Does your proposed research involve deception?	☐	☐
12.	Will your proposed research require the gathering of information about unlawful activity?	☐	☐
13.	Will invasive procedures be part of your proposed research?	☐	☐
14.	Will your proposed research involve prolonged, high intensity or repetitive testing?	☐	☐
15.	Does your proposed research involve the testing or observation of animals?	☐	☐
16.	Does your proposed research involve collection of DNA, cells, tissues or other samples from humans or animals?	☐	☐
17.	Does your proposed research involve human remains?	☐	☐
18.	Does your proposed research involve human burial sites?	☐	☐
19.	Will the proposed data collection in part or in whole be undertaken outside the host country	☐	☐
20.	Does your proposed research involve Health Service patients, staff or premises/ Other Higher Education Institutions (HEI), Non-Governmental Organisations (NGO's) or other agencies?	☐	☐

If the answers to any of these questions change during the course of your research, you must alert the EMDR Europe Ethics Committee

Signatures

By signing below I declare that I have answered the questions above honestly and to the best of my knowledge:

Lead researcher: ---------- **Date:** ----------

(**Please note** that the Lead Researcher is, where applicable, signing on behalf of all researchers involved with the research)

If you have answered **NO** to all questions you should still submit this form to the EMDR Europe Ethics Committee.

If you have answered **YES** to one or more questions you must now complete **Section C** (below) and submit the completed and signed form to the EMDR Europe Ethics Committee.

Section C: Full Application

Details of the research Outline the context and rationale for the research, the aims and objectives of the research and the methods of data collection
Who are your participants/subjects? (if applicable)
How do you intend to recruit your participants? (if applicable) This should explain the means by which participants in the research will be recruited. If any incentives and/or compensation (financial or other) is to be offered to participants, this should be clearly explained and justified.
How will you gain informed consent/assent? (if applicable) Where you will provide an information sheet and/or consent form, please append this. If you are undertaking a deception study or covert research please outline how you will debrief participants below
Confidentiality, anonymity, data storage and disposal (if applicable) Provide explanation of any measures to preserve confidentiality and anonymity of data, including specific explanation of data storage and disposal plans.
Potential risks to participants/subjects (if applicable) Identify any risks for participants/subjects that may arise from the research and how you intend to mitigate these risks.

Other ethical issues Identify any other ethical issues (not addressed in the sections above) that may arise from your research and how you intend to address them.
Published ethical guidelines to be followed Identify the professional code(s) of practice and/or ethical guidelines relevant to the subject domain of the research.

Declaration of Researcher

I have read the **EMDR Europe Research & Development Ethics Policy** and any relevant codes of practice or guidelines and I have identified and addressed the ethical issues in my research honestly and to the best of my knowledge

Signature: ---------- **Date:** ----------

Chair of the EMDR Europe Ethics Committee Declaration

(Tick as applicable)

☐ The EMDR Europe Ethics Committee is satisfied that the researcher has identified and addressed the ethical issues and grants ethical approval for this research.

☐ The EMDR Europe Ethics Committee is **not** currently satisfied that the researcher has identified and addressed the ethical issues and grants ethical approval for this research and request re-submission. Permission cannot be granted until the subsequent modifications have taken place

☐ The EMDR Europe Ethics Committee is **not** satisfied that the researcher has identified and addressed the ethical issues in this research and **does not** grant ethical approval for this research.

Signature: ---------- **Date:** ----------

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