

D6.1 Ethics Policy Handbook

116019 - RESCEU

**REspiratory Syncytial virus
Consortium in EUrope**

**WP6 – Project management
and outreach to stakeholders**

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Acronyms

Participants of the RESCEU Consortium are referred to herein according to the following codes:

- **AE.** Adverse Event
- **CA.** Competent Authority
- **CIOMS.** Council for International Organizations of Medical Sciences
- **CRF.** Case Report Form
- **CRO.** Clinical Research Organisation
- **EAC.** Ethics Advisory Committee
- **EC.** Ethics Committee
- **EMA.** European Medicines Agency
- **EU.** European Union
- **GCP.** Good Clinical Practice
- **IF.** Investigator Folder
- **PAB.** Patient Advisory Board
- **PI.** Principal Investigator
- **SC.** Scientific Committee
- **TMF.** Trial Master File
- **WHO.** World Health Organization

Publishable Summary

The application of robust ethics procedures is an integral part of RESCEU research and is aimed at ensuring that all project activities are conducted safely and in compliance with agreed principles, standards and codes of practice.

All research activities in RESCEU will be conducted in accordance with the Charter of Fundamental Rights of the European Union (EU), the Declaration of Helsinki in its latest version, the Convention of Council of Europe on Human Rights and Biomedicine (Oviedo Convention), the CIOMS International Ethical Guidelines for Health-related Research involving Humans, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity and the Ethical Rules outlined in the regulation of the European Parliament and of the Council establishing Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020).

This handbook summarises the ethics principles guiding the implementation of good conduct during the RESCEU research activities, the application and assessment of ethical approval requests, the preparation of study specific operating procedures and the prevention of any misconduct during the execution of research activities in RESCEU. This is to ensure that RESCEU researchers and investigators operate at the highest quality standards and eventually to help developing, building and sharing a working knowledge of ethical research.

Additional information on specific topics may be complemented by seeking advice to the local Ethics Committee (EC) or Competent Authority (CA) as most appropriate. Both EMA and the national regulatory agencies will be contacted for information and advice, where appropriate.

Clinical recruitment centres located in participating countries in Europe will comply with the GCP guidelines on good clinical practice in therapeutic trials and the Directive 2001/20/EC, whose validity has been recognised in the form of national regulations also for low interventional studies and will be applicable until the new Clinical Trial Regulation No 536/2014 will enter into force. All centres participating in RESCEU clinical studies will ensure that the Ethics Committee of the institution has approved the study.

Ethical issues will be monitored throughout activities and at the end of the project an Ethics Report (D6.15) will detail how ethical issues have been dealt with in practice.

The independent RESCEU Ethics Advisory Committee (EAC) will provide advice for all Ethics related aspects in the studies conducted by RESCEU consortium.

1. Overall ethics principles underpinning the RESCEU project

The RESCEU consortium aims to uphold the highest standards of ethical practice in research and integrity. Irrespective of the nature and ethical complexity of a research project, participants to any RESCEU activity are expected to ensure that their conduct is driven by the ethical imperative of respect, the intent to do no harm and to contribute to society's knowledge and practice through engagement in research that has beneficent intent.

To achieve a high-quality research culture and in line with the recommendation for EU-funded research, the following key elements are promoted within RESCEU:

- personal and scientific integrity;
- excellence;
- honesty;
- accountability;
- transparency;
- cooperation.

The recommendations outlined in this handbook are intended to complement existing and forthcoming International and National guidance on research conduct, such as those related to the conduct of clinical trials (Clinical Trial Regulation EU No. 536/2014) [1], the data protection (EU General Data Protection Regulation EU No. 2016/679) [2], WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks [3] and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity as adopted by European legislation through Regulation (EU) No 511/2014 [16].

The ethical aspects of any activity conducted in RESCEU will be kept under review by the project governance as the project progresses, and additional ethical approval will be sought if deemed necessary.

Each participant to RESCEU activity is expected to know and understand the ethical implications of the research they are involved in and to ensure that appropriate ethical approval has been obtained.

1.1. Potential ethics liabilities in RESCEU

The activities conducted in RESCEU may potentially pose significant ethics issues as project activities include:

- analysis of existing data, including unpublished studies, from systematic reviews of epidemiological and cost studies, data collection from large-scale disease registries, surveillance programmes and healthcare datasets;
- collection of human biological samples from infected patients as well as healthy controls;
- assembling of biobanks of clinical specimens to be used to identify candidate biomarkers for RSV
- analysis of already collected samples and existing material in biobanks to study associations between severe disease/sequelae and a range of biochemical and immunological parameters.

Ethical approval for each planned study is required to safeguard researchers conducting the study and protects the rights, safety, dignity and well-being of research participants. By obtaining ethical approval from an impartial committee and having in place robust systems for the review of studies RESCEU can ensure that the research conducted is of high ethical standard, sound integrity and in

accordance with good research governance and legal requirements.

The ethical and governance principles outlined in this Handbook will apply across all studies executed by the RESCEU consortium.

The following sections outline recommendations and reference to the governing rules organized by field of application. In addition, the ethics requirements included in the RESCEU Screening Report during the Ethics Review Procedure are addressed.

1.2. Project governance approval

Any study protocol and study related documentation must be approved, prior to submission to the concerned Ethics Committee (EC) and/or Competent Authority (CA), by the RESCEU EAC and SC, which are the committees responsible for advising and monitoring RESCEU research integrity and ethical scrutiny.

1.3. Studies' Ethics approval

Formal ethical approval will be sought from the concerned ECs and Cas in the countries where the studies are conducted.

All centres (EU and non-EU) participating in RESCEU clinical studies will ensure that the Ethics Committee of the concerned institution has approved the study as appropriate. The authorisations will be obtained individually by each participating centre, which will keep its own copy for record. Copies of all Ethics approvals will be also centrally filed by the RESCEU consortium and will be provided to Cas and/or IMI as needed.

