

**Research Action Group**  
**Date: Tuesday 30<sup>th</sup> October 2024**  
**Time: 10am**  
**Venue: By "Teams"**

## MINUTES

PRESENT		ATTENDANCE 2024			
		23.7.24	30.10.24		
Adam Watts – Clinical Director for Research (AW) CHAIR		Apols	✓		
Alison Robinson – Head of Research (AR)		✓	✓		
Abhishek Kumar – Divisional Research Lead - Medicine (AK)		x	x		
Ali Aghabeigi – Clinical Trials Pharmacist (AA)		✓	✓		
[REDACTED] – Research Personal Assistant ([REDACTED])		Apols	✓		
Alison Unsworth – Clinical Audit & Effectiveness Manager (AU)		✓	In part		
Amanda Cheesman – Deputy Chief Nurse (AC)		✓	✓		
[REDACTED] – Senior Research Nurse Oncology ([REDACTED])		x	✓		
[REDACTED] – Senior Research Nurse ([REDACTED])		✓	✓		
[REDACTED] – Research Management Edge Hill ([REDACTED])		✓	Apols		
Christina Heaton – Senior Research Lead - NMAHPs (CH2)		x	✓		
Chye Yew Ng – Divisional Research Lead - Specialist Services (CY)		✓	x		
[REDACTED] – Divisional Research Lead - Community ([REDACTED])		✓	✓		
[REDACTED] – Research Sponsorship Manager		✓	✓		
[REDACTED] – Research Manager ([REDACTED])		Apols	✓		
Lee Unsworth – Directorate Manager Radiographer & Cancer (LU)		x	x		
[REDACTED] – PPIE Representative ([REDACTED])		✓	✓		
[REDACTED] – Pharmacy Technician ([REDACTED])		Apols	x		
[REDACTED] –Library Manager ([REDACTED])		✓	x		
Richard Mundon – Director of Strategy & Planning (RM)		Apols	Apols		
[REDACTED] – Assistant Librarian ([REDACTED])		✓	✓		
Sonny Singh - Divisional Finance Manager (SS)		✓	✓		
Tasadooq Hussain – Divisional Research Lead - Surgery (TH)		x	x		
[REDACTED] – Senior Research Nurse ([REDACTED])		Apols	Apols		
IN ATTENDANCE: See attendance list above.					
Agenda Item no	Item				Action by
1 MEETING ADMINISTRATION					
1.1	<b>Welcome and Apologies</b> AR welcomed everyone on Teams (see attendance list above).  <b>Apologies:</b> As above  <b>Minutes:</b> [REDACTED] (AH).				
1.2	<b>Minutes of the last meeting 23<sup>rd</sup> January 2024</b>  Reviewed and accepted as true record.				



