**I: So just to confirm you sent your, you sent your consent form already?**

**R: Yep.**

**I: Yes, and you’re happy to be recorded today?**

R: I am happy yeah.

**I: Great and I just wanted to clarify one thing on your consent forms. I had the two yes/no questions about being contacted for follow-up and receiving a copy of any outputs and they were yes/no and you crossed no so that just confirms that you mean yes for those, right?**

R: Yes, that’s correct yes.

**I: Just making sure. Okay excellent [Study introduction]**

R: Brilliant, excellent.

**I: Great so [um] to get us started why don’t you tell me a bit about about your role?**

R: Okay so I am the Senior Clinical Research Governance Manager at [University]. I’ve been in position since [Early 2020]. It’s a new position in the University. I am responsible for creating SOP structures, improving the governance around out clinical research providing support to researchers at all levels the Ph.D. candidates, long term researchers and ensuring that any of the, the governance and the legal things that are required around the clinical research are done correctly, audited and things like this.

**I: Great and had you been working in like Research Governance prior to this position?**

R: Yeah prior to this role I was Clinical Trial Monitor for [NHS Trust] worked there for a few years and I had another role in that department as the Information Officer, so, again, responsible for governance of the Trust.

**I: Okay great I’d be interested to hear things, any, any reflections you have both in your current position or in past positions we can talk about today. And so are you, can you talk about like anyone else in your organisation who sort of has similar responsibilities to you or are you the main person?**

R: I’m the main person in our university like I said it was a new role, it was identified as a potential gap in the structure because we obviously had governance in place but there was no one overseeing it specifically before I was put into role. We do have [an innovation office]. They’re heavily involved in sort of governance structures and the, the contracts and all of that aspect of the research.

**I: Great so can you building off of that a little bit can you just talk about sort of how the clinical research endeavour is organised at your institution?**

R: Yep so, I am based in, it’s called the [school within the university], so that’s where basically most the vast majority of the clinical research is done. We have a number of diff-, the way its separated in that school is that we have a number of different kind of themed areas so you have [various specialties], groups like this, think there’s about nine groups in total and they’re all headed up by senior people within those departments and then we all come together for general oversight of everything that’s happening.

**I: Okay great and you’re doing is the type of research focused on any specific like area, either broadly or like are you doing drug trials or other types of intervention, like what sort of research endeavour is generally going on at university?**

R: We do not do CTIMPs but we do below CTIMP there’s I would say the vast majority would be at the lower end of, the easiest way to explain the lower end of IRAS form is the way I look at it, qualitative, so your basic science. We do have some quite large groups who do very large [country-wide] studies but the vast majority is smaller projects particularly with our PhD students.

**I: Gotcha and so just to, so you don’t have a CT, a specific delegated CTU?**

R: No, we don’t.

**I: Okay great.**

R: We would rely we can do CTIMPs, I think we’ve been involved in a couple in the past. We’ve non currently. We would heavily rely on co-sponsorship with [NHS Trust].

**I: Gotcha, okay yeah and they sponsor lots of CTIMP studies. Great, so can you explain to me in your own words why requirements for the registration and reporting of clinical trials are in place?**

R: I think and my personal views the reason that those are in place it’s a number of reasons; transparency first and foremost so that it’s publicly accessible to see what’s running, how it ran allowing the public to review any ongoing trials potentially give them access to trials they may be interested in and I think general again really good governance oversight so that’s a reportable structure.

**I: Mhm and do you think that there’s any sort of disagreements or downside that can arise from these expectations to register and report clinical trials?**

R: Mm yes, not particularly in my university. We’re quite proactive with putting things on. We use clinicaltrials.gov mainly.

**I: Yeah.**

R: I’m responsible for that system but from working in previous places, I know that the general concerns around competitiveness of a study can be an issue Generally, people not having study teams not having the time to update these systems, forgetting about them, not really understanding the value of them was a problem I believe. There was a report I don’t know maybe two years ago now where almost every Health Board or Trust in the UK got a bit of a telling off and had to go run to their clincialtrials.gov sites and update everything pretty quickly.

