



A Building Block for FAIR Data Use and EHDS

Demonstration

MIE 2026 | 27.05.2026

Dr. Martin Bialke & Christopher Hampf & Dana Stahl | University
Medicine Greifswald, Germany



- About us
- Legal basis for data processing
- Short overview gICS®
- Configuration of modular consent templates
- Mapping consent documents to digital structures
- Documentation of consents and withdrawals with the option to integrate mobile devices
- Consent status verification
- Integration of scenarios for heterogeneous research IT environments based on HL7 FHIR
- Implementation of opt-in and opt-out scenarios





The Data Trustees.

*With 10 years of experience, the Trusted Third Party of the University Medicine Greifswald supports medical research in Europe. Person-identifying data are sensitive information. Therefore, it's extremely important to protect access to this data – this is especially true for research with patient data in studies and registries. The organisationally Independent Trusted Third Party develops and operates specialised software to protect this data and, thus, offers data protection compliant solutions for medical research. As data trustees, we form the bridge between study participants, researchers and project partners and, thus, create trust, because: **Trust makes medical research successful.***



TTP easily explained (German Video)

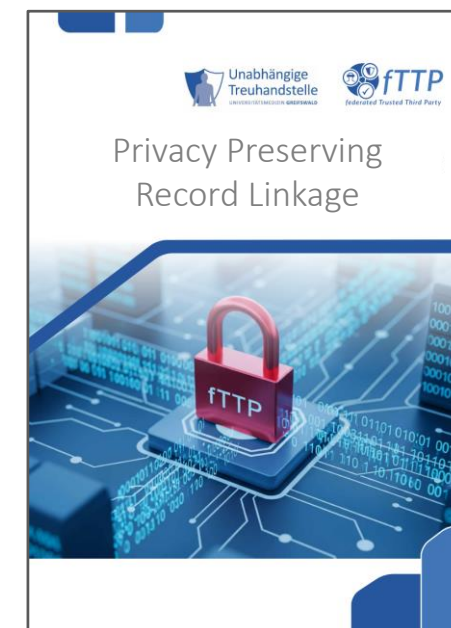
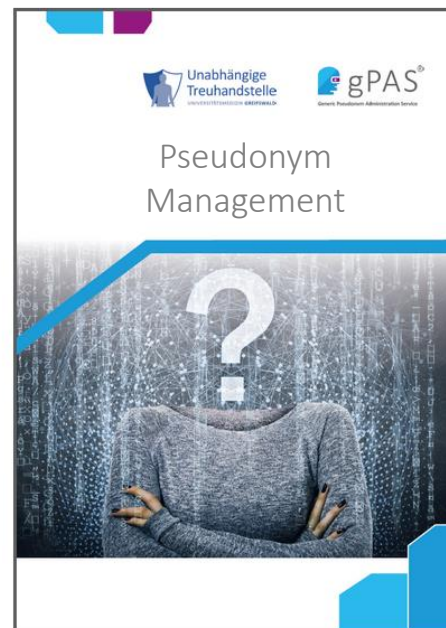
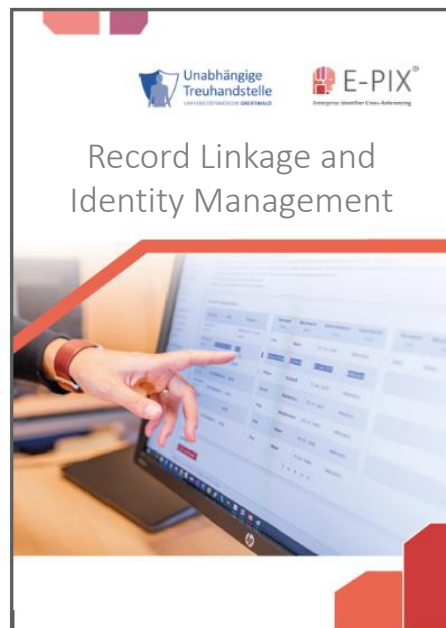


