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## Editorial

A very warm welcome to all our readers. This issue of the EuroCareCF newsletter will focus on a subject of great interest to the CF community; the CF Patient Registry and the activities of the workpackage that is leading this project.

There is tremendous enthusiasm for a patient registry and a willingness to make it succeed. Already nearly 35 countries from all over Europe have agreed to collaborate, and others from outside Europe are asking if they can join, taking us a step closer to implementing a world-wide solution. Equally exciting is the partnership between the European Cystic Fibrosis Society (ECFS), the CF Foundation (CFF) of the United States and EuroCareCF, which is key to making this happen.

**"All our patients, clinicians and researchers deserve a good European Registry to move forward in the fight against CF"**

*Professor Marie Johannesson  
President  
European Cystic Fibrosis Society*

Let us, for a moment, look back on the long path we have travelled to arrive here. We discussed the original concept of a pan-European registry in 1995 in Paris at a meeting hosted by the French CF association, Vaincre la Mucoviscidose. The Epidemiologic Registry of Cystic Fibrosis, funded by F. Hoffman-La Roche, Switzerland, was implemented in approximately ten European countries in the late 1990s. In 2003, representatives from some national registries met to discuss the building of a Europe-wide registry under the auspices of ECFS. In 2004, my discussions with CFF leaders in Bethesda, Maryland, USA, Dr Preston Campbell, Executive Vice President for Medical Affairs and Dr Bruce Marshall, Vice President for Clinical Affairs, led to our agreement to standardise registry information in order to facilitate international research and in 2006 funding was successfully won for just such a uniform registry as an important component of EuroCareCF.

It is this shared global vision which underpins the work that the EuroCareCF-ECFS-CFF partnership is taking forward. Our ambition is to build a truly global registry which will facilitate outstanding international research to improve the care of all people with cystic fibrosis. The ultimate success of this registry depends on the active participation of all CF centres and I invite you to join us if you have not already done so.

I would like to express my sincere thanks to the ECFS, Professor Marie Johannesson, President, Dr Christine Dubois, Executive Co-ordinator and Dr Hanne Olesen (Denmark), Chair of the ECFS Registry Board, and to the CFF, Dr Robert Beall, President and CEO, Dr Preston Campbell and Dr Bruce Marshall. My thanks also to my EuroCareCF registry workpackage colleagues, Professor Milan Macek (Prague) and Professor Eitan Kerem (Israel) and to all the representatives from all the countries who so willingly give of their time and expertise for this worthwhile cause as together we move forward towards a global patient registry.

The following pages will provide a guide to where we are today and what we hope to achieve in the future, but do feel free to contact me, or the European registry project manager, Gita Mehta (g.mehta@dundee.ac.uk) if you have any questions or comments.

**"We are excited about the potential for this international collaboration to benefit all patients and families with CF"**

*Dr Bruce Marshall  
Vice President for Clinical Affairs  
Cystic Fibrosis Foundation*

# Participating Countries

As a result of overwhelming enthusiasm and support, the CF patient registry will permit international research on shared, anonymous patient data for approximately 60,000 patients from countries across two continents, Europe and the USA.

Representatives from the countries listed below will form the European registry working group, the first meeting of which is scheduled for 15th December 2006 in Amsterdam. If you wish to participate and your country is not included in this list, please contact Gita (g.mehta@dundee.ac.uk) urgently.

This working group is being constituted to represent widely the interests of all users of the European registry and to elect a steering committee, as required by the consents that have been provided by patients.

The UK Data Protection Officer welcomed the formation of the steering committee with the words: "The oversight of the steering committee also helps to provide an additional welcome safeguard to ensure the proper use of the data on the register".