**I: Mhm and so you said that at your first point was on like some sort of competition I believe you said. Can you just expand on what you mean by that a little bit more please?**

R: So not, again, not in my university, we don’t have this problem, but I have worked elsewhere people may not want to put a great deal of infor-, they’ll put the basic bare minimum on that system. There are options to put, you know, protocols, patient forms things like this on there. It may be that people want to keep their study relatively competitive if there’s, they know of I don’t know if say, another cardiac study that’s similar.

**I: Yeah so they might essentially revealing, they might be revealing a little too much?**

R: Yeah, revealing, they would want to keep a competitive edge.

**I: Gotcha, great so can you talk me through like sort of in, in your role it sounds like you have a very active in making sure things are registered and stuff at your university, can you talk me through the process, we’ll start with registration first, sort of like, I want to start a trial. I want to get it registered, how are you involved and what does that process look like at your university?**

R: So, at the moment it is very much about myself being proactive in contacting researchers, so I’m aware of everything that’s coming up. So, they get sort of a, a bullet point list of things I need done straight away. So, I would say if your study applies and requires to be registered please ensure that’s done. I then go and check that it is done. So I chase that up.

**I: So how do you first become aware of a study that does need to be registered, so how, like what is the, is that from ethics or is that from earlier on in the process sort of like what does that how do you become aware that research is upcoming?**

R: So, I am involved from very earliest point of a study so literally when they Professor comes to the Uni and says, “I want to bid for this grant.” I’m aware then and then, “Oh I got the grant.” “Oh, I’m starting a IRAS.” At every single stage I’m aware so I’m aim to get in quite early.

**I: Great and so you and then once this study gets underway how do you, like, what is the ongoing monitoring process look like?**

R: So once the study, so asked them to put the initial information on. I then when I know that study started, ask them to review, check everything’s okay in there. Then I’ve not not been in my role for long enough for this part yet. But the next part is to do annual checks of the system. Make sure anything that’s closed out also says that it’s closed out on there. Preferably when I know that study’s shutting remind them to set that system up on then, nothing has closed yet during the time I’ve been here because of the delays, because of Covid and things like this. Just about putting structures in place, just more prompts to people to keep the system clean.

**I: Great and you mentioned that you, you maybe use clinicaltrials.gov and since you don’t do CTIMPS, I imagine you don’t have a ton of interaction with the EU clinical trials register, do you use any other registries or routinely have any contact with any other registries?**

R: No, it’s mainly clinicaltrials.gov.

**I: Okay, great and there is a reason, is there a particular reason for that?**

R: [No just] for ease it’s a, it’s a system that I’m, when I came in the system was already in place. I’m very familiar with it because I worked with it at [my previous position] as well.

**I: Gotcha.**

R: It’s a free system, it’s a quite popular system so.

**I: Is that a detriment so is the free, would that for instance influence your choice between choosing clincialtrials.gov or the ISRCTN because it’s not, or it’s not really, it’s just what you-?**

R: No not really, it’s mainly because it was the one that they were using already.

**I: Okay excellent great and then moving on to you said you haven’t had much experience with this yet in your current position because not much has closed yet since you’ve been there but whether you, whether there was stuff that was sort of in the middle that has since closed or from previous positions. Can you talk about your experiences with getting the results of trials, of trials reported either to a registry or otherwise and how you’re involved in that process or how you might envision yourself being involved in that process at your current role?**

R: So, I’ve not been involved in that process yet. I recognise it’s important to get those results up. I think I can’t imagine there’d be much resistance to that. We are very, we have policies, very open policies about data making data available to the public. It’s something that we promote quite well internally. So, I don’t envisage that being a problem.