1.3	<p><b>Action Matrix from April 2024</b></p> <p><u>1.3. Action Matrix from 25th October 2023 (Clinical Staff in research)</u>          [REDACTED] to create a paper describing who's out there, their level, their stage is in terms of research and create plan to progress them into the next stage. To be presented at next RAG meeting.</p> <ul style="list-style-type: none"> <li>- In progress as there are two pieces of work that will feed into the paper.</li> <li>- AC to follow up with EA</li> <li>- <b>To produce paper and circulate in December ready to discuss at next RAG meeting.</b></li> </ul> <p><u>2.2. Research Strategy</u>          Write a financial management policy incorporating financial oversight of sponsored studies (in response to internal audit recommendations)</p> <ul style="list-style-type: none"> <li>- Made progress with financial strategy and financial oversight of sponsored studies. Will provide update on next RAG meeting.</li> <li>- <b>Set a different date, as this is the first year of managing the accounts.</b></li> <li>- <b>Publish end of financial year. Set end March 2025 date</b></li> <li>- <b>Set items for the RAG agenda from RFIG due November 2024.</b></li> <li>- <b>To be signed off in February 2025 RAG meeting.</b></li> </ul> <p><u>2.3. Patient, Public Inclusion &amp; Engagement</u>          HS to create to a summary document and key thoughts on the strategies for addressing the areas where there is imbalance in PPIE diversity.</p> <ul style="list-style-type: none"> <li>- PPIE members completed the EDI survey, few key areas that we need to focus on. HS report highlights how we plan to achieve focus on those areas and diversify the group.</li> <li>- HS to finalise report and to circulate with minutes</li> <li>- <b>COMPLETED</b></li> </ul> <p><b>NEW ACTION:</b> to request feedback on HS PPIE Diversity report by December.</p> <p><u>2.3. Patient, Public Inclusion &amp; Engagement</u>          HS to develop a plan to engage opinions from the PPI&amp;E group about what their needs are and then we can start to plan some training around communication etc. to retain interest.</p> <ul style="list-style-type: none"> <li>- HS to arrange meeting with whole group to explore further.</li> <li>- <b>Ongoing</b></li> <li>-</li> </ul> <p><u>2.5. Grant Applications/Sponsorship Report</u>          AR To report on the induction about how research is delivered, and minimising risk of Good Clinical Practice (GCP) being breached etc., in the next meeting.</p> <ul style="list-style-type: none"> <li>- Report included with agenda regarding minimising risk of GCP breaches.</li> <li>- <b>COMPLETED</b></li> </ul> <p><u>2.8. Research Delivery Team</u>          CF/TT/JF to investigate breaking down the diabetes portfolio to do some targeted work.</p> <ul style="list-style-type: none"> <li>- <b>COMPLETED</b></li> </ul>	
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	<p><u>7.1. AOB. Pharmacy – Commercial Leaflet</u></p> <p>AA to write up a small piece to be added to the expressions of interest template. AA advised would send the wording from the leaflet to CF.</p> <ul style="list-style-type: none"> <li>- Created piece and included in leaflet - es, we wrote a piece that was included in a general leaflet that is going to be disseminated by Greater Manchester. That's all the trust across Greater Manchester, so they have our own section and page.</li> <li>- For commercial sponsors and we use the same write up for our own expression of interest that was sent to [REDACTED] and [REDACTED], which I think was satisfactory.</li> <li>- <b>COMPLETED</b></li> </ul>	
<b>2 PROGRESS AND REVIEW</b>		
<b>2.1</b>	<p><b>New Appointments</b></p> <p>No new appointments currently.</p>	
<b>2.2</b>	<p><b>Research Strategy – Research Assurance Report</b></p> <p>Report to be circulated with minutes. Highlights below:</p> <p><u>PPIE group</u></p> <p><u>Relationships with other organisations, wigan council, voluntary sectors, EHU, PCN</u></p> <p><u>Progress of recruitment of patients</u> First 6 months of the year we have overachieved the target set by the network.</p> <p><u>Study delivery through Ashton Clinical Research Hub</u> Study that will be wholly delivered through the Ashton Clinical Research Hub, EuroAspire. Currently going through risk assessment in readiness for the study.</p> <p><u>Commercial trials and Expressions of Interest.</u> Can deliver late phase trials but currently cannot deliver early phase trials that are higher risk. The reasons for declining studies are changing. Clinician declines are lower than previous reports. Currently there are more protocols which are advised as unfeasible for delivery at WWL.</p> <p><u>Research Incubator.</u> There is still a very healthy flow of staff who are interested in research. AR thanked the clinical leads and others, such as CH2, HH, HS, TT and CF for their hard work and effort in promoting research and research careers. AR noted the culture has improved over the last two years. There has been good support from the research committee, senior nursing and clinician management.</p> <p><u>Clinical Academics</u> The University Hospital Group is chaired by [REDACTED] The target to reach for Clinical Academic posts is approx. 13/14, currently have 6/7 that are appointed or in progress.</p>	



