

# Preserving participant anonymity during remote preenrollment consent form checking

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**Background** In biomedical research, the consent form must comply with regulatory requirements. Checking for compliance typically has been performed on-site and most frequently after a participant's final enrollment. We use a procedure for remote preenrollment checking of consent forms that protects participant identities. This procedure requires a copy of the consent form that partially masks the fields for participant's name and signature; this copy is faxed to the clinical trials unit for checking.

**Purpose** To describe our efforts to identify an appropriate printed masking pattern. We tried several patterns that permit ascertainment of the presence of signatures and names and evaluated each one with respect to degree of masking participant identities.

**Methods** We assessed the efficiency of a satisfactory pattern through an experiment. We created forms with variants of the masking pattern on the copy to be faxed. We completed the forms with fictitious identities before copies were faxed and checked by clinical research associates. We measured the rate of empty and filled fields detected and the rate of letters and names correctly read. The target was defined as 100% for the rate of empty and filled fields detected and 0% for the rate of letters and names correctly read.

**Results** The best masking pattern allowed the detection of 100% empty and filled fields and the reading of 0% names and 19% letters. Consequently, the consent form with the selected masking pattern has been used routinely in our clinical trials unit.

**Limitations** We tested only five fictitious identities, five individuals who completed forms, and three who checked forms. Also, we initially considered only four patterns and variations in them.

**Conclusions** We defined a masking pattern that satisfactorily fulfilled our needs for confidentiality. This and other procedures for remote preenrollment checking of consent form can be a key component of a risk-based monitoring strategy. *Clinical Trials* 2013; 0: 1–3. <http://ctj.sagepub.com>

## Introduction

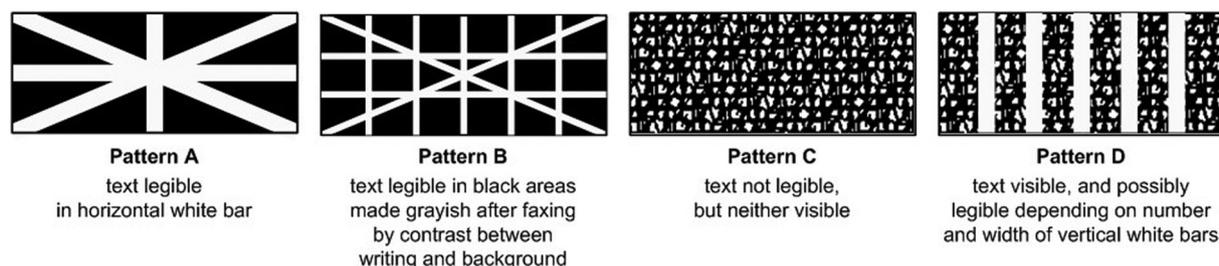
Since 2005, our clinical trials unit (CTU) has been using a remote preenrollment procedure to check

remotely for required signatures, dates, and other information on faxed consent forms. As described

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**Figure 1.** Successive patterns used to partially mask participants' names and signatures on the additional copy of the consent form and their deficiencies (CMG-EC INSERM U897/ANRS).

elsewhere, the procedure respects participant anonymity and allows the investigator to bring nonconforming forms into compliance with study and regulatory requirements before participant enrollment [1]. We describe how we created a pattern partially masking participant identities and how we assessed its efficiency to preserve participant anonymity during the faxing of consent form and central review.

## Methods

In order to render the participants' signatures and names and content of other fields illegible but still to be able to confirm that the required information had been recorded, we successively tried different masking patterns printed in such fields, as shown in Figure 1. For patterns C and D, the background was designed by randomly placing letters throughout the field, thus creating an irregular weave.

Our goal was to make the identifying field content visible but not legible on the faxed copy of the consent form. With pattern A, the text was sometimes legible in the horizontal white bar. With pattern B, the faxing process changed contrast levels so that the written information became legible. With pattern C, the field content was never legible, but none of the content was visible. With pattern D, the field content was visible, with the amount depending on the number and the width of the vertical white bars.

We designed eight variants of pattern D by varying the zoom of the background (50% or 100%) and spacing (5.0 or 7.5 mm) and width (1 or 2 mm) of the vertical white bars. Eight test consent forms, each with one original, two blank copies, and one copy with a variant of pattern D in the selected fields, were printed and collated. Each consent form contained six lines with two fields for a name and a signature on each line.

Five surnames were selected from <http://www.geopatronyme.com/disparu/30>: one short surname (four letters), one medium surname (eight letters), one long surname (11 letters), one hyphenated surname, and one surname with letters uncommon in French. These five surnames were associated with

five common first names chosen from <http://meilleursprenoms.com/site/EnVogue/Antan/Antan/1960a1969.htm>, yielding five fictitious names: Bacquellier Jean, Lers Didier, L'Hermet-Gros Michel, Passevin Philippe, and Wozpanyak Alain.

To obtain different samples of handwriting on the test forms, we randomly selected five staff members who were not clinical research associates (CRAs) or project leaders. The five fictitious names were allocated randomly to the five staff members. For each test form, positions of the fictitious names and signatures were distributed randomly among the six lines of the form, with one line left empty. Each staff member completed the eight test forms with the allocated fictitious identifiers in the specified fields. We instructed the staff members to write surnames in uppercase, first names in lowercase except for the initial letter, and to write the fictitious surnames again in uppercase letters in the signature field.

The masked copies of the forms were faxed to the CTU and checked by three experienced CRAs who had not participated in the completion of test forms. These CRAs were asked whether something was visible in each field and, if so, which letters or names could be read. We coded the correct identification of empty or filled fields and correct reading of names or letters.

We defined the most efficient masking pattern to be the one that allowed the correct identification of empty and filled lines, and no correctly read names and letters in 100% of cases.

## Results

All empty lines were detected as empty (24 checks); the filled lines were detected as filled for 116 checks and as empty for 4 (overall error rate 3%). Errors concerned two fictitious names and appeared in two variants of the pattern that we consequently excluded from further consideration.

Among the six remaining patterns, names were read correctly for three patterns, indicating that larger white bars (2 mm) facilitated reading. Three first names and a component of the hyphenated

surname, that is, Philippe, Alain, Michel, and L'Hermet, were read correctly despite the masking pattern variant. Very few letters were directly legible for these names, but the CRAs guessed them.

## Discussion

Since the preservation of participant anonymity is a crucial condition for the implementation of remote checking of consent forms for most trials, we tried different patterns to mask names and signatures and empirically selected one that was satisfactory after trying several variations in properties. We now use the experimentally selected pattern to prevent reading of participant names and signatures but to permit the CRAs to confirm that something has been recorded in the masked fields of consent forms. Despite the small size of our experimental study, results were convincing enough to decide to implement this pattern and the related procedure in all CTUs working for the *Agence nationale de recherches sur le sida et les hépatites virales* (ANRS). This procedure is also a key component of a risk-based monitoring strategy that is being compared in a randomized clinical trial (Optimon) to a typical strategy with more site visits [2].

## Conclusions

Although a participant's existence must still be confirmed during on-site monitoring, our remote checking procedure for the presence of names, signatures,

and other protected information is a key component of an efficient monitoring strategy.

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## Conflict of interest

The authors declare that there is no conflict of interest.

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