**VolREthics initiative**

**DRAFT - Global Ethics Charter for the Protection of**

**Healthy Volunteers in Clinical Trials**

**Comments document**

**Please provide comments using the template below and return by e-mail to** **hvworkshop.disc@inserm.fr** **by March 30, 2024**

|  |
| --- |
| **Comments provided by** |
| **Name**  |  |
| **Institution** |  |
| **E-mail contact address** |  |
| **If you are sending comments on behalf of an organisation, institution, initiative, etc. please specify** |  |

|  |
| --- |
| **General comments on the draft Charter** |
| e.g. Is the draft Charter relevant? Is any major issue not addressed? Is its format appropriate? Is its target audience(s) clear and relevant?Is it easy to understand?Any other comment |

|  |
| --- |
| **Comments on specific Charter articles****Please provide comments on the most salient issues you identify.** **To facilitate the process of comments review, please consider focusing on no more than 3 top priorities.** |
| **Section 1: Valuing the difference: general recommendations** |
| **Article Number** | **Text** | **Your proposed reworded text** | **Your comments/suggestions** |
| 1 | **Laws and regulations to protect healthy volunteers.** Countries should develop laws and regulations specifically intended to protect healthy volunteers. These should address the risks of harm and of exploitation, as well as promote healthy volunteers’ wellbeing in clinical research. |  |  |
| 2 | **Healthy volunteers’ representatives.** Countries should support the formation of groups of past and present healthy volunteers to represent their interests in the development of laws and regulations aimed at protecting them, and in key steps of the design, conduct, and closure of the clinical trial process. Interactions with associations representing healthy volunteers should be facilitated to fight double standards, avoid ethics dumping, and to ensure appropriate medical care for the duration of the clinical trial, and after in the event of adverse events. |  |  |
| 3 | **Recruitment practices.** Countries should develop frameworks to ensure that recruitment practices adhere to ethical standards that prevent excessive emphasis on financial compensation and misleading language. Specific attention should be paid to prevent targeting disenfranchised populations. |  |  |
| 4 | **Preventing over-volunteering.** There should be a mandatory system in place in all contexts of clinical research to prevent over-volunteering (e.g., enrolling in more than one trial at a time or not observing the required “washout” period between studies), within and across national borders. Depending on national/regional circumstances, the system could be managed by regulators or the private sector. While ensuring the protection of data concerning both clinical trials and healthy volunteers, these systems must be designed to enable participant identification, so that exclusion can be respected during the trial, as well as wash-out periods between trials. |  |  |
| 5 | **Informed consent.** Informed consent materials and processes should be adapted to the specificities of healthy volunteers in terms of age, education level, social circumstances, and other potential situations of vulnerability\*. Complete information on the research objectives, the study demands and its risks and benefits for volunteers should be presented in a fair way using simple and concise language. A specific focus should be the about risks of over-volunteering. |  |  |
| 6 | **Sharing trial results with healthy volunteers.** After the trial is completed, healthy volunteers should be informed about key aggregated trial results in a fair and understandable way, through appropriate means e.g. written communication or invitation to an in-person meeting. |  |  |
| 7 | **Conflict reporting and management.** Processes should be set up for healthy volunteers to report any concern to the clinical site staff, during and after the clinical trial with no risk of prejudice. In addition, processes for reporting issues to a neutral person (e.g. ombudsman) or body (e.g. ethics review board) in a way that ensures confidentiality of the person’s identity should be set up. These processes should be detailed in the protocol and the informed consent documents. Written records should be kept of reported issues and of the actions taken. |  |  |
| 8 | **Research ethics oversight**. Ethics review boards involved in assessing healthy volunteer trials should have the skills, training, and capacity to review such trials. Members should understand the risks specific to healthy volunteer trials and how to minimise them. |  |  |
| 9 | **Site and investigator oversight**. There should be local oversight systems to ensure that sites conducting clinical trials are appropriately resourced, with staff appropriately trained to ensure the quality of the science and the protection of healthy volunteers. This system should be maintained under a mandatory regulatory process that includes inspection of research facilities, and review of staff credentials.  |  |  |
| **Section 2: PROTECTING FROM RISKS OF HARM** |
| **Article Number** | **Text** | **Your proposed reworded text** | **Your comments/suggestions** |
| 10 | **Protection from physical harm.** Risks to healthy volunteers should be minimised through the design of the clinical trials which should include only medical procedures that are scientifically necessary for the research questions. Access to acute medical care should be provided throughout the trial. |  |  |
| 11 | **Protection from psychological harm**. Research clinics should address the potential for psychological harm that results from strict trial conditions, especially clinic confinement (such as by providing access to telephones, Wi-Fi), and may be exacerbated for participants in situations of vulnerability. Facilities should have sufficient space to accommodate participants and be designed to maximise the safety and well-being of the trial participants. Medical staff must remain attentive to participants’ needs and provide them with appropriate support and resources. |  |  |
| 12 | **Monitoring of potential long-term harms**. There should be a post-trial system of follow up to ensure long-term monitoring of adverse events and healthcare for healthy volunteers. This system should ensure all adverse events that occurred during the trial have been recorded and resolved as well as collect data on any additional adverse events that may develop post-trial. |  |  |
| 13 | **Insurance for research-related injury**: There should be requirements that sponsors and/or research clinics have insurance to cover all harms caused by clinical trial participation, including post-trial care for injuries related with the clinical trial. |  |  |
| **Section 3: PROTECTING FROM RISKS OF EXPLOITATION** |
| **Article Number** | **Text** | **Your proposed reworded text** | **Your comments/suggestions** |
| 14 | **Attend to potential situations of exploitation.** All clinical trial stakeholders should attend to the large variety of potential situations of exploitation that are of special relevance to healthy volunteers. They should be educated on ways to identify collective and individual healthy volunteers’ circumstances that may expose them to risks of exploitation and to ensure that steps are taken to address these risks.  |  |  |
| 15 | **Financial compensation.** Compensating healthy volunteers for trial participation has the potential to compromise trial results by inducing concealment of health conditions and adverse events, as well as over-volunteering to earn more income. Financial compensation should be reflective of the demands associated with each trial and approved by local ethics review boards. Countries should develop guidelines on compensation to provide fair and equitable compensation across research fields. Trial information and informed consent documents should include explicit information on how payments will be made, including provisions that will apply in case of early withdrawal from the trial. |  |  |
| 16 | **Well-being during the clinical trial.** Specific attention should be paid to ensuring the well-being of volunteers during the trial. Clinical trial sites should identify and train staff members in charge of ensuring that healthy volunteers are treated respectfully, and their well-being is ensured throughout the research process. Clinical trial information and informed consent documents should include information on how to confidentially report, within and outside the study staff, issues related with well-being. |  |  |
| **Section 4: TOWARDS RESPECTING, REDUCING, REFINING AND REPLACING HEALTHY VOLUNTEERS** |
| **Article Number** | **Draft text** | **Your proposed reworded text** | **Your comments/suggestions** |
| 17 | All stakeholders should carefully consider the application of the 4Rs principles —Respect, Reduce, Refine, and Replace in all clinical research stages involving healthy volunteers. |  |  |
|  |
| **Please tell us below which of the above 17 articles are most relevant to your organization. Thank you for your comments.** |
|  |