	<p>The deadline is within the next two years and needs a committed focus to try and achieve this.</p>	
<b>2.3</b>	<p><b>Patient, Public Inclusion &amp; Engagement</b></p> <p>Two PPIE meetings due this week, SOFFT and Total Hip Replacement meeting.</p> <p>During the summer months we have had two PPIE members of the group join the Wigan Health and Care Research Forum that took place in October, who were very keen and interested in continuing with the forum.</p>	
<b>2.4</b>	<p><b>Finance Report</b></p> <p><u>2023-24 Finance Report as at Month</u> Please see report circulated with minutes, highlights below.</p> <p><b>YTD 24-24, Month 6</b></p> <ul style="list-style-type: none"> <li>- Favourable income by £263,000</li> <li>- Total deferral income is £243,000 committed to future spend.</li> <li>- Just less than 1.2 million total research income at month 6</li> <li>- £33,000 generated from commercial income in the first six months of the financial year</li> <li>- Aged Debt Summary, invoices that haven't been paid, over the 361 days, such as LIMA Orthopaedics.</li> </ul> <p>RAG questioned if the Lima monies related to a specific project? SS will investigate and advise the sponsorship and governance teams.</p> <p>Slightly behind from last year's figures at mid-point in year.</p>	<b>SS</b>
<b>2.5</b>	<p><b>Grant Applications/Sponsorship Report</b></p> <p>Please see Sponsorship Report circulated with agenda and minutes, see highlights below.</p> <p><b><u>NIHR Grant funded studies in early application or planning stages.</u></b></p> <p><u>Assessing different types of stems in total hip replacement (THR)</u></p> <ul style="list-style-type: none"> <li>- Led by Mr J. [REDACTED] Clinical Academic</li> <li>- Very early-stage ideas for a grant application submission</li> <li>- PPI planning meeting taking place this week to support a grant funding application.</li> </ul> <p><u>ILD Study</u></p> <ul style="list-style-type: none"> <li>- A study planning meeting took place on Monday 14th October 2024 - project to progress with aim to submit application for RfPB in early/mid 2025. RSS to be contacted to expand collaboration.</li> </ul>	



	<p><b><u>TOTES Study</u></b></p> <ul style="list-style-type: none"> <li>- Stage 1 application unfortunately rejected</li> <li>- Received feedback from RfPB, 'The proposal did not convincingly articulate the need for a separate feasibility trial' 'that an internal pilot study within the full trial may be adequate'</li> <li>- Further meeting to be arranged to discuss developing a full HTA grant application.</li> </ul> <p><b><u>Virtual Ward</u></b></p> <ul style="list-style-type: none"> <li>- Nothing further to report.</li> </ul> <p><b><u>NIHR Funded studies</u></b></p> <p><b><u>SOFFT</u></b></p> <ul style="list-style-type: none"> <li>- Final report preparation in progress. The database has been locked and final datasets transferred to statistician and health economist to run the final analysis</li> </ul> <p><b><u>RAPSODI</u></b></p> <ul style="list-style-type: none"> <li>- Plans to recruit first site from private sector (Sulis), TSC and DMEC approved and NIHR notified and agreeable. Currently preparing amendment submission to HRA/REC. Submitted, awaiting response.</li> </ul> <p><b><u>Other Funded studies (External/charitable funding)</u></b></p> <p><b><u>Origin Study</u></b></p> <ul style="list-style-type: none"> <li>- All actions identified within the FSN have been completed and a signed certificate has been returned to Symbios to reflect that.</li> <li>- Study extension required for two months to allow the last follow up visit to be completed. Amendment to be submitted to REC– End date now 31-12-2024.</li> </ul> <p><b><u>LIMA S41 and S43</u></b></p> <ul style="list-style-type: none"> <li>- Recruitment on pause until the replacement RSA gun has been approved for use by the patient safety governance administrator. A risk assessment is in the process of completion and is pending completion from theatre at present.</li> </ul> <p><b><u>LOVE DEB</u></b></p> <ul style="list-style-type: none"> <li>- Recruitment target met, expected to close recruitment for the end of October.</li> </ul> <p><b><u>Serious Adverse Events (SAE)</u></b></p> <p><b><u>SCRIB – Superior Capsular Reconstruction with Internal Brace for Irreparable Rotator Cuff Tears</u></b></p> <p>Subject had an MRI after reporting pain in the shoulder. MRI scan showed SCR failure with glenoid detachment and loose anchors.        Patient did not want further surgery at that point, and it was agreed she would be reviewed in 6 months' time (review still pending)</p>
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	<ul style="list-style-type: none"> <li>- Onset of event – 16/11/2023</li> <li>- Reported to sponsor – 4/10/2024</li> <li>- Outcome - Related to the surgery but expected (reported within the protocol as a known risk)</li> </ul> <p>Discussions on how to resolve the processes on reporting the SAEs as this was reported 12 months after the event.</p>	
2.6	<p><b>R&amp;D SOPs and Policies – for review</b></p> <p><u>Managing Risk of Breaching GCP in Research – Paper to Research Committee (Sept 24)</u> Circulated with the agenda and minutes. AR summarised the paper. Due to previous incidents summarises a plan to introduce more training across the Trust beyond the standard Good Clinical Practice training already in place for staff involved in research.</p> <p><b>Request for feedback from RAG.</b> Paper shows levels of risk and proposes risk tiers of staff. Currently all our staff receive GCP training and local competency induction. There isn't formal training in place for investigators, but SOPs are in place covering investigator responsibilities.</p> <p>Introduction to research is imperative, consider options to add such training to the eLearning platform for all staff, noting induction programme is already quite large.</p> <p>AR suggested mandated requirements for Chief Investigators, Principal Investigators and Co-Investigators, plus extending localised, tailored context training in departments that are hosting research and routinely hosting research.</p> <p><b>Question to RAG</b>, should Research Chief / Principal Investigators and Co-Investigators (currently listed as Tier 2 in table), have their own training in place, signed off and cover 'When GCP goes wrong' training?</p> <p>Other research active clinical staff, if they are or will be on the delegation log can also be involved in reading or acknowledging investigating responsibilities, as it is important that the other members of the team understand if someone's leading a study as a principal investigator, what their responsibilities are.</p> <p>AC supports suggestion. Commented on trust consistency, change the words Tier to Level, tier one to level one and the most specialist you get would be Level 3 and level 4. This will be consistent with current trust policies and levels.</p> <p><b>ACTION:</b> AR to convert tiers into levels on the training plan.</p> <p>Asked if the Education Governance Committee would have oversight of this? Agree RAG to sign off but note that in terms of overall organisational governance, will need to go through the appropriate committees as well.</p>	AR