Building blocks for data protection in medical research



Independent
Trusted Third Party

UNIVERSITY MEDICINE GREIFSWALD

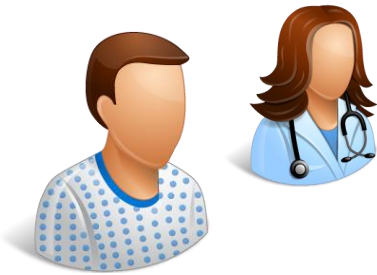


Live-Demo available: ths-greifswald.de/demo





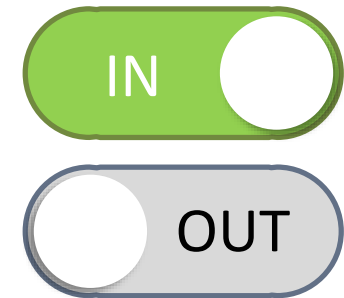
- Opt-In: patient gives **consent**, right to **withdraw** (Art. 6 and Art. 7, EU GDPR)
- Opt-Out: applicable law exists (e.g. German Health Data Use Act, GDNG), right to **object**



Health research, e.g.
studies and registries



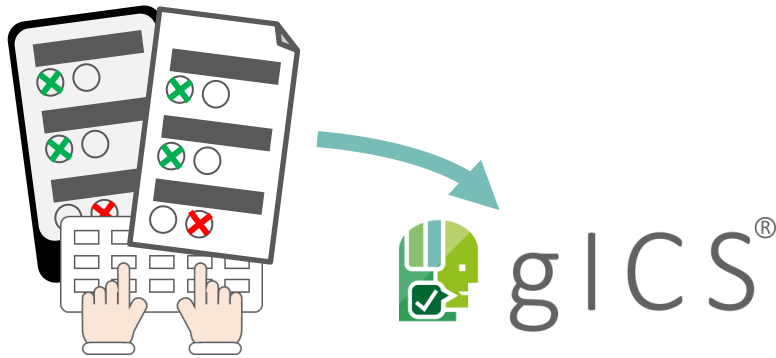
Paper-based & digital



Opt-In & Opt-Out

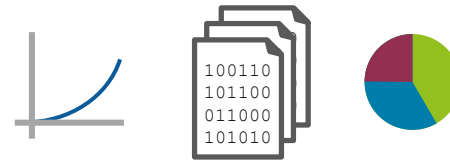
Documenting Consents

- Participant fills out consent
- Consents can be entered digitally (e.g. via tablet) or paper-based (e.g. via scan)
- gICS supports quality checks



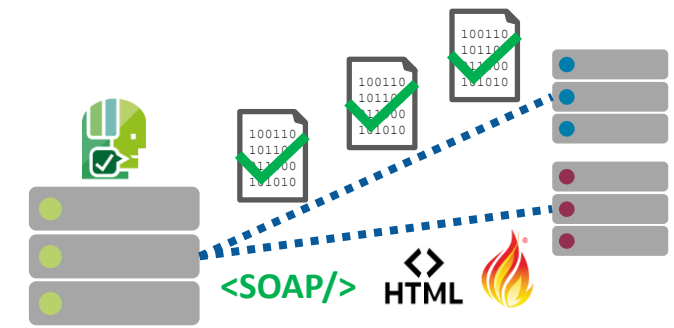
Managing Consents

- Project specific templates for consents and withdrawals
- Consent's digital representation including recent consent status
- TTP Staff comprehensively overviews consent information including key metrics