Austria		Angela Zacharasiewicz	Lithuania		Sigitas Dumcius
Belgium		Claude Sevens	Macedonia		Svetlana Kocheva
Bulgaria		Alexey Savov	Norway		Olav-Trond Storrøsten
Croatia		Duska Tjesic-Drinkovic	Poland		Jaroslav Walkowiak
Cyprus		Tonia Adamidis	Portugal		Luisa Pereira
Czech Republic		Milan Macek	Romania		Ioan Popa
Denmark		Hanne Olesen Tanja Pressler	Russia		Nataliya Kashirskaya
Estonia		Tiina Kahre	Serbia		Predrag Minic
France		Sophie Ravilly	Slovakia		Hana Kayserova
Germany		Martin Stern	Slovenia		Andreja Borinc Beden
Greece		Sanda Nousia-Arvanitakis	Spain		Silvia Gartner
Hungary		Rita Ujhelyi	Sweden		Marie Johannesson Anders Lindblad
Iceland		Olafur Baldursson	Switzerland		Martin H. Schöni
Ireland		Linda Foley	The Netherlands		Vincent A.M. Gulmans
Israel		Meir Mei-Zahav	Turkey		Deniz Dogru
Italy		Baroukh Assael	UK		Elaine Gunn
Latvia		Vija Svabe			

# Overview

## Objective

To build a uniform European patient registry. This registry will:

- Identify how many patients there are in each country
- Determine their demographic profile
- Where possible, identify their clinical status

## Description of Work

- Obtain patient consents
- Create the registry software
- Collect data from each country
  - Demographic data are compulsory
  - Clinical data are optional
- Report on the data collected

## Data Protection and Obtaining Patient Consents

Ethics and patient consents for the registry are a crucial issue, and protocols have been designed such that patient anonymity is guaranteed while retaining the research potential of the data.

Within the European Union (EU), European Directive 95/46/EC on the protection of personal data governs the framework for legislation within each member state. Each country must work within these guidelines to formulate its own laws. The individual interpretation of this directive in each country is therefore often slightly different from that of the others although all countries take a broadly similar approach. Outside the EU, in the rest of Europe and beyond, each country is again responsible for passing and implementing its own laws on data protection, although the approaches are all essentially similar as regards the requirements for patient confidentiality and consent. **Therefore, participants from each country MUST check the patient consents and procedures with their own local data protection officers.**

For our registry consents, an extensive investigation was undertaken of the European Commission FP5 funded project (<http://www.privireal.org/>) examining the implementation of the Data Protection Directive 95/46/EC in relation to medical research. Following from this, and taking into account that the software design of any proposed registry system would need to be compliant with patient confidentiality issues, a template was drawn up for patient consent forms together with a set of procedures for access to anonymous data and guidelines for each country to obtain informed patient consent.

These templates and procedures were forwarded to

**“You make it clear in your information sheet that the basis for entry onto and further disclosure from the register is clear unambiguous consent which can be withdrawn by the patient at any point. Such consent sits well with the provisions of the Data Protection Act.”**

*- UK Data Protection Office*

the UK Data Protection Office for their views and criticisms, which were overwhelmingly positive. They said:

“You make it clear in your information sheet that the basis for entry onto and further disclosure from the register is clear unambiguous consent which can be withdrawn by the patient at any point. Such consent sits well with the provisions of the Data Protection Act.”

The documents were then forwarded to legal and ethics experts of EuroCareCF Workpackage 8 for their approval before being sent to each country representative who have been requested to check them with their own local data protection and ethics laws, prior to getting them translated for patients to sign.

Copies of these templates and procedures are included on pages 9 to 12.

**Each country/ CF centre owns its own data. The patient’s local hospital and the ECFS are the Data Controllers for data sent to the European registry.**

**The European Registry is registered under the Danish Data Protection Agency, file no 2005-41-5321.**

At the present time, the patient consent forms are being actioned at individual country level. Some countries will use these forms (translated if necessary into the local language) to get new patient consents. Others will use them to re-seek consent to be compliant with the new European registry requirements. Some countries have existing satisfactory consents and once their data protection officers have confirmed their agreement, need take no further action.