	<p>Education Governance Chair is [REDACTED] and [REDACTED] AR and AC will discuss further outside of meeting to work on further for trust wide.</p> <p><u>SOPs List - submitted to PARG for RAG information only (RAG members can request copies for interest).</u> Noting Terms of Reference outline that RAG members approve policies and receive full list of SOPs for information/oversight. Department has updated and received approval on 12 SOPs this year, 4 going through at present. AR thanked all the team for their hard work in developing and editing these SOPs.</p>	
<b>2.7</b>	<p><b>Research Partnerships</b></p> <p><u>Wigan Health and Care Research Forum</u> Successful second event, organised alongside Wigan Council, public health team and the transformation team. Reflected on the outputs from the July meeting to facilitate progressing some of the items focussing on communities that don't access health care research.</p> <p>Discussed the Joint Needs Assessment Strategy as part of the Healthier Wigan Partnership, Progress with Unity and looked to identify people to work with and the areas to continue working in.</p> <p>Generating a register of projects and activities that are currently ongoing where we can continue and consult to see if there are any funding opportunities available.</p> <p>HS presented funding opportunities that are available for people to develop their research careers and/or projects across social care and the NHS. AR presented basics of research, so to understand what research is and how to get started. The last session was a workshop designed to further develop the key themes from the first meeting. It was a successful event and will continue to develop information and potentially generate new projects through the forum.</p> <p>Will continue to work with Wigan Borough Council on developing the next forum, which will be Tuesday 4<sup>th</sup> February 2025.</p> <p>CH2 confirmed there are spinouts from the forum already as a small group are looking at fall's prevention with [REDACTED] CH2 and AW.</p>	
<b>2.8</b>	<p><b>Research Delivery Team</b></p> <p><u>Trust Portfolio of Activity – Final Recruitment Figures, Open Data Platform (ODP) Report</u> Please see the report circulated with agenda and minutes for full details, highlights below.</p> <p>Greater Manchester has now merged with North-West Coast from the 1st of October 2024 and are now the North-West Regional Research Delivery Network (RRDN).</p>	



