MINUTES OF UKBTS/NIBSC EXECUTIVE COMMITTEE MEETING

HELD ON 19TH JUNE 1997

AT WEST MIDLANDS BLOOD CENTRE - BIRMINGHAM

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	Present Dr. T Snape Dr. W Wagstaff (Chair) Dr. P Flanagan Dr. P Phillips Dr. V James Dr. A Robinson Dr. E Love Dr. R Warwick	
1.	**Apologies** Prof. I. Franklin Dr. M. DeSilva Dr. M. Kavanagh Dr. G Shields Dr. L. Williamson Dr. Wagstaff welcomed Terry Snape to his first meeting as the new Chair of the SAC on Plasma for Fractionation.	
2.	**Minutes of the 8th Meeting - 9th October 1996** There were no corrections	
3.	**Matters Arising from 9th October 1996** 5.3. Post Donation Illness - Dr. Wallington has submitted a report which will be discussed at a meeting on 23rd June 1997. 6.2 Dr. P Flanagan has produced a "dossier" on the virological safety of fresh frozen plasma which has been passed on to Dr. Lorna Williamson 8.1 Dr. Lorna Williamson is the new Chair of the SAC for components 8.1.2 Statutory position of the guidelines - Meeting held on 19th December 1996 Following discussion with Stephen Janisch, Dr. Robinson had presented the proposal to the NBA Board that the NBA should act as the sponsoring authority on behalf of the other UK services in addition to the NBS. This had not been well received.	

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	The legal position is that if a member is acting on behalf of the Authority they are legally covered and this applies to all consultants during the course of their work. Dr. Robinson will obtain a letter to this effect from Stephen Janisch. The same situation should apply to all the other Authorities.	**Dr. Robinson**
	Dr. Robinson will ask Stephen Janisch to provide a suitable letter which she will send to each Authority requesting their agreement to this and accepting part share in the unlikely event of legal repercussions.	**Dr. Robinson**
	Peter Phillips has explored the position with NIBSC: work on Committees is regarded as part of professional duties but it is not clear what the legal liability position is.	
	It was agreed that responsibilities of the Chairman of SACs are as follows:-	
	• To assure themselves of individual members competencies in serving on Committees; • To ensure that all state-of-the-art information is available to SAC members	**All Chairmen of SACs**
	It was suggested that ultimate responsibility for provision of state-of-the- art information should rest with the National Medical Directors. In the light of these discussions Dr. Wagstaff recommended that all the National Medical Directors be invited to the Executive meetings and he will send an invitation to Wales and Northern Ireland, Scotland and the NBS being already represented.	**Dr. Wagstaff**
	Dr. Wagstaff has investigated with the Medical Defence Organisations the position of medical staff with respect to legal liability when serving on Committees. It is considered that these duties are part of normal consultant duties which should be covered by the employing Authority.	
	With respect to non-Authority members, Dr. Robinson mentioned that the legal liability of those outside the employing Authorities is likened to those serving on Ethics Committees when the host Health Authority is required to indemnify. Dr. Robinson will clarify this point with the Department of Health.	**Dr. Robinson**
	Once this point has been clarified it will be necessary to approach each individual hospital for members who are outside the UK Blood Service Authorities to ensure that the Member has the support of the Authority.	**Dr. Wagstaff**
	Dr. Wagstaff made it clear that SAC Chairmen have the right and obligation to co-opt on to Committees those individuals who represent the most expert knowledge available and reiterated that the National Medical Directors should ensure that state-of-the-art communications are available to Standing Advisory Committees.	**National Medical Directors**
4.	**Donor Questionnaire - EC10/97**	
	Dr. James spoke about the paper which accompanied the agenda and emphasised that this would be a permanent record. The questionnaire will be printed on National IT system session slips i.e. PULSE for the NBS and	