**I: Great and so do you, could you just explain a little bit about what those policies look like, so what are the, like what are the, like how does the University communicate to researchers about what they should do as far as dissemination in what is expected of them as far as dissemination of results goes?**

R: Yep, so let me just bring up the page so I have it in front of me.

**I: Sure.**

R: So, okay so just so I could remember the exact wording. It was part of our [local goals statement]. I believe we’re working on our [next] statement at the moment. So, it’s, its internally it’s just about the Heads of the Research groups are responsible for making sure that that data’s accessible for others. It’s not something I have particularly had a lot of involvement in yet due to the newness of my role.

**I: Yeah, do you envision that you will, so like when those first studies start to complete and, you know, get into the parts where they’re writing the papers or preparing the data, do you envision that you will be involved and do you have any idea what that might look like?**

R: Yes, I think so, so we’re currently in the process of reviewing our current SOPs and improving that SOP structure so it is data assimilation is one of the ones that we’re working on at the moment to, so that’s, that one has to go to all the research leads for improvement so we’re still at the very early stages of putting down a new SOP structure for that. At the moment it’s up to the, is the responsibility of the lead researchers in each group.

**I: Okay great so so in your experience either in this role or in previous roles, what do you think has worked well in ensuring that you know, trials are registered completely and on time and that, you know, eventually results might or could should get reported, like what do you think is sort of key to these areas being successful?**

R: I so in a previous role it was about changing internal systems to ensure that we were covering that step so obviously there’s a whole process before the green for go was allowed. The registering of trials was on there but often it was a, there would be a place holder on it, saying, “We’ve asked them, and they’ll say they’ll do it.” So now it has to be on there, there has to be a number, we have to be able to, they have to be able to see that before we could, they could move onto actually initiating their study. And then again similarly for my current role it’s just I find it’s just about reminding people, ensuring it’s, they understand it the policies in place and they know where to look for that policy and just following up when changes occur.

**I: Yeah, and that communication that you just described, how have you found what, like what sort of works best and how do you, how do you, like how do you feel implementing that has worked and like can you describe that process a bit for me please?**

R: Mhm so it is, it is just through email communication. Reminders are sent out. I’ve not had any, I really haven’t had any problems with people doing it, I just remind people.

**I: Great.**

R: They thank me for the reminder, they get it on the system. I’m the approver for our university so I can go through it, check it and then approve it our onto clincialtrials.gov

**I: Okay and then on the flip side what have sort of been challenges that you’ve come across in trying to, you know, you said you haven’t specifically had any problem with anyone resisting it but have there been challenges both in, you know, setting this up or if you look forward to the results reporting aspects or other things, you know, what have been challenges to ensuring that these landmarks and steps occur?**

R: Mm I think people I think there’s two things, there’s the usability of the system I think it’s quite a, a particularly clincialtrials.gov I personally think it’s quite a clunky system. Mistakes are quite easily made on that system as well which is one of the reasons I have to go in and check and approve everything and I’m sorry could you repeat your question again because I had another bit?

**I: Oh, it was just sort of what challenges or barriers either in this role or your last role have like, you know, presented, yeah?**

R: It’s people not understanding the importance of registering the trials I would say. We’re getting better at that, we’ve got other, I’d say more experienced researchers understand but say the the newer ones maybe they’ve not been involved in the process before. It’s about educating people about the requirements and the reasons around putting those things on the system.

**I: Okay great and would you say, so mm I’ll save that question. So as you, at your current institution as you, you know, are involved in these processes to improve these SOPs and these policies around you know, ensuring that these trials transparency requirements are being met and sort of are a priority, do you have examples from that process at all that have been either illuminating or, you know, there’s been difficulty or that have worked, you think have like, you know, are really good examples of what has worked?**

R: Do you mean when you say examples of what has worked, do you mean in terms of the governance of clinical research?

