



OVERCOMING CHALLENGES IN DNA SAMPLE COLLECTION

HOW EPIDEMIOLOGICAL RESEARCHERS ARE MAXIMIZING
COMPLIANCE RATES WITH NON-INVASIVE DNA SELF-COLLECTION

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 www.info.dnagenotek.com/compliancesurvey. You can provide your information and help us keep this report up to date.

Enjoy!

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MAJOR FINDINGS

We asked our contributors to describe the nature of their studies. All contributors used the Oragene®•DNA 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.

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 SELF-COLLECTION WITH ORAGENE•DNA	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 & 1950	Mail
Danish Nurse Cohort ²	72%	31%	Female nurses aged 51+	Mail for Oragene•DNA & 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 & 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 50-100%.

2) **No significant difference in compliance rates was observed when collection was on site 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.

The contributors experienced no significant difference in compliance rates when using centralized collection versus mail-based collection but they did acknowledge that having the option of using mail-based collection with Oragene•DNA 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•DNA.**

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 Oragene•DNA. We are not equipped to collect blood. If we had to collect blood, a large portion of our recruits would not participate. Operationally, Oragene•DNA is much easier than blood – the room temperature storage and the long term stability at room 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•DNA 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 Oragene•DNA 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.

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.



REFERENCES

1. Nishita D, Jack L, McElroy M, McClure J. Clinical trial participant characteristics and saliva and DNA metrics. *BMC Medical Research Methodology* 2009: 9:71
2. Hansen TV, Simonsen MK, Nielsen FC, Hundrup YA. Collection of blood, saliva, and buccal cell samples in a pilot study on the Danish nurse cohort: comparison of the response rate and quality of genomic DNA. *Cancer Epidemiol Biomarkers & Prevention* 2007:2072-6
3. Bahlo M, Stankovich J, Danoy P, Hickey P. Saliva-derived DNA performs well in large-scale, high-density single-nucleotide polymorphism microarray studies. *Cancer Epidemiol Biomarkers & Prevention* 2010: 19(3): 794-8
4. Rylander-Rudqvist T, Hakansson N, Tybring G, Wolk A. Quality and quantity of saliva DNA obtained from the self-administrated Oragene•DNA method -- a pilot study on the cohort of Swedish men. *Cancer Epidemiol. Biomarkers & Prevention* 2006: 15: 1742-5.

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