Gaining the required ethics approval for any research study is the responsibility of the Principal Investigator (PI). Once ethics approval has been given, the PI must ensure that the conducted research complies with the approved study protocol. If, as the research progresses, changes need to be made to the protocol, the PI will need to apply for approval of the changes before they can be implemented. Study progress reports will be submitted to the concerned authorities, when required.

The above procedure applies to all research studies involving human subjects.

For those study applications to be assessed in Europe after October 2018, the new Clinical Trial Regulation No 536/2014 will apply [1].

Both EMA and the national regulatory agencies will be contacted for information and advice, where appropriate.

A copy of submission dossier and approval document will be retained by the centre and a copy will be filed in a dedicated reserved area by the RESCUE PMT, to be made available for external audit/inspection (refer to ANNEX I).

Reference to all the concerned Cas in countries participating in RESCEU studies is provided in *Table 1*.

1.4. Studies execution

All clinical study protocols will be finalised after consultation with the RESCEU Patient Advisory Board (PAB) and EAC.

All RESCEU clinical studies will be conducted in accordance with the Charter of Fundamental Rights of the EU Union [4] and the Declaration of Helsinki [5] and the CIOMS International Ethical Guidelines

for Health-related Research involving Humans [6].

All studies and study centres participating to the study will comply with the principles of Good Clinical Practice (GCP) [7] and the Directive 2001/20/EC [8] to ensure that data and results are credible and accurate and that the rights of participants (including safety and confidentiality) are protected.

For each study the following provisions will apply:

- a Sponsor will be designated;
- the study Principal Investigator (PI) will be qualified to assume responsibility for the study;
- the participating centre staff will be adequately trained on the protocol procedures;
- the centre facilities will be adequate and maintained to conduct the protocol procedures;
- the protocol (and the Consent/Assent form, see below) must describe the procedures that will be used to assess the decision-making capacity of the participants and the collection, transfer, storage, analysis of biological samples or any personal data between partners and any third parties;
- informed consent will follow GCP recommendations and the WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks [3] and the patient information sheet will include a description of risks and benefits, a statement on data confidentiality, the right for subjects to withdraw consent/approval, a statement that a summary of study findings will be made available to participants and contact details for questions. When minors will be involved, special considerations will be implemented, as further detailed in section 1.2.2.1 below;
- the adherence to the protocol will be closely monitored throughout the study, deviations will be recorded and, when appropriate, reported to the concerned authorities;
- Case Report Forms (CRFs) will kept accurate, complete, available for audit and retained for several years after the study as detailed in the Ethics approval; key RESCEU documents (such as protocols and standard procedures) will be locally (at site, in the site Investigator Folder, IF) and centrally (in the Trial Master File, TMF) stored in case of review/audit;
- adverse events (Aes) specified in RESCEU protocols will be recorded and securely stored;
- RESCEU will adopt a policy of publication of study results in open access journals and set aside a budget to meet these open access fees.

1.4.1. Special provisions for parent(s)/legal guardian(s) of minors

Since the RESCEU studies include minors, a comprehensive Information and Consent Form for parent(s) and legal guardian(s) will be prepared in compliance with the Directive 2001/20/EC, the “Ethical Considerations for Clinical Trials on medicinal products performed in Children – Recommendations of the Ad Hoc Group for the development of implementing guidelines for Directive 2001/20/EC, relating to good clinical practice in the conduct of clinical trials on medicinal products for human use” (EC 2008) released by the European Commission [9], the Declaration of Helsinki [5] and the Oviedo Bioethics Convention (Treaty no. 164) [10].

The information form addressed to parent(s)/legal guardian(s) will contain comprehensive information about the study, the planned procedures in the protocol, patient’s rights and their safeguard, all provided in language and wording appropriate to take account of cultural and linguistic differences. Topics include: explanation of the disease condition, study objective and design, the possibility to refuse or withdraw the child from the study insurance coverage, use and publication of results and findings, confidentiality of personal data, collection, use and storage of data and biological samples during the study, information about the outcomes of the research.

To facilitate the reading, the information document will be organised in a question/answer format and will include the following topics:

- why do we want to carry out this study?
- what will happen during this study?
- general recommendations
- what will happen when the study finish?
- which side effects can be expected during this study?
- which burden can be expected during this study?
- what are the benefits in taking part in this study?
- what happens if you decide not to let your child participate in this study?
- is there any insurance provided?
- what are the costs for taking part in this study?
- will your child's medical data be kept private?
- which information will be made public?
- what do you have to do to allow your child to take part in this study?
- who can answer your questions about this study?

The consent form contains the following declarations:

- confirmation of the child participation to the study;
- to have understood the information materials;
- to have had the opportunity to ask questions and to have received satisfying answers and sufficient time to take the decision;
- to be aware that participation in the study is fully voluntary and that at any time consent can be withdrawn without providing any justification;
- understanding that authorised people will review the child's personal data;
- consent that the child will follow the protocol procedures and biological specimens will be collected;
- the primary care paediatrician/general practitioner will be informed about the child participation in the trial;
- authorities and other personnel will have access to child's medical data;
- the child's personal data will be used only for the purposes described in the information document;
- the research data will be stored according to the applicable national legislation.

One copy of each consent form will be archived with the accompanying information document in the site IF, and one copy will be left with the patient's parent(s)/legal guardian(s).

Both parents' signatures, or legal guardian(s)' as appropriate, will be collected, unless the national legislation states differently. The signature of the investigator is also required.

For illiterate parents/LARs, the witness's signature and the thumb prints of the father and mother, or legal guardian(s) as appropriate, can be collected in the consent form.

1.4.2. Ethical misconduct

Investigators, researcher and staff involved in RESCEU studies are required to conduct their research to the same standards of honesty and probity in compliance with the RESCEU Ethical Principles as outlined in this Handbook. Supervisors and Principal Investigators should remind their researchers and staff of the significance of the RESCEU Ethical Principles, should ensure that their research activities are carry out in accordance with these Principles and that they are informed on Study Procedures, and that all the conditions of their ethical approval are met.

Where there are concerns around potential ethical misconduct, these must be reported to the RESCEU SC, PMT, EAC who will evaluate the appropriate actions.

