<table>
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<th>Use of 9(2)(j) opening clause?</th>
<th>Processing for scientific research without consent? Safeguards beyond art.89(1) for scientific research</th>
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| ITALY                          | May process health data for scientific research purposes in the medical, biomedical or epidemiological fields where:  
  - research is carried out on the basis of a legal provision (including research projects regulated by art. 12-bis of the Legislative Decree no. 502/1992) and a DPIA has been put in place and made public; or  
  - for exceptional reasons, informing the data subject will be impossible/involve disproportionate effort/compromise the research objectives and the relevant ethics organisation has approved and the Supervisory Authority been consulted.  
  
  Further processing by third parties for statistical and scientific purposes – consent needed unless at least one of the conditions above is met and authorisation of the Supervisory Authority obtained.  
  
  The Supervisory Authority has opened a public consultation on some of the provisions set forth by General Authorisation no. 9/2016 on the processing of personal data for purposes of scientific research. This Authorisation requires:  
  - encryption or pseudonymisation (or other solutions that do not allow direct identification of the data subject); | ✓                                    | In the event that the data subjects exercise his/her right under art. 16 of the GDPR, the rectification/integration of his/her health data processed for the purposes of scientific research shall be tracked in order to give evidence of these changes. |
- use of codes that are not inferred from personal data where feasible.
- Any storage of identifiers with research samples must be justified in writing.

| GERMANY | ✓ | Controllers interest must significantly outweigh data subjects  
Must apply “suitable and specific” measures which may include  
- technical and organisational measures  
- audit measures for data input, alteration & removal  
- staff training  
- designation of DPO  
- access control  
- encryption  
- measures to ensure confidentiality, integrity, availability and resilience  
- process to regularly test and assess security measures  
- rules re: data transfers and purpose limitation | ✓ | Anonymisation (as soon as the research or statistical purpose allows, unless this conflicts with individual’s legitimate interests).  
Until anonymisation: identifiable characteristics to be stored separately. They may be combined with other information only to the extent required by the research or statistical purpose.  
Publication of personal data only with consent or if doing so is indispensable for the presentation of research findings on contemporary events. |

| NETHERLANDS | ✓ | Health data may be processed without explicit consent for scientific research purposes under the following (cumulative) conditions:  
a. Processing is necessary for scientific research purposes in accordance with art. 89(1) GDPR;  
b. The research serves a public interest;  
c. It is impossible or would involve disproportionate effort to obtain explicit consent; and  
d. During the processing safeguards are provided to the extent that the privacy of the data subject(s) is not disproportionately damaged. | ✓ | Where a processing is carried out by scientific research or statistics institutions or services, and the necessary provisions have been made to ensure that the personal data can only be used for statistical or scientific purposes, the controller may choose not to apply Articles 15 (access), 16 (rectification) and 18 (suspension of processing) (art. 44 Dutch Implementation Act GDPR).  
The requirement to take the "necessary" provisions aims to ensure that the personal data can only be used for statistical and scientific purposes, and not for other |
Which safeguards need to be taken will depend on the risk assessment in the specific case. Examples include access controls, confidentiality, anonymisation/pseudonymisation and the presentation of the results of the investigation. Only with historical research will it be possible to make personal data public in the results. The benchmark is always that the privacy of the data subject may not be disproportionately damaged.

| SPAIN | X | Additional conditions for use of pseudonymised data for investigations in the field of public health: (i) technical & functional separation between the investigation team and whoever pseudonymises information; (ii) access to pseudonymised information must be restricted to investigation team by confidentiality commitments & appropriate security measures; report from relevant sectoral public health investigation ethics committee; or the DPO, or an expert in data protection law and practices per Article 37(5) of the GDPR) prior to the use of pseudonymised data. Pseudonymised data used for investigation purposes may be re-identified if a real and specific risk for the security/health of an individual or group of individuals or a serious threat to their rights is identified or if it is necessary to provide appropriate medical assistance. Additional conditions for investigations concerning public health: (i) data protection impact assessment; (ii) international quality standards, (iii) appropriate security measures to avoid investigators having access to data. | Access, rectification, purpose limitation and objection may be limited when carrying out a health investigation when: (i) rights are exercised against the investigating individuals/entities using pseudo/anonymised data, (ii) the exercise of the rights may jeopardise the results of the investigation; or (iii) the purpose of the investigation is a matter of essential public interest related to national security or other general public interests as provided by applicable law. |
subjects’ identification details; (iv) appointment of legal representative within the EU promoter of the clinical trial is not within the EU.

| UK     | ✓ | • Must be in public interest  
|        |   | • Must not be likely to cause damage or distress  
|        |   | • Only approved medical research can take measures or decisions with respect to a particular data subject  
|        | ✓ | Results must not be made available in identifiable form  |