

COST Action: GYNOCARE

European Network for Gynaecological Rare Cancer research: From Concept to Cure CA18117

Establishing a common Patient Information Sheet/Leaflet and a Consent Form for Biobanking of

Samples from Patients with Rare Gynaecological Tumours

COLLABORATOR COUNTRIES:

Malta (Dr Bridget Ellul lead for ethical questions); Greece (Dr Olga Tzortazou lead for legal questions), Italy, Ireland

OBJECTIVES

To establish a common Patient Information Sheet /Leaflet and a Consent Form for biobanking of samples from patients with rare gynaecological tumours.

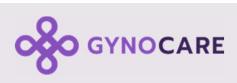
To establish

i) what documentation is available in the countries represented by the members of this COST Action; and

ii) whether it is fully compliant with GDPR and national legislation or if updates/ amendments are in progress so that we can identify the ideal information that should be in these forms.

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METHODOLOGY	EXPECTED OUTPUT
 Develop a Questionnaire to ascertain what information is included in existing Patient Information Sheets/Leaflets (ISs) and Informed Consent Forms (ICFs) Distribute via Google Forms to COST members Analyse responses Possible future re-contact Possible future wider distribution Basis for future development of harmonized documents, to minimize the need for country specific appendices to be added to cover the legal requirements in different countries, thus facilitating collaborative research. 	 collect all current documentation dealing with Patient Information Sheets and Consent Forms; compare the themes covered and analyse these in relation to the national legislation; establish if content has been approved by the national Data Protection Authorities; and establish whether the expectations of patients and lay organisations are fulfilled.



Questionnaire

Section A: Biobank Profile

general information, including type of biobank (public or private), type of collections available, the type of legal entity and legislation regulating the biobank and contact details of the biobank

Section B: Information Sheet

information included in form - structure of biobank, potential benefits & risks to participants, storage details, patient rights (withdrawal of consent, data protection), use of & access to samples and data, return of results

Section C:Informed Consent Form

information on type of consent, re-contact, and re-consent

Section D: Patient Engagement

one question to ask who was involved in preparing the forms

Section E: Legal Issues (another VM grant) legislation related to copyright, patents and innovative knowledge

Section F: Request for Forms and Legislation