Ethical misconduct behaviours include:

- failure to observe the RESCEU ethical principles;
- conducting a study without the appropriate ethical approval
- breach of ethical approval conditions;
- failure to renew/reapply for ethical approval when changes have occurred.

1.5. Concerned Competent Authorities

Table 1 reports the web links of the concerned national Regulatory Authorities in the countries involved in RESCEU studies. Although the majority of information refer to experimental clinical trials testing IMPs, they are reported here as reference for further contacts on specific information or issues applicable to RESCEU (low interventional) studies.

Denmark	<p>The Danish Medicines Agency (https://laegemiddelstyrelsen.dk/en/licensing/clinical-trials/trials-in-humans/guideline-for-applications-for-authorisation-of-clinical-trials-of-medicinal-products-in-humans)</p> <p>The National Committee on Health Research Ethics (http://www.nvk.dk/english)</p>
Finland	<p>The Finnish Medicines Agency (http://www.fimea.fi/web/en)</p> <p>The Act on Status and Rights of Patients (2013) contains legislation on patients' rights, including the confidentiality of information in medical records (http://www.finlex.fi/fi/laki/kaannokset/1999/en19990523.pdf)</p> <p>The Medical Research Act (2010) contains detailed guidance on performance of medical research (http://www.finlex.fi/fi/laki/kaannokset/1999/en19990488.pdf)</p>
Italy	<p>The Italian Medicines Agency: for information (http://www.agenziafarmaco.gov.it/en) for study submission: (https://www.agenziafarmaco.gov.it/aifaossc)</p> <p>D.Lvo 211/2003 on good clinical practice in the execution of clinical trials (http://www.agenziafarmaco.gov.it/sites/default/files/tipo_filedf1a.pdf)</p>
Netherlands	<p>The Dutch National Institute for Public Health and the Environment (http://www.rivm.nl/en/About_RIVM/International)</p> <p>Medical Research Involving Human Subjects Act (WMO) (http://www.ccmo.nl/en/medical-scientific-research-and-the-wmo)</p>
Spain	<p>Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) (https://www.aemps.gob.es/en/home.htm)</p>
United Kingdom	<p>Medicines and Healthcare product Regulatory Agency (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)</p>

Table 1. Concerned national Competent Authorities.

2. Specific responsibilities in RESCEU studies

In this section, specific study related responsibilities of key roles having access to research data and biological materials during a clinical study are summarised.

2.1. Study Sponsor

The study Sponsor has the responsibility of:

- detailing provisions in matter of data protection and biological samples management in the study protocol;
- assuring that RESCEU consortium's staff involved in the study, and external parties (CROs) performing monitoring and verification of the study, will manage data, documents or other material that is identified as confidential in confidentiality;
- assuring that the unambiguous subject identification code (assigned by the investigator) is used for data and biological material collection;
- establishing and indicating how long identifiable data/material will be kept;
- releasing raw data related to the study only in strictly anonymous forms;
- preparing informative material for patients and their parents, according to the dispositions set out by this Handbook;
- verifying that each subject has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, audit, EC review, and regulatory inspection;
- ensuring the processing and sharing of data among authorised persons, according to dispositions set out by this Handbook;
- reporting any transfer of responsibility of the data to the appropriate authorities;
- retaining all sponsor-specific essential trial documents for at least five years after its completion or longer in compliance with the national applicable regulatory requirements;
- informing the investigator/institution as to when trial documents no longer need to be retained;
- ensuring confidentiality among independent external experts, according to dispositions set out by this Handbook.

2.2. Investigator(s)/researcher(s)

The Investigator(s)/researcher(s) has the responsibility of:

- safeguarding privacy and confidentiality during the recruitment process;
- key-coding health data of trial subjects to be included in CRFs in line with the procedure set out in the study protocol;
- informing trial subjects and/or their legal representatives on the health and on the updated data of the trial subject get during the research and on the global results of the research;
- keeping a separate, secured, confidential Trial Register which matches the subject's trial number with their name;
- using the key-code in lieu of the subject's name when reporting adverse events and/or other trial related data;
- retaining trials documents for at least 5 years after the trial completion or longer in accordance with the national applicable regulatory requirements;
- retaining the Trial Register in strict confidence for 15 years;
- taking all reasonable measures to prevent accidental or premature destruction of study documents.

2.3. CRO

The CRO, when involved, has the responsibility of:

- managing data in confidentiality;
- ensuring the processing and sharing of data among authorised persons, according to dispositions set out by this handbook;
- retaining trials documents in conformance with the national applicable regulatory requirements.

3. Data Protection

3.1. Governing legislation

Access to, control of and dissemination of any data must rest on the principle that personal information must be protected from inappropriate disclosure and treated as confidential underpins all research activities on RESCEU.

In compliance with GCP and all the applicable privacy and confidentiality rules, the relationships between patients, investigators, sponsors, and eventually Clinical Research Organizations (CROs) are governed by a variety of instruments (patient informed consents, research protocols, patient medical records and contractual arrangements) where the confidentiality of data potentially identifying subjects should be protected.

Article 6(1)(b) of Directive 95/46/EC on the protection of individuals in relation to processing of personal data and on free movement of such data [11] lists the purpose limitation principle among the key data protection principles. The Directive clearly indicates that personal data *must be collected for specified, explicit and legitimate purposes and not further processed in a way incompatible with those purposes*.

Provisions established in this directive are summarised as follows:

- the principles of protection must apply to any information concerning an identified or identifiable person;
- very stringent rules apply to processing sensitive data: the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life are prohibited;
- personal data must be processed fairly and lawfully, accurate and, where necessary, kept up to date;
- personal data must be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed;
- the processing of personal data must be carried out with the consent of the data subject.

The Directive sets provisions also for accessing the data:

- any person must be able to exercise the right of access his/her data being processed; this right must not adversely affect trade secrets or intellectual property and the copyright protecting the software;
- access by health authorities to official documents is allowed.

The Directive regulates flow of data in ‘Third Countries’:

- personal data can only be processed or transferred to non-EU countries that guarantee an “adequate” level of protection;
- specific measures may be taken to compensate for the lack of protection in a third country (i.e., a controller offering appropriate safeguards).

