



THE UNIVERSITY OF
MELBOURNE

Data Collection via 3rd Party Online Platforms

**Legal and ethical obligations and implications for
clinical trial design**

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Online platforms (APP or website)

Definition

- An **application** is a software program that is designed to perform a function directly for the user, often downloaded by a user to a mobile device.
- A **website** is a set of related web pages located under a single domain name.

Use

- About 20% of UoM sponsored clinical trials use an APP or website for information display and/or participant-entry data collection.

Purpose

- Displays information only.
- Collect general data such as time spent viewing the APP, pages viewed etc.
- Collects personal and health data such as name, date of birth, medical conditions.

What is not a third party online platform in this context?

- University assessed, endorsed and centrally-provided platforms including REDCap and Qualtrics etc.



Privacy and data protection

- Legal and ethical obligations for collection, storage, use and disclosure of personal or health information including sensitive information.
- University's Policies
 - Research Data Management Policy (MPF1242): <https://policy.unimelb.edu.au/MPF1242>
 - Privacy Policy (MPF1104): <https://policy.unimelb.edu.au/MPF1104>
- Clinical trial data is classified as sensitive health information which is regulated under
 - Commonwealth's *Privacy Act* 1988
 - State based health information or records legislation, including *Privacy and Data Protection Act* 2014 (Vic) and *Health Records Act* 2001 (Vic)
- Research Gateway Articles:
 - Managing Sensitive Data (<https://gateway.research.unimelb.edu.au/resources/data-and-computation/research-data-management/manage-sensitive-data>)
 - General Privacy Statement (<https://about.unimelb.edu.au/strategy/governance/compliance-obligations/privacy/privacy-statements/general-privacy-statement>).



What needs to be considered?

Disclosure to participants

- Participant Information Sheet; and/or
- APP/website disclaimer at time of download/sign-in.

Agreements with the third parties

- Acquisition of Services to develop APP/website
- Data Transfer



Participant disclose and consent

- Need to inform participants that their data will be collected by an independent third party.
- Participant Information Sheet/Consent Form needs to state:
 - The online platform is owned and controlled by a third party including data collected and stored.
 - UoM has no control over the online platform or will assume no liability for use, misuse, data breach etc.
 - When they download the APP or log into the website they will be asked to agree to the third parties legal terms and conditions.



Participant disclose example

- The Study involves the use of an App downloaded to your smartphone, known as STEP1®, that collects data during use. The App has been developed by an independent third party (STEP1, www.step1.com) which is based in New Zealand. The App is owned and controlled by the independent third party, including the data that is collected at any time when the APP is used by you (the Controlled Data).
- By agreeing to participate in this Study, you acknowledge that the Researchers will require access to the Controlled Data that is collected during the course of the Study and you permit the Researchers to do so solely for the purpose of the Study (the Study Data). The Study Data will be handled by the Researchers as set out in this Participant Information Sheet. You acknowledge and understand that the collection, use and disclosure of the Controlled Data which includes your personal information, will be handled in accordance with STEP1's Privacy Policy which may be found on its website at the following address (www.step1.com/privacypolicy).
- By downloading the App for this Study, and, if you chose to keep the App at the end of the Study or after withdrawing from the Study, you acknowledge and understand that you are agreeing to the terms and conditions of use of the independent third party's, which may be found on its website at the following address (www.step1.com/terms-and-conditions).



Online platform disclaimer

- Suitable for in-house developed APP/website.
- Included at the time of sign-up.

Example

- “By agreeing to participate in the “Asthma Self-help” Study, you acknowledge and understand that you are agreeing to the terms and conditions of use of the independent third party’s, WPCContent™ web hosting. You acknowledge that the researchers at the University of Melbourne (Sponsor of the Study) (Researchers) will require access to the data that is collected during the course of the Study and you permit the Researchers to do so solely for the purpose of the Study (the Study Data). The Study Data will be handled by the Researchers as set out in the Participant Information Sheet. You acknowledge and understand that the collection, use and disclosure of the data which includes your personal information, will be handled in accordance with WPCContent web hosting’s Privacy Policy which may be found on its website at the following address ([www. WPCContent.com/legal/privacy/](http://www.WPCContent.com/legal/privacy/)). Contact the research team asthmaselfhelpstudy@unimelb.edu.au



