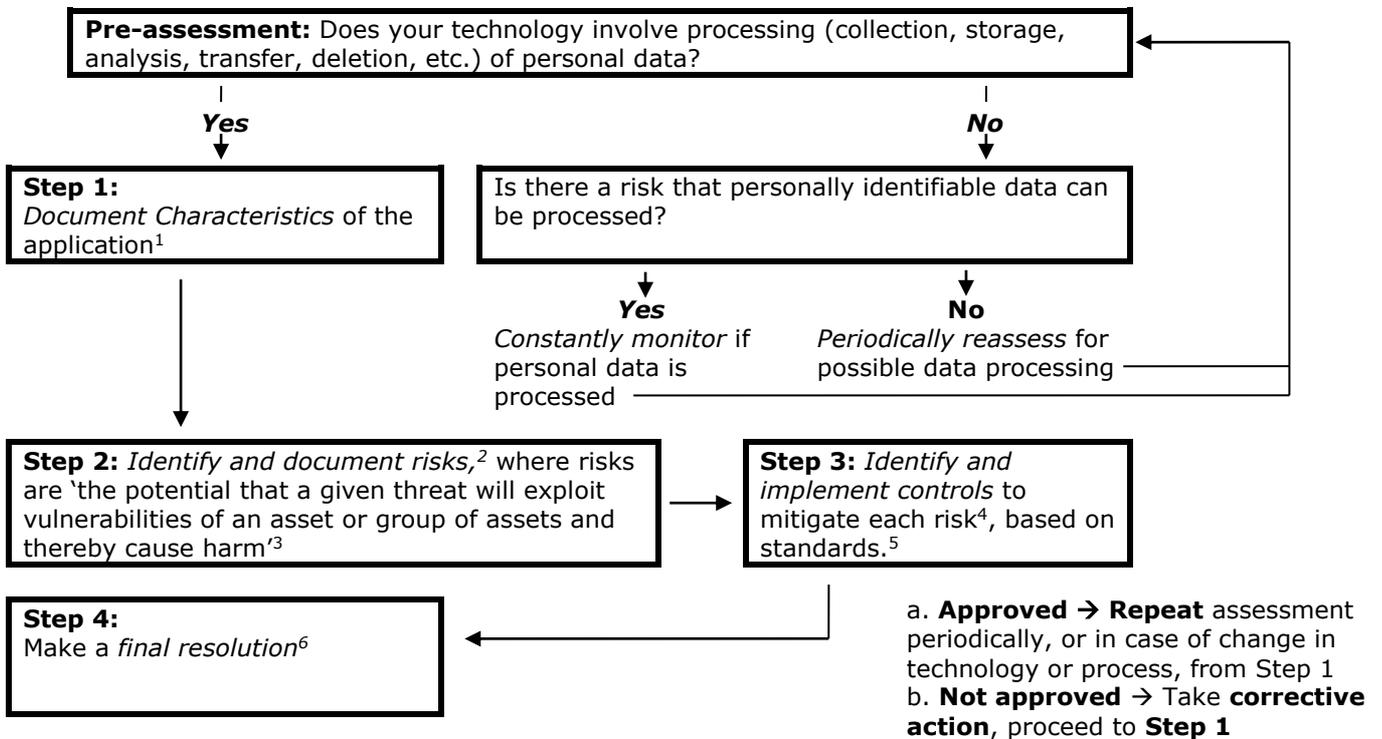


# fi star Data Protection Impact Assessment Flowchart



Compliance with data protection law is an ongoing effort that cannot be ensured by one-time measures. But some strategies, such as Data Protection Impact Assessment (‘DPIA’), may facilitate this process. Including DPIA in the development and implementation of your application does not guarantee legal compliance, but may decrease chances of a data protection or data security violations. **This flowchart does not constitute legal advice.**

<sup>1</sup> Including but not limited to: *a comprehensive description of the application, its environment and system boundaries, interfaces with other systems; personal data flows, operation and strategic environment, e.g. stakeholders involved in information collection, the system’s mission.*

<sup>2</sup> Namely, *map conditions that may or compromise personal data; consider the significance and likelihood of privacy risks occurring, considering likely uses and misuses of the application, as well as the magnitude of the impact if such risks occur; address the potential impact on a data subject (a patient or other technology user); account for the sensitive nature of the health data processed, and the vulnerabilities of the patients/users whose data is processed; document the outcomes (among others, to ensure that the process and results of PIA can be audited).*

<sup>3</sup> ISO/IEC 27005:2008 definition of risks

<sup>4</sup> Namely, *analyse measures the technical measures, implemented into the application’s architecture (‘privacy by design’) like default settings, encryption, authentication, etc.; analyse the non-technical measures like management and operational procedures; match each identified risk with a control measure to eliminate or mitigate the risk; Identify residual risks that cannot be addressed by the controls; Document the outcomes.*

<sup>5</sup> E.g. e.g. by ISO/IEC 27001:2013 available at <http://www.iso27001security.com/html/27005.html>

<sup>6</sup> Assess the trial and the application in the context of its environment and system boundaries: *check if the data protection requirements are met, such as (1) safeguarding quality of personal data; (2) legitimacy of data processing; (3) legitimacy of processing special categories of personal data; (4) compliance with the data subject’s right to be informed; (5) compliance with the data subject’s right of access to data, correct and erase data; (6) compliance with the data subject’s right to object; (7) safeguarding confidentiality and security of processing; (8) compliance with notification requirements, and others.*