Analysing Consent-Status

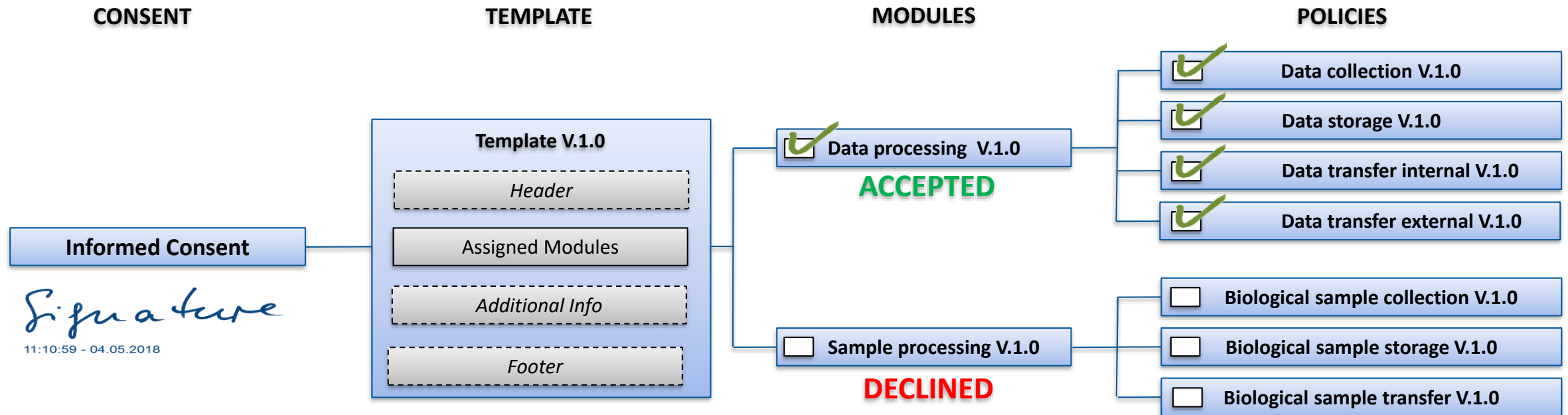
- gICS provides current status of the participant's consent
- Integration into infrastructures is possible via various well-documented interfaces






Configuration, Documentation, Consent Status Verification

HANDS-ON



Bialke et al. MAGIC: once upon a time in consent management—a FHIR® tale. J Transl Med 16, 256 (2018). <https://doi.org/10.1186/s12967-018-1631-3>




Demo Consent for MIE2026

Version 1.0

Use for demonstration purposes only.

Privacy Statement
I don't usually read privacy policies; I just tick the box 'accept'. This time, however, I'm making an exception and I can see that everything is well-written and easy to understand. So I'm not worried and am happy to take part in the demonstration study. As I'm not entering any real data, it's safe.

☒ Yes ☐ No

Biomaterial
Biomaterials are frequently used in studies to uncover new information and correlations through analysis. After the presentation, I like to leave my coffee cup behind so that any traces of saliva on it are available for future generations to study.