	<p>Unfortunately, the Open Data Platform hasn't yet merged the areas together yet and are still coming under Greater Manchester at the moment.</p> <p><b>2613 participants recruited</b>  <b>59 studies recruiting.</b></p> <p>National Portfolio Activity 24/25: GM are in 6<sup>th</sup> place in England.</p> <p>CRN Greater Manchester Portfolio Activity 24/25: WWL are in 5<sup>th</sup> place.</p> <p>Top speciality recruiters:</p> <ul style="list-style-type: none"> <li>- Cancer</li> <li>- Musculoskeletal Disorders</li> <li>- Cardiovascular Disease</li> </ul> <p>Areas of focus for this year are diabetes, community, reaching patients in hard-to-reach communities, paediatrics and the delivery of research through the Clinical Research Hub.</p> <p><u>Speciality Areas of Focus 2024/25</u></p> <p><b>Reproductive Health</b></p> <p>Active studies</p> <ul style="list-style-type: none"> <li>- OBS UK</li> <li>- Early v's Late (PI –diabetes)</li> <li>- Rainbow</li> <li>- Feed 1 (follow up)</li> </ul> <p>Pipeline</p> <ul style="list-style-type: none"> <li>- Unity –EOI submitted</li> <li>- LAMP –EOI submitted</li> <li>- Cape –EOI to be submitted</li> </ul> <p><b>Diabetes</b></p> <p>Active studies</p> <ul style="list-style-type: none"> <li>- Address 2</li> </ul> <p>Pipeline</p> <ul style="list-style-type: none"> <li>- Transition child to adult (PIC-posters)</li> <li>- Transend T2D (PIC –posters)</li> </ul> <p><b>Paediatrics</b></p> <p>Active studies</p> <ul style="list-style-type: none"> <li>- CMVnet(Community audiology)</li> <li>- Cleft (PIC)</li> </ul> <p>Pipeline</p> <ul style="list-style-type: none"> <li>- NeoGastric(In set up)</li> </ul>	
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	<ul style="list-style-type: none"> <li>- Comet –EOI submitted</li> <li>- Paloh–EOI submitted</li> </ul> <p><b>Summary</b>          Reproductive Health –Increase in studies since Feb 2024. OBS UK highest recruiting study on portfolio to date.</p> <p>Diabetes portfolio - 7 studies declined - protocols advised as unfeasible e.g. Phase II; Dietician capacity. There appears to be a lack of studies on ODP currently.</p> <p>Paediatrics – Is improving however 14 studies declined – lack of patient population (seen in children’s hospital), unfeasible protocols, clinical capacity.</p> <p>AC noted that considering diabetes is a focus area for the Trust and there are difficulties in accepting diabetes research studies due to clinical capacity, if this should be raised with the Medical Director and/or the Research Committee.?</p> <p><b>ACTION:</b> AW to discuss if there are difficulties in accepting diabetes research studies due to clinical capacity with Medical Director.</p> <p>AC noted the challenge is there are different diabetes teams, such as primary care, community diabetic team and there are groups of staff in these areas that are hard to recruit to, such as speech therapists and dieticians.          Consider triangulating all these areas and take to the research committee.</p>	<b>AW</b>
<b>2.9</b>	<p><b>Oncology update</b></p> <p>AP noted there are 13 studies in Oncology that are open, 3 more are in collaboration with The Christie, therefore there are 16 studies open with 3 more in the pipeline.</p> <p>AW thanked AP and team for all their hard work.</p>	
<b>2.10</b>	<p><b>Research Governance and Audit Report</b></p> <p>Please see Research and Governance report included with minutes, highlights below.</p> <p>Covering quarter 2 (July-September) FY24/25</p> <p><u>Expressions of Interest (EOI) and Studies currently in Set-up</u>          75 EOI covering 22 specialities          38 Commercial studies and expressed an interest in 9          347 Non-Commercial studies and expressed an interest in 15</p>	