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	Northern Ireland. MAK for Scotland and TRACE for Wales.	
	It was agreed that the questions requiring tick box answers and appearing on the IT system session slips should be those applying to recipient safety as required by Council of Europe guidelines. There is still some work to be done in simplifying the questions, separating them into those necessary for all donors and those for new and lapse donors.	**Dr James**
	Dr. Flanagan pointed out the need to include specific questions on HIV related risk and there is also the need to clarify the position on dura mater grafts. Dr. Robinson has been asked to prepare for the MSBT meeting on 8th July 1997 a pragmatic exclusion list for dura mater grafts and will work with Dr. James on this.	**Dr. Robinson/ Dr James**
	There was some discussion on confidential unit exclusion (CUE) and whether this would be required for urban areas only or all donors. Dr. James said that London will not give up CUE. It has been agreed to trial CUE in East Anglia where there has never been a HIV positive donor and in one other big city area. Dr. Flanagan pointed out that methods used need to show that CUE actually improves safety of the blood supply. Dr. James replied that Mary Brennan's impression to date is that it does.	
	With respect to the donor questionnaire the possible difficulties in implementation on sessions were pointed out and it was recommended that carefully controlled introduction is essential and that it should be piloted before general introduction. There is already experience in the SNBTS and Dr. James will provide Dr. Robinson with a copy of the SNBTS session slip.	**Dr. James**
	It was agreed that the deadline for implementation should be 1st April 1998 and Dr. James will bring to the Executive Meeting in November the final questionnaire which will have been presented to the donor consultants on 8th October 1997.	**Dr James**
5.	**Recommendations for haemoglobin testing**	
	Dr. James said that Dr. Frank Bolton's group had reviewed haemoglobin testing levels and had produced comprehensive document on the subject. The final recommendations were that for capillary testing the threshold should remain as they are i.e. 135g/l for males and 125 g/l for females. If a valid, accurate venous method is used the thresholds could be lowered to 130 g/l for males and 120 g/l for females. It was confirmed that there remained room for discretion on Hb levels in the Council of Europe guidelines.	
	Dr. Wagstaff will copy Dr. Bolton's report to all Executive members for discussion in the November 1997 meeting.	**Dr Wagstafff**
6.	**Standing Advisory Committee on Donor Selection**	
6.1	• **Minutes 22.10.96 - EC01/97** • **Minutes 13.1.97 - EC02/97**	

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	• **Minutes 11.3.97 - EC03/97** • **Minutes 13.5.97 - EC1497**	
	The main themes of meetings have been haemoglobin work, the donor declaration form which will have to be modified as discussed, CJD and donor age. With respect to donor age the SAC opinion is that this could easily be changed to 17-70 years. Although deferral rates/loss of donors etc. has not been examined in this age group there is no evidence that it is unsafe in any way. Northern Ireland and Scotland already have this practice and Dr. James will get further information from Dr. Chitra Barucha and Marie Thornton.	**Dr James**
	The Council of Europe guidelines allow discretion for collections from donorsoutside the 18-65 year range.	
	There is no legal bar to taking donations from donors aged 17 but it is incumbent on the Authority to ensure that the 17 year old has the competency to understand the implications of their actions. This has training implications but the necessary assurance could be accomplished as part of the work carried out by nurses at the first time interview.	
	It was suggested that a summary document from the SAC would be useful for the NBA group which exists to consider how to implement the changes.	**Dr. James**
6.2	**Minutes 13.5.97 - Point 11.3 - Function of the Red Book Committee and its relationship to the European Guidelines.**	
	Dr. Wagstaff confirmed that currently the Council of Europe guidelines have no legal standing but anyone not subscribing to them must have valid reasons why they do not do so. The relationship with the UK Red Book is on this level and there is no standard laid down in the Red Book which does not meet the Council of Europe recommendations. The only exception is on donor selection guidelines which must be identical to those issued by the Council of Europe because of the acceptance by the European Pharmacopoeia Sub-Committee 6B of the donor selection guidelines contained within the Council of Europe Recommendations.	
7.	**Standing Advisory Committee on Information Technology**	
7.1	**Minutes - 2nd October 1996 - EC04/97**	
7.2	**Minutes - 25th February 1997 - EC05/97**	
	Dr. Wagstaff asked whether there had been any feedback on problems encountered with dual coding. There is no evidence of widespread problems but Dr. Love commented that she did not think that all problems would have been brought to her attention. Some substitution errors in labels using code ISBT 128 had been noted in Manchester and further feedback is required on the outcome of these investigations. A trawl of PULSE Centres to enquire about any difficulties was suggested.	**Dr. Love**
	Dr. Love updated members on the discussions which took place at the ISBT	