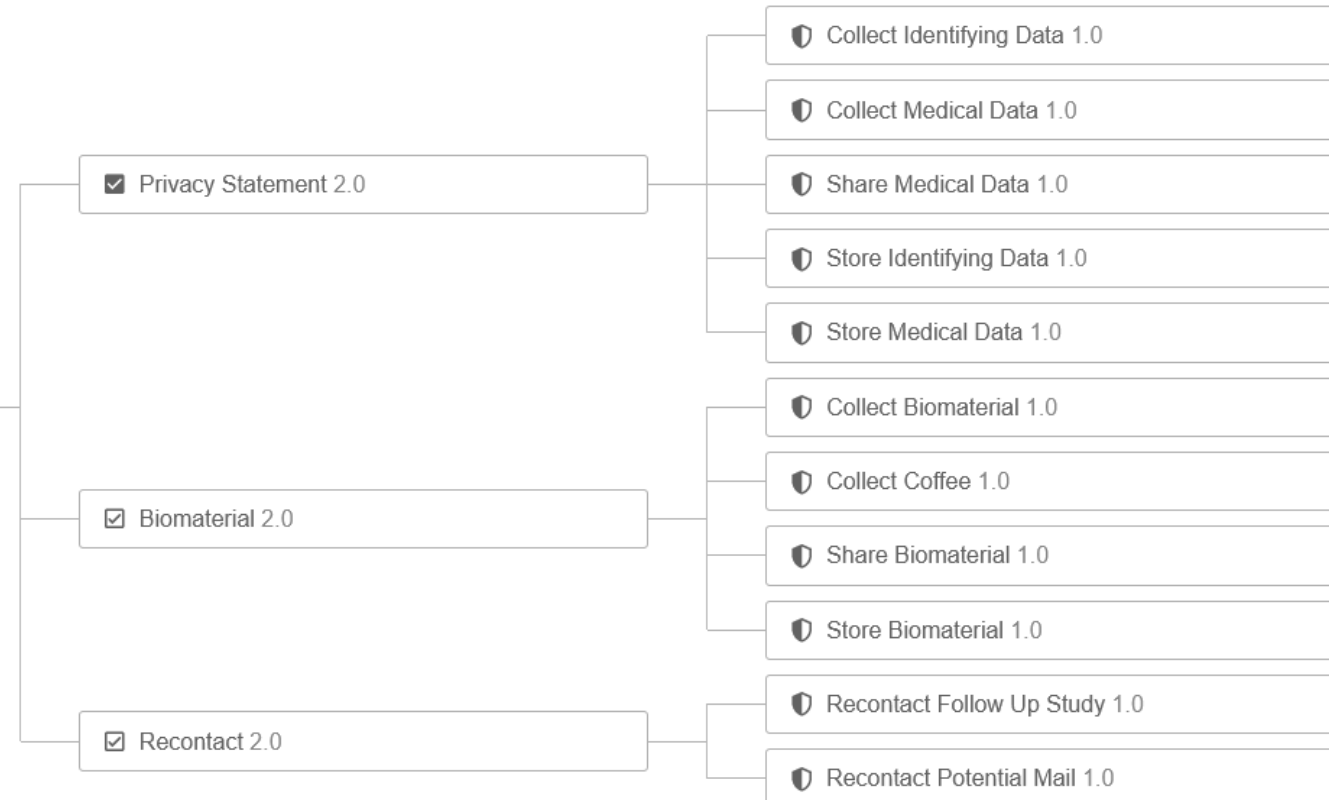
☒ Yes ☐ No

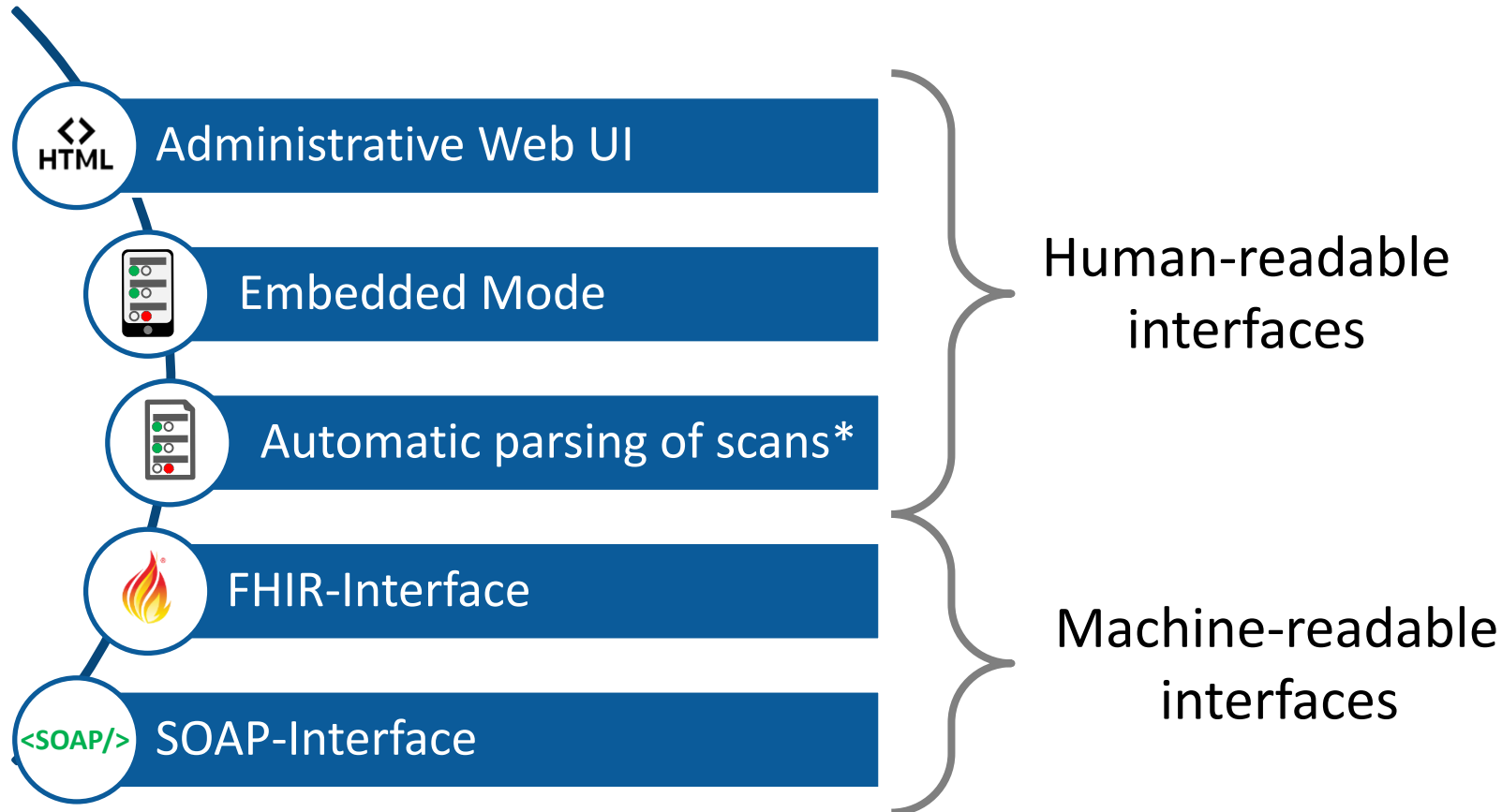
Recontact
The re-contact option is frequently used to get in touch with participants at a later date and inform them about how their data is being used and any new exciting projects. This channel can also be used to communicate incidental findings. If I have any questions following the fascinating demonstration, I would be happy to contact <https://www.ths-greifswald.de/en/contact/> directly.

