**I: Great so to confirm do you give me your permission for me to interview you today and audio record our conversation?**

R: I do.

**I: And do you understand that your participation is voluntary and you can halt this interview at any time for any reason without penalty?**

R: Yes.

**I: And do you give me permission to quote you anonymously in any output resulting from this study including the sharing of the anonymised transcripts?**

R: Yes.

**I: And do you understand how to raise a concern or make a complaint?**

R: I do.

**I: And do you understand that any information you reveal that presents an immediate risk to patient safety [er] will be reported accordingly?**

R: Yes.

**I: And do you give me permission to recontact you to clarify any information if necessary?**

R: Yes.

**I: And [er] would you like to be contacted via your email on file with any results of this study when they become available?**

R: Yes, I would.

**I: Great and are you, so you’re happy to take part?**

R: Yes absolutely,

**I: Great excellent so that’s it for the oral consent and then we can go ahead and get started. Okay so first of all why don’t you tell me a bit about your role please?**

R: So, I’m Head of Clinical Governance for [University] and so that means, broadly speaking that means that I manage the team and I oversee processes relating to research involving human subjects so it’s a very broad remit. Within the University we have [numerous] School and Faculty ethics committees[…]and we have [um] and so those deal with anything that’s not on the Health and Social Care side. So, research not requiring NHS Ethics Committee approval essentially so that’s one element of the role is overseeing the, the processes for those committees making sure that that approvals are sought and are granted appropriately. Then we also have our portfolio of research that does require NHS, NHS ethics committee approval so at any given time it’s between well, it’s, it’s not always easy to say because we have a lot of student projects that are brief. But currently we have in total around [over 200] studies that fall into that category that are in set-up or ongoing and, and, obviously, then as a, as a subset of that also overseeing clinical trials of investigation or medicinal products and so, again, sort of broadly speaking I have one member of staff responsible for each of those three areas

**I: Okay.**

R: and then other staff under them. We are currently very understaffed as a result of recruitment freezes due to Covid. We’re in the process of replacing some staff but those are, I have overall oversight of those areas and then we have sort of specialists in each of the three who take responsibility for those particular areas. So am I right in assuming that your interest here is clinical trials in the UK regular definition?

**I: Yes, exactly so clinical trials but not…so including but not limited to CTIMPs, yeah.**

R: Right so more the World Health organisation definition, anything interventional?

**I: Yes, basically so if you were doing, say, a trial of a you know, psychotherapy, I would be like, broadly like, we can talk about differences between the two and like CTIMPs and non-CTIMPs but broadly, yeah, just in how you sort of handle both.**

R: Right yes so that’s, so my role is having oversight of both types potentially.

**I: And about how long have been working in this role and then the broader area of research governance in general?**

R: I’ve been in this role since [early 2020], where I am, [early 2019] so just over eighteen months. I have [over 15] years’ experience of working in clinical research generally so I worked as a, as a trial administrator and a trial co-ordinator in first [medical specialty] and then in [medical specialty] for about ten years altogether and then I worked for [UK clinical academic institution]. I worked there as a clinical research trainer so providing good clinical practice training and sort of practical training for research staff for four years as a trainer and then two years managing the training department before moving to [current institution].

**I: Okay great I welcome throughout the, you know, our conversation today, if you would like to compare or contrast or reflect on any of your experiences at these past organisations that are relevant to our discussion including, you know, your current role if you’d like to do that feel free. I’d be interested to hear about, you know, comparisons to your current role or the processes of how you’ve seen these processes evolve throughout your career.**

R: Okay, okay, thank you.

**I: So you kind of mentioned a bit about how research is organised at your institution. So you have CTIMPs, are they organised in a CTU or are they sort of, does [your institution] not have a CTU?**

R: [The institution] does…[have a CTU that recently restructured]. **[Note: This section of the response summarized to remove details that could be seen as identifiable information]** And whether or not the CTU is involved in the studies depends a lot on really the area in which the research is being conducted. CTU historically were particularly involved with [medical specialty] research. [um] [Another unit] specialise in primary care research, so it is really very much on a case-by-case basis as to whether or not they’re involved. It depends on the area, it depends on the staff involved but we do, we work with those and, also, obviously the Trusts within [the city] have their own CTUs so there’s only really one example currently which is a Trial has just recently recruited our last patient which was working in [medical specialty]. It was, well not a trial of [a treatment] but a trial with..patients [on treatment] and they worked with the [local specialty hospital] Centre so that’s a CTU within the Trust so it does, it does vary depending on the nature of the study.

**I: Great excellent and just to clarify one of the things you stated earlier so you have one, three people underneath you and one, one handles non-NHS research, one handles non-CTIMPs NHS research and one handles CTIMPS research, was, is is that correct?**

R: Broadly, yes so, the person who handles the CTIMPs [their] role is essentially CTIMPs and human tissue research.

**I: Okay.**

R: So, it’s the high-risk, the more complex studies and then [they] directly line manages one other member of staff. So they’re, they’re both responsible for that remit and then in better times we also have an administrator who assists both of those sites of the health and social care research.