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	Working Party on Automation and Data Processing and the European Technical Advisory Group Meetings which took place 10th-13th June in Edinburgh. These minutes will be circulated to Dr. Wagstaff as they become available. Many countries outside the USA, including several countries in Europe have registered their intention to implement ISBT 128. Common problems are being encountered such as difficulties with diverse hospital IT systems or no systems at all, money and time. As a result the ICCBBA (International Council for Commonality in Blood Banking Automation) has accepted that the "roll out" schedule is too tight and that the date for implementation is the responsibility of the National Authorities of each country in accordance with their means. Unfortunately there has been dissent from Germany which has also involved Austria. Germany is planning to introduce its own EUROCODE later this year. EUROCODE is a numeric code whereas ISBT 128 is alpha numeric. It is also intended that national flexibility will exist for EUROCODE, flying in the face of the recommendations for international coding. Whilst a great deal of the argument has centred around the cost-per-unit licensing fee (currently 1.5 cents), it is felt that the underlying problems for Germany are related to a lack of feeling of "ownership" of ISBT 128. At the WPADP it had been agreed that Dr. Ed Steane, Executive Director would meet Dr. Hans Dieter Weisshaar the proponent of EUROCODE to try to reach some common agreement ISBT 128. This is an urgent matter and Dr. Robinson urged that Harold Gunson, as Secretary General of the ISBT should be invited to mediate, together with Jukka Koistinen who is the ISBT representative on the ICCBBA Board. Dr. Love to discuss urgently with Harold Gunson.	**Dr. Love**
	Note added after meeting:- *Dr. Love spoke to Dr. Gunson, then to Susan Steane, Chairperson of the WPADP, who will invite Dr. Gunson, Dr. Contreras and Dr. Koistinen to the proposed meeting.*	
8.	**Standing Advisory Committee on Transfusion Transmitted Infection**	
8.1	**Minutes - 4th November 1996 - EC06/97**	
8.2	**Minutes - 30th January 1997 - EC07/97**	
8.3	**Minutes - 14th May 1997 - EC08/97** Dr. Flanagan summarised the work which has taken place over the past year and has largely been resolved, i.e. malaria testing, storage of archive samples and the definition of requirements of a confirmatory laboratory. There is continuing debate on HTLV, solvent detergent FFP which has now been passed on to the components SAC, CJD and nucleic acid amplification technology (NAT) testing. There was considerable discussion over malaria testing. The SAC has endorsed the Launch malaria test subject to the availability of an in-process control sample and suitable batch pre-acceptance testing. As yet no summary document is available - this is being prepared by Alan Slopeki. An interim	

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	control sample has been identified but there is still a need to collect suitable donations from patients recovering from malaria for batch pre-acceptance testing.	**Dr. Flanagan**
	It was noted that Birmingham may be using this test (but Birmingham has been carrying out malaria testing for some years). Bristol is about to start. Dr. Robinson urged that Bristol should be asked to delay implementation in the absence of resolution of the in-process control sample and batch pre-acceptance testing samples.	**Dr. Robinson**
	The circulation of SAC minutes was discussed at this point (see minute 08/97 item 11). It was agreed that the circulation of SAC minutes should be restricted to members of the Groups and Red Book Executive members. SACTTI and other updates provide essential information for individuals outside these groups. SAC Chairmen were reminded that minutes of SAC meetings were open to disclosure and should be treated as archive material, but may be distributed to other Executive Committee members as soon as they are available.	**All SAC Chairmen**
9.	**Joint meeting of SAC on transfusion transmitted infection and FFP on Tissue banking.**	
9.1	**Minutes - 14th April 1997 - EC09/97** Dr. Warwick said that the remit of SACTB had been to write a section for the Red Book so the minutes of her meetings reflect this. The joint meeting was held to endorse the recommendations for microbiology testing for tissue donors. These were put to SACTTI with the help of an expert from the American Red Cross.	
	It had been agreed that a Group should meet to consider the validation of virological testing in cadaver samples. The Group has been chosen but the meeting has not yet taken place.	
10.	**Standing Advisory Committee on Tissue Banking**	
	Dr. Warwick requested members of the Executive to review the draft Section 4 with appropriate consultation if deemed necessary and report back in two weeks time.	**All**
	The aim is to publish the document this year as an update of the Red Book, which will be in loose leaf format, for direct insertion into the new edition which will be published before Section 4. Section 4 should be read in conjunction with donor selection guidelines for tissue donors (MATD) and these will be forwarded to Dr. Wagstaff within the week.	**Dr. Warwick**
	Updating of the MATD A-Z will be in line with Dr. James' system with a similar fast track notification. The position of supplying non-NBA Centres was discussed and Dr. Warwick was asked to consider this further with respect to possible charges.	**Dr. Warwick**
	Dr. Warwick pointed out that there was nothing in Section 4 to cover progenitor	

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	cells including cord blood and marrow. She recommended that a Group should consider this large section which encompasses a number of disciplines including donor care, components and apheresis. No decision was made on this.	
11.	**Any other business** None	
12.	**Date of next meeting** 21st November 1997 - 11am - West Midlands Blood Centre	