**I: I would say, yeah so I would say sort of what has come out of that process that seems like it, you know, like let me separate this into two questions, so first of all the outputs of that process so far, what are, you know, are you looking, what seems to be moving forward. What is grow-, what is expanding what is new that has come out of that process that you think will be good for, for these, these processes at your, your university?**

R: Mm I think there’s a, so my role was put in place because there was a genuine desire to improve the governance process around clinical research, so it’s been very positive people keen to adapt to these new processes or even some aren’t new they’re just improvements on current processes. I think it creates, it provides better oversight of everything that’s going on within the school. It creates a level of what would the word be, reassurance for the school, everything’s being conducted properly. It’s giving people a central point of contact if they do have queries. It’s improving the training as well around clinical governance research, clinical governance for people as well.

**I: Yeah, and just to build directly off of that response, so do you feel like, so do you feel like there’s top level support for this work at your institution for these priorities?**

R: Oh yeah absolutely there’s a very clear support for it. They’re al-, always very welcome to the option to improve the systems that we have already.

**I: Great okay so you’ve mentioned earlier about how the letters I believe you were referring to the letter from the House of Commons that sort of they sent**

R: Yes.

**I: out to all the**

R: Yes.

**I: about the reporting and] how that sort of had an impact. Can you talk about sort of the impact that had at your institution specifically?**

R: Yes [um] so that was my time at [my previous job] and I wasn’t involved in updating the system at that time, that wasn’t within my role. However, the sponsor representatives were heavily involved. We have a very large research department [at my previous institution].

**I: Yeah.**

R: They, it was a priority for [them] when that information was provided to us, the system was given a very good clean-up and a lot of data, again I don’t know exactly how much because I wasn’t fully involved, but it appeared that a lot of things were missing and were rectified very, very very quickly. That also changed like I said previously, it changed the policies going forwards to ensure that we couldn’t make those mistakes again.

**I: Great and at your current role, it sounds like, you know, you mentioned that your position is new and sort of the Institution felt that there was a need for this position, do you have any insight or thoughts about what led them to that, to that realisation that this position was needed?**

R: Yeah, I think] it’s something that I think was in the pipeline for quite a while. Clinical research governance was done sort of, certain people had little bits of those roles, there was no joined-up person with oversight of all the things that were going on in terms of governance. So I think the thinking behind the role was just to create that and they’ve got big plans for me improving the training, improving other systems and things like this so I think it was more about it allows more oversight and responsibility as they continued to expand their research portfolio.

**I: Mhm and just because you’ve had the sort of the, even if you weren’t directly involved like in this, quite the same things at both organisations you mentioned that you’ve worked at I am interested to hear since you have one that was sort of a major research hub doing CTIMP doing like a different type of research from the type you’re working with now, I’d just be interested to hear how you would compare and contrast between those two organisations and how they are inter-, like how they encounter and work like trials transparency issues.**

R: Yeah so [the previous institution] like I said, big [institutional] research department, big CTUs involved, very closely linked to [a university] not the one I’m currently working for. They were very very on the ball with their research governance. They obviously had to be, they had hundreds of CTIMPs, department dedicated to it. Constant training, constant input to and from [NHS organisations], the overarching group. At [my current institution] they’re also very proactive with their governance. It’s very different because of the type of research we’re doing and it’s not the same, nowhere near the same level of output that’s required. I’d say that understanding of clinical research governance is very different at [my current institution]. They don’t know what they don’t know. I personally, personally think that [um] because we’re not a medically affiliated University, we miss out on a lot of key updates particularly key updates from [the government] that’s one of the main, I’m very lucky, I’m still very closely linked to [my prior job] so they do send on that information to me. I imagine it’s not the same at all for other Universities like [mine] that are in the same position but also do clinical research.

