DNA genotek

Overcoming challenges in DNA sample collection

How epidemiological researchers are maximizing compliance rates with non-invasive DNA self-collection

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Letter from the author

The number of clinical trial and epidemiological studies collecting genomic DNA from a large number of individuals is increasing rapidly. These studies need high quality biospecimens from a representative sample of participants to investigate genetic influences on treatment response and disease[1].

There are many options for obtaining these biospecimens including blood collection, saliva collection, tissue and more. Obtaining quality samples from the groups defined in a study in sufficient quantities has often been a major challenge to the success of studies. Potential study participants are often reluctant to participate because they are needle phobic, do not want to travel to a specific location to participate in the collection process or are otherwise inconvenienced by the study criteria.

At DNA Genotek, we set out to discover how several successful studies have been able to meet their recruitment and compliance goals in a timely way and to summarize their success criteria in this report. We accomplished this through telephone interviews and by reviewing published research. Many of your peers provided the kind of insight that previously had not existed.

If you're considering starting a clinical trial or epidemiological study, it's our hope that these findings will help you build the criteria for successful DNA collection and for maximizing your compliance rate. If you're already working on a study, feel free to examine what these experienced researchers are doing (and use this study to help others).

I hope you enjoy the report. If you find value here, please let your peers know about this report. You can find the original page for the report here: **http://info.dnagenotek.com/compliancereport**

We'd love to know how this report helps you or a colleague. Tell us what you think by sending an email to **info@dnagenotek.com**. If you'd like to contribute to this paper by providing information on how you achieved a high compliance rate with your study, go to **http://info.dnagenotek.com/compliancesurvey**. You can provide your information and help us keep this report up to date.

Enjoy!
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In appreciation

DNA Genotek would like to extend a sincere thank you to the following organizations for their contributions to this report:

- Alberta Cancer Board
- Children's Hospital Boston
- Coriell Institute
- Generation Scotland
- Institut Gustave Roussy
- University of Arkansas Medical School
- University of Cambridge
- and the hundreds of other organizations who have completed successful studies using Oragene self-collection kits†

† Saliva samples were collected with Oragene®•DNA or Oragene®•DISCOVER.

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Executive summary

This report is intended to describe how scientific researchers maximize their compliance rate with potential study participants and if there are commonalities among these approaches. A number of significant findings were identified.

The group providing input to this report was relatively demographically diverse with representation from Canada, France, the United Kingdom, and the United States. We saw correlation in many findings across organizations within and outside North America.

We learned that the DNA collection process can sometimes be much more complex than many of us assume. Collecting a single DNA sample can involve in-person presentations by the recruiter, consent forms, medical questionnaires, online or in person surveys, or even travel to central locations for the donor. We believe many will benefit from understanding, based on these best practices, how to work within typical constraints and yet achieve very high compliance rates.

On the following pages you will discover:

- How successful researchers are achieving dramatically higher compliance rates
- What processes (from qualifying participants to analyzing results) most contribute to higher compliance rates
- Whether centralized or mail-based collection impacts compliance rates
- How to overcome challenges to maximize compliance
- How to take a good compliance rate and make it an outstanding compliance rate
- What issues most affect compliance rates

How to use this report: Regardless of your experience with DNA sample collection methods, this report contains helpful tips. If you're new to non-invasive DNA collection methods, take a look at what these successful researchers have accomplished and see what your peers are doing to maximize success. Even if you are an experienced recruiter, you can use this information to evaluate where there may be opportunities for improvement.

This report is designed to help researchers identify opportunities to improve compliance rates in advance of conducting a research study or clinical trial. Through obtaining a deeper understanding of the key challenges in maximizing compliance rates, researchers will be able to provide vital input into the early stages of their programs to help ensure their success and maximize efficiencies.

Major findings

We asked our contributors to describe the nature of their studies. All contributors used the Oragene® self-collection kit for sample collection. Some were using the product exclusively and others were using it in conjunction with blood collection methods. Responses ranged from:

- research into the genetic basis of drooping eyelids;
- creating DNA banks for future studies;
- genotyping studies;
- studies targeting unaffected siblings of diabetic children;
- collection of bio-samples from those unaffected with cancer to study in the event they are diagnosed with cancer in the future;
- building a breast cancer bio-repository; and
- a personalized medicine project.

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We also asked the contributors to describe the demographics of their study participants. Some studies had very broad criteria while others had much more narrow criteria. Responses ranged from:

- adults and children from all ethnicities;
- French women born between 1925 and 1950;
- children over the age of 5 who had a sibling with diabetes;
- any adult between the age of 35-69; and
- women over 18 years of age.

It is the input of these organizations that are outlined in this report. You will see which tools and methods are most used by those who have conducted successful studies and the benefits achieved by these experienced researchers.

