

Electronic Informed Consent

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July 11, 2013



Introduction

- What is the scope of electronic informed consent?
- What are the issues?



Examples - Mechanisms

- Computer on-site
- Computer remote, using internet
- i-pads, smart phones, other PDAs.
- What type of communication? E-mail, instant messaging, twitter, tumblr, etc.
- Fax?



Examples - Signature

- Electronic consent form to be signed using a formal electronic signature.
- Electronic consent form signed using a digital pen.
- Electronic consent form “signed” by checking a box that says “I agree.”
- Electronic consent form where hitting “next” leads directly to the research project.



Examples – IC Process

- In person consent using an electronic device
- Real time conversation over the phone, webex, etc.
- Ability to ask questions, but only if subject reaches out.
- No plan for interaction, consent takes place electronically only.



Legal/Regulatory Issues

- For FDA regulated research, compliance with 21 CFR Part 11, “Electronic Records; Electronic Signatures.”
- OHRP has an FAQ on electronic consent.
- HIPAA
- State law - 47 states have adopted the Uniform Electronic Transactions Act (UETA).
- Laws of other countries, such as PIPEDA in Canada.
- Which law applies when PI in Kansas and subject is in Washington state or Canada?
- When can waivers of consent or waivers of documentation of consent be used under HHS, FDA and HIPAA regulations?



Finer Points – Example

Email from last week:

- I have a question regarding one of the recruitment materials for the US central IRB sites and the Canadian central IRB sites. With regards to google and Facebook ads, the pixel tracking involves placing in one pixel of the site a tracker for Facebook that will be able track users who visit the site through Facebook so that it is possible to re-target them (similar to cookies but specific to the Facebook media). It is allowed by law, but it is something we would like to confirm with IRB and the ECs to make sure we have their approval to run it. According to the [company's] Privacy Policy, cookie tracking is allowed. We would also like to confirm that IRB and the ECs are fine with this type of tracking, as well.”



TOPIC | WoW Research at the University of Denver



Endersgame ▾
74 Human Warrior
Golden Redemption
860 🍌

Hi, if anyone could take the time to complete a bried survey about gaming habits in WoW, it would be greatly appreciated, as this is essential for completing a university research project. If you should choose to take this voluntary survey, know that none of your personal information will be shared with anyone at any time. Your anonymity will always be protected. The link to the survey is below.

Thanks!

<https://spreadsheets.google.com/spreadsheet/viewform?formkey=dEpJQXM4bmhjUjRVOFBaER3OS1KVXc6MQ>



Omegi ▾
85 Draenei Priest
Apathy
2735 🍌

Being as this is research conducted by the University of Denver, shouldn't you like to the Universities website regarding the research and from there the data will be collected?

Seems a bit more above board when considering uncontrolled data collection can be manipulated or misinterpreted and the end result would be void.



Adzon ▾
90 Night Elf Druid
Nerfed
7535 🍌

Im guessing this is for an undergraduate paper, whos results cant be published anyway because of IRB issues. Lets help them out!