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COMBINA Implementation Initiation Report

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D3.2: COMBINA Implementation Initiation Report

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1. Executive Summary

Deliverable 3.2 – COMBINA Implementation Initiation Report (D3.2) is the second deliverable for Work Package 3 – COMBINA Delivery. The purpose of the Implementation Initiation Report is to provide all key documents related to the COMBINA study, namely: ethical approvals and supporting documentation (study protocol, participant information, list of translated languages and vulnerable groups per country).

D3.2 aligns closely with D3.1 (Implementation Protocol) and D4.1: COMBINA Evaluation Manual and is a key deliverable in the preparatory stage ahead of the COMBINA implementation study commencing in M18.

2. Introduction and Background

2.1 Role of this Deliverable in the Project

The overarching aim of MENTBEST is to support vulnerable groups (*migrants/refugees, older people, younger people, long-term unemployed, and those with mental disorders*) in the general population especially at risk of being disadvantaged by dramatic societal change, of experiencing stressors, and of suffering (further) negative impacts on their wellbeing, including mental health.

MENTBEST will first characterise the scale of change-related mental health challenges in Europe and then working with patients, healthcare and other stakeholders, identify interventions and tools that best build resilience and maintain mental health.

By expanding existing MENTBEST partner expertise in community-based interventions to reduce depression and suicidal behaviour (EAAD 4-Level-Intervention) and including the identified interventions and tools, MENTBEST will create and then deliver and validate in five model regions across five countries (Spain, Ireland, Estonia, Greece, Albania), a comprehensive community-based intervention, known as COMBINA.

An innovative addition will be the MENTINA App, that will first be tested via a randomised controlled trial (RCT). It will then be available for app-based self-monitoring and self-management for mental health, using n=1 longitudinal statistics to create individualised predictive models and provide users with individualized feedback and self-management support.

MENTBEST is an ambitious project, led by the European Alliance Against Depression (EAAD) with a multi-disciplinary consortium of a further 13 partners, collectively covering 10 countries.

Work Package 3 – COMBINA Study (WP3) is responsible for carrying out the 24-month validation of the COMBINA programme, its objectives are:

- To establish the regional alliances for mental health in the five intervention regions.
- To secure ethical approval in each region.
- To ensure the collection of the evaluation data at each time point by cooperating with the local partners in the five intervention and the five control regions, in close cooperation with WP4.
- To ensure the COMBINA intervention programme is accessible to the target population, including vulnerable groups, in the intervention regions via translation and local adaptation.
- To implement the COMBINA intervention programme in the five intervention regions.

There are six tasks in WP3, of which three tasks lead to D3.2:

- Task 3.2: Localisation and translation of the COMBINA Programme
- Task 3.3: Ethical approvals for COMBINA
- Task 3.4: Establish regional alliances for mental health in each of the five model regions.

This report describes the work and outputs of these three tasks. With the successful delivery of D3.2, the project will work towards the following specific objectives, as depicted in Figure 1 below:

- SO3: *to combine these interventions, plus the first version of the MENTINA self-management app (SO5), with the adapted and expanded EAAD 4-level intervention programme, to create COMBINA- a community-based intervention programme focused on sub-clinical mental health, resilience and mental disorder prevention*

- SO4: *to implement COMBINA in five model regions, and evaluate its clinical and cost effectiveness, and user usability/acceptability, with the ultimate aim to use these results to enhance COMBINA*

