Digital Consent Process for Minors: Extension of gICS® to Enable Flexible Capture of Multiple Signatures

Dittmann K[1], Blumentritt A[1], Bialke M[2], Moser F-M[1], Fiedler-Lacombe L[1], Heim E[1], Stahl D[1]

[1] Trusted Third Party of the University Medicine Greifswald, Greifswald, Germany
[2] Institute for Community Medicine, Section Epidemiology of Health Care and Community Health, University Medicine Greifswald, Greifswald

Background

Including minors in clinical trials introduces unique legal and organizational challenges. Key among these are the legal requirements for guardian consent and the need to adapt consent forms for different age groups. For more than 10 years, the Independent Trusted Third Party (TTP) has offered the 'generic Informed Consent Service' (gICS®) to digitally manage these documents. Although the system can handle various forms and versions, it was previously limited to a single signatory, typically an adult with the capacity to give consent. With the growing number of research projects involving vulnerable groups—such as minors or those lacking the capacity to consent—gICS® needed to be updated. The objective was to implement support for multiple signatures on a single form and to ensure that the forms are designed appropriately for different ages.

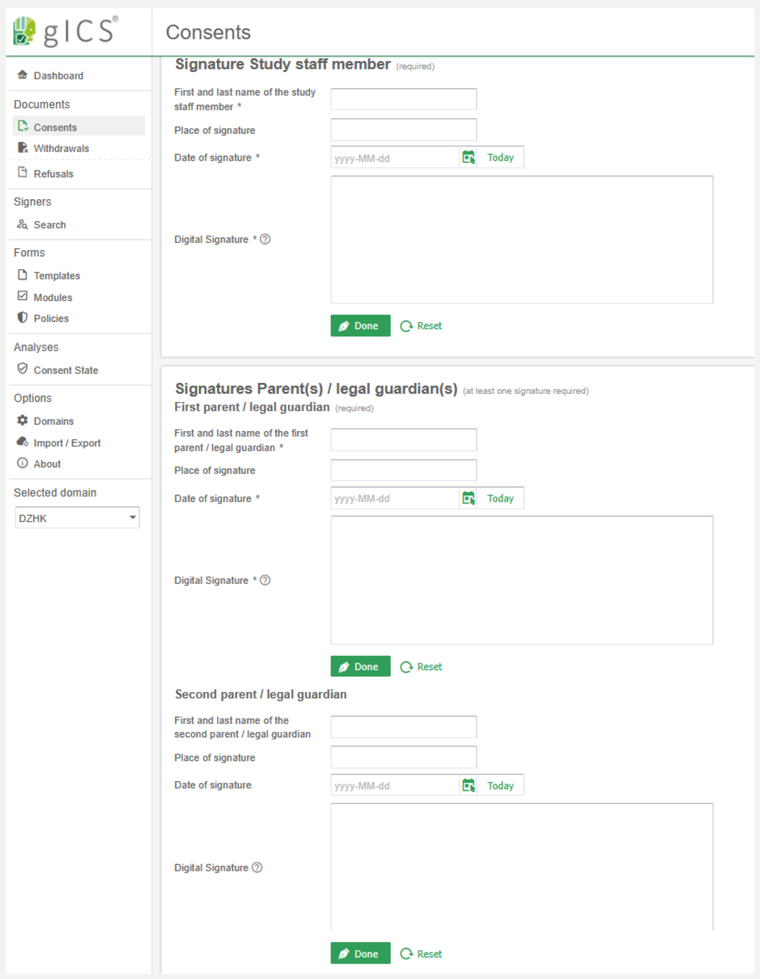

Figure 1: Example of configuring signature fields for IC templates in gICS®

Methods

In gICS®, 'Policies' serve as the smallest units to define the scope of consent, which can be grouped into 'Modules' (e.g., combining sample collection, storage, and processing) where consent applies to the entire module. Previously, validity was set based on study duration for GDPR compliance. However, minors require legal guardian signatures, and reaching majority age necessitates re-consent—requiring system support for both child and guardian signatures.

To address this, the system now enables configurable signatory roles (see Figure 1) and age-triggered signature types. Consent templates for minors can include expiration dates, automatically marking the consent invalid upon adulthood to allow re-consent as an adult. Finally, these new data points have been integrated into the reporting system to ensure comprehensive analysis.

Results

The system has been enhanced with a group-specific and type-oriented configuration logic, enabling multiple legal guardians of a minor to sign the same template. Following the approach of the Cross-Sectoral Platform (SÜP) of the NAPKON studies, three distinct sets of documents were established for different minor age groups: children aged 6-11, those aged 12–17 lacking capacity to consent, and those aged 12–17 with the capacity to consent. For six-year-old children, for example, only an information disclosure form is provided, requiring no signature. Regardless of the minor's consent status, the legal guardians must always sign; for this purpose, a separate informed consent (IC) is provided.

The date of the age of majority is calculated dynamically and rule-based using the participant's date of birth (see Figure 2). The expiration date is generated automatically, and the date of birth itself is not stored, in accordance with the principle of data minimization. Upon reaching adulthood, the system can trigger automatic notifications to the study center, ensuring that participants are re-contacted to provide renewed consent.

Together, the new signature concept and these rule-based mechanisms enable a fully digital, precise, and legally compliant management of consent in studies involving minors and other vulnerable populations, such as adult patients lacking the capacity to consent.