	<p><u>Expressions of Interest – Reasons for Decline</u></p> <ul style="list-style-type: none"> <li>- Unfeasible protocol</li> <li>- Patient population</li> <li>- Clinical capacity</li> </ul> <p><u>Studies Currently in Set-up</u></p> <p>10 studies in 4 specialities currently in set-up 3 commercial and 7 non-commercial</p> <p><u>DATIX Incident</u></p> <p>There has been one incident occurred within the last quarter that has been reported on Datix. The incident was categorised as a GCP Confidentiality breach and involved a member of the research team:</p> <ul style="list-style-type: none"> <li>- Two patient images which were downloaded to a secure study database which documented patient names. As the images were uploaded the study team immediately removed them from the database.</li> <li>- Further training and awareness with the staff involved has been put into place.</li> </ul> <p><u>R&amp;D Updates</u></p> <p>Focus on achieving 2 performance indicators:</p> <ul style="list-style-type: none"> <li>- 60 day activation of study</li> <li>- Achieving commercial trials – recruitment of participants to time and to target We currently have three commercial studies in set-up and will be able to report on their performance at the next RAG meeting.</li> </ul> <p>Audit on consent, detailed overview in the report. If there are any questions, please direct them to [REDACTED]</p>	
2.11	<p><b>Edge Hill University</b></p> <p>No attendance.</p>	
<b>3. Research Outcomes</b>		
3.1	<p><b>WWL Library Services and Research Repository</b></p> <p>Discontinued the previous repository software, inputting extracted information into new software before testing. Will update at the next meeting.</p> <p><b>ACTION:</b> AH to move up the agenda for next RAG</p>	<p><b>AH</b></p>
3.2	<p><b>Publications and Research Outputs</b></p> <p>None currently.</p>	



4 Funding and Training Opportunities		
4.1	<b>Funding Opportunities</b>  Links to funding opportunities on NIHR website. <a href="#">Funding Opportunities   NIHR</a>	
4.2	<b>Research Career Development – NMAHPs</b>  Two members of staff are on the internship programme with RD Northwest, [REDACTED] [REDACTED]-Physiotherapist and [REDACTED]-Cardiology ACP.  Next opportunity available through R&D Northwest (RDNW) Early Careers Research Programme. This is a new online pilot version which starts in September 2024. RDNW have invited those on the waiting list to join the pilot and [REDACTED], Research Associate-Radiographer has been invited and allocated a place on the pilot.  HH advised [REDACTED] Clinical Lead 0-19 Health Visitor is applying for a masters and funding via a bridging scheme.	
4.3	<b>Research Career Development – Consultants</b>  None to add.	
5. Research Highlights		
5.1	<b>Research stories</b>  None to add.	
5.2	<b>Intranet/Virtual Portal</b>  None to add.	
6 Identified Key Risks and Successes		
6.1	<b>Identified Key Risks</b>  <u>Clinical Trials Pharmacist</u> [REDACTED] current Clinical Trials Pharmacist soon to leave WWL. RAG congratulated AA and thanked for hard work, input, and support over the last couple of years. Wished well for future.  Lack of Clinical Trials Pharmacist in post identified as a risk, AR spoke to senior management in clinical trials pharmacy, they have a plan and are recruiting a replacement.  AA thanked all the members and advised that a locum colleague, [REDACTED] will be taking over role as the Clinical Trials Pharmacist, currently going through induction.	



7 ANY OTHER BUSINESS		
7.1	<p><b>AOB</b></p> <p><u>Biomedical Research Centre (BRC)</u> Biomedical Research Centre (BRC) in Manchester have requested WWL's expression of interest in contributing to studies in Rheumatology and other areas.</p> <p>Noted the biomedical research centres are focused on early phase trials, but they're also focused on new biomarker discovery through collection of samples. Working with the BRC would give access to more research to the Wigan residents.</p>	

Next RAG Group meeting		
Date	Time	Venue
Tuesday 4 <sup>th</sup> February 2024 – 2pm	14:00	Teams
<p style="text-align: center;"><b>PLEASE NOTE</b></p> <p style="text-align: center;">THE DEADLINE FOR SUBMITTING AGENDA PAPERS FOR THE NEXT MEETING IS <b>7-DAYS</b> PRIOR TO THE MEETING DATE</p>		

