

The Ethics Policy on the Implementation and Use of the J-PDX Library

1. Safeguarding the dignity of individual patients in relation to PDX models

PDX models and clinical information stored in the J-PDX Library are derived from individual patients who are to be treated with dignity. Thus, those samples and that information should not be treated as mere objects or data but as “human-derived” materials in accordance with *the Ethical Guidelines for Life Science and Medical Research Involving Human Subjects (MEXT, MHLW, and METI Notice no. 1 of 2021)*. The National Cancer Center Japan (NCC) and the users of the Library must be always aware that their greatest responsibility is to safeguard the dignity of individual patients who contribute to the Library.

2. Trust-based management and governance of PDX models

PDX models and clinical information stored in the J-PDX Library are a valuable resource for medical research and development of pharmaceutical products, and they are entrusted to the NCC by individuals who agree with the mission and purposes of the Library. Thus, the NCC will be responsible for operating the Library ethically and to provide them only to trustworthy users including academia as well as the medical industry, which will use them for the public good in accordance with the goals of the Library.

3. Temporary lending of PDX models for limited purposes

The provision of PDX models and clinical information in the J-PDX Library to Library-users will be limited to temporary lending for limited purposes of proper use based on a contract between the users and the NCC in order to prevent unethical behavior by users such as the sale or sublease of human-derived materials. The NCC will properly monitor and manage the use of PDX models by users with the utmost attention.

4. Ethical considerations in the care and use of laboratory animals

Laboratory animals are essential for the construction and implementation of the J-PDX Library. The NCC will take care of the welfare of laboratory animals used for PDX models, refining how PDX models are created to minimize potential pain and distress of the animals, using methods to minimize the number of animals used, and making efforts to find and use better alternatives when possible. Everyone involved in the Library must never forget to be grateful to the animals that make the Library possible.

5. Compliance with relevant laws, ordinances, and regulations

In implementing the J-PDX Library, the NCC will comply with relevant national and international laws, ordinances, and regulations, such as those concerning the personal data protection, protection of human subjects, laboratory animal welfare, and intellectual property.