**I: Mhm great [that actually leads perfectly to my next question which is so you are, so it sounds like the main way you’re hearing about changes about these pro-, registration and reported requirements or other things in the field comes from your connections to the previous job? You wouldn’t necessarily have access to them in your current role if you were just coming in to it new and fresh?**

R: Mhm yeah, I think it would be, I mean I there’s lots of other places I go and get the information; the HRA, NHS Research networks, these places I hear about things but things particularly that are [locally] centric I think there is a real disconnect between the overarching NHS [research organisation] information flow to non-affiliated, non-medically affiliated schools.

**I: Right and are you part of any other sort of like professional or other types of groups in which you would hear about or communicate about, you know, these, these areas of research governance and transparency?**

R: Mhm so I’m member of the RQA [Research Quality Association] so that’s quite handy for UK-wide changes to things. Locally, we have I can’t remember the name of it but it’s the, it’s a network of small [local] groups so [a local Trust] and ourselves are very closely linked. We have very good connections between there so get a lot of information from them as well.

**I: Great and great and then so as far as resources at your University, so they obviously hired you which was a big a resource that they put in place and then how are you then like sort of resourced to do your job, you know, like how, like you don’t, you know, not in a specific, not necessarily in like very specific ways but broadly like, you know, how are you, like what do you need to do your job and how does the organisation provide that essentially?**

R: Let me think, I think I hope this is touching what your question means so do correct me if I’m going down the wrong way

**I: Okay.**

R: but I am how would I put it? So most important thing for me is that communication channels are open and the information is going out because the school is quite, there’s so many different groups that making sure all that information flows down could be tricky so it’s just about making sure that the heads of those groups are open to providing me with the ability to communicate with the wider group of people within the school that are doing the clinical research.

**I: Mhm yeah no that’s that’s excellent and you said, and you mentioned that you sort of to date haven’t hit many barriers so there hasn’t been much resistance in your, in you encountering this role. You said you have leadership but now when your communication with researchers and students or anyone sort of people with capacity there, you haven’t met much resist-, have you met much resistance at all?**

R: No, I mean there’s always going to be a little bit of resistance from some people to change particularly if I’m putting in a process that maybe creates a step for them. I’m trying my very best to streamline as much of that as possible because I know no-one likes getting anything extra to be doing but I think there’s no real resistance. I think particularly students are very open to learning as much as they can about clinical research governance particularly those who want to go on potentially with the career in the area. It’s about supporting them and making sure that they understand from the beginning everything that’s required.

**I: Great and I guess the last question I have here based on something you sort of said earlier, so now that these policies and procedures and stuff are being developed and you mentioned like sort of a large organisational priority around results availability and transparency so can you just speak about your role in that process and sort of like, like how are you plugged into that process and participating in it?**

R: So, my role will be mainly to ensure that people are aware of it, to champion it to make sure it’s happening. The ultimate responsibility will lie with the] the, oh my goodness, what’s the word, the supervisors in case of, in case of students and also the actual, the tutorial candidates, the Professors who are doing the research so it’s ultimately their responsibility, but it would be my, my role would be to prompt, to remind, to explain the reasons for getting that information out there.

**I: Great so I think that is the end of my questions specifically, but I wanted to ask if you had any sort of, you know, final thoughts or would like to expand, expand about anything we talked about today?**

R: No, I don’t think so Nick, I think that was pretty comprehensive.

**I: Great and so the last question which you may have just answered, is there anything that, you know, I think that I should have asked or that a piece of information you feel like you would have liked to have told me, but I didn’t specifically ask for.**

R: No, I think that was really good. I really like that you let me speak previous roles as well. I think that was really handy, I think that got a good bit more information out of that.

**I: Yeah.**

R: I think it was really good.

**I: So the last thing administratively I want to ask, so don’t hesitate to let me know if you have any questions related to your participation or if you want to note something additional comes to mind, feel free to send me a note, that would be perfectly fine. So I also am offering people if you would like to see, I’m going to get these transcripts made and I also noted that I’d share my final analysis. Would you be interested in seeing, receiving the transcript of this?**

R: No that’s okay but thank you for the offer.

**I: Okay great.**