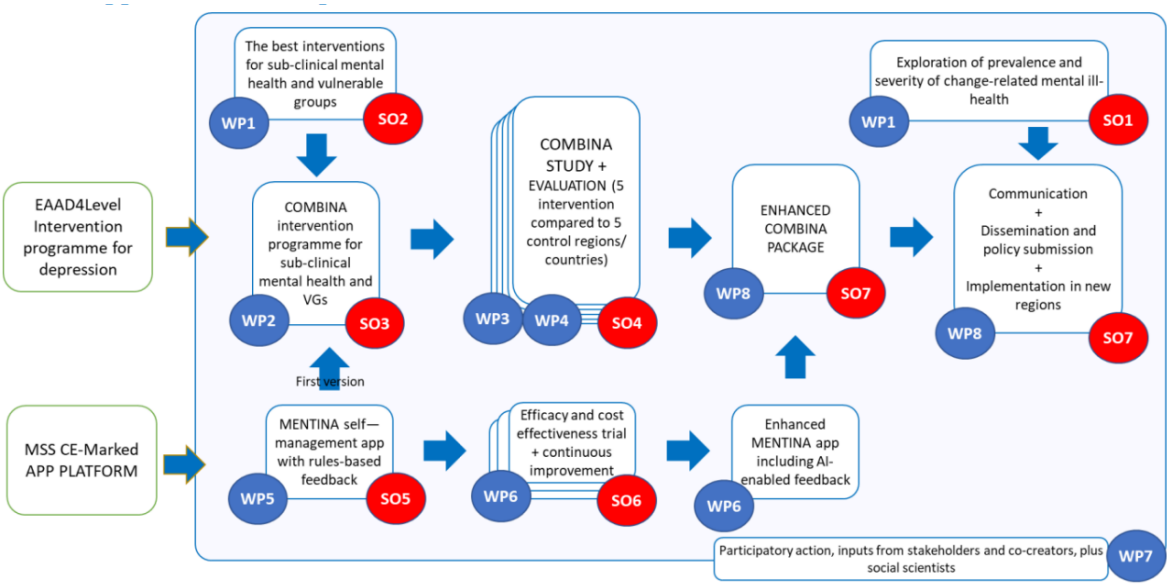

Figure 1. MENTBEST approach and inter-relations between WPs**.**

3. Approach

This deliverable comprises several tasks which are detailed separately below. To ensure that a consistent approach was applied across each of the five local regions, the tasks were coordinated by WP3 in regular bi-weekly, and at times weekly, meetings attended by each of the partners of the local COMBINA intervention regions, as well as WP2, WP4, and EAAD. These meetings were initiated in September 2023 and will continue until the end of the COMBINA implementation. During these meetings, the steps to complete each task and timeline were agreed, while allowing each country to proceed in the most culturally appropriate way for their region.

3.1 Localisation and translation of COMBINA programme (Task 3.2)

The COMBINA programme was developed by WP2 in Task 2.2 and a translation kit was developed by WP2 in Task 2.3, to facilitate the translation of all COMBINA material into the necessary COMBINA languages.

Each local partner where English is not the main regional language (IMIM: Spain, ERSI: Estonia, SEERC: Greece, and CCHW: Albania) had to source material for the COMBINA programme in their local language and, where this was not available, translate to their local language. With the exception of the iFightDepression tool, which was not modified for COMBINA and already available in each of the necessary languages, it was necessary to translate all the materials, as there were developed and revised specifically for COMBINA. This process was coordinated by WP3, and through the regular WP3 and partner meetings, the timelines and methods for the translations were agreed. The languages to be translated to were Spanish and Catalan (IMIM, Spain), Estonian (ERSI, Estonia), Greek (SEERC, Greece), and Albanian (CCHW, Albanian). WP2 coordinated producing the finalised materials with the translated content.

Local partners preferred to use research officers and members of the team to carry out translations, which were then reviewed by each country's research officer, to ensure the translations were carried out by people with knowledge of appropriate mental health terminology.

The local partner in Ireland (NSRF) did not need to translate into another language as English is the main official language and Irish is spoken by a small minority who also speak English. However, examples and wording can be altered as appropriate to ensure the material is culturally appropriate.

For migrant languages, feedback from research officers and a workshop with the co-creators were used to define the potential languages for translation. It was agreed for migrant languages that external translators would be used, but that research officers with the language skills or co-creators in regions where the language is spoken would review the language for accuracy and for cultural sensitivity.

3.2 Ethical approvals for COMBINA (Task 3.3)

IMIM (WP3) created a generic ethical approval document to be adapted to each local language. The inputs for this generic document were the WP2 implementation handbook, the WP3 implementation protocol, and the WP4 evaluation manual.

Each country then adapted the generic ethical approval document to the local requirements of their local ethics committee (e.g. translating the informed consent forms into the local language and sourcing/translating the evaluation scales in their language and submitting for approval).

