Lowering the regulatory barriers to clinical data reuse for research and quality improvement

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ABSTRACT

Clinical and research data are increasingly collected and aggregated in clinical data warehouses (CDWs). Access to these data is subject to local, state and national regulations. For multiple reasons, institutions differ in how they interpret and apply these regulations. Sometimes, inter-institutional differences are unavoidable, such as when regulations clearly require specific practices. However, in some cases, institutional practices can change. Therefore, sharing of institutional practices may lower the barriers to clinical and translational research while still complying with applicable regulations.

The University of Texas Health Science Center at Houston (UTHSC-H) has maintained a CDW since 2006. The CDW currently contains fully-identified data on over 5.2 million individuals derived from multiple sources, including administrative/billing systems, multiple institutional EHRs dating back to 2004 and research data (e.g., from clinical trials or survey studies). In addition to structured data, the CDW contains over 30 million notes, updated on an as-needed basis.

Access to these data is governed by an "umbrella protocol" approved by the institutional review board (IRB) in 2013. Since then, investigators can access these data via a streamlined process administered by our CTSA informatics component. Research covered by the umbrella protocol must meet three criteria: 1) the data must remain on institutional servers with access to these servers controlled by the CTSA informatics group (i.e., data are read-only and cannot be copied from these servers), 2) no contact with patients/subjects (e.g., cannot obtain additional data) and 3) no protected health information can be released (e.g., published). As long as the research complies with the above, no further IRB approval is necessary.

Recently (October 2020), we implemented an additional feature to help the growing number of investigators who apply and receive funding for research that complies with the rules of the umbrella protocol. In many cases, investigators must demonstrate that their specific project is approved by the IRB; umbrella protocol documents are not sufficient. To address this need, and working with our IRB, we created a REDCap form that documents compliance with the umbrella protocol and generates an official letter that can be submitted to the funding agency. We do not yet have quantitative data regarding usage, but anecdotal feedback from investigators is very positive.

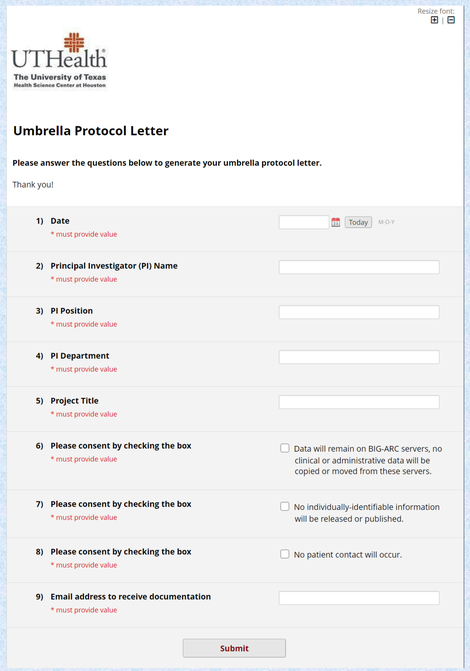
Background

- Clinical data warehousing is increasingly common and useful for clinical and translational research
- National, state and local (institutional) rules govern the reuse of routinely collected clinical data
- Institutions vary in their interpretations of these rules; some are more permissive than others.
- Sharing the processes developed at CTSA hubs can help decrease regulatory barriers across the CTSA Network.

Clinical Data Access Process

- Since 2013, the "**umbrella protocol**" covers research that complies with the following:
  1. Data remain on the BIG-ARC (CTSA Informatics Group) servers
  2. No protected health information (PHI) is published or released
  3. No contact with patients (e.g., no additional data can be collected)
- If a project complies with the above, no additional IRB review or approval is required.
- Typical time to obtain access to identified data is 24 hours

"Real-time" umbrella protocol documentation



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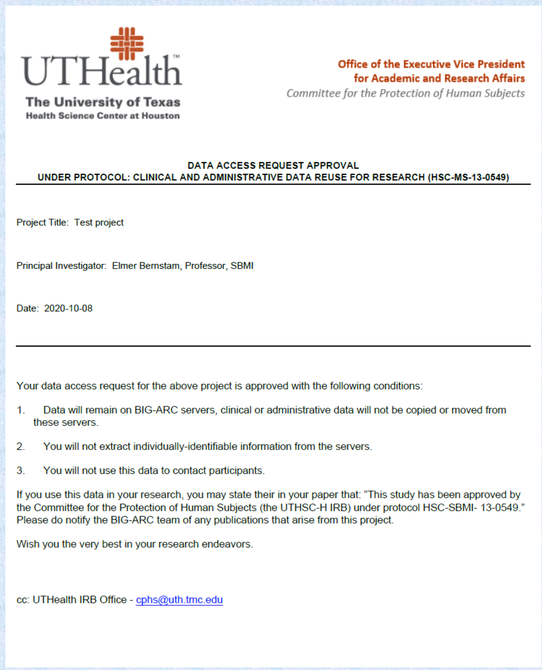
Umbrella Protocol Letter

Please answer the questions below to generate your umbrella protocol letter.

