

## EARLY REMOTE CHECK OF THE EXISTENCE AND THE COMPLIANCE WITH REGULATORY REQUIREMENTS OF SIGNED INFORMED CONSENT IN A FRENCH ACADEMIC CLINICAL TRIAL UNIT (CTU)

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**Background:** Every patient participating in a biomedical research must first sign an informed consent. On site check for its existence and its conformity to regulatory requirements shortly after patient's screening requires resources rarely available in an academic clinical research context.

**Objective:** We propose an innovative tool for remote monitoring of patient's informed consent in clinical trials.

**Methods:** A duplicate sheet was added to the informed consent form. Patient's name and signature were partially masked, so as to make this information unreadable, but its presence detectable. This sheet was faxed immediately after patient's screening to the CTU, where its completion in accordance to regulatory requirements was monitored. If at least one item was absent or erroneous, patient's inclusion was delayed until reception of the properly completed duplicate sheet. We describe the number of nonconformities and the time for their detection after implementation of this tool in several clinical trials conducted by our CTU, and sponsored by the French National Agency for Research on AIDS and Viral Hepatitis.

**Results:** From November, 2003 to November, 2008, 5 clinical trials conducted in our CTU used this tool, and screened 695 patients, whose duplicate sheets were checked before inclusion. Fifty-six sheets (8%) presented a regulatory nonconformity: 20 (3%) related to patient's items, 15 (2%) to investigator's items, and 21 (3%) to informed consent versioning. Investigators were systematically contacted to correct the duplicate sheet and the original form in compliance with regulatory requirements. The median delay before detection of a nonconformity was lower than 24 hours after patient's signature.

**Conclusion:** The use of this anonymised sheet allows to check the existence of the informed consent before inclusion, and to undertake quick corrective action if needed. Yet on site monitoring of the original informed consent form remains mandatory.