

## **LUDWIG INSTITUTE FOR CANCER RESEARCH**

### **MAINTENANCE OF LABORATORY NOTEBOOKS AND RECORDS POLICY**

Keeping accurate, complete, authentic and reliable records of research data is essential for the scientific integrity of staff as well as the Institute. Such records provide critical evidence of inventorship, including the dates of conception and 'reduction to practice' (completely defining the process by which the invention can be realized) of any invention.

Research data and records should include sufficient detail to establish their authenticity and confirm the validity of any conclusions, and to enable responses to questions that may result about the research. Additionally, it is not unusual for investigators to need to revisit results and methods months, or even years, after an experiment was performed; clarity of presentation and good record keeping are essential for reconstructing experimental details that may have been forgotten.

Set out below is the policy of the Ludwig Institute for Cancer Research on laboratory notebook and record-keeping. Existing policies of the local host institution or regulatory body supercede this policy if they exceed the minimum requirements set out below. This policy may be revised or modified by the Institute at its discretion.

1. Each research staff member must maintain all laboratory results and experimental procedures in a bound notebook that is supplied by the Branch and has consecutively numbered pages. Pages may not be added or removed. An index should be maintained to facilitate access to data. The investigator's name, Group and Branch must be clearly printed on the first page in the book.
2. Each entry should be a) clearly dated and b) written in permanent ink. Erasure of records and the use of 'white-out' are not permitted. Errors should be scored out with a single line, so that the original entry is still legible. All record-keeping must be either in English (preferred) or one of the official languages of the country in which the Branch is located.
3. Laboratory notebook entries that describe a potential invention or novel finding of importance should be signed daily by the investigator, and dated and countersigned periodically by an individual who is familiar with the research but could not be considered as a co-inventor. Thereafter, all pages relating to the 'reduction to practice' should also be dated and countersigned by an individual who is familiar with the research but could not be considered as a co-inventor.
4. Where practical, experimental results obtained on laboratory equipment should be printed and affixed securely into laboratory notebooks. Where it is not practical to print results, the experimental result files should be properly backed up on the Branch's server or tape system, and not only the hard drive of the laboratory equipment or personal computer. It is the responsibility of the investigator to ensure that the experimental result files are also saved on a second, preferably removable, medium such as a compact or zip disc. The full file-paths and file names of both copies, plus the source of the data, should be entered onto the notebook page describing the experiment.

5. Data management and recording relating to human samples must comply with all relevant privacy policies, all local data protection laws, and all ethics boards' mandates of the hospital/institution in which the research is being conducted.
6. Laboratory results for tests that are conducted for subjects in LICR's clinical trials shall be reported on respective standardized forms (see attachment). These forms are to be signed by the responsible laboratory investigator. The original signed form shall be returned to the clinical study investigator for the patient charts. A copy shall be retained for the laboratory files. It is the responsibility of the laboratory investigator to ensure that the data reported on these forms are consistent with the respective data in the laboratory notebooks.
7. Primary laboratory notebooks must be retained within the Branch in which they are generated for a period of no less than 10 years. The investigator may make copies of the primary data for his/her own use, but notebooks are not to be removed from the Branch under any circumstances.

I understand, and agree to abide by, the LICR's Maintenance of Laboratory Notebooks and Records Policy as set out above.

_____	_____
Signature	Name
_____	_____
Branch	Date (DD/MM/YY)