Secondary use of data.

A separate consent, meaning a separate signature for secondary use of data, on the same sheet related to the trial, is required.
Information should cover:

- Reasons for data sharing - benefits for society and research should be included.
- Use of external repositories.
- Data preparation for sharing – it should be stated that data will be de-identified
- How and where the data will be stored.
- How confidentiality will be maintained, including the measures that will be used to protect participant privacy
- The type of requests that will be considered and the scrutiny to which they will be subjected, for instance which access model will be applied, such as publicly accessible web-based systems, or through request/review mechanisms, etc.
- Trial participants have to be informed that not giving consent to share their data will not affect their participation in the study or the care they receive.
- They should be informed that the lack of large amounts of data would invalidate all data sharing.
- The right of participants to withdraw consent for secondary use – the practical difficulties of implementing this however, should also be made clear to participants and stated clearly in the information sheet.

Texts source: Colombo, C., Mayrhofer, M.T., Kubiak, C. et al. The CORBEL matrix on informed consent in clinical studies: a multidisciplinary approach of Research Infrastructures Building Enduring Life-science Services. BMC Med Ethics 22, 95 (2021)