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THE HARVARD CLINICAL
AND TRANSLATIONAL
SCIENCE CENTER



Research Electronic Data Capture

REDCap and eConsent

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Partners HealthCare | Enterprise Research Infrastructure & Systems

Harvard Catalyst | The Harvard Clinical and Translational Science
Center

Partners HealthCare Access: <https://redcap.partners.org/redcap/>

Partners users can log in with their Partners usernames and passwords

Language for grant and IRB submission:

<http://rc.partners.org/boilerplates>

Getting Started website:

<http://rc.partners.org/redcapgettingstarted>

Support:

1.5 FTE : 10,016 Projects : **11,633** Active Users

1-2 Business Days for most responses

2-5 Business Days for some requests

Contact EDC Support edcsupport@partners.org

Training:

There is no formal training required to use REDCap. Video tutorials and Help&FAQ page in REDCap contain a lot of useful information.

There are many types of informed consent docs / processes:

1. Informed Consent in Online Research:

- IRBs may waive the requirement for written documentation of informed consent when the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context or when the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Online research involving adults often meets one of these conditions. A consent procedure in which subjects are provided with a written statement about the research followed by a button to click that states, “I AGREE TO PARTICIPATE IN THIS RESEARCH” is often acceptable.
- PHRC Guidance for [Guidance on Research Using the Internet > Informed Consent in Online Research](#)

2. Informed Consent obtained via paper then scanned to electronic certified copy

- PHRC Guidance for [Electronic Storage of Research Documents](#)
- [HOW TO: Scan and Store Research Documents in REDCap](#)

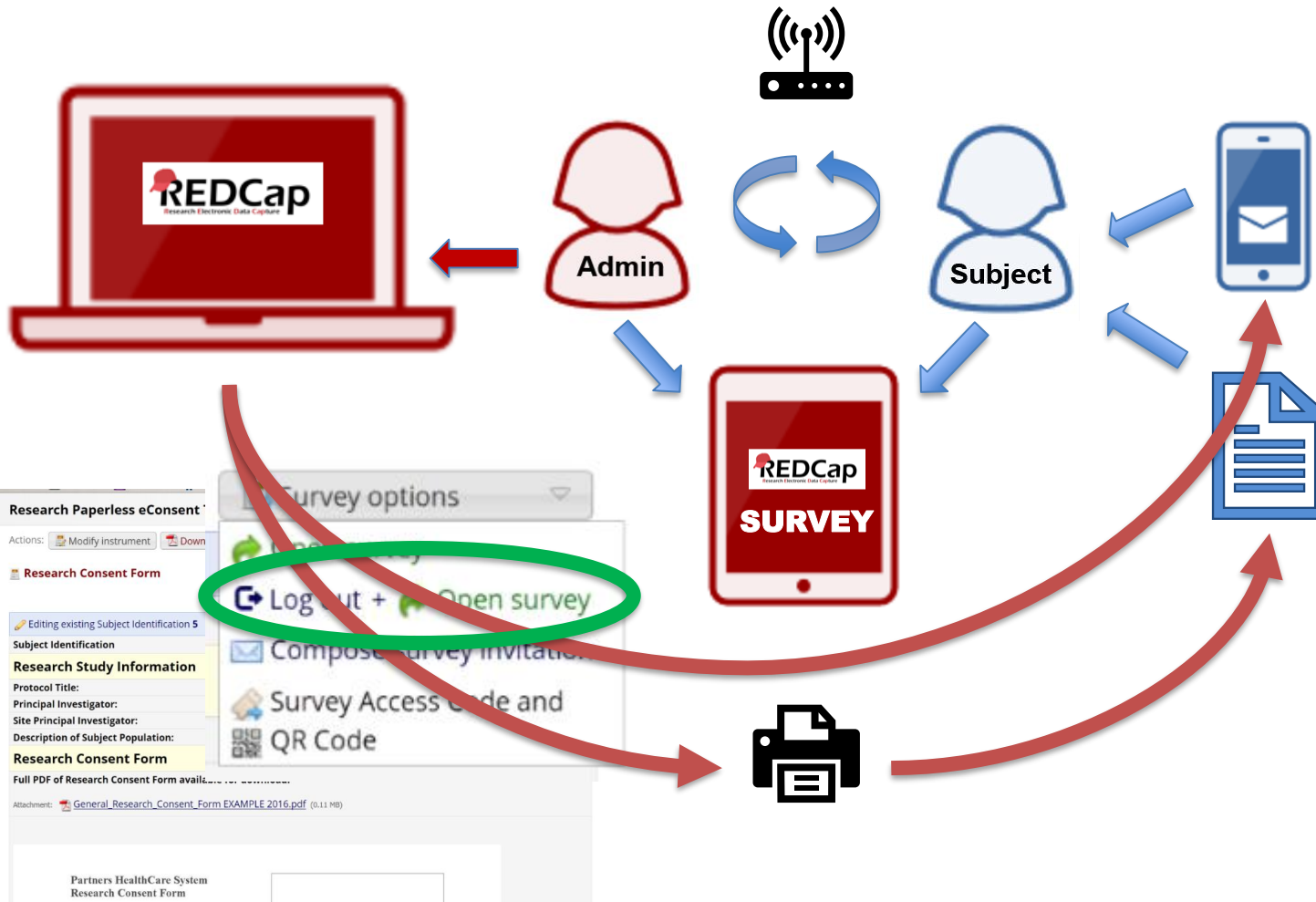
3. Informed Consent where a computer/device can be substituted for paper; study team interaction is same as paper process; also know as Paperless Consent or eConsent

- This is a Handwritten Signature applied to electronic media (21 CFR Part 11 Training 25 Oct 2017)
- [HOW TO: REDCap eConsent / Paperless Consent](#)

4. Electronic Informed Consent (eIC) where a computer / device takes the place of paper and people (everything is online/electronic).

No “template” REDCap solution. Requires participant identity management and demonstration of understanding of IC.

Workflow Logistics



Requirements

- Must have an email address
- Must use secure email protocol

eConsent email Distribution

- **Consent forms are PHI**
- **PHI cannot be directly emailed to participants because email is not secure.**
 - Use SEND SECURE or
 - Use REDCap Survey Login Feature or
 - Document Participant Encrypted Email Opt-Out
 - Print
- [PHS IS Email Security Policy](#)
- PHRC IRB [FAQ's about email communication with research subjects](#)
- ERIS [REDCap and SEND SECURE](#)

How do document someone's agreement to communicate by non-secure email?

Individuals may read or have read to them the following information, and then can agree by signing or verbally acknowledging that they agree to receive un-secured email.

Researchers are required to document this agreement, including the date of the agreement, by noting it in research records, or retaining the participant's a signature.

Required Warning Language: Before sending or responding to an unencrypted email message to an individual, the individual must acknowledge understanding of, and agreement to accept the risks as communicated to them via the following language (this language must be copied into an email response to an individual, or may be read over the phone to the individual, or an individual could agree by reading this in person and signing this or simply agreeing verbally):

“The Partners standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. If you prefer, we can send you “unencrypted” email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.”

HOW TO: eConsent / Paperless Consent

- HOW TO: Project Setup
- HOW TO: Production Project - General instructions to consent the participant
- HOW TO: Make Changes / Amendments to Consent Forms

Contact Information for Harvard Catalyst REDCap Support Staff

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edc@bidmc.harvard.edu

<http://www.bidmc.org/Research/CoreFacilities/REDCapEDC.aspx>

For support for other Harvard schools or affiliated academic health care centers,
contact edcsupport@partners.org