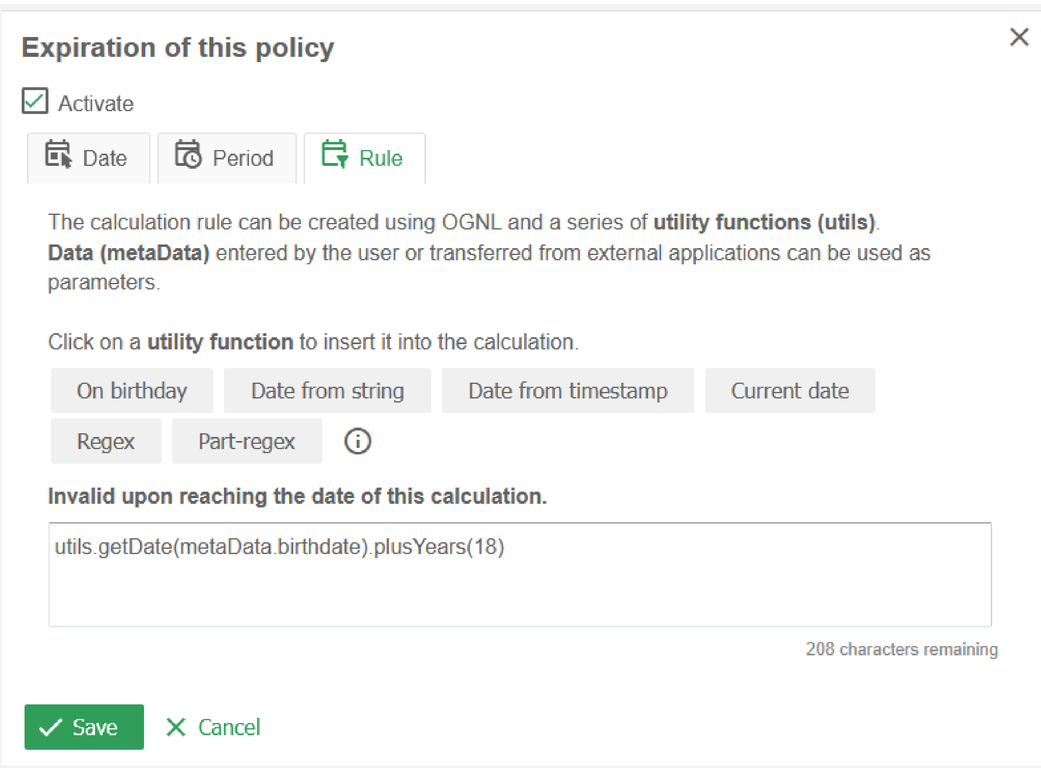

Figure 2: Example of configuring expiration dates for policies in gICS®

Discussion & Conclusion

Determining whether minors should provide consent depends on the study setting and requires consultation with pediatric experts and patient representatives. Legally, the situation is unclear: some experts argue re-consent upon reaching majority is unnecessary, whereas certain ethics committees strictly require it—otherwise, data must be deleted.

Previously, gICS® required up to three manual contact attempts after a participant turned 18. This labor-intensive process is now replaced by automated notifications, optimizing data management. These gICS® enhancements improve usability for complex consent scenarios, such as vulnerable populations or delegated consent for incapacitated patients. By offering a digital solution compliant with § 126b BGB, gICS® enhances the quality and transparency of medical research consent procedures. gICS® is freely available at www.ths-greifswald.de/gics.

References

[1] C. Hampf, “Handbuch gICS.” Jan. 30, 2026. Accessed: Jul. 23, 2026. [Online]. Available: https://www.ths-greifswald.de/gics/handbuch
[2] H. Rau et al., “The generic Informed Consent Service gICS®: implementation and benefits of a modular consent software tool to master the challenge of electronic consent management in research,” J Transl Med, vol. 18, no. 1,
p. 287, Dec. 2020, doi: 10.1186/s12967-020-02457-y.
[3] “Datenschutz-Grundverordnung: Finaler Text der DSGVO,” Datenschutz-Grundverordnung (DSGVO). Accessed: Feb. 18, 2026. [Online]. Available: https://dsgvo-gesetz.de/
[4] D. Stahl et al., “The benefits of fully electronic consent management and consent collection via a tablet PC in supporting time-critical pandemic research—an example from a NAPKON COVID-19 project,” Front. Digit. Health, vol. 7, p. 1489176, Sep. 2025, doi: 10.3389/fdgth.2025.1489176.
[5] A.-L. Hofmann et al., “Integration von Bestandsdaten aus Kohorten- und Registerstudien in ein existierendes Forschungsnetzwerk: Nationales Pandemie Kohorten Netz (NAPKON),” Gesundheitswesen, vol. 86, no. 10, pp. 647–654, Oct. 2024, doi: 10.1055/a-2346-9680.
[6] R. Heyder et al., “Das Netzwerk Universitätsmedizin: Technisch-organisatorische Ansätze für Forschungsdatenplattformen,” Bundesgesundheitsbl, vol. 66, no. 2, pp. 114–125, Feb. 2023, doi: 10.1007/s00103-022-03649-1.
[7] Bürgerliches Gesetzbuch (BGB). 1896.
[8] J. Taupitz, “Biobanken: Re-Consent des volljährig gewordenen Minderjährigen erforderlich?,” MedR, vol. 39, no. 8, pp. 703–708, Aug. 2021, doi: 10.1007/s00350-021-5946-3.

gICS® Generic Informed Consent Service

Poster Download