

APPENDIX

Data Distribution Checklist: Research

Please check-off the appropriate boxes below for all studies using data from the Regenstrief Medical Record System and other data warehouses stored and accessed. All activities described after the check-box must be completed before data are provided to study investigators.

The investigator is using the data for a research project.

If data are to be used for research:

- Copies of the IRB approval letter and Summary Safeguard Statement have been provided and are on file.
- The investigator's description of the intended use of the data agrees with the description on the Summary Safeguard Statement.
- Upon completion of this study, provided patient-specific data will be destroyed or returned to Regenstrief Institute.

Study Title:

Investigators Name:

Address:

Phone #:

Signature of Principal Investigator

Date

Data Distribution Checklist: Quality Improvement

To be completed by investigators using data only from the Regenstrief Medical Record System and other data warehouses stored and accessed to perform quality improvement studies. Before data can be provided, all items must be checked or completed, and this form signed and dated by the principal investigator.

- The investigator is using the extracted data only for internal quality improvement.
- The investigator will not be using the data to perform research (i.e. intended for publication or public presentation).*
- Upon completion of this study, provided patient-specific data will be destroyed or returned to Regenstrief Institute.

*Data for research purposes requires copies of the signed and dated IRB approval letter and Summary Safeguard Statement. The Summary Safeguard Statement and the intended use of provided data must agree.

Study Title:

Investigators Name:

Address:

Phone #:

Brief Description of the Study:

Signature of Principal Investigator

Date

Data Distribution Sign-off Sheet

Please check-off the appropriate boxes below for all studies wherein data provided from the Regenstrief Medical Record System and other data warehouses stored and accessed by Regenstrief Institute Data Analysts. All activities described after the check-box must be completed before data are provided to study investigators.

- Requesting investigator is using data for RESEARCH.
- Requesting investigator is using data for QUALITY IMPROVEMENT.

Both of the following activities have occurred (Both items must be checked):

- Copies of the signed IRB approval letter and Summary Safeguard Statement ave been provided and are on file.
- Investigator's description of the intended use of the data agrees with the description on the Summary Safeguard Statement.

One of the following activities has occurred (Check one item only):

- In agreement with IRB documents, no patient-specific data are contained in the data set for distribution.
- The data set contains patient-specific data as specified by the investigator AND approved by the IRB.

Study Title:

Investigators Name:

Signature of Primary Data Analyst

Date

Signature of Validating Data Analyst

Date