

<b>Work package number</b> <sup>9</sup>	WP8	<b>Lead beneficiary</b> <sup>10</sup>	1 - FISABIO
<b>Work package title</b>	Ethics requirements		
<b>Start month</b>	1	<b>End month</b>	60

### Objectives

The objective is to ensure compliance with the 'ethics requirements' set out in this work package.

### Description of work and role of partners

**WP8 - Ethics requirements** [Months: 1-60]

**FISABIO**

This work package sets out the 'ethics requirements' that the project must comply with.

### List of deliverables

<b>Deliverable Number</b> <sup>14</sup>	<b>Deliverable Title</b>	<b>Lead beneficiary</b>	<b>Type</b> <sup>15</sup>	<b>Dissemination level</b> <sup>16</sup>	<b>Due Date (in months)</b> <sup>17</sup>
D8.1	HCT - Requirement No. 2	1 - FISABIO	Ethics	Confidential, only for members of the consortium (including the Commission Services)	12
D8.2	POPD - Requirement No. 3	1 - FISABIO	Ethics	Confidential, only for members of the consortium (including the Commission Services)	12
D8.3	POPD - Requirement No. 5	1 - FISABIO	Ethics	Confidential, only for members of the consortium (including the Commission Services)	12
D8.4	POPD - Requirement No. 6	1 - FISABIO	Ethics	Confidential, only for members of the consortium (including the Commission Services)	12

### Description of deliverables

The 'ethics requirements' that the project must comply with are included as deliverables in this work package.

D8.1 : HCT - Requirement No. 2 [12]

The applicants must provide detailed information on the human samples to be used by the project. The applicants must also report on the collection and analysis of samples by third parties if the sample collection and/or analysis is informed by or steered by the project. If applicable, relevant approvals / authorisations and transfer agreements must be obtained and copies of these must be submitted to the IMI prior to the start of relevant research activities.

D8.2 : POPD - Requirement No. 3 [12]

The applicants must provide, update and maintain an internal register with data sources and must demonstrate for each data source that the primary or secondary use within the project is lawful. Depending on the legal framework

in the relevant jurisdictions, the applicants must obtain authorisations/approvals/clearances/notifications from the relevant competent data protection bodies or clearance from the dedicated data protection officer of the institution in charge of the data processing / transfer.

**D8.3 : POPD - Requirement No. 5 [12]**

When applicable, ethical approval/authorisation by the competent national/regional Data Protection Authority or clearance from the dedicated Data Protection Officer of the institution for the intended data collection, processing and transfer must be provided to the IMI before the commencement of the related project activities. When relevant, the authorisations must provide evidence that the intended data transfer between partners and third parties, and the cross-border transfer from Non-EU countries are in compliance with national and EU legal framework.

**D8.4 : POPD - Requirement No. 6 [12]**

In case data that are to be anonymised (and not de-identified /coded/pseudonymised) the applicants must provide details on the protocols and how the applicants ensure that data cannot be re-identified with reasonable efforts. In case data are processed in a person-identifiable manner, the applicants must provide details how data subjects will be informed or must justify, in line with Directive 95/46/EC and the upcoming EU General Data Protection Regulation, why data subjects are not informed about the use of data. If applicable, the applicants must also outline how the project will ensure the rights of data subjects and how these rights of data subjects will be organisationally managed.

**Schedule of relevant Milestones**

<b>Milestone number<sup>18</sup></b>	<b>Milestone title</b>	<b>Lead beneficiary</b>	<b>Due Date (in months)</b>	<b>Means of verification</b>
--------------------------------------	------------------------	-------------------------	-----------------------------	------------------------------