3.3 Establish regional alliances for mental health in each of the five model regions (Task 3.4)

A major focus for each regional partner was forming the regional alliances for mental health in their region. Firstly, local partners reached out to local officials whose support was needed for the successful implementation of COMBINA. This varied according to each region; for example, in Spain, the local mayor's office was involved, while in Albania, the Ministry of Health had to give their official support to the project for it to be viable. Next, a wide range of institutions and associations were contacted to explain the project and invite them to join the alliance. An important part of this step was hosting a network planning meeting, which was a meeting where all potential stakeholders, representing community institutions and associations, including the police, teachers, pharmacists, religious leaders, GPs, healthcare works, psychiatric services, the local council, youth workers, workers in geriatric services, unemployment offices, and migrant/refugee associations. During this meeting, the project was presented, and first steps were taken to understand how the project could best be adapted and implemented to the local region, and which stakeholders were interested in being actively involved,

which were interested in being involved in a less active role, and to understand any concerns from other stakeholders.

Following the network planning meeting, the research officers in each location worked actively with the different local alliance stakeholders to prepare for the opening launch and the first activities. This phase included a huge amount of activity, in terms of meetings with stakeholders, recruiting and training trainers, scheduling workshops, translating and culturally adapting materials, preparing the opening ceremony, and preparing the first activities.

4. Results

4.1 Overview of the intervention regions

In each intervention country, there is an intervention region and a comparable control region with similar characteristics where no intervention will take place. A pragmatic approach was taken in identifying the intervention and control regions. While each region focuses on the general population and the five vulnerable groups, there will be a special focus on certain vulnerable groups according to the needs of each region, and to ensure that, within the resources of the project, each vulnerable groups will be given a strong amount of focus in at least three regions. The details can be seen in Table 1 below.

Table 1. Intervention and control regions in each COMBINA implementation country.

Country	Intervention area (Number of inhabitants)	Control area (Number of inhabitants)	Vulnerable groups focused on in each region				
			Existing mental health difficulties	Young people	Older people	Migrants/ refugees	Long-term unemployed
Albania	Central Tirana (350,000)	Elbasan (252,719)	X	X	X		
Estonia	Mustamäe & Haabersti (117,538)	Lasnamäe (119,092)	X	X		X	X
Greece	Thessaloniki municipality (324,766)	Larissa (144,651)	X	X	X	X	
Ireland	Limerick City & County Council (209,536)	County Galway (277,737)	X	X	X		X
Spain	Santa Coloma de Gramenet (119,195)	Sant Marti (242,752)	X			X	X

In Ireland, the initial focus for the intervention region was on County Cork and Country Kerry, and the planned control region was County Limerick. However, as some prior EAAD activity had taken place in this region which could potentially have a confounding effect on the COMBINA intervention, a decision

was made in May 2024 to concentrate on County Limerick where there had been no previous intervention. Country Galway was then identified as a suitable control region.

4.2 Localisation and translation of COMBINA programme (Task 3.2)

Translations were carried out as per the agreed process described in Section 3.1, resulting in all the COMBINA material being translated into Albanian, Estonian, Greek, Spanish, and Catalan. In each country the translations were reviewed by the research officer with specialised knowledge of mental health to ensure the quality of the translations. Translations were provided to WP2 through an excel spreadsheet, from which WP2 could create the final translated materials. Translations were completed by 2nd September 2024.

For the migrant languages, a survey was sent to research officers in May 2024 to gather feedback from stakeholders in each region on which languages were needed. Based on these results, a co-creator workshop was held on 17th July 2024 to gather further feedback. The results of this were then discussed in a WP3 meeting on 16th September 2024 and it was agreed that COMBINA materials should be made available in Arabic, Chinese, Farsi, Lithuanian, Polish, Russian, Ukrainian, and Urdu. WP3 is coordinating centrally the translations for these migrant languages, with research officers in each location working with co-creators to review the translations.

4.3 Ethical approvals for COMBINA (Task 3.3)

The generic document for ethical approval was created by IMIM, WP3. This document can be seen in Appendix A. This document covered extensively an overview of the project, the methodology, the evaluation procedure and ethical considerations. Ethical approval documents submitted for prior EAAD projects were reviewed as a guide, and then the generic document was developed based on the inputs from WP2's implementation handbook, WP3's implementation protocol, and WP4's evaluation manual. When developing the generic ethical approval document, key decisions or points for discussion were reviewed in the biweekly MENTBEST WP3 meetings and in the monthly plenary meetings on 13th and 14th May and again on 12th June. The document was sent out to all partners for feedback, revisions were made, and then final feedback was provided by EAAD and WP4, before it was distributed to all partners for adaptation and submission to their local ethics committee on 19th June.