# Registry Software—Port CF

In the work relating to the registry software, we have forged an excellent opportunity to create something truly global for the CF registry. Our collaboration with the CFF has led them to provide us with their excellent software, Port CF, free of charge. The CFF have over 40 years of registry experience and this collaboration represents an enormous step forward in patient care.

Port CF allows the patient's local care team to record and follow the progress of individual patients while keeping the identity of the patient anonymous outside this team.

Our use of Port CF for Europe allows us to allocate a 'European CF Centre number' which further safeguards patient anonymity. This was commended by the Data Protection Officer for the UK as follows:

"We also positively note the use of European centre numbers as opposed to a...[country specific]... centre number to help protect the privacy of patients by ensuring anonymity. As we discussed some data protection authorities in Europe may have a different view of the extent to which the data is anonymous where a key to recombine it with an identifiable individual exists."

ECFS are firmly supportive of this initiative, with the successful pilot of the American software, Port CF in Sweden in September.

Evaluative work has also been done by several countries on the use of Port CF for Europe, an example of which is Germany.

There are two typical paths to participating in the European registry:

1. Using the Port CF software to record and monitor the progress of your patients, e.g. Sweden
2. Sending anonymous, electronic data for merging with the Port CF registry data, e.g. Germany

Both methods are feasible and your participation is welcome by whichever route you prefer.



*We are grateful to Brian Hughes, CFF Patient Registry Project Manager, for an excellent Port CF workshop for European participants at the recent North American CF Conference in Denver. Pictured with Brian (3rd from left) are Christine DuBois (Executive Co-ordinator, ECFS), Marie Johannesson (President of ECFS), and Gita Mehta (European Registry Project Manager)*

"In Sweden we have been using Port CF in all 4 centers as a pilot project since September 2006. Our experience is very positive. Port CF is easy to use for anyone familiar with CF care. It is divided in different parts including demographic and clinical data. It can be used in the outpatient clinic to keep track of trends in lung function, height and weight. It has a powerful tool to select the information you are interested in from your data collection. With small changes it can be fitted to be used in all European countries that need a patient data base. In Sweden we will continue to use also the clinical part of Port CF as a pilot study during 2007."

*Dr Anders Lindblad  
Center Director, The West Swedish CF Center,  
Göteborg, Sweden*



*Port CF records demographic data as well as clinical data for encounters, care episodes (e.g. IVs) and year end survey data*

"Germany has specific local requirements for full therapy evaluation and practical use directly in clinic. We will therefore continue to use our own registry software and will provide data anonymously to the European registry"

*Professor Martin Stern  
Professor of Paediatrics and  
Chairman, Board of German Quality Assurance Project*



# Registry Implementation Plan for Europe

There are two ways to participate in the European registry. The steps for each of these are outlined below:

- (i) Individual centres can use the Port CF software to enter their data directly into the database. We request that this is coordinated through the representative for each country where possible
- (ii) Anonymous data can be provided electronically for merging with the European data for centres and countries that do not wish to use the Port CF software

For an initial period of 12—18 months, Port CF software will be used unmodified from its original American version as it is assessed by European users and experience is built up regarding what we would like to see in the long-term European registry.

Based on this experience, a full list of demographic and clinical data variables will be drawn up, along with the definitions of these variables. Discussion and continued cooperation with CFF will ensure common definitions to allow international consensus on the data. The tasks are listed in (iii) below.

## (i) Centres or Countries wishing to use Port CF as their Patient Registry

- Ensure you have obtained the necessary patient consents and met all your country's legal and ethical requirements
- Contact your country representative to confirm your readiness
- The country representative should contact the registry project manager Gita (g.mehta@dundee.ac.uk)
  - To confirm that all your country's legal and ethical requirements have been satisfied
  - To ask that your centre is set up to use Port CF
- Use Port CF software for collecting the compulsory demographic data (see page 7) and, if you wish, clinical data to track the progress of your patients

## (ii) Centres or Countries wishing to send anonymous patient data to the European Registry and not use Port CF software

- Ensure you have obtained the necessary patient consents and met all your country's legal and ethical requirements
- Contact the registry project manager Gita (g.mehta@dundee.ac.uk)
  - To confirm that all your country's legal and ethical requirements have been satisfied
  - To make the arrangements for sending your anonymous data. There is a Microsoft Excel worksheet which specifies the required fields (see page 7) and their format.

