*“How can we safely store research data?”*

The goal of this project is to create a piece of software that employs best practices for maintaining participant privacy while facilitating data analysis for research.

Sharing data safely while preserving privacy

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| --- | --- | --- | --- |
| **Existing Solution** | **Availability (open source, license, etc)** | **Ethical regulations/compliance** | **Notes** |
| REDCap (Research Electronic Data Capture) | Not open source, requires a license agreement | “capable of compliance with just about any standard – for example, HIPAA, Part-11, and FISMA standards… as week as other standards (including similar international regulations like GDPR)[1] | Browser-based, metadata-driven EDC software and workflow methodology for designing clinical and translational research databases[2]. Organisations can extensively customise their REDCap system with built-in software development tools; open architecture. |
| Castor EDC | Has a free trial, main program requires a license | Compliant with ISO standards, has certificates:   * ISO 27001 * NEN 7510 * ISO 9001   Also FDA 21 CFR Part-11 compliant. | Cloud-based clinical data management platform, enabling researchers to easily capture and integrate data from clinicians, patients, devices, wearables, and HER (electronic health record) systems[3]. |
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References:

1. <https://projectredcap.org/about/faq/>
2. <https://en.wikipedia.org/wiki/REDCap>
3. <https://www.castoredc.com/>

**Compliance Standards**

# The Privacy Act 1988

# The Privacy Act 1988 is an Australian law dealing with privacy. It was introduced to promote and protect the privacy of individuals and to regulate how Australian Government agencies and organisations with an annual turnover of more than $3 million, and others, handle personal information.

# HIPAA (Health Insurance Portability and Accountability Act)

# The Health Insurance Portability and Accountability Act of 1996 is a United States federal statute. It was created primarily to modernize the flow of healthcare information, stipulate how personally identifiable information maintained by the healthcare and healthcare insurance industries should be protected from fraud and theft, and address limitations on healthcare insurance coverage.

# Part-11

* FDA 21 CFR Part 11 compliance dictates that those companies who use electronic systems for document and signature control must provide assurance that the electronic documents are authentic. The regulations all stipulate the necessity of the confidentiality of electronic records.
* FDA 21 CFR Part 11 compliance dictates that all system users have the training necessary to perform their assigned tasks and projects.
* FDA 21 CFR Part 11 compliance dictates that electronic records that are signed must contain a name, the signature meaning and the date/time of signing.
* FDA 21 CFR Part 11 compliance dictates that signatures whether electronic or handwritten be linked to their respective records.
* 21 CFR compliance dictates that an FDA-regulated company's electronic system must be validated according to the FDA's validation standards.

**ISO 27001:**

ISO 27001 is a standard that requires an organization to set up an information security management system (ISMS) that will safeguard the availability, integrity and confidentiality of the data that is handled by the organization. Castor has been ISO 27001 certified since 2017.

**NEN 7510:**

NEN 7510 is a standard for information security in healthcare. It is the Dutch equivalent for ISO 27001 with additional requirements on how to handle patient data. Castor has been NEN 7510 certified since 2017.

**ISO 9001:**

ISO 9001 is a standard that requires an organization to set up a quality management system (QMS) to consistently provide products and services that meet customer and regulatory requirements. Castor has been ISO 9001 certified since 2018.

List of REDCap Alternatives and Competitors:

<https://www.g2.com/products/redcap/competitors/alternatives>

<https://multisearch.mq.edu.au/discovery/fulldisplay?docid=cdi_springer_primary_2018_10916_42_8_995&context=PC&vid=61MACQUARIE_INST:MQ&lang=en&search_scope=MyInst_and_CI&adaptor=Primo%20Central&tab=Everything&query=any,contains,sharing%20data%20safely%20while%20preserving%20privacy>

<https://search-proquest-com.simsrad.net.ocs.mq.edu.au/docview/2061282109?pq-origsite=primo>

<https://www-sciencedirect-com.simsrad.net.ocs.mq.edu.au/science/article/pii/S0140673619326030>

<https://gdpr-info.eu/>

<https://www.hhs.gov/hipaa/index.html>

<https://www.health.nsw.gov.au/patients/privacy/Pages/default.aspx>

<https://empowers.brother.com.au/2019/03/21/what-is-the-australian-equivalent-of-hipaa-why-does-it-matter/>