1. Compliance rates were often dramatically higher with non-invasive self-collection.

The compliance rates achieved with these studies ranged from 95% to 70.52% positive return in the first phase of collection. See the following table for details:

	Compliance rate with non-invasive Oragene self-collection kit	Compliance rate with blood (if available as comparison)	Demographics of participants	Mail or centralized collection
Personalized medicine study	95%	N/A	Adults aged 18+	Centralized
Create DNA bank for future studies	70.52%	N/A	French women born between 1925 and 1950	Mail
Danish Nurse Cohort[2]	72%	31%	Female nurses aged 51+	Mail for Oragene saliva collection and centralized for blood collection
Multiple Sclerosis GWAS[3]	95%	N/A	Multiple Sclerosis patients	Mail
Create DNA biobank[4]	80%	N/A	Swedish men born between 1918 and 1952	Mail

Some of the participants did not actively calculate their response rates but their general feel was that the compliance rate was very high and that the sample was almost always returned to the study coordinator. One contributor collected primarily at large community events and when the appropriate event was targeted, estimated their compliance rates to be between 50% to 100%.

2. No significant difference in compliance rates was observed when collection was onsite vs. via mail but mail collection opened the study to a wider audience.

The contributors had a range of collection practices ranging from mail-based only studies, to both centralized collection and mail-based options, and centralized collection only. The two highest collection rates (95%) varied in their collection practice. One was a centralized collection only and the other was mail-based only.

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The contributors experienced no significant difference in compliance rates when using centralized versus mail-based collection but they did acknowledge that having the option of using mail-based with Oragene self-collection kits opened their study to a much wider group of potential participants. This made it more likely they could reach their targeted participation numbers.

3. **The greatest challenge in maximizing compliance was generally related to the paperwork/consent process and not DNA collection with Oragene self-collection kits.**

Contributors stated that the greatest challenge to compliance was often related to the paperwork, and not the collection of DNA. If the consent form was lengthy to read and if the medical questionnaire was long, people could be deterred from participating. However if a blood collection were required, the feeling was that they would not have nearly as many people willing to participate. One contributor stated:

> "Most of our high compliance rate can be attributed to the Oragene self-collection kit. We are not equipped to collect blood. If we had to collect blood, a large portion of our recruits would not participate. Operationally, Oragene/saliva samples are much easier than blood – the ambient temperature storage and the long-term stability at ambient temperature have been big benefits for our study."

For one contributor to this report, the recruitment process required volunteers to attend a presentation, consent to participate, and provide a saliva sample. Every participant asked how long it would take prior to agreeing to participate. Even with a lengthy process, they still achieved a very high compliance rate (95%) with Oragene self-collection kits. Other contributors to this report were prevented from doing mail-based collection as their IRB required the consent process to be completed in person.

Generally, the highest compliance rates were achieved when the consent forms and medical questionnaires were brief.

4. **The response rates of mail or home-based DNA collection can be improved with a follow-up phone call.**

Several contributors to this report indicated that while the compliance rate of mail and home-based DNA collection with the Oragene self-collection kit was high, it could be improved with a follow-up phone call. For the 5-30% who initially did not return their samples, a much greater percentage of them did return the sample after one follow-up phone call. The contributors felt that compliance rates could generally get much closer to 100% when resources were available for telephone follow-up.

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5. **Web-based enrolment can improve compliance.**

Even those organizations who reported high compliance rates felt that web-based enrolment and follow-up would improve their compliance rate even further. Several of these organizations are transitioning to web-based questionnaires to allow them to reach a broader audience of potential study recruits. This allows them to reduce the time required for the qualification step. It also demonstrates donor commitment which, in turn, will help contribute to a higher compliance rate.

6. **Non-invasive methods had the greatest impact on compliance rates followed by ease of product use.**

The contributors to this report felt that the non-invasive saliva based collection method provided by the Oragene self-collection kit was the single most significant contributor to their high compliance rates. One contributor switched to the non-invasive Oragene self-collection kit from blood and was able to improve their compliance rate and save money by not having to hire nurses to do blood draws. They used the money saved to hire administrative staff to phone potential study participants, send consent forms, and follow-up on the sample collection. For other contributors, they used Oragene self-collection kits for those who were needle phobic or who could not get to a clinic where a nurse was present, allowing them to increase their study enrolment.

As stated by one contributor to this report:

> "The Oragene self-collection kit has determined our ability to have a study or not – it has been hugely beneficial".

Summary

The number of studies collecting genomic DNA from a large number of individuals is increasing rapidly. Non-invasive methods and techniques that permit self-collection are often preferred because they increase compliance rates and reduce costs. For this reason, many large-scale studies now use saliva as the source of DNA. The Oragene self-collection kit is non-invasive and intuitive to use. In addition, it can be used by untrained study subjects, including children and the elderly.

The contributors to this report experienced high compliance rates when using Oragene self-collection kits. Therefore, non-invasive DNA collection methods can have a significant contribution to the compliance rates of studies.

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