## (iii) ECFS / EuroCareCF and Members of the Registry Working Group

- Elect a registry steering committee to oversee the use of patient data
- Determine which variables should be collected for the European registry, based on a considered use and experience of the registry software over a 12—18 month period
- Agree definitions of key variables e.g. chronic Pseudomonas
- Discuss and where possible agree with CFF common definitions for the variables
- Explore and apply for further funding to ensure the continuity of the registry beyond December 2008

# Demographic Data for the European registry

In the initial stage of the registry, only demographic data collection is compulsory. Demographic data variables collected in Port CF are shown below. Not all these variables will be required for Europe. The compulsory variables are shown in red and marked with an asterisk (\*) but participants are asked to provide as much of the information as they are able.

## 1 Patient Identifying Data:

Country  
Centre Code

\* National Patient ID code

**OR**

Full Name

\* Month and year of birth: MM / YYYY

**OR**

Full date of birth: DD / MM / YYYY

## 2 Gender:

\* Male/Female

## 3 Race:

\* White

\* Black

Asian or Pacific Islander

Aleut, Eskimo or American Indian

\* Unknown

\* Other (specify)

## 4 Ethnicity:

\* Is patient of Hispanic origin? Yes / No / Unknown

## 5 Social Security Number:

Do not complete

## 6 Zip Code:

Do not complete

## 7 Biological Parental Height:

Height measurements in inches / cm

Mother's height / unknown

Father's height / unknown

## 8 Genotype:

\* Has the patient been genotyped? Yes / No

If patient has been genotyped,

\* Date genotyped: DD/MM/YYYY or Unknown

\* Mutation 1:

\* Mutation 2:

## 9 Complications at Birth:

\* None

\* Meconium ileus

\* Unknown

## 10 Death: If patient has died:

\* Date of death

Primary Cause of death:

Respiratory

Liver disease/liver failure

Trauma

Suicide

Transplant related

Unknown

Other (specify)

## 11 Diagnosis suggested by/symptoms at first CF work-up (select all that apply):

\* Acute or persistent respiratory symptoms

\* Edema

\* Electrolyte imbalance

\* Failure to thrive/malnutrition

\* Family history

\* Genotype

\* Liver problems

\* Meconium ileus/other intestinal obstruction

\* Nasal polyps/sinus disease

\* Prenatal screening (CVS, amnio)

\* Neonatal screening

\* Rectal prolapse

\* Steatorrhea/abnormal stools/malabsorption

\* Unknown

\* Other (specify)

## 12 Date, value & type of documented positive quantitative pilocarpine iontophoresis sweat test:

\* Not Done

\* Date done

\* Date Unknown

\* Type: Sodium / Chloride / Unknown

\* Value:

## 13 If sweat test value $\leq 60$ CF diagnosis was suggested by (select all that apply):

DNA Analysis/genotyping

Transepithelial potential differences

Clinical presentation (pancreatic fxn tests, microbiology, etc.)