☒ Yes ☐ No

Name of Demo user The presenter
Date of demonstration 2026-04-27

Thanks for your support!





Get your phone out.
You'll be able to fill out a
consent form.

* Use of neuronal networks as described in YouTube-Video (German): <https://www.youtube.com/watch?v=E8tdhf1rbt0>

Documenting the participant's will



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Your turn!
Use your phone or tablet
to fill out a consent live!



Live-Demo: You can use any pseudonym you want

gICS® Consent documentation demo

Medical Informatics Europe
MIE 2026
EFMI

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Version 1.0

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☐ Yes ☐ No

Embedded Mode

Depicting documents' and participants' details

Search results

Here you can see a list of all existing documents. The symbol in the most left column indicates the document type.

Signer Press1

Created at 2026-04-27 11:06:11

Fill in consent

Fill in withdrawal

Merge with signer

1 Documents

11 Current policies

0 Invalid policies

Columns

Type	Created	Signature Participant	Valid until	Signer-IDs	Details
Consent	2026-04-27 11:06:11	2026-04-27 00:00:00	2026-05-31 00:00:00	Press1	

1-1 of 1

Consent

Withdrawal

Refusal

Search

Status
Accepted
Accepted
Accepted
Accepted
Accepted
Accepted
Accepted
Accepted

1-10 of 11


Simplified integration into external applications via embedded mode.
See for yourself!



Embedded Mode

Consent status verification

Which participants consented to their coffee cups to be collected for future research?



Dashboard

Documents

Consents

Withdrawals

Refusals

Signers

Search

Forms

Templates

Modules

Policies

Analyses

Consent State

Options

Domains

Import / Export

About

Selected domain

Demo EU MIE

Policy State

Here you can determine the current policy state of all signers for the chosen policies.
The gICS takes into account all participant consents, withdrawals, and refusals, as well as the quality status of the documents.

Select mode

Upload list with signer IDs

Use all signer IDs in domain

1. Load signer IDs

Type of signer IDs

Study-ID

Load data again

2. Found 6 IDs in the current domain

Study-ID	Collect_Coffee_Cup 1.0
Participant1	DECLINED
Participant2	DECLINED
Participant3	ACCEPTED
Participant4	ACCEPTED
Participant5	ACCEPTED

1-5 of 5

<< 1 >>

3. Determine policy status

Select a policy, set the query options and click **Process**.
After that you have the possibility to repeat the processing as often as you like for further policies and thus to fill your result table.

Name and version of the policy

Collect Coffee 1.0

Detailed result

☒

Query time

☒ Now

☐ At date: 2026-05-06

Process again



Integration of scenarios for heterogeneous research IT environments based on





gICS provides a HL7 FHIR-interface for the most commonly used features.