In Table 1 can be seen the details of which ethics board the project was submitted to, the date of submission, and date of approval, in each of the five partner regions.

Table 1. Ethics submission and approval in each of the five intervention regions.

Country	Local Ethics Board	Date of Submission	Date of Approval received
Albania	Ethics Committee, University of Medicine Tirana	03/07/24	29/08/24
Estonia	Research Ethics Committee of the National Institute for Health	09/08/24*	19/09/24
Greece	CITY College, University of York Europe Campus, Research Ethics Committee of the Psychology Department.	03/07/24	18/07/24
Ireland	Education and Health Sciences Research Ethics, University of Limerick	26/08/24*	Pending feedback from ethical committee
Spain	Ethics Committee for Clinical Investigation (CEIm), Hospital del Mar Barcelona	27/06/24	Evaluated 17/09/24, waiting for feedback

*In both Estonia and Ireland, they were not able to submit until the next agreed date from the ethics board for receiving submissions.

4.4 Establish regional alliances for mental health in each of the five model regions (Task 3.4)

A core element of the COMBINA intervention is the formation of a regional alliance where stakeholders from a range of institutions in the community are involved as partners. This is crucial for ensuring the COMBINA intervention is implemented in a successful and sustainable way, and how to achieve this is explained in detail in the implementation handbook (D2.1) and the implementation protocol (D3.1). In Figure 1 can be seen the different stakeholders who can be reached out to.

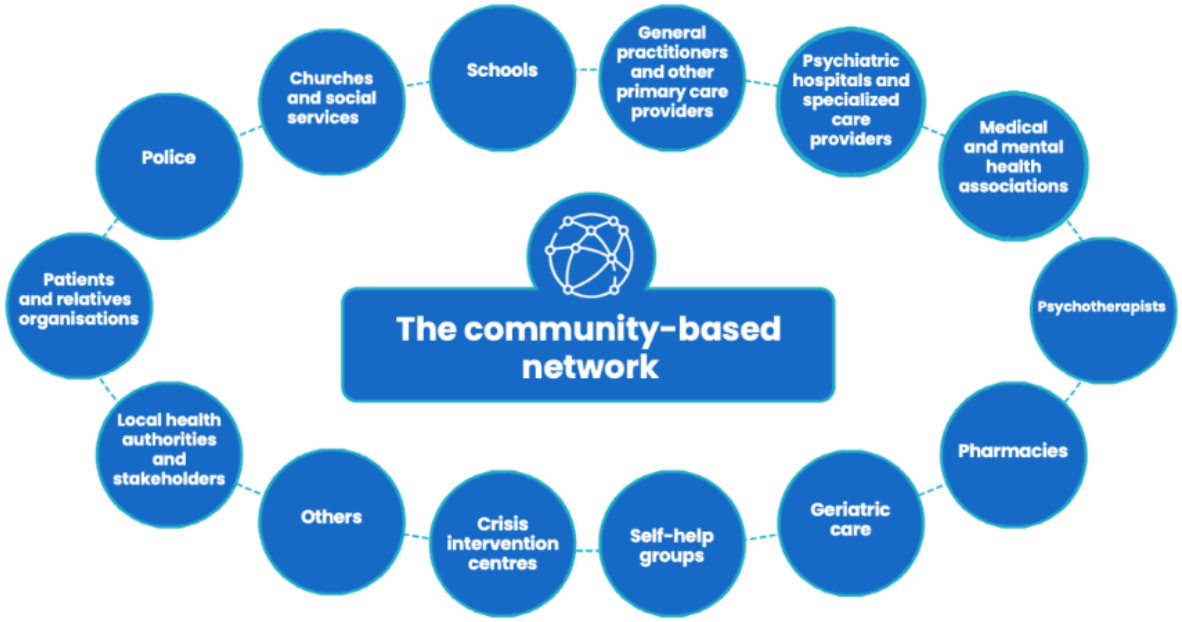

Figure 1. Potential regional alliance partners.