Unknown

### CF diagnosis reversed during year

If reversed, select reason diagnosis was reversed

DNA Analysis

Transepithelial Potential Differences

Repeat Normal Sweat Testing

Other

## Interesting Links

### **EuroCareCF:**

- *EuroCareCF*  
<http://www.eurocarecf.eu/>
- *EuroCareCF Registry workpackage page*  
[http://www.eurocarecf.eu/index\\_files/Page739.htm](http://www.eurocarecf.eu/index_files/Page739.htm)

### **European Cystic Fibrosis Society:**

- *ECFS Registry page*  
<http://www.ecfsoc.org/EuropeanRegistry.html>
- *Annual Reports of European CF registry*  
<http://www.ecfsoc.org/ECFRegistry/AnnualECFRegistryReports.htm>  
<http://www.ecfsoc.org/ECFRegistry/AnnualReportSummary2006.pdf>  
[http://www.ecfsoc.org/ECFRegistry/ECFR\\_annual\\_report\\_2003\\_Final.pdf](http://www.ecfsoc.org/ECFRegistry/ECFR_annual_report_2003_Final.pdf)

### **Cystic Fibrosis Foundation:**

- *US Cystic Fibrosis Foundation*  
<http://www.cff.org/>
- *CFF Annual Patient Registry*  
<http://www.cff.org/research/ClinicalResearch/PatientRegistryReport/>  
<http://www.cff.org/ID=4573/TYPE=2676/2004%20Patient%20Registry%20Report.pdf>

## Forthcoming Events

- Joint Meeting of EuroCareCF WP3 & The CF Diagnostic Working Group of the ECFS  
University Hospital Gasthuisberg - Leuven, Belgium, February 9 - 10, 2007  
Organisers: Kris De Boeck and Michael Wilschanski ([christiane.deboeck@uz.kuleuven.ac.be](mailto:christiane.deboeck@uz.kuleuven.ac.be) ; [michaelwil@hadassah.org.il](mailto:michaelwil@hadassah.org.il) )
- Hands-on training workshop for clinical microbiologists:  
Diagnostic and molecular microbiology of bacteria retrieved from the CF lung habitat  
Hannover Medical School, Hannover, Germany, May 3 - 6, 2007  
Organiser: Burkhard Tümmler ([tuemmler.burkhard@mh-hannover.de](mailto:tuemmler.burkhard@mh-hannover.de))
- Workshops at the ECFS Basic Science Conference, Tavira, Algarve, Portugal 25-29 April 2007
- Workshops at the 30<sup>th</sup> European Cystic Fibrosis Conference, Belek, Antalya, Turkey, 13-16 June 2007

Please see the EuroCareCF website ([www.eurocarecf.eu](http://www.eurocarecf.eu)) for further information.

## Contacts

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### **Deputy Scientific Coordinator:**

Margarida D. Amaral, PhD  
E-mail: [mdamaral@fc.ul.pt](mailto:mdamaral@fc.ul.pt)

### **Project Secretary:**

Vicky Nelson  
E-mail: [pyven@bristol.ac.uk](mailto:pyven@bristol.ac.uk)

# Sample Patient Information Sheet

*Please check with your local Data Protection Agency before using to obtain patient consents.*

## **Cystic Fibrosis Registry Patient Information Sheet**

Registries containing clinical information about people with cystic fibrosis (CF) are used in many countries throughout the world to help with medical research and improve the care and treatment of patients with CF. We are setting up such a CF registry for our country and are asking your permission to include your data. There are also plans to create Europe-wide and global registries for CF patients that will share anonymised data from many countries in order to give us even better information on how to improve the treatment for CF.

All information available from our national registry will be anonymous. Similarly, it will not be possible to identify specific individuals from the European or global registries.

Your own hospital team will enter your data and keep it up-to-date and may use it to follow your progress. However, any information that could allow you to be identified will be removed from the data held in the national and European registry. Very strict controls will be put in place to make sure you cannot be identified from the national or European registry.

Apart from your local clinic team, trusted third party/parties will also be able to identify you if required to do so on a strict need-to-know basis. This is necessary to make sure that the registry works efficiently throughout Europe as well as to ensure that your anonymity is safeguarded by releasing data for research only according to national and EU laws and carefully monitored procedures. The trusted third party may sometimes also be asked by your local hospital team to help them by entering data into the registry in order to get it up-to-date.