In accordance with this Directive, Member States shall protect the fundamental rights and freedoms of natural persons, and their right to privacy with respect to the processing of personal data, without restricting nor prohibiting the free flow of personal data between Member States.

In line with the principles outlined in the Directive, the EU Charter of Fundamental Rights [4] dedicates Art.8 to the protection of personal data, the right to the protection of personal data, the fair processing of data for specified purposes and on the basis of the consent of the concerned person, the right of

access to personal data which has been collected, and the right to have it rectified. Importantly, the Charter states that the compliance with these rules shall be subject to control by an independent authority.

The right to know any information collected about the health of a person is additionally laid down in Article 10 of the Convention of Human Rights and Biomedicine [10] as applied to research. Research participants are not only entitled to have this information as acquired in the course of a research project but also to refuse this information. The 2005 Additional protocol to the Oviedo Convention on Biomedical Research [12] states that research participants shall be specifically informed of the arrangements on:

- the respect for private life and the confidentiality of personal data;
- secure access to information on the trial subject deriving from the research and to its overall results;
- any foreseen potential further uses, including commercial uses, of the research results, data or biological materials.

The Directive will be replaced by the EU General Data Protection Regulation EU No. 2016/679) [2] which is expected to come into force in June 2018.

3.1.1. Specific provisions for minors

Additional recommendations about individual data protection, specifically in the context of the paediatric research are included in the EU Ethical considerations for clinical trials on medicinal products conducted with the paediatric population (Ethical Considerations for Clinical Trials performed in Children – Recommendations of the Ad Hoc Group for the development of implementing guidelines for Directive 2001/20/EC relating to good clinical practice in the conduct of clinical trials on medicinal products for human use, EC 2008 [9]). This document, which provides a new regulatory context integrating principles contained in international ethical/legal sources (the Oviedo Convention and its Additional Protocol), has the aim of insuring the protection of minor subjects involved in biomedical research, while recognising the importance of benefits derived from research.

In line with Directive 1995/46/EC, the EU Ethical Recommendations states that the processing of personal data related to the child involved in the research, and to his/her family must be protected and carried out with the consent of the data subject.

Where personal information on a child is collected, stored, accessed, used, or disposed of, a researcher should ensure that the privacy, confidentiality and cultural sensitivities of the subject and the community are respected. Children participating in a trial and/or their legal representatives are entitled to know any information collected on their health. Other personal information collected for a research project will need to be made accessible to them in conformity with national laws on the protection of individual data. Confidentiality results one of the items recommended to be covered in the information sheets.

An additional element discussed in this document is the protection of confidentiality, especially for research on socially sensitive issues such as illicit drugs, sexuality, and violence, in case of trials in adolescents.

3.1.2. Specific provisions for Third Countries

The Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA (EMA/712397/2009, under revision after public consultation) [13], recommends that ethical principles applied to the clinical trials in the EEA should also apply to trials conducted in non-EU Countries,

taking into account local legal requirements and cultural background. Therefore, EU standard on confidentiality and data protection should be applied also in non-EU Countries, in line with the Declaration of Helsinki [5] and the International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva 2002 [6] which highlights the responsibility of the investigator in the collection and storage of information during the process of obtaining informed consent.

3.2. Data protection principles in RESCEU

The lack of harmonised interpretation of the provisions mentioned above has led to divergent applications of the notions of purpose limitation and incompatible processing even within Europe. The lack of a consistent approach may weaken the position of subjects providing personal data and may also impose unnecessary regulatory burdens on businesses and organisations operating across borders. Differences in levels of protection of the rights and freedoms (and to privacy) of individuals may prevent the transmission of such data from the territory of one Member State to that of another Member State. Therefore, the obstacles to flows of personal data have to be removed and the level of protection of the rights and freedoms of individuals with regard to the processing of such data must be equivalent in all Member States.

This has gradually become a serious concern as the volume of data and their global availability have increased exponentially and the processing of personal data has become an increasingly prominent feature of modern society, both in on-line and off-line environments.

These considerations are particularly relevant to the RESCEU consortium which has committed to establish information governance arrangements in compliance with relevant European legislation and requirements and applicable regulations established by each country, including Article 29 Working Party No. 243 of the planned EU General Data Protection Regulation [14], and repealing Directive 95/46/EC [11] which will come into force in May 2018 and which will supersede national legislation within the 28 EU Member States.

In compliance with all these provisions, all the organisational and technical details about data collection, storage, retention, destruction, privacy and confidentiality will be provided in a RESCEU Data and Knowledge Management Plan (D6.3), including details of the procedures for the transfer of data.

In general, it is the responsibility of all researchers undertaking research activities in the context of the RESCEU project to follow and maintain the highest standards of practice when processing information about living individuals (personal data) as part of their research.

Whilst approvals will need to be secured individually in each country, the following sections provide an overview of the principles guiding the methods with which personal data is collected and the content of the information in the context of RESCEU research activities.

The provisions included in these sections have been agreed with the concerned Institutions managing the data in RESCEU studies and they will apply to all participating centres.

3.3. Data collection in RESCEU studies

During the RESCEU project, and for any other period thereafter as established in the consortium agreement, the following provisions apply:

- confidentiality of any data, documents or other material that is identified as confidential in relation to the execution of the project will be preserved;

- data will not be shared with or given to anyone except the appointed researcher(s)/investigator(s) analysing the results;
- data will be anonymised: in order to maintain anonymity, patients will be identified by a code on all CRFs and specimens;
- RESCEU consortium’s participants, CRO, Competent Bodies (Ethics Committees and National Health Authorities) will receive information concerning children participating in RESCEU studies in a coded format to ensure the anonymity;
- independent external experts will be asked to sign an agreement to ensure confidentiality within the EAC (Ethic Advisory Committee);
- all documentation containing information on privacy/confidentiality, as well as the procedures that will be implemented for data collection, storage, protection, retention, merging, reuse and destruction, will be included in the study protocol and Information document for the participant/parent(s)/legal guardian(s) and reviewed by the concerned Ecs when applying for the ethical approval;
- any researcher, investigator/staff involved in the study will be bound by professional secrecy in relation to personal data;
- all audits and reviews foreseen in the project will be carried out on a confidential basis;
- records identifying the subject will not be made publicly available. If the results of the trial are published, the subject’s identity will remain confidential;
- if a third country does not ensure an adequate level of protection, adequate safeguards will be put in place to ensure compliance to the protection of privacy and fundamental rights and freedoms of individuals and about the exercise of the corresponding rights.

