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Consent Tracking for Clinical Trial Samples

Informed consent basics

There are several parameters that describe what the FDA considers informed consent. In general, the FDA requires a patient to have adequate information to allow them to make an informed decision about participating in a clinical trial and an appropriate amount of time to ask questions. There must be a process with documentation in place to demonstrate that the patient understands all of the information about the study, as well as a way to document that the patient may have agreed to only certain parts of a study or subsequent use of their samples.

Nested within this whole process, and the documentation, is the information about biological samples. In other words:

- What is being collected?
- How often?
- For what purpose?
- Will the patient be provided the results of any testing?
- How long can those samples be stored?
- And can they be used for other purposes outside of the original reason that they were collected?

When someone gives consent to participate in a trial, they can choose which uses of a sample to allow. Therefore, there may be multiple variables to track on multiple samples.

There must also be a process to provide information about and give consent for changes in the trial as it progresses. Almost every protocol is amended for one reason or another. It could be a change to a testing procedure. It could be an addition of a visit, changes to the actual sample collection or the addition of a new lab or a new site. Consent is not required for every change, unless it's going to impact the patient, such as a new visit or an additional collection.

This is a lot for the patient to understand. Historically, consent to collect and analyze biological samples from patients in clinical trials was captured on paper. Patient consents were designed as a set of documents intended for a patient to sit down with a clinical investigator or a nurse and go through all the documents together to fully understand how the samples would be used.

Future use

Typically, the future use of the sample data and the actual sample itself is unknown at the time of collection. But these samples can be very valuable to the research community. Therefore the data and samples are stored in repository for a certain amount of time, with the capability to be traced back to the original donor, if necessary.

Electronic consent

Samples can also be stored in an anonymized way, including data without any identifiers that can be linked back to the individual donor. This is typically also covered in the consent documentation.

Documentation around consent has not always been captured in an easily analyzed format; the information was not in a database. Knowing what use of a sample has been approved was difficult. Recently more of this process is becoming digitized. There are now e-consent, or electronic consent tools that investigators can use to digitize the documentation and capture information in a format that can be analyzed and queried.

A good practice is to extract some of the key information from the consent documents in a computable format. The best practice is to collect it in a database directly. That allows the investigators to easily determine which samples can be used for what purpose.

Risks of paper tracking

If investigators can't get the information because it's not captured in a digital format, and they're not able to review it prior to running a test or storing samples, perhaps not knowing if proper consent was collected, this can be a huge non-compliance issue, and can actually lead to significant risk for the trial, and even for the organization.

Consent attributes

There are a few common consent attributes. In general, there is the main study consent – what samples are collected specifically for the study and the study's analysis plans. This often includes the basic safety samples like blood panels and pregnancy tests. Beyond that, there may be genetic testing, which includes samples that are targeted for specific genetic analysis, which in itself is a bit of a moving target.

Consent for a particular genetic test might extend to or include other genes. The consent process needs to be clear about any genetic testing, whether a patient can opt in or out of any of the selected or extended tests. There can be consents for additional genetic testing which accounts for these extended testing situations, when panels are overly inclusive for genes outside of the specific scope of a trial. Storage duration, the length of time sample can be stored in the repository after a study is done and completed, and future use are other common consent attributes.

Disposition of samples

One might hear whisperings such as "We have 17,000 samples in the freezer and we don't know what they're for, or where they're from." Researchers need to have a process in place to track that data.

When was the end of the study? How long has this the sample been in storage? And how long is the consented storage duration? It can be 15 or 20 years after the study closes. Having a process in place is important not only to avoid non-compliance, but also the unnecessary expense of storing samples that can no longer be used. Capturing this data electronically allows software to track it and notify researchers when samples are due to expire. They can be notified when it's time to release these samples for destruction.

Requirements for different sites or countries

Different sites and countries will have organizations or committees overseeing the consent process. Are samples being collected and stored according to their ethical standards? An institutional review board or IRB will preview all consent documentation, and give their approval when they feel that ethical standards are being met. There isn't one global governing body. There are different institutional review boards for different institutions. These IRBs may have their own opinions or approaches to their interpretation of ethical standards for samples and consent.

Each IRB has the right to approve or disapprove of the consent language used in a trial. Ethical standards may not be the same across different institutions that are performing research in both developed and developing countries. Therefore, the consent language needs to be captured clearly for each country, and maybe even each site within those countries.

Ideally there would be system in place that can define, for each country and site, the specific consent attributes for samples collected there. Although it's been done like this for many years, managing this level of detail on paper is horrendously time-consuming. The alternative is an electronic or e-consent model, where this information is all digitized, and we know in which country and site a patient is enrolled, which consent the patient agreed to and when, all in one place.

One can know the specific attributes for that country and site for each type of sample. Take that data and pair it with each individual sample that was collected. This will provide a concrete list of what samples can be used, when and how. This is the direction that we want to go. It's definitely a tall order. Sponsors know that this data and the ability to understand and have access to their it is essential in getting things right, from an ethical perspective.

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From a sponsor perspective, the process can be made easier by having a global template to start with, including the same basic elements for each of their consents. Any deviations from that global consent template specific for countries or sites are minor changes that can also then be digitized.

Capturing consent information electronically at all levels saves time and reduces risk and expense for clinical trial investigators.

Contact us

Toll free: +1 855.277.9929
Direct: +1 919.998.7000
International: +44 (0) 1506 814000
Website: www.Q2LabSolutions.com

Q² Solutions®