

Obtaining Research Ethics Approval in the International, Multisite PREDICTOM Study

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Introduction

Early, accurate detection of dementia could open a window for timely intervention.

Remote clinical research assessing early markers of Alzheimer’s disease (AD) has many advantages over standard in-clinic assessments, such as scalability and accessibility for individuals in rural areas. At the same time ethical concerns across multiple sites and countries can vary significantly and are underrepresented in the current literature¹.

Aims

To identify ethical challenges raised by research ethics committees (REC) in the context of a large European PREDICTOM study.

Methods

Feedback from RECs at seven sites (UK, Norway, Belgium, Spain, Germany, France, and Switzerland) for the project “Prediction of Alzheimer’s Disease Using an AI-Driven Screening Platform” (PREDICTOM)² was collected. Key themes were identified using a qualitative analysis approach by the research site team members.

Results

Ethics Review Processes Varied Widely Across Sites

Review processes differed across sites, with REC process durations ranging from 30 to 264 days. Similarly, the number of issues raised varied considerably, ranging from 4 to 33 per site. Approval from a Data Protection Officer was required at two sites, while Health Research Authority approval was required at only one site (UK). The most frequently raised ethical concern related to the content of study information (31.67%; $n = 38$), followed by data management (22.50%; $n = 27$), methodological issues (17.50%; $n = 21$), participant wellbeing (12.50%; $n = 15$), other issues (9.17%; $n = 11$), and biofluid-related issues (6.67%; $n = 8$).

Country	Institution	REC Name	Level
Norway	Stavanger University Hospital	Regional Komiteer for Medisinsk og Helsefaglig Forskningsetikk	Region specific
United Kingdom	King's College London	Wales REC 4	Region specific
Spain	Fundacion para la investigacion del hospital universitario la fe de la comunidad Valenciana (HULAFE)	Comité de Ética de la Investigación con medicamentos (CEIm) del Instituto de Investigación Sanitaria La Fe (IISLaFe)	Site specific
Switzerland	University of Geneva	CCER Commission cantonale d'éthique de la recherche (CCER)	Region specific
Germany	Ludwig Maximilian University of Munich	Ethics Committee of LMU Munich	Site specific
Belgium	Vrije Universiteit Brussel (VUB)	Ethische commissie Universitair Ziekenhuis Brussel	Region specific
France	Qairnel (QAI)	Comité de Protection des Personnes (CPP) Nord Ouest II	Region specific

Table 1. The participating sites and the REC that approved the study.

Number of Changes Requested by the REC across Countries								
CATEGORY	UK N	Norway N	Switzerland N	Germany N	France N	Spain N	Belgium N	TOTAL N
 DATA MANAGEMENT	Data access	1	0	0	0	1	0	2
	Data protection	0	2	1	1	1	3	9
	Data security	0	1	0	0	2	0	3
	Data sharing	1	1	0	0	1	2	5
	Data storage	2	1	0	1	0	2	7
	Data transfer	0	1	0	0	0	0	1
	SUBCATEGORY TOTAL	4	6	1	2	1	7	27
 PARTICIPANT'S WELLBEING	Comfort	0	0	1	1	0	0	3
	Duration of assessments	0	0	0	0	0	0	0
	Competence	0	0	0	0	0	0	0
	Incidental findings	2	0	0	1	0	1	4
	Privacy	1	0	0	1	0	0	3
	Proportionality	0	0	0	1	0	0	1
	Resistance	0	0	0	0	0	0	0
	Safety	1	0	1	1	0	0	3
	Stigmatisation	0	0	0	1	0	0	1
	SUBCATEGORY TOTAL	4	0	2	6	2	1	15
 METHODOLOGICAL ISSUES	Liability	2	0	2	0	0	1	5
	Methodological concerns	1	3	2	1	0	2	9
	Recruitment	1	0	1	0	1	0	3
	Devices	0	0	0	1	0	0	1
	SUBCATEGORY TOTAL	4	4	5	2	1	4	21
 BIOFLUIDS	Transportation of biofluids	1	0	1	1	0	0	4
	Collection process	1	0	2	1	0	0	4
	SUBCATEGORY TOTAL	2	0	3	2	0	0	8
 CONTENT OF STUDY DOCUMENTS	Participant facing material	0	1	0	0	0	3	4
	Invitation letter	1	0	0	0	0	0	1
	Consent form	1	1	2	0	0	7	11
	Participant Information Sheet	13	2	2	0	0	2	19
	Leaflets	0	0	0	0	0	0	0
	Language	1	0	0	0	0	2	3
	SUBCATEGORY TOTAL	16	4	4	0	0	14	38
 ADDITIONAL EXAMPLES (OTHER EXAMPLES NOT COVERED ABOVE)	Clarity of study phase	0	1	0	0	0	0	1
	Retrospective Data	1	0	1	0	0	1	3
	Compensation (lunch voucher)	1	0	0	1	0	1	3
	Feedback	1	1	0	0	0	1	3
	Transparency	3	3	1	1	0	3	11
	SUBCATEGORY TOTAL	3	3	1	1	0	3	11
	OVERALL TOTAL	33	17	12	13	4	15	120
	N = Number of changes requested by the REC							

Table 2. Number of Changes requested by the REC across Countries.

Ethical Concerns	N	%
Data management	27	22.50
Participant wellbeing	15	12.50
Methodological issues	21	17.50
Biofluid	8	6.67
Content of study information	38	31.67
Other	11	9.17
Total	120	100.00

Table 3. Ethical concerns raised by the research ethics committee boards across sites.

Key findings

- Ethical concerns varied across sites, reflecting differences in local review priorities and regulatory approaches.
- Most REC feedback focused on study documents and data management, particularly participant information, consent, and data protection.

Conclusion

A Clear Need to Improve Harmonisation in Ethical Review Across Remote AD Studies.

- Ethical concerns varied across sites, reflecting differences in local review priorities and regulatory approaches.
- Most REC feedback focused on study documents and data management, accounting for the majority of requested changes. Common issues centred on participant information, consent forms, and data protection, highlighting a strong emphasis on clarity and governance.
- Standardised, harmonised ethical frameworks are needed to reduce variability across sites and streamline approvals in multisite remote AD research.

References

1. Muurling M et al. (RADAR-AD). BMC Med Ethics, 2022
2. Brem AK, Khan Z et al. PREDICTOM study design. J Prev Alzheimers Dis, 2026.



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