3.3.1. *Personal data*

The ruling principle in any RESCEU study is that the use of personal data must be limited to include only that information which is legitimately and exclusively required to complete the task for which it is deemed necessary. This requires researchers to clearly define before they begin collecting and processing the data exactly what personal information it is required and for what purpose it is to be used. Any additional information that is not relevant to the study should not be collected.

When creating new datasets, data will be extracted from national datasets/registers by staff authorised to work with patient identifiable data and appropriately trained to the standards required by their national authorities to comply with Data Protection legislation (*Table 2*). Only named RESCEU research staff in each country will have access to de-identified data.

Personal data must not be disclosed to any third party individual without the consent of the individual. A third party is anyone who is not the data subject or those permitted to process the data. Only the researcher(s) working with the data should be accessing it.

If the research requires the publication of personal data, this must be done in accordance with the process described when consent was provided by the individuals. Thus, it is important to provide subjects contributing to data collection with comprehensive information on the aims of the study when they are deciding whether or not to provide consent (refer to section 2.3.2.).

3.3.2. *Double coding*

Any data is double coded (i.e., anonymised) when it can no longer be used to identify the individual subject either by itself or in conjunction with any other information available on the same subject. In RESCEU anonymization will be created by generating two lists to manage the data subjects:

- the first list, the “index list,” contains a unique reference number next to the names of each subject contributing to the data collection
- the second list, the “working list,” uses the same reference numbers against each set of data collected.

Neither list identifies the specific subject, even though they both contain personal information. Data can become identifiable only when the reference is used to cross-link the details each specific subject has submitted.

The two lists will be archived separately and personnel with specific access to either lists will be identified and specified in study documents (Statistical Analysis Plan and or Data and Knowledge Management Plan).

The index list is still an important project record and must be retained for as long as the contained information still has a legitimate purpose, for example as required for the study documentation.

3.3.3. Consent to use the data

The processing of personal data should only take place when the subject to whom the data relates has freely (i.e., without coercion) provided their consent for its use, having been fully informed as to how the information will be used.

The Informed Consent will explicitly state that:

- the information collected in the study will be kept confidential;
- the information collected will not be shared with or given to anyone except the researcher(s)/ investigator(s)/staff involved in the study and/or analysing the results;
- personal data will be protected in accordance with the European, international and each national legal framework;
- any information will be fairly, lawfully processed and securely stored;
- all data (and biological samples) obtained during this research procedure will be processed and used only for this research, and will be destroyed when the research is completed, unless otherwise clearly stated;
- the subject has the right to request her/his own data;
- the subject has the possibility to withdraw the consent any time, without any justification and to ask for the disruption of collected samples and data.

In addition, the information will include any specific requirements from each concerned EC and CA.

Some exemptions from obtaining consent apply:

- when proof can be provided that (within the law) there is substantial public interest in processing the information without first obtaining consent;
- when it is not possible to obtain consent and its use is ‘fair and ethical’ so that it does not result in the unwarranted prejudice to the rights, freedoms or interests of the data subject.

Exemption from obtaining consent will be specified in the study protocol.

Examples of personal data processed without the explicit consent of the data subject may include:

- studies where the information has been collected for a previous research project and the new project is a continuation of or is related to that project. In this situation, consent to use the data should be obtained from the original researcher(s);

- studies where the information is already in the public domain and the use of such data is not likely to cause unwarranted prejudice to the rights, freedoms or interests of the data subject.

Subjects over 18 years of age contributing to RESCEU studies with personal data must provide free and fully informed consent on the use of the data. Consent can subsequently be withdrawn.

For minors, provisions set in section 2.1.1. apply.

3.4. Data linkage

Data linkage will be undertaken by authorised staff such as those authorised by the relevant national authorisation body. Data will be linked by unique patient identifier and supplemented if necessary by checks using gender, date of birth, area of residence and treatment centre. Data linkage processes/methods are described in the RESCEU Data Knowledge Management Plan.

3.5. Data storage

Clear, secure and accurate records can protect researchers against allegations of misconduct, show good ethical practice or legal compliance and ensure protection against intellectual theft. Appropriate security measures shall be taken for the protection of all RESCEU collected data stored in automated data files on secure servers against accidental or unauthorised destruction or accidental loss as well as against unauthorised access, alteration or dissemination.

Where possible, records will be created and stored electronically. However, the format will depend on the nature of the record itself and the reason for its existence. Records will remain secure through controlled access or regular backup. Electronic records will be stored in logical file structures and indexed using logical file naming conventions and appropriate security measures (password protected, limited access, regular back-up, encryption).

Study records containing 'sensitive' or identifiable personal data as hard copy materials or removable media (memory sticks, disks etc.) need to be stored in a manner that will prevent unauthorised access (in lockable filing cabinet or room restricted to authorised members of staff).

The extent and degree of security required is closely linked to the nature and sensitivity of the data, the risk from accidental loss, damage or theft.

It is the responsibility of the Principal Investigator on any study conducted within the RESCEU project to ensure that accurate records are maintained and securely stored for the duration of the project. This includes identifying when the project is subject to all the applicable provisions in matters of Data Protection and how information will be collected and stored.

The Principal Investigator will also ensure that where there is staff involvement on the project, whether in a support or direct involvement, responsibilities are clearly defined and documented.

At the end of the study, the Principal Investigator will ensure that the records are retained, transferred or, where required, disposed of securely in accordance with the retention schedule detailed in the study protocol.

An electronic copy of archived material will be retained centrally by the Sponsor. Authorised and certified destruction will then be arranged at the appropriate time.

