

# The Research that Time Forgot

There was once a young clinician who went by the name of Sue  
She was bright and she was caring and she knew just what to do  
For a fractured neck of femur or a fever of the brain  
So she thought she'd be a surgeon but one day she thought  
again

Because Sue was academic and she often found herself  
With a yearning to do research in the field of human health  
When she read of great advances in the journals of the day  
She was gripped by inspiration and was often heard to say:  
'I must join this great endeavour; I must do a PhD  
So I'll have to find a unit that will take a chance on me.'

So Sue met a young professor and she showed him her CV  
And he said: 'It would be perfect if you came to work with me  
For I have a little project that I'm doing with the French  
It is hot and it's translational – from the bedside to the bench  
And we have a source of funding; it will last you for a year  
You can get some pilot data – then the future will be clear'  
Well Sue said: 'That sounds wonderful, but what will it  
involve?'

The Prof said: 'There's a problem that we really need to solve  
For we have this group of patients – they're beset by cough and  
wheeze

And we think abnormal cytokines are causing their disease  
So we need to take some blood from them and test it in the lab  
It isn't very much at all – it's just a little jab  
And we'd like to start the project now but there's just one  
aggravation

I haven't had the time to write the ethics application  
So when you start on June the 1st that will be your first task  
It shouldn't take you very long and isn't much to ask.'

So, full of hope, our heroine went to the REC  
And asked what their procedure was saying: 'Please explain to  
me

The paperwork I need to do – I know there must be some  
Though I only need a tube of blood no bigger than your thumb.'

The REC said: 'You must make an on-line application  
And it may take you several months to get the information  
Because the form is thirty pages long and has a lot of sections  
And every section must comply entirely with directions  
We need to know just who's involved and all their main degrees  
Their telephone and e-mail and if they've done GCP  
And all about the project and what you intend to do  
And how, and what and when and where and which and why  
and who

How many samples will you take and how did you decide  
We think you'll need a team of statisticians at your side  
Then you must write a protocol which details all these issues  
And get it peer-reviewed because you're using human tissues

**Professor Anisur Rahman** is Professor of Rheumatology in the Rayne  
Institute, University College London, London WC1E 6JF  
([anisur.rahman@ucl.ac.uk](mailto:anisur.rahman@ucl.ac.uk))

Then write an information sheet that you can give to those  
Who give you that small tube of blood to say what you propose  
To do with all their samples and it should be very long  
As it needs to cover everything that could possibly go wrong  
Make sure it's couched in language that is not too scientific  
And if it's not on headed paper that would be horrific  
Which will mean your application form is sent straight back to  
you  
So if you want our REC approval that's what you must do.'

Well Sue was shocked; her face went red, the colour of a plum  
She cried: 'It's just one tube of blood no bigger than your thumb  
From only thirty patients so I'm sure it can't be true  
That this colossal enterprise is what I need to do!'

But the REC committee were unmoved – they said: 'Our word  
is law

And it's simply useless to protest – we've heard it all before  
The form may well repeat itself – that's not for you to say  
For if you want to do research, you must do things our way.'

Well Sue was a determined girl – she wasn't one to cry  
She worked hard on the papers and was done by late July  
But when she went back to the REC, they said: 'It's not  
complete

Till we've seen some lay involvement in your information sheet  
Because PPI is all the rage, this target must be met  
And please don't try to ask us why or we may get upset.'

And this would cause a further pause because you must  
remember

That August is vacation month and so it was September  
Before the patients that Sue chose could tell her what they  
thought

So she could change her PIS as she'd been told she ought  
The patients said: 'This tube of blood is no big deal to us  
We'd love to help in your research and see it as a plus

But this long information sheet is far too dense to please  
It's tedious and boring and it's couched in legalese  
We really cannot understand the need for all this fuss  
We'd happily sign up today if it was left to us.'

But at the REC committee they took quite a different view  
They said: 'Despite this lay opinion we maintain it's true  
That patients need these detailed sheets, although it may alarm  
That they're full of quasi-legal terms like non-negligent harm.'

But after sundry alterations, queries and so forth  
Sue finally got her REC approval on November 4th

But Sue was quite mistaken if she thought that she was free  
To start her research project because now the R&D  
Department called upon her and they said: 'Let's make it clear  
You will need our approval too if you're doing research here.  
We're sorry this will cause delay but still insist we must  
Apply the strictest governance to research in the Trust  
And just to add another hurdle to your merry dance  
You need a legal contract if you want to work with France.'