Thank you!

1) **Date** — * must provide value — Today M-D-Y
2) **Principal Investigator (PI) Name** — * must provide value
3) **PI Position** — * must provide value
4) **PI Department** — * must provide value
5) **Project Title** — * must provide value
6) **Please consent by checking the box** — * must provide value — ☐ Data will remain on BIG-ARC servers, no clinical or administrative data will be copied or moved from these servers.
7) **Please consent by checking the box** — * must provide value — ☐ No individually-identifiable information will be released or published.
8) **Please consent by checking the box** — * must provide value — ☐ No patient contact will occur.
9) **Email address to receive documentation** — * must provide value

Submit



UTHealth
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Office of the Executive Vice President for Academic and Research Affairs
Committee for the Protection of Human Subjects

DATA ACCESS REQUEST APPROVAL
UNDER PROTOCOL: CLINICAL AND ADMINISTRATIVE DATA REUSE FOR RESEARCH (HSC-MS-13-0549)

Project Title: Test project

Principal Investigator: Elmer Bernstam, Professor, SBMI

Date: 2020-10-08

Your data access request for the above project is approved with the following conditions:

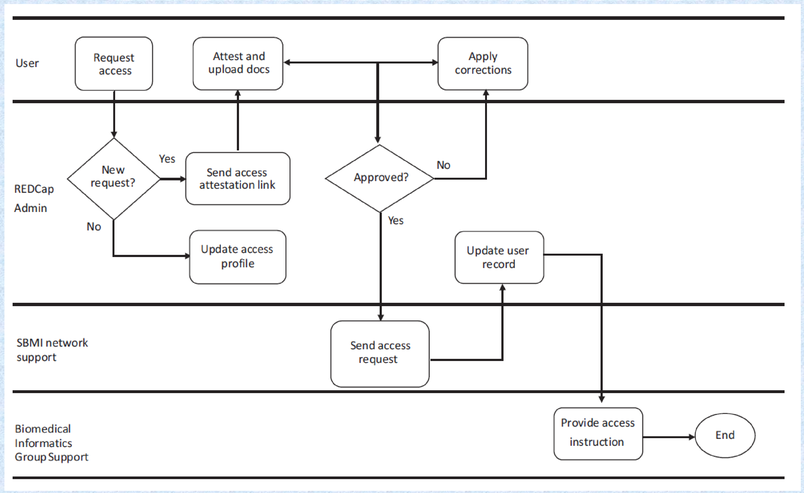
1. Data will remain on BIG-ARC servers, clinical or administrative data will not be copied or moved from these servers.
2. You will not extract individually-identifiable information from the servers.
3. You will not use this data to contact participants.

If you use this data in your research, you may state their in your paper that: "This study has been approved by the Committee for the Protection of Human Subjects (the UTHSC-H IRB) under protocol HSC-SBMI- 13-0549." Please do notify the BIG-ARC team of any publications that arise from this project.

Wish you the very best in your research endeavors.

cc: UTHealth IRB Office - cphs@uth.tmc.edu

Data access process using the umbrella protocol



Obstacles

- Need project-specific documentation of approval under the umbrella protocol. Not new approval, since the protocol is already covered by the umbrella protocol, but documentation of existing approval.
- Most common scenario is in the context of grant submission or "just-in-time" (JIT) requests from funding agencies.
- Previously required formal change requests to be approved by the IRB.
- Now documentation can be obtained in near "real-time" using a REDCap form.
- Benefits include:
  1. Improved tracking of projects (IRB receives copy of letter).
  2. Explicit acknowledgement of compliance with the umbrella protocol rules.

Current state

- Systems implemented and in routine use.
- Tracking usage.
- Documenting benefits challenging, except anecdotally (e.g., researcher feedback).

References

Guerrero SC, Sridhar S, Edmonds C, Solis CF, Zhang J, McPherson DD, **Bernstam EV.** Access to routinely collected clinical data for research: A process implemented at an academic medical center. Clin Trans Sci, 2019 May;12(3):231-235. doi: 10.1111/cts.12614.