3.6. Data transfer

No routine datasets will be transferred between RESCEU Partners. Fully anonymised summary tables

will be transferred between RESCEU Partners using only secure routes such as secure file transfer protocol and only within Europe. The process for transferring data within Europe will be detailed in the RESCEU Data and Knowledge Management Plan.

3.7. National Data Protection Agencies, applicable legislation and regulatory documents

Denmark	<p>The Danish Data Protection Agency (https://www.datatilsynet.dk/english/the-danish-data-protection-agency/introduction-to-the-danish-data-protection-agency)</p> <p>The Act on Processing of Personal Data (Act No. 429 of 31 May 2000 as amended, implementing Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (https://www.datatilsynet.dk/english/the-act-on-processing-of-personal-data/read-the-act-on-processing-of-personal-data/compiled-version-of-the-act-on-processing-of-personal-data)</p>
Finland	<p>The Ministry of Justice, the Finnish Data Protection Board (http://oikeusministerio.fi/en/index/theministry/neuvottelu-jalautakunnat/thefinnishdataprotectionboard.html)</p> <p>The Personal Data Act (1999) contains guidance on the use of personal data, including subjects participating in medical research (http://www.finlex.fi/fi/laki/kaannokset/1999/en19990523.pdf)</p>
Italy	<p>The Italian Data Protection Authority (http://www.garanteprivacy.it/web/quest/home_en)</p> <p>Legislative Decree no. 196/2003 Data Protection Code sets provisions to regulate the processing of medical data in the health care sector (Sections 75-94) (http://www.garanteprivacy.it/home_en/italian-legislation)</p> <p>Code of conduct and professional practice applying to the processing of personal data for statistical and scientific purposes (http://www.garanteprivacy.it/web/quest/home/docweb/-/docweb-display/docweb/1115480)</p> <p>Authorisation no. 9/2014 to process personal data for scientific research purposes (http://www.garanteprivacy.it/web/quest/home/docweb/-/docweb-display/docweb/3786078)</p>
Netherlands	<p>The Dutch Data Protection Authority (https://autoriteitpersoonsgegevens.nl/en)</p> <p>The Dutch Personal Data Protection Act, under review (http://hrlibrary.umn.edu/research/Netherlands/Personal%20Data%20Protection%20Act%202000.pdf)</p>
Spain	<p>Agencia Española de Protección de Datos (https://www.agpd.es/portalwebAGPD/index-iden-idphp.php)</p>

United Kingdom	Data Protection Act 1998 (http://www.legislation.gov.uk/ukpga/1998/29/contents) NHS Code of practice for handling information in health and care (https://digital.nhs.uk/codes-of-practice-handling-information) NHS Information Governance Alliance on guidance on using and sharing information in health and care (https://digital.nhs.uk/information-governance-alliance)
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Table 2. Data Protection Agencies' web link, applicable legislation and reference documents in countries participating to RESCEU studies.

4. Biological material

4.1. Governing legislation

The legislative framework in matters of biological materials of human origin in Europe is provided by the previously mentioned Council of Europe Convention of Oviedo, 1997 [10] and the Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin [15]. The Convention requires participants' free informed consent for the storage and use of materials for a purpose other than that for which it was removed. It further stipulates that the human body and its parts shall not, as such, give rise to financial gain. This does not of itself preclude the licensing/selling of intellectual property rights arising from research in which the samples are used (i.e. this is the same as for other intellectual property rights) but it does mean that those who donate their materials should be informed if those materials might be used for commercial purposes. Besides, it does not prevent that a person, from whom an organ or tissue has been taken, to receive compensation which (while not constituting remuneration) compensates the expenses incurred or the loss of income (for example as a result of hospitalisation).

The Recommendation Rec(2006)4 further highlights the extent to which the participants could be identified from their biological materials or associated personal data. In general, identifiability may be achieved directly via accompanying personal data or indirectly via a code held either by the researchers or by a third party. Non-identifiable materials are those for which, with reasonable efforts, there is no possibility of identifying the donor.

The Recommendation additionally covers interventions to obtain the materials to be stored for future research, the principles governing collections of materials and population biobanks, and the research use of previously stored materials (i.e., residual material from clinical, research, or forensic purposes). This document establishes that research on human materials should only be undertaken after independent scientific and ethical review and, mirroring the Convention, provided the use is within the scope of the donor's consent.

The recent Recommendation CM/Rec(2016)6 of the Committee of Ministers to member States on research on biological materials of human origin [15] is the outcome of a re-examination of Recommendation Rec(2006)4 and takes into account new developments in the field, such as the increasingly diverse origin of biological materials stored in collections, the difficulty of guaranteeing the non-identifiability of such samples, the increasing amount of research involving materials from different collections, and the importance of protecting the rights of persons not able to consent. The purpose of this recommendation, is to set out and safeguard the fundamental rights of individuals whose biological materials are intended for biomedical research. Their dignity, integrity and privacy must be guaranteed, while the continued benefits of research should be ensured by providing researchers with appropriate access to biological materials. It is particularly relevant to RESCEU research because it takes into account new developments in the field of bio-banking, such as the increasingly diverse origin of biological materials stored in collections, the difficulty to guarantee non-identifiability of such samples, the increasing amount of research involving materials coming from different collections, and the importance of research on biomaterials removed from persons not able to consent. The new legal instrument sets out the conditions for obtaining and storing materials for future research as well as for using them in specific research projects, in particular regarding appropriate information and consent of the persons concerned.

Finally, the sharing of microbial genetic resources will follow the principles of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, a supplementary agreement to the Convention on Biological Diversity and adopted by European legislation through Regulation (EU) No 511/2014 [16]. The Nagoya Protocol provides a transparent legal framework for the fair and equitable sharing

of benefits arising out of the utilization of genetic resources, establishing more predictable conditions for access to genetic resources and ensuring benefit-sharing when genetic resources leave the country providing the genetic resources. By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to development and human well-being.

The provisions to be included in these sections were agreed with the concerned Institutions. They will apply to all participating centres (EU and non-EU).