Data from the Registry will have many uses. A few examples of these are:

- To measure the performance of your particular clinic as well as your particular country against that of other CF clinics and other countries both in Europe and across the world
- To judge which treatments are of greater benefit and how care is improving
- To identify new trends, for example an increase in a new infection or complication
- To provide information for planning future services for people with CF
- To identify patient groups who could be approached to take part in particular research studies. Contact for this would only come through your local CF clinic
- Data will only be released for commercial purposes if there are direct treatment benefits for patients with CF and if all ethical requirements have been met

The use of any information from the European registry will require the approval of a Steering Committee. This will be made up of elected CF specialists from across Europe, representatives from other world registries with whom we are working to fight the disease (e.g. the US), the trusted third party and a data protection legal and ethics expert to safeguard the use of your data. If the Registry closes, your data will be returned to your local clinic team if requested by them, otherwise it will be destroyed.

Your participation is entirely voluntary and you have the right to withdraw at any time without stating a reason.

The Data Controller is your local hospital and the European Cystic Fibrosis Society (ECFS) for the European Registry. If you have any questions about the use of your data, or if you want your information removed from the registry, please contact your local clinic team.

# Sample Patient Consent Form

Please check with your local Data Protection Agency before using to obtain patient consents.

## Cystic Fibrosis Registry Patient Consent Form

Dear Patient or Parent

To ensure that the care of people with cystic fibrosis (CF) continues to improve, it is essential we have detailed information on the state of health and treatment of as many people with the condition as possible. We are setting up such a CF registry for our country and are asking your permission to include your data. There are also plans to create Europe-wide and global registries for CF patients that will share anonymised data from many countries in order to give us even better information on how to improve the treatment for CF.

A short descriptive sheet provides further details about the registry and its uses.

Recent regulations state that to include your data we require your written permission. We do hope you will agree to have your medical details being included on this registry. Your participation is entirely voluntary and any information that would allow you to be identified directly or indirectly will be removed. Also you can withdraw your permission at any time.

If you agree to participate please would you sign below as indicated.

Thank you for your help.

The person with CF whose data is to be entered into the CF Registry:

**Name** :.....

**Name** :.....

[If not the patient]

**Signature** :.....

**I am a Patient .... Parent .... Guardian.... Other .....** (give details)

[Please tick as appropriate]

**Date** :.../.../...

The Data Controller is your local hospital and the European Cystic Fibrosis Society (ECFS) for the European Registry. If you have any questions about the use of your data, or if you want your information removed from the registry, please contact your local clinic team.

# Explanatory Information for getting Patient Consent for CF Registry

## 1. Participating in the European Registry:

The European Registry is collaborating with the CF Foundation of the US to provide a Global Registry for CF.

There are two stages for participation in the registry:

- 1a. Getting informed consent for your patients
- 1b. Entering patient demographic data, and optionally, clinical data

### 1a. Steps to getting informed consents for your patients:

**Please email Gita Mehta ([g.mehta@dundee.ac.uk](mailto:g.mehta@dundee.ac.uk)) to confirm your participation in the European Registry so you are kept informed as work progresses.**

#### If you have existing consents which satisfy your local laws:

- **Compulsory Step:** If you already have existing consents, please check with your local Data Protection Officer to make sure these forms meet the requirements of the new European Registry or whether you will need new patient consents using the ‘*Sample Patient Information Sheet*’ and ‘*Sample Patient Consent Form*’ attached.
- **Compulsory Step:** If your local Data Protection Officer approves your existing consents, please inform the European Registry Project Manager, Gita Mehta on [g.mehta@dundee.ac.uk](mailto:g.mehta@dundee.ac.uk) along with a copy of the consent form. As soon as the legal and ethics experts of EuroCareCF have also approved this consent, you are ready to place your patient data in the European registry [step (1b) below].