Feature Set

- FHIR Search API: Retrieving details for domain, template, documents, signature, scan, etc.
- custom FHIR operations for comfortable consent status retrieval (isConsent, currentPolicyStatusFor, ...)
- creating consents (both opt-in and opt-out)
- fully supporting German HL7-FHIR Consent Management Standard 2.0

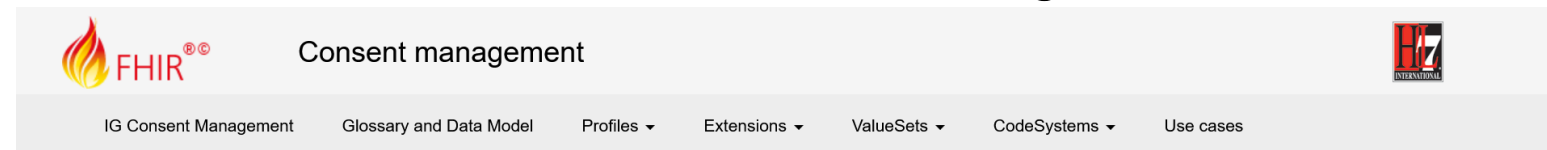
More Information

- <https://ig.fhir.de/einwilligungsmanagement/stable/Home.html>
- <https://www.ths-greifswald.de/gics/fhir>





Official HL7-D FHIR Standard for Consent Management in Medical Research (v2)



Implementation Guide of the Working Group on Consent Management

Version: 2.0.3

Status: STU

Status: 02.03.2026

Objective of the working group

The aim of the working group is to establish existing standards with a focus on consent management, such as Use and customize HL7 FHIR and IHE so that they can be used for interoperable applications. This is to be achieved by profiling FHIR resources, which can be used in software products to define consent templates, to process consent documents and to enforce consent.

Permanent members working group

- [Stefan Lang](#) (Gefyra GmbH, Lang Health IT Consulting)
- [Martin Bialke](#) (University Medicine Greifswald, MII Consortium MIRACUM)
- [Sebastian Stäubert](#) (University Medical Center Leipzig, MII consortium SMITH)
- Angela Merzweiler (University Hospital Heidelberg, MII Consortium HiGHmed)
- Jörg Römhild (University Hospital Tübingen, MII Consortium DiFUTURE)
- Daniel Scholz (Thieme Compliance)

With previous cooperation of

- Lars Geidel (University Medicine Greifswald, MII Consortium MIRACUM)
- [Danny Ammon](#) (Uniklinikum Jena, MII consortium SMITH)
- Tarik Idris

Authors of the Implementation Guide

Martin Bialke, Stefan Lang, Sebastian Stäubert, Angela Merzweiler, Jörg Römhild

Source: <https://ig.fhir.de/einwilligungsmanagement/stable> , Accessed 2026-05-04 (German only)

Read the most recent publication:

<https://doi.org/10.3233/SHTI251389>





Demo-FHIR-Interface:

<https://demo.ths-greifswald.de/ttp-fhir/fhir/gics/metadata?format=json>

Example:

Query **consent-state** for policy **Collect_Coffee_Cup** of all participants within the domain "**Demo EU MIE**".

(all documents are analysed, and for each participant a ConsentRessource is generated)

Get the result



URL with parameters to encode the question

[base]/Consent?

domain:identifider=Demo%20EU%20MIE

&_format=json

&provisionCode=Collect_Coffee_Cup

&category=http://fhir.de/ConsentManagement/CodeSystem/ResultType | consent-status