4.2. Biological material collection in RESCEU studies

As the collection of human biological material infected with pathogenic human viruses will be involved in the RESCEU research, researchers and investigators must ensure that appropriate health and safety procedures conforming to relevant local/national guidelines/rules are followed for staff involved in this project. In addition, participants to RESCEU studies and the public should have confidence that the materials will be handled and used not only responsibly but also sensitively. Special consideration must be given to obtaining ethics approval and consent; and the safe disposal of human tissue.

The materials that are taken from human beings for research use may be destined for immediate use in a specific research project or stored for future use (in biobanks) according to the provisions detailed in the study protocol and the Information and Consent form which will be reviewed by the concerned Ecs and Cas.

The Information document must provide the involved subject with information on:

- location of the biobank/biorepository (if applicable);
- type and amount of materials to be stored;
- research scope for the stored biological materials;
- indication if participation in the biobank is an option to participation in the study (if applicable)
- overview of the scientific relevance of biobanks and their importance to human well-being (if applicable);
- specific health and personal data to be collected (if applicable);
- nature of the research activities in the field of biological materials;
- choice of whether or not to be contacted in the case of discovery of meaningful personal information;
- statement that researcher has moral duty to contact donor to inform them of results and given an opportunity to decide whether or not to be informed at that time;
- risks related to the collection of the sample;
- voluntary character of the donation;
- right to withdraw the material and duration of storage;
- identifiability of biological materials, if applicable;
- the physical, administrative and technical safeguards which will protect the human biological materials and any information about participants from unauthorized handling. This may include information about the governance structure of the biobank or repository (if applicable);
- confidentiality;
- prohibition of financial gain such that participants should not receive any payment for the gift of biological material and the biobank/biorepository should be forbidden to sell the collected biological samples (these does not include reimbursements for incurred costs);
- assurance of independent Ethics review.

5. Reference documents and EU legislation

1.	Clinical Trial Regulation No 536/2014 (http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_536/reg_2014_536_en.pdf)
2.	EU General Data Protection Regulation EU No. 2016/679 (http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&qid=1491557076246&from=en)
3.	WMA Declaration of Taipei on Ethical Considerations regarding Health Databases and Biobanks (https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks)
4.	Charter of Fundamental Rights of the EU Union, (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012P/TXT&from=EN)
5.	Declaration of Helsinki – ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS (https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects)
6.	International Ethical Guidelines for Biomedical Research Involving Human Subjects Prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), Geneva 2002 (http://www.cioms.ch/publications/layout_guide2002.pdf)
7.	Guideline for Good Clinical Practice (https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R1_Guideline.pdf)
8.	Clinical Trials Directive 2001/20/EC (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:121:0034:0044:en:PDF)
9.	Ethical Considerations for Clinical Trials on medicinal products performed in Children – Recommendations of the Ad Hoc Group for the development of implementing guidelines for Directive 2001/20/EC, relating to good clinical practice in the conduct of clinical trials on medicinal products for human use, EC 2008 (http://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/ethical_considerations_en.pdf)
10.	Oviedo Bioethics Convention (Treaty no. 164) (https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168007cf98)
11.	Directive 95/46/EC on the protection of individuals in relation to processing of personal data and on free movement of such data (http://ec.europa.eu/justice/policies/privacy/docs/95-46-ce/dir1995-46_part1_en.pdf)
12.	2005 Additional protocol to the Oviedo Convention on Biomedical Research (https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168008371a)
13.	Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA (EMA/712397/2009, under revision after public consultation (http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2010/06/WC500091530.pdf))
14.	Art. 29 Data Protection working Party No. 243 (http://ec.europa.eu/information_society/newsroom/image/document/2016-51/wp243_en_40855.pdf)
15.	Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin (http://www.coe.int/t/dg3/healthbioethic/Activities/02_Biomedical_research_en/Rec%20biomat)

	%20CM.pdf)
16.	Regulation EU No.511/2014 on on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511)

Table 3. Reference documents and EU legislation

6. ANNEXES

6.1. ANNEX I. RESCEU compliance with ethics requirements derived from the proposal review

The RESCEU project needs to address the ethics requirements received during the proposal evaluation. This consists mostly in compiling a series of documents related to ethics clearances, procedures, etc. and providing them to IMI upon request. For this purpose, RESCEU has prepared a table which contains the requirements, where they will be filed, who will be providing those documents and when they are due. Those documents will be organized following a folder structure created in RESCEU SharePoint (the internal intranet created for the project) – see Annex II.

ETHICS REQUIREMENTS	SCHEDULE	WHERE	WP / Institution / Person	WHEN (Project month)	STATUS (available, pending, overdue)
HUMANS					
1. Copies of ethical approvals by the competent legal local/national Ethics Bodies for all locations where studies on humans will be conducted must be submitted to the IMI.	<i>Prior to the commencement of any research involving human participants.</i>	SharePoint folder “Clinical studies” >> Subfolder “Ethical approvals”	WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale	M6	
2. The ethics approvals must cover transfer of any biological samples or any personal data between partners and any third parties.	<i>Prior to the commencement of any research involving human participants</i>	SharePoint folder “Clinical studies” >> Subfolder “Ethical approvals” i.e. Kilifi approvals to share samples.	WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale	M6	
3. A complete portfolio of current copies of ethical approvals that cover all aspects of the RESCEU research by all of the partners of	<i>Throughout the lifetime of the research involving human</i>	SharePoint folder “Clinical studies” >> Subfolder “Ethical approvals”	WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge	M6-M60	