Agreements between UoM and third parties

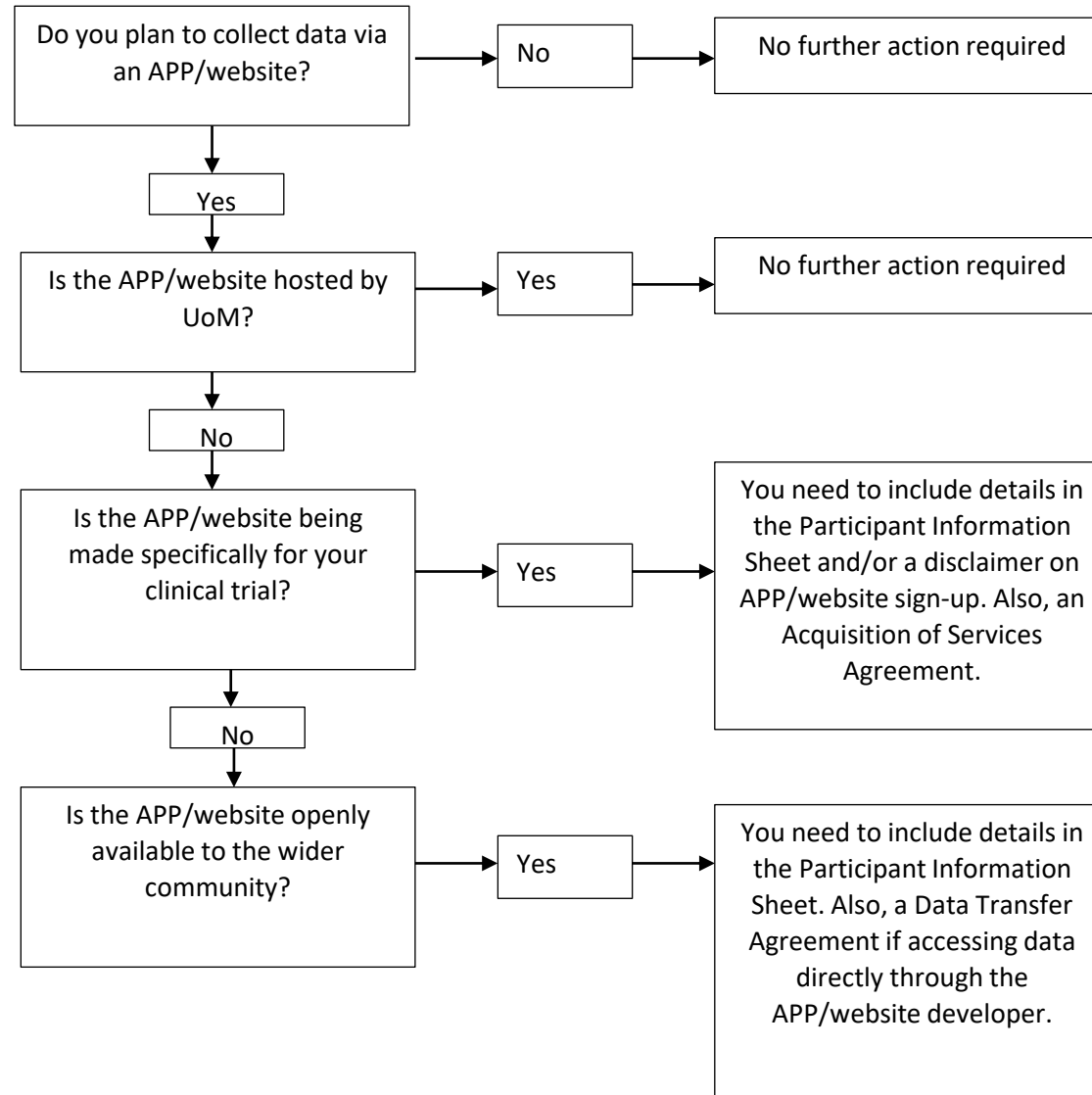
UoM owned APP/website

Acquisition of Services to develop APP/website – also includes data transfer terms.

Third party owned APP/website

- Data Transfer Agreement - between UoM and third party.
- Allows for the third party to share the participant data with UoM and set out what, when and how the data will be shared.

Flow chart of decision making





How to prepare for APP/website use

- **Consider your options:**
 - Commercially available APP/website.
 - Self designed APP/website.
 - Do you want the APP/website to collect data?
 - Will you access the data directly or will the participants relay the data back to you?
- **Think about it early:**
 - Before deciding on the APP/website examine their T's&C's and privacy policy.
 - Before ethics submission consider what information you need to include in the PICF.



Thank you