In vain did Sue protest at length that this would take too long  
 She thought it would be several weeks but sadly she was wrong  
 Negotiations with the French were slow beyond belief  
 And it was February 12th before she got relief  
 But even then the R&D said: 'There is something new  
 For we have changed our policy and this pertains to you  
 We can't allow this project now – we're not trying to be funny  
 But we must maximise our cash, because research does cost  
 money  
 So like Falstaff and Malvolio,  
 You're caught in an imbroglio  
 We won't approve your project – because it's not on the  
 portfolio!'

The NHS portfolio – it shouldn't be a curse  
 It should ensure clinicians access to a research nurse  
 But Sue just didn't need one and she cried: 'Why this condition?  
 I do not need a nurse from you, I just need your permission!  
 But R&D said 'Rules are rules and so with all due speed  
 We recommend you take your case to CRN in Leeds.'  
 But CRN declined her suit and said: 'You can't do more  
 to get portfolio status. Well, you should have asked before  
 We don't like retrospective things and really can't see why  
 Your R&D are saying this, so good luck – and goodbye.'  
 But Sue refused to be deterred – she mounted an appeal  
 And wore down the resistance by her diligence and zeal

And so persuaded R&D to sing a different tune  
 They finally gave her permission on the 1st of June.

But sad to say her year of funding had completely gone  
 No single sample had been tested – no, not even one  
 The whole twelve months was wasted in this bureaucratic  
 fashion

And Sue found clinical research was really not her passion  
 She felt a great sense of release and, now that she was free  
 She never did research again and trained as a GP  
 And so in closing, let us ask – does anybody gain  
 From all these needless hurdles and administrative pain?  
 Why do we have these regulations, whom do they protect?  
 And how much research is delayed, how many projects  
 wrecked?

How many good research ideas lie fallow across the nation  
 Because nobody can bear to write the ethics application?  
 My poem is a work of fiction – there's no girl called Sue  
 But I leave it to the reader to decide how much is true.

### Abbreviations

CRN = Clinical Research Network; GCP = Good Clinical Practice; PIS = Patient Information Sheet; PPI = Patient and Public Involvement; R&D = Research and Development; REC = Research Ethics Committee

## Make sure you're up to date with patient confidentiality

*Bridgit Dimond*

Legal Aspects of Patient Confidentiality is written in a practical, jargon free style and covers:

- Dealing with children
- HIV/AIDs patients
- The recipients and donors of transplants
- Terminally ill patients
- The issues of human fertilisation and embryology
- The notification of infectious diseases

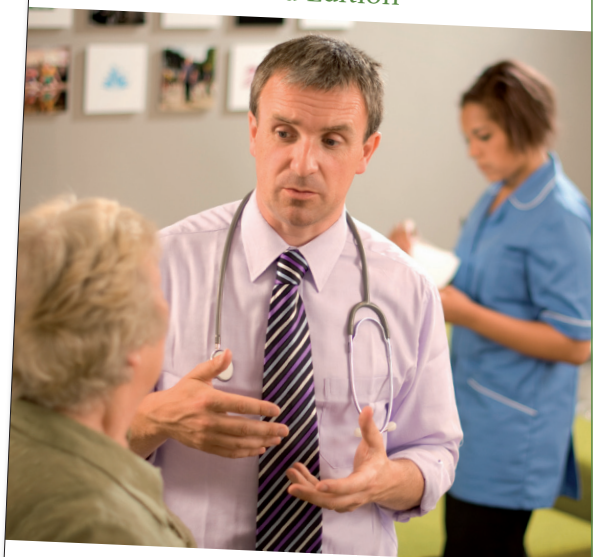
Case studies are included as well as questions and answers to reinforce understanding.

ISBN-13: 978-1-85642-396-0; 234 x 156mm; paperback; 180pp; publication 2010; £22.50

Order your copies by visiting [www.quaybooks.co.uk](http://www.quaybooks.co.uk) or call our Hotline +44(0)1722 716 935

## Legal Aspects of Patient Confidentiality

2nd Edition



Bridgit Dimond

Legal Aspects of Healthcare series