ETHICS REQUIREMENTS	SCHEDULE	WHERE	WP / Institution / Person	WHEN (Project month)	STATUS (available, pending, overdue)
the Consortium must be compiled and retained by the Ethics Advisory Committee and must be available to the IMI if requested.	<i>participants.</i>		WP5/Oxford/Simon Drysdale		
4. Copies of templates of the Informed Consent Forms and Information Sheets for all of the different participant cohorts involved in RESCEU must also be provided to the IMI.	<i>Prior to the commencement of any research involving human participants in any of the different cohorts.</i>	SharePoint folder “Clinical studies” >> Subfolder “Templates informed consent forms and information sheets”	WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale	M6	
5. A complete portfolio of copies of templates of Informed Consent Forms and Information Sheets that cover all aspects of the research by all of the partners of the Consortium throughout the lifetime of the RESCEU project must be compiled and retained by the Ethics Advisory Committee and must be available to the IMI if requested and for Ethics Checks or Audits.	<i>Throughout the lifetime of the research.</i>	SharePoint folder “Clinical studies” >> Subfolder “Templates informed consent forms and information sheets”	WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale	M6-M60	
6. Vulnerable patients will be involved in the research; therefore, the procedures that will be used to assess the decision-making capacity of these participants must be provided to the IMI in order to ensure that only those able to give	<i>Prior to the commencement of any research involving human participants.</i>	SharePoint folder “Clinical studies” >> Subfolder	WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale	M6	

ETHICS REQUIREMENTS	SCHEDULE	WHERE	WP / Institution / Person	WHEN (Project month)	STATUS (available, pending, overdue)
consent will be involved in the research.		“Protocols” ¹			
HUMAN CELLS/TISSUES					
7. In the case of human cells/tissues that are obtained within the project, ethics approval must be provided to the IMI.	<i>Before the use of any human biological samples and derived data obtained from this project.</i>	SharePoint folder “Clinical studies” >> Subfolder “Biological samples”	WP4/UMCU/Joanne Wildenbeest ² WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale	M6	
8. In the case of human cells/tissues that are obtained within another project, details on cells/tissues type and authorisation by primary owner of data (including references to ethics approval) must be provided to the IMI.	<i>Prior to the use of any human biological samples and derived data obtained from another project.</i>	SharePoint folder “Clinical studies” >> Subfolder “Biological samples”	WP4/UMCG/Maarten van den Berge (tbc) WP5/Oxford/Simon Drysdale SSI – serum samples RIVM – serum samples ICL – human cells/tissues	M6	
9. In the case of human cells/tissues stored in a biobank, details on cells/tissues type must be provided, as well as details on the biobank and access to it.	<i>Prior the use of any human biological samples and derived data obtained from a biobank.</i>	SharePoint folder “Clinical studies” >> Subfolder “Biological samples”	WP5		

¹ The birth cohort and case control studies will be conducted in infants (<1 year) and it is clear that they cannot make a decision. Therefore there is no need to assess the decision-making capacity. Consent will be gathered through the parents and the templates are available in the protocols.

² At the moment it is not expected that UMCU will obtain samples from other studies or use them in other studies, but this may change with time. The table will be updated accordingly.

ETHICS REQUIREMENTS	SCHEDULE	WHERE	WP / Institution / Person	WHEN (Project month)	STATUS (available, pending, overdue)
PERSONAL DATA					
<p>10. The applicants must provide the IMI with a "Data Protection Policy" including a description of the measures that will be implemented in the institution(s) where the research will be carried out.</p> <p>This Data Protection Policy must describe the organisational and technical details about data collection, storage, retention, destruction, privacy and confidentiality. The Policy must also include details of the procedures for the transfer of data. Additionally, the Policy must be accompanied by confirmation of compliance with national and EU law on the protection of individuals with regard to the processing of personal data. This confirmation must be issued by the responsible entity within the institution(s) where the project is carried out (e.g. local Data Protection Officer, local head of data security department, or the body identified as overall "data</p>	<p><i>Prior to the collection/storage/use of personal data.</i></p>	<p>SharePoint folder "Personal data" >> Subfolder "Data Protection Policy"</p>	<p>WP4/UMCU/Joanne Wildenbeest WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale</p>	<p>M6</p>	

ETHICS REQUIREMENTS	SCHEDULE	WHERE	WP / Institution / Person	WHEN (Project month)	STATUS (available, pending, overdue)
<p>controller" within the concerned institution).</p> <p>If the national legislation requires prior notification to, and subsequent authorisation/ approval/opinion by, the competent national Data Protection Authority for the intended data collection, processing and transfer, the applicants must provide a relevant copy to the IMI.</p>					
<p>11. In the case of any previously collected personal data that will be used in RESCEU, authorizations must be provided.</p>	<p><i>Prior to the use of previously collected data.</i></p>	<p>SharePoint folder "Personal data" >> Subfolder "Compliance with EU Law"</p>	<p>WP4/UMCU/Joanne Wildenbeest WP2 / Harry Campbell³ WP4/UMCG/Maarten van den Berge WP5/Oxford/Simon Drysdale</p>	<p>WP2 – M9-18 WP4 – M6 WP5 – M6</p>	
THIRD COUNTRIES					
<p>12. The ethical standards and guidelines of FP7 must be rigorously applied, regardless of the country in which the research is carried out.</p>	<p><i>Throughout the lifetime of the research.</i></p>	<p>SharePoint folder "Third countries"</p>	<p>WP5</p>		
<p>13. A non-EU country (Kenya) will</p>	<p><i>Throughout the</i></p>	<p>SharePoint folder</p>	<p>WP5</p>		

³ WP2 will be aiming to get approvals for access to routine data sets.

ETHICS REQUIREMENTS	SCHEDULE	WHERE	WP / Institution / Person	WHEN (Project month)	STATUS (available, pending, overdue)
<p>be involved in RESCEU; as such details of the planned transfer of human biological material and any sensitive personal data, together with appropriate authorisations, must be provided to the IMI.</p>	<p><i>lifetime of the research.</i></p>	<p>“Third countries”</p>			
<p>ENVIRONMENT & HEALTH AND SAFETY</p>					
<p>14. As human biological material infected with pathogenic human viruses will be involved in the RESCEU research, the applicants must ensure that appropriate health and safety procedures conforming to relevant local/national guidelines/legislation are followed for staff involved in this project.</p>	<p><i>Throughout the lifetime of the research.</i></p>	<p>SharePoint folder “Health and safety procedures”</p>	<p>WP4/WP5</p>	<p>M6-M60</p>	

6.2. ANNEX II. RESCEU filing structure for ethics documents in SharePoint