4.4.1 Network planning meeting

In order to create this alliance, a crucial first objective was to hold a network planning meeting, in which the project was presented to people from this range of institutions, the benefits of the intervention could be explained, and partners could provide their expertise regarding how best this could be implemented in the local context. This important meeting marked the beginning of the formation of the alliance where partners could feel a sense of ownership in the project and collaborate in its implementation, which is essential for a wide community reach. It was also essential that all relevant people felt they were invited to participate and understand the project's aim.

The network planning meeting was carried out in each region following approximately two months of preparation, focused on contacting all potential stakeholders to invite them, finding a suitable venue in the local community/intervention area, and informing the media of the event.

The network planning meetings were carried out in the months of March and April as the final part of the planning phase (Step 1), before embarking on the preparation phase (Step 2). Below, Table 2 shows the dates and attendees of the network planning meeting in each region, showing the diverse stakeholders who attended each meeting and its reach.

Table 2. Details of the network planning meeting in each of the intervention regions.

Country	Date held	Number of attendees	Institutions/groups represented
Albania	06.03.2024	30	Ministry of Health, Ministry of the Interior, journalists, pharmacists, psychologists, community mental health workers, education
Estonia	26.03.2024	17	NGOs, ministry of social affairs, women's shelters, psychologists, child protection services, administrative district workers, youth workers
Greece	01.04.2024	34	Mayor's office, education, social services, geriatric services, police, the church, YMCA, migrants NGOs, children/youth NGOs, health centers and mental health professionals from public and private organisations.
Ireland	09.04.2024*	12	National Irish College of General Practitioners, the Health Service Executives involved in suicide prevention, the Gaelic Athletic Association, priests, and representatives of local associations.
Spain	08.04.2024	33	Mayor's office, police, church, press, drug services, youth mental healthcare services, community mental health services and specialist mental health services, general hospital, psychiatric hospital, personal support for severe mental health problems, youth associations, pharmacists, local mayor's office, pharmacists, community organisations, families of people with mental health problems, families of children with ADHD, unemployment office, work insertion charity

*In Ireland, the timeline for the network planning meeting was different due to the change in intervention region described above in section 4.1. In Ireland, an initial meeting took place on 9th April with the stakeholders from Cork and Kerry Alliance, and these contacts helped the team form relationships afterwards in County Limerick. Following a series of individual meetings with a range of stakeholders across County Limerick, they have planned a network meeting for October 2024. Due to the previous relationships established through the first network meeting, and hard work reaching out to potential partners in County Limerick, they have been able to present the project and plan collaborative activities with stakeholders alongside organising the network planning meeting there. This activity helps mitigate any difficulties created by the later date for the network meeting, meaning that Ireland will begin with the opening ceremony and first COMBINA activities at the same time as the other countries.

Photos of the network meetings can be seen in Figure 2.

Figure 2. Photos from the different alliance network meetings. Top left and bottom left: Estonia. Middle top: Greece. Top right and middle: Albania. Bottom middle: Spain. Bottom right: Ireland.

All countries reported a very positive reaction from the local community stakeholders towards the project. Regional differences in terms of the most important aspects and challenges to providing improved care could be seen. In Albania, the discussion was very positive and engaged, focused on how the EAAD 4-level model can be adapted to Albania, understanding specific challenges and how the project can fit in with the existing structure, and identifying who to engage. In Estonia, they received very valuable perspectives from meeting participants. They identified options for improving gatekeeper networks, raising awareness of mental health issues in the broader public, strengthening the role of primary healthcare, and enhancing support for patients and their families were explored. Throughout the discussions, several key action points were identified, including the need for awareness-raising, increased collaboration between various stakeholders, and the creation of specific support structures. In Greece, there were also high level of enthusiasm and support for the project. Needs were identified, such as training for priests, mental health support for secondary school adolescents (13-16 years old), and fighting stigmatisation in the general public. Local regional challenges were identified: lack of public mental health services to refer to, no effective primary health services and difficulty to reach (and potentially train) any general doctor working in public or private services, difficulty to find voluntary mental health professionals (psychiatrists/psychologists) in the public sector that would be willing to be trained to be trainer. In Spain, there was similar high enthusiasm for the project and especially for implementing Level 3 trainings, as professionals from a range of institutions shared their concerns after seeing recent suicide attempts amongst their users. Some local challenges were also identified: high levels of loneliness, especially amongst the elderly, a high incidence of self-harm in young people, difficulties due to a significant minority of local people in extreme poverty with basic needs not met, a lack of digital literacy among many people, and a long

waiting list for referral to mental health services. Consolidating the alliance to prepare for the opening launch and first activities

