

DRDL

The Duke Research Data Lifecycle Plan is a tool designed to elucidate the various attributes and complexities in research projects that would require process or infrastructure support.

The following represents an early draft of the DRDL and is focused on questions that will show how much support a project needs.

Thank you!

[pro_short_title]
[pro]
[pi_name]

Please describe the funding for this project

- Federal
- Non-federal
- Not sponsored research

Questions from here forward will be part of the DRDL that users will be asked to complete.

The following questions are about the type(s) of data you will be collecting or working with for this study.

Click to select all of the following types of data that apply to this project
(Identifiers: Names, Geographic Subdivision Smaller than State, All Dates (except year) Directly Related to Individual, Telephone Numbers, Fax Numbers, E-mail Addresses, Social Security Number, Medical Record Number, Health Plan Beneficiary Number, Account Number, Certificate/License Number, Vehicle Identifiers and Serial Numbers, Device Identifiers and Serial Numbers, URLs (Web Universal Resource Locators), IP (Internet Protocol) Address Numbers, Biometric Identifiers, Full Face Photographic Images, Another Unique Identifying Number, Characteristic, Or Code)

- Identifiable Duke patient data
- Identifiable patient data (not Duke)
- Identifiable non-patient data
- Data with no identifiers
- Administrative student data
- Financial data
- Not Human Subjects Data
- Other

You selected "Other". Please describe your data type

For identifiable data, are you collecting SSNs and for what purpose?

- For payment purposes
- For research purposes
- I am not collecting SSNs

Please specify where you will store SSNs for Administrative or Financial projects

We now want to know a little more about the types of data you indicated you will be collecting or working with for this study.

Describe how your data were deidentified

- De-identified by external source
 - I de-identified the data
 - Duke certified honest broker
 - Data were anonymous
 - I don't know
-

How do you plan to obtain the identifiable Duke patient data? (select all that apply)

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
 - Prospectively, no consent
 - Secondary data, via consent for broad use
 - Secondary data, no consent or contract/agreement (includes chart review or cohort from EHR)
-

How do you plan to obtain the identifiable non-Duke patient data?

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
 - Prospectively, no consent
 - Secondary data, via contract
 - Secondary data, via consent for broad use
 - Secondary data, no consent or contract
-

How do you plan to obtain the identifiable non-patient data?

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
 - Prospectively, no consent
 - Secondary data, via contract
 - Secondary data, via consent for broad use
 - Secondary data, no consent or contract
-

How do you plan to obtain the data with no identifiers?

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
- Prospectively, no consent
- Secondary data, via contract
- Secondary data, via consent for broad use
- Secondary data, no consent or contract

How do you plan to obtain the administrative student data?

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
- Prospectively, no consent
- Secondary data, via contract
- Secondary data, via consent for broad use
- Secondary data, no consent or contract

How do you plan to obtain the financial data?

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
- Prospectively, no consent
- Secondary data, via contract
- Secondary data, via consent for broad use
- Secondary data, no consent or contract

How do you plan to obtain the other data?

(Broad consent is an alternative to study-specific consent, not a waiver of consent. It allows an investigator to obtain data or biospecimens in association with a current study that can be used in future research without having to re-consent the participants. It may also be known as Consent for Future Research.)

- Prospectively, with consent
- Prospectively, no consent
- Secondary data, via contract
- Secondary data, via consent for broad use
- Secondary data, no consent or contract

Please select all of the options below for the locations or systems that you will use to collect or store any electronic data.

- Duke Supported Internal Fileshare/Server
- Duke Box
- PACE
- Duke University/OIT
- Duke Internal Sharepoint
- Duke REDCap
- Duke Qualtrics
- Duke OnCore
- Advarra eReg
- DCI Vendor platforms
- DCRI Vendor platforms
- Durham VA
- Research sponsor (including sponsor's contracted vendors/EDC systems)
- Personal devices (not issued or managed by Duke)
- Encrypted storage devices
- Unencrypted storage devices
- Other storage or systems internal to Duke (including software installed locally)
- Other storage outside Duke Health

Please describe the other location or systems where electronic data will be collected or stored.

Will your study have paper documents?

- Yes
 No

Please describe where paper data for the study will be stored.

You indicated that your project will include identifiable data from Duke patients without consent. Your data must be stored within PACE

If you have not selected PACE as a storage location for this study. Please go back and edit your response to select PACE as a storage environment.

You indicated that your project will include SSNs for research use with consent. This data must be stored in PACE.

You can use REDCap, provided you use the PACE user rights template for this project, and any de-identified data will need to be downloaded into PACE.

If you have not selected PACE as a storage location for this study. Please go back and edit your response to select PACE as a storage environment.

The next questions are about any websites or technology you may be using in this study.

Click to select all of the following types of website/tech/apps that apply to this project

- Website Web application Mobile application Wearable Medical device
 Other technology No technology beyond web-based surveys or management/analysis software involved

You selected other technology. Please describe your technology below.

Who built/developed the website for this project?

- It was built at Duke
 It was built outside of Duke
 The website is being provided by the Industry sponsor of the study

For your website, please check any of the following that apply.

- The website will collect data
 The website is hosted outside of Duke (i.e., on non-Duke servers)
 The website will be Duke branded
 None of these apply

Who built/developed the web application for this project?

- It was built at Duke or on behalf of Duke
 It was built outside of Duke - e.g., by a collaborating institution
 It is commercially available - i.e., this can be downloaded from an app store
 It is being provided by the Industry sponsor of the study

Who built or developed the mobile application?

- It is commercially available
 Built by Duke student

Who built/developed the wearable for this project?

- It is a commercially available device (for example a Fitbit or Apple Watch)
 It was built outside of Duke and is not commercially available
 It was built at Duke
 It is being provided by the Industry sponsor of the study

Are all medical devices being provided by the Industry sponsor of the study?

- Yes No

Is the other technology being provide by the Industry sponsor of the study?

- Yes No

Please provide details on the other technology, including who provided it for use in the study.

Next we would like to know about your data storage and computational needs.

Will your total data storage exceed 1TB or will you require a specialized computational environment?

- No Yes (this is not common) Unsure

Please describe your storage or specialized computational needs

Finally, we want to know about any parties outside of Duke that you may be working with on this study. This could be a sponsor, a collaborator, another site, or another type of third party entity. This includes receiving data from a source outside of Duke, including a government source.

Are any of the following true about this project? Select all that apply

- I will be receiving data from a government source (including the VA)
 I will be receiving data from an outside source other than the government
 I will be collaborating with someone at another institution or site
 I will be working with data in a secure enclave not located at Duke
 I will be collaborating with a company
 I will be collaborating with individuals outside of Duke not affiliated with another institution or company
 I will be using data that was previously collected under an commercially funded agreement or project
 None of the above are true

Do you have any federal funding associated with this project?

- Yes No

Is this collaboration outside of the terms of the award as specified in your Notice of Award?

- Yes No

Does the current award, contract, or agreement have specific terms and conditions associated with the handling, protection, or use of data?

- No Yes Unsure I don't have a contract/agreement

Please describe your collaboration

DRDL URL
