

Guidance: Use of Third-Party Vendors in studies

There is an increasing trend to utilize third-party vendors to manage certain aspects of studies. Third-party vendors may include service vendors for things like:

- travel arrangements (e.g. Clincierge),
- participant reimbursement services (like Greenphire's ClinCard),
- participant home delivery of study drug,
- home health care service providers to conduct study assessments in a participants home

Other third party vendors may include things like:

- technology apps or platforms to collect study data directly from participants (e.g. eDiaries, personal monitoring equipment like actigraphs, etc)

Many third party vendors require the collection of personal information from study participants to utilize the service. Participants who are considering joining a study must be informed of the kind of personal information that will be collected from them when participating in a study. The REB review of these third party apps will be proportionate to the level of sensitivity of the data being required of participants (i.e. Full name, DOB, SIN), as well as the location of the data servers for the third-party vendor (i.e. within Canada versus outside of Canada). Wherever possible, study teams are encouraged to manage this locally and/or utilize Canadian providers. Researchers should attempt to collect the least amount of identifiable data required to provide the service to participants. The risks that study participants may encounter by using these services/platforms must be clearly defined in the ARISE application and in the participant consent form.

Privacy and Security Reviews

A privacy and security review (PSR) by the University of Alberta Information and Privacy Office (IPO) is required when any study proposes the use of a third-party vendor that seeks to collect personally identifiable information from study participants. The Research Ethics Office holds a list of systems which have been reviewed and vetted. You may be asked to complete the [Privacy and Security Review Checklist](#) for a third-party vendor if highly sensitive personal data about study participants is being requested as

part of their study participation. PSR's can take 6-8 weeks to complete. If the vendor you are using has already received a favorable review, the following text can be added to the consent form:

*As part of this study, the Sponsor is using a third-party (service/technology) to **[enter what third party services will be used and for what purpose]**. If you participate in this study you will be asked to provide **[enter details about what the participant will need to provide ie. identifiable, banking info etc]**. A privacy and security review of **[system]** has been undertaken by the University of Alberta. The purpose of this review is to make sure that the system has appropriate practices in place to protect your privacy. We cannot guarantee that there will not be a privacy breach, but we have taken these measures to try to minimize any possibility that your information will be at risk. If you are not comfortable with the potential privacy risks, the study team will explain the alternatives to you.*

Information Required by the REB

If your study proposes to utilize a third-party vendor which may be collecting personally identifiable data from study participants, the researcher should understand the following and articulate responses to these questions in the ethics application and consent form, as applicable.

Information about third-party vendor	Participant Consent form *	Ethics application
What is the name and address of the third-party vendor?	YES	YES
Are there agreements in place between the Sponsor and the third party vendor? And if so under which legal jurisdiction do they fall?	YES, if Outside of Canada	YES
What specific services will the vendor be providing?	YES	YES
What data will they be collecting?	YES	Section 5.2 (1.0 and 2.0) should clearly outline what will be collected
Provide a justification for the collection of all data elements	YES	Section 5.2 (3.0) should outline WHY it is needed. Minimal personal identifiers should be collected.
Who will have access to the data?	YES	YES

Provide names and business addresses.	YES – name	YES
Where will the data be kept?	YES	YES
How long will the data be kept?	YES	YES
What happens to the data at the end of the study?	YES – outline if data will be destroyed by the vendor at the end of the study AND if the participant withdraws early, what is the mechanism to have the data destroyed.	YES – can be outlined in Section 4.5 (6.0).
Will the data be sold?	This should be explicitly stated in the consent form	YES
Will advertising materials be sent to the participants?		Researchers should ensure that advertising materials would not be sent to study participants by third party vendors simply by enrolling in this study.
What provisions are in place for Confidentiality and Data Security?	YES	Section 5.3 of the ethics application.
Who do they contact if there is a concern regarding data handling or data breaches?	YES	

* Any language in consent forms related to Privacy Policies, End User Licenses Agreements or Terms of Use for any third-party vendor system, must be written in accordance with the HREB Guidelines: Grade 8-10 level of understanding, lay language, non-legal. Simply referring people to the vendor’s Privacy Policy, End User License Agreements or Terms of Use will not be approved by the HREB.