4.4.2 Opening Ceremony and First Activities

With the alliance formed in the network meeting, each local region has worked in an aligned way, coordinated by WP3, to prepare for the opening ceremony and first activities, in line with the implementation protocol. In Table 3 on the following page can be seen the timeline for the activities carried out across the different regions in the preparation phase.

Regarding this timeline, a key factor was the order in which each event can occur. The ethical approval needs to be received first in each local region before the baseline general population survey can be carried out. In turn, the general population survey must be carried out before the opening ceremony, to provide baseline data which is not influenced by the COMBINA implementation. Therefore, there is a strict order of: 1) receipt of ethical approval, 2) baseline general population survey, and 3) opening ceremony, and each part cannot begin until the preceding activity has been completed.

The ethical approval document was prepared for June 2024 in accordance with the project timeline. However, there were challenges with some local ethics boards: in Ireland, the County Limerick ethics board did not accept ethics submissions from mid-June until 26th August, while in Spain the ethics committee had a backlog in being able to review applications due to a lack of resources. As a result of this, the opening ceremony is scheduled in the below timeline for October/November to allow for ethical approval to be received across the countries and the general population survey to take place beforehand.

As an example of some of the activity being planned post-opening ceremony, in Greece once the COMBINA intervention starts, they will be carrying out training and distributing material across the 500 pharmacies in the region, and working across all the secondary schools (approximately 60 centres). Similarly, in Spain, all public sector workers in unemployment services with a public facing role will participate in the L3 trainings within the first few months of COMBINA, along with public sector workers working in social services and child and adolescent services, and professionals from a range of associations working with young people, while material will be distributed across the unemployment services, and a wide range of other organisations, hospitals and healthcare services. In Ireland, discussion is underway with the Ministry of Health regarding the use of the iFightDepression tool across GP services, and they are working closely to reach young people through work with the Gaelic Athletics Association. In Estonia, the first activities including Level 1 trainings for primary care physicians and mental health professionals, as well as a public awareness campaign, gatekeeper trainings, and supportive activities for patients and high-risk groups. Meanwhile, in Albania, a wide range of Level 3 trainings have been planned with groups such as youth workers, school support staff, and journalists.

Table 3. Overview of tasks carried out across regions in the preparation phase.

	06/24	07/24	08/24	09/24	10/24	11/24
Ethics						
Ethics submission	X	X	X			
Translations and adaptations of materials						
Translations and cultural adaptation of training materials		X	X	X		
Translation: translation tables for WP2 developed content		X	X	X		
Adaptation of materials to vulnerable groups			X	X	X	
Trainings						
Identification of specific training needs and groups	X	X				
Recruitment of trainers			X	X		
Training of trainers				X	X	
Recruitment of spokesperson			X	X		
Evaluations						
Contract process for external market research company for general population survey	X	X	X			
General population survey takes place				X	X	
Translation of surveys		X	X			
Opening ceremony						
Preparation of content of opening ceremony			X	X	X	
Contract PR firm	X	X				
Contact media				X	X	
Schedule first workshops				X	X	
Preparation of logo and banners			X	X	X	
Printing of materials				X	X	
Opening ceremony takes place					X	X
First COMBINA intervention activities post-opening ceremony						
Scheduling activities		X	X	X		
Beginning of activities						X

4.5 Impact and Conclusions

The tasks detailed in this document are key to the successful launch and implementation of the COMBINA project. As a result of the work detailed in this document, each local partner region has prepared thoroughly for the start of the COMBINA intervention, including creating a strong regional alliance and working towards the opening ceremony and the first activities. This work was carried out in an aligned way, coordinated by WP3, meaning that although the COMBINA intervention will be implemented in each region according to local circumstances, all partner countries are following the same framework and process, and are prepared for the initiation of the COMBINA intervention. This will have a direct positive impact on the COMBINA intervention which will be reported on in D3.3.

5. Appendix A – Generic ethical approval document