

PAN-ASIAN TRAUMA OUTCOMES STUDY (PATOS)
DATA AGREEMENT VER 1.0

The Pan-Asian Trauma Outcomes Study (PATOS) Research is managed and organized by the PATOS Steering Committee. This Data Agreement outlines the principles of data sharing and use within the guidelines of the PATOS Steering Committee. This document should be complied without exception by all members of the PATOS Network. On behalf of the PATOS Steering Committee, the Seoul National University Hospital Laboratory of Emergency Medical Services (SNUH LEMS) will assume the roles and responsibilities as the default custodian of the PATOS data and agrees to fully comply with this Data Agreement.

The PATOS Steering Committee, upon consensus of all committee members, reserves the right to amend this Agreement in future if needed.

Preparation of Participation in PATOS Research

- ◆ Each participating site is responsible for assuring all relevant approvals and ethical clearance for data release.
- ◆ Budgetary costs and management plan for each participating site should be worked out by the principal investigator of the study site.

Contribution of Data

- ◆ Any registered member of the PATOS Network *must* choose to contribute one of the core, comprehensive, or minimum datasets. Details and degrees of contribution to the PATOS Database should be approved beforehand by the PATOS Steering Committee. Please refer to the Data Dictionary for complete lists of the PATOS datasets.
- ◆ Contribution to the optional dataset is subject to feasibility in each participating institution and is highly encouraged if available.
- ◆ Abstraction and input of information into the web-based PATOS database will be handled by each participating site. Alternatively, raw data can be sent in a specified format for direct upload by the Data Management Team of the SNUH LEMS. Instructions pertaining to the entering of data will be conveyed to the participating sites by the SNUH LEMS. Enquiries regarding the data contribution shall be communicated to the SNUH LEMS.
- ◆ From the participating sites, selected documents shall be collated by the PATOS Steering Committee for the purpose of ensuring data quality in accordance to the study outline.

Cleaning and Management of Data

- ◆ Variables with personally identifiable information (e.g. name, address, patient number) will not be used for other purposes but to solely facilitate linking of data (e.g. to link separately entered data from an EMS agency and a hospital).
- ◆ Once linked, all variables with any personal identifiers or can be potentially used to identify a

patient will be de-identified permanently. The resulting de-identified dataset will have all unique personal identifiers stripped off.

- ◆ Data would be cleaned by the Data Management Team of the SNUH LEMS to address errors and/or incomplete entries.
- ◆ Any data available for use from the PATOS Database will be in de-identified format.

Data Ownership

- ◆ SNUH LEMS will be the default custodian of all data contributed to the PATOS Network.
- ◆ Members of the PATOS Network whose sites or institutions have contributed to the Network continues to own their source data and are free to use it for any purposes which does not require collaboration with any other site(s) and/or institution(s). Any use of PATOS data beyond their contributed portions of data would require approval of the PATOS Steering Committee.
- ◆ Guests and non-members of the PATOS Network does not own any data of the Network. If they wish to access or use the data, approval must be obtained from the PATOS Steering Committee.

Requesting and Use of Data

- ◆ Data that is property of the PATOS Network can only be used upon receiving written approval from the PATOS Steering Committee, unless the requested subset of data was contributed solely by the proposer.
- ◆ Request of data for any purposes including publication should be in a form of research proposal with at least one PATOS member listed in the proposal. The proposal will be reviewed by a member of the PATOS Steering Committee to evaluate the scientific merits and feasibility of the research question.
- ◆ Any member who holds more than one position in multiple institutions cannot use the data collected across those institutions and should also obtain approval for data use.
- ◆ Upon approval, data should be only used as permitted and should not be distributed for a third party outside the PATOS Network without approval. When sharing of the data is permitted, the PATOS member involved in the particular research is responsible of ensuring that the third party complies with this Agreement.

Security of Data

- ◆ As the default custodian of the PATOS data, SNUH LEMS agrees to use appropriate safeguards to ensure the security of data.
- ◆ Contributors and users of the Data also share joint responsibility in ensuring data security during data entry and/or use.
- ◆ When data security is breached, all responsible parties should assume the responsibility to inform the PATOS Steering Committee and take reasonable measures against the extent of the breach.