#### If you do not have existing consents, or you need new patient consents:

- **Compulsory Step:** Please check this Explanatory Information sheet, the accompanying ‘*Sample Patient Information Sheet*’ and ‘*Sample Patient Consent Form*’ with your local Data Protection Officer to make sure these forms meet the requirements of your local legal and ethics laws.
- For more information for your local laws, please consult <http://www.privireal.org/>
- If you would like any further information, please email the European Registry Project Manager, Gita Mehta on [g.mehta@dundee.ac.uk](mailto:g.mehta@dundee.ac.uk)
- **Compulsory Step:** If any changes are required for your country to comply with these sample forms, please let Gita know on the above email.
- **Compulsory Step:** Please get the ‘*Sample Patient Information Sheet*’ and ‘*Sample Patient Consent Form*’ translated if necessary, before getting your patients to sign
- Participation as a CF center where there is no national registry. While it is obviously far better for a country’s national registry to be part of the European Registry, it is possible for a single CF center to join the European Registry where it is not possible for the national registry to participate for any reason. If you fall into this category, please let Gita know as special arrangements may apply.
- **Compulsory Step:** Patients can only be entered into the registry once you have received their signed, informed consent to do so.
- **Compulsory Step:** Please store all the consent forms that your patients have signed safely in your local hospital.

## **1b. Entering data into the registry**

Countries with existing patient demographic data can either enter this directly into the registry themselves, or this can be entered on their behalf by a trusted third party. Countries who do not currently have patient demographic data should collect these on paper forms prior to this being entered into the registry. Please contact Gita when you are ready to start collecting demographic data.

Countries who wish to do so may also enter clinical data into the registry, and several countries have expressed a wish to use the registry to monitor the progress of their patients in this way. It is the intention that eventually all countries in Europe will use this registry, along with CF centers in the US. Thus the global registry will have a crucial role to play in the treatment of patients with CF.

## **2. Background to the requirement for getting consents:**

- The ‘*Sample Patient Information Sheet*’ and ‘*Sample Patient Consent Form*’ have been checked with the UK Data Protection Office and the legal and ethical experts of EuroCareCF
- They have been written to reflect the design and procedures of the proposed European registry and allow patients to be identified by their hospital teams, but anonymous at a European level.
- Some countries have existing registries (and hence patient consents), others do not
- The ‘*Sample Patient Information Sheet*’ and ‘*Sample Patient Consent Form*’ are to be circulated to those with no consents or those that may require new consents
- EuroCareCF requirements are:
  - Compliance with EC and local laws (to be done by each country locally)
  - Approval by EuroCareCF legal and ethics experts (done for sample forms, required for all others)
  - Patients to be fully anonymous (done via design of registry software)
  - Anonymous data to be released for commercial or research purposes (after approval by ECFS Steering Committee)
    - only if authorised by consents
    - only after ethical approval
    - only if direct treatment benefits result
- Clinical requirements are that patients should be known to their own care teams so that they are provided with the optimum treatment (done by design of registry software)
- 

## **3. System Design and procedures relevant to patient consents:**

- Very secure, web-based software
- A two-tier software model. Patients will be identifiable only by their local hospital teams or a trusted third party (data processor). An extraction routine will exclude information that could allow patients to be identified such as their name, country & hospital code etc. This extracted data will form the European registry.
- For countries with existing registries, data will be mapped directly into the EU registry but again strict controls will allow only anonymous data to be available at a European level.
- Access to the European data for research etc will be by application to a registry steering committee of the European CF Society (ECFS)
- The intention is to use the software of the American CF registry and share outcome data with them to improve treatment and carry out research. This will be at the level of anonymous European data.
- To further guarantee anonymity, each hospital will be allocated an ‘EU-Centre’ code rather than a country & hospital code. Thus for countries with only one hospital, or small hospitals, where it might have been possible to identify patients from a combination of factors, this will be difficult as only the hospital would know its own ‘EU-centre’ code. I understand this model has been used for CF DNA diagnostics EQA scheme organised by the Center for Medical Genetics in Leuven since 1996.