Consent2Share – Study Subject Recruitment

Modified: August 2019

Background:

Obtaining sufficient subjects into research studies is an ongoing barrier to conducting clinical research. Consent2Share is a process by which patients in certain UF clinics, coming to their clinically scheduled appointments are asked to consent to having researchers review their electronic medical records (EHR), and if they meet study criteria for future research, being contacted by those researchers and asked if they wish to be involved in a research project.

1. **Q: How is Consent2Share used to determine if there are potential study subjects for a particular research protocol?**

By using i2b2, an NIH sponsored Query and Analysis tool from an investigators computer, one has access to clinical data from a variety of clinical and administrative information systems within the institution. Currently, i2b2 http://idr.ufhealth.org/i2b2/ can be used by faculty researchers to query clinical data across Gainesville and Jacksonville area UF health system locations. When using i2b2, in addition to determining how many patients meet study specific inclusion\exclusion criteria, the query can determine how many patients with particular clinical characteristics, have also consented to be contacted for future research through the Consent2Share Program.

2. **Q: Once it is known how many potential subjects agreed to being contacted for future research, how is their contact information obtained?**

The steps are as follows:

- Submit your protocol to the UF IRB for approval. Check the box that indicates you would like to use the Consent2Share program as one of the means for study subject recruitment.
- Once IRB approval is obtained, contact the UF Consent2Share Helpline: 352-265-DATA (352-265-3282). You will need to provide your IRB approval letter.
- The IDR staff will provide you a list of those potential study subjects as approved by the IRB.

3. **How many names and contact information can be requested from the IDR staff?**

The IRB requires all investigators to determine how many study subjects are needed to complete the research project. If an investigator is using Consent2Share to obtain potential study subjects, the IDR staff will work with the study team to determine how many potential study subject contacts they will provide. The IDR staff will send out potential subjects in batches until the study team reaches the "screening number" listed in the IRB. The IDR staff will determine together with the researcher the frequency and the number of patients to be released in each batch.

4. **Q: When contacting potential study subjects from Consent2Share, are there any special instructions?**

   Yes. To help remind the potential subject as to how the UF researcher obtained their contact information, the follow language should be used based on the type of contact:

   - **Cover letter or recruitment language for contacting potential subjects obtained from the Consent2Share Process**

     Dear <potential subject name>,

     My name is <name> and I <title or study staff relationship> from <UF or Shands>. I am contacting you to see if you are interested in participating in a research study <describe the topic briefly [eg. On diabetes]> . During a past clinic visit, you signed a consent form telling us you were interested in being contacted for future research that you might qualify for. The following is information about a research study on <state topic [eg. Diabetes]> that you might qualify for. If you are interested, please read the following and <include the process for the subject to complete something, call you back, etc.>

   - **Phone Script for contacting potential subjects obtained from the Consent2Share Process**

     Hello, my name is <name> and I am <state your research related title or function> calling from <UF or Shands>. I am contacting you to see if you are interested in participating is a research study <describe the topic briefly [eg. On diabetes]> . During a past clinic visit, you signed a consent form telling us you were interested in being contacted for future research that you might qualify for.

     Are you interested in hearing more about this research study <state topic [eg. Diabetes]>??

     If no, thank them for their time
     If yes, proceed with your description, include language below