Encoded Domain-Name

Name of queried consent-policy

Aggregated consent-status



Implementation of
OPT-* SCENARIOS

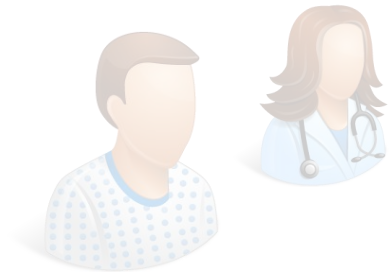


Lawful processing of health data requires a legal basis



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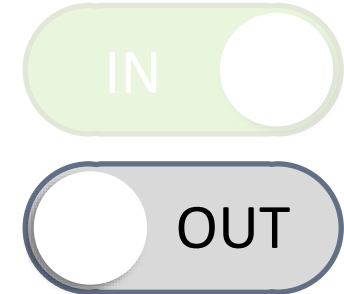
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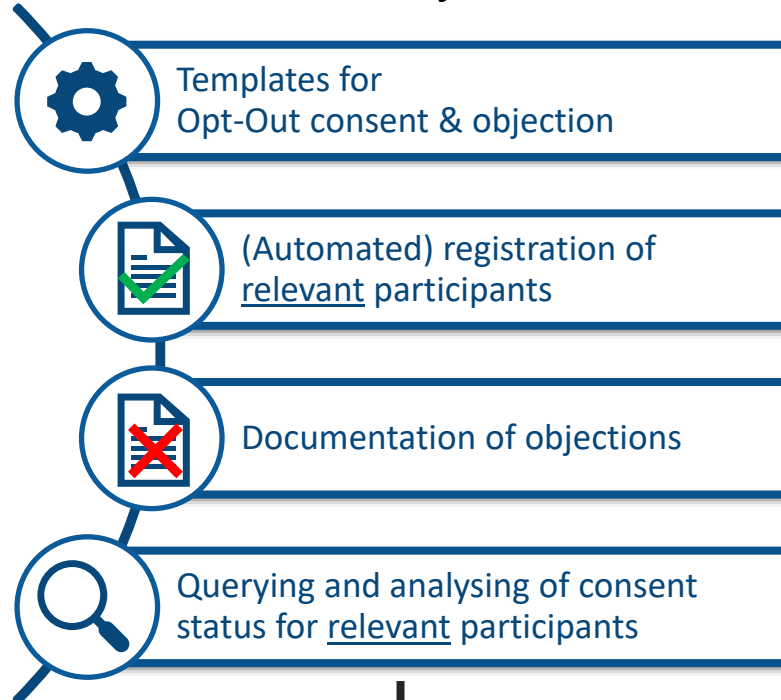
Opt-In & Opt-Out

RECAP



1. Full documentation

permissible actions and objections

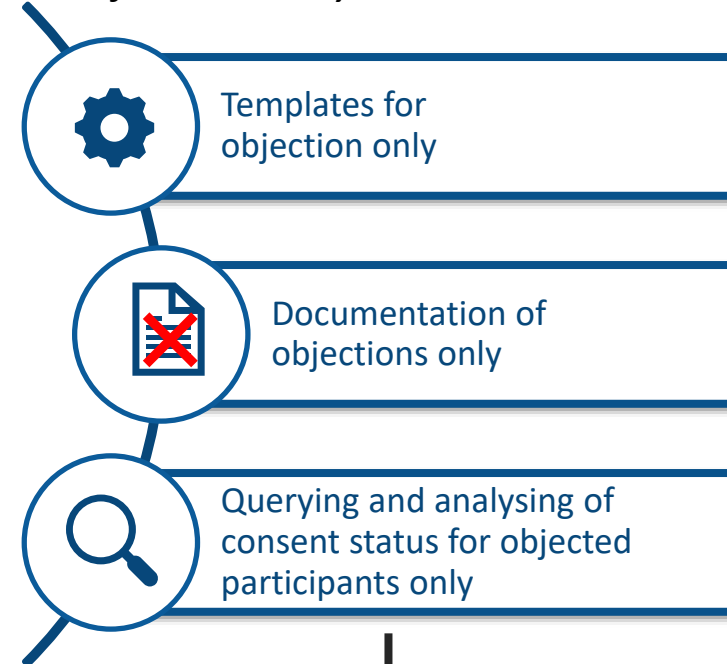


Can Person P's coffee cup be collected for research?

Yes / No

2. Reduced documentation

objections only



Person P is unknown → Yes / No



DISTRIBUTION & INTEGRATION





Developed by the University Medicine Greifswald (Institute of Community Medicine)

- published in 2014 as part of the MOSAIC project (funded by the DFG HO 1937/2-1)
- selected functions of gICS® were realised within MAGIC (funded by the DFG HO 1937/5-1), MIRACUM (funded by the BMBF 01ZZ1801M) and NUM (funded by the BMBF 01KX2021)
- gICS® is continuously enhanced based on project-specific requirements and community feedback



Selected publications

- [MOSAIC – A Modular Approach to Data Management in Epidemiological Studies](#)
- [MAGIC: once upon a time in consent management—a FHIR® tale](#)
- [#consented – A semantic consent code to facilitate consistent documentation and implementation of consent in collaborative medical research](#)
- [A FHIR has been lit on gICS: facilitating the standardised exchange of informed consent in a large network of university medicine](#)



Contact

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