**I: Okay excellent so taking a step back now briefly, so can you explain to me in your own words why requirements for registration and reporting of clinical trials are in place?**

R: Yes, so historically there have been concerns about selective reporting of research and non-reporting of negative findings essentially and obviously the sort of first concern for this was, was pharmaceutical companies was the drug companies. So now I should remember this from my training days, as of, I think it was about 2014 a requirement was brought in by ethics committees where previously it had been somewhat discretionary for all types of research. It became a requirement ethical committees, ethical committees required that studies be registered on a clinical trial database. Prior to that, it had only been CTIMPs that were required to be registered on EudraCT in the UK and the reasons for both of those is to ensure that there is a public record. There’s a public record of studies that have been conducted and obviously there are multiple benefits to that. Also, it means that people with a given condition can find out whether their trials being conducted, can see whether there are things they could potentially volunteer for and maybe benefit from. But the other reason and the reason that it was, it was brought in as a requirement by the ethics committee was in large parts to ensure that there is that clearer record to say these are the studies that have been conducted and when looking to make decisions based on research you can see everything that’s been conducted and ideally also you can see the, the results of those. The example that I used to cite in training was Tamiflu. That Tamiflu was shown by a number of studies to have a percentage efficacy and was widely stockpiled as a result and only subsequently it became apparent that actually a very very small number of the studies that had been conducted were actually published and what that efficacy figure was based on. So, in order to have a full understanding of the benefits of treatments, somebody who’s making that decision needs to be able to see all of the research that’s been conducted.

**I: Great and then so, oh can you think of any potential disagreements or downsides to this expectation that all research is registered and reported?**

R: Not to the actual fact of it.

**I: Okay.**

R: As a, as a requirement I think it is a, it is a beneficial requirement. I think there’s a, there’s a risk that it gets confused as being the only outlet, the only way in which information is shared and so I think sometimes there’s, there’s a risk that people overlook the fact that a lot of research actually is published through peer review journals and is published in the appropriate way and so the requirement for the publishing of findings I think it’s, it’s appropriate to have a system in place where that can be seen where we’re not reliant just on the database reporting which is only limited but actually that it’s there as a back-up. It’s there in case things aren’t being reported in case there are errors or in case there are unscrupulous practices and that perhaps it’s on the only route.

**I: Great so coming back to your organisation now, can you talk me through the process of, we’ll start with registration of sort of how trials go about getting registered, like, you know, I’m an investigator. I want to start a trial what process do I go through, I assume that you’re involved in to ensure, or your office is involved in to get that trial registered?**

R: It depends where they’re going to be registered. So for a CTIMP study that’s going to be registered on EudraCT that’s managed internally, that’s managed by my team [um] so we would sort of have a general oversight and management of the account and at the point that a CTIMP is being set up and I should probably clarify that we actually have a relatively small proportion of CTIMPs.

**I: Okay.**

R: So over the past, over the past ten years we’ve had [less than 20] ongoing in total so it is, it is a small proportion, it’s maybe five per cent at any given time of our ongoing portfolio which means that we are able to focus particular resource in that area where it’s there’s additional requirements. So for those studies it’s made clear to the team from the outset that they’re going to need to register the details on EudraCT and we oversee the account, so it is the member of staff who’s responsible for CTIMPs that that has oversight of the EudraCT for the University. Obviously, when it comes to the uploading of results, there it’s the researchers themselves that have the results but it’s, it’s the role of my team to essentially track the process. And to make sure that within an appropriate time of the trial declaration that those results have been uploaded and to continuously follow-up with those teams until they, until they actually are uploaded.

For other trial registration, what we’ve done in the past four years, so essentially since the post note enquiry and a rise in questions on exactly this topic we’ve really tried to rationalise our processes. It was found at that time that one of the problems was that studies were often registered independently, might be registered on multiple databases with things like inconsistency in in the name of the organisation that, for example, looking to see what we had on a, on a given database, we’d have to search for [variations of the institution name] and various different combinations of that. So what we now do is make sure that it’s very clear right from the outset so when a team approaches us to begin the process of set-up and applications for ethical and HRA approval we’re clear right from the start that our guidance is always that a given study be registered on one database to make sure that then it’s very clear that there’s only the one that we’re tracking that the results will definitely be uploaded. Our, our recommendation for non-CTIMPs is always ISRCTN.

**I: Is there a reason for that, just curious?**

R: It was because of the, the way in which ISRCTN can be managed that again we’re able to have a university account and actually track things more appropriately. It’s not an absolute rule so there are studies where for whatever reasons of visibility requirements of funders is also sometimes an issue. There are some studies who will say we particularly also need to be on ClinicalTrials.gov. We’re less able to directly manage ClinicalTrials.gov and so we agree with very clear caveats to the research team that it’s their responsibility to maintain those records.

And, you know, and that we will follow up with them to ensure that they are. Whereas with ISRCTN, we have a university account, we’re able to track and maintain those records centrally so that’s why it’s our preferred. Obviously, the downside that’s raised is, is the cost and so that’s sometimes some teams would prefer ClincialTrials.gov because perhaps they haven’t got the funding to use ISRCTN but that’s always our requirement.

**I: Great and then so when a trial, so you mentioned a little bit about the following-up for results reporting specifically around the EU requirement and the cha-, a bit of chasing for that. Are you involved in making sure results are reported sort of in any of these other formats, like, do you have any role in making sure like a paper gets disseminated or or the absence of a CTIMP and the absence of EUCTR registration that the results are made available in some way.**

R: We, we’re responsible for the tracking of, of the database results so we ensure that those results are uploaded onto EudraCT, loaded onto ISRCTN whatever it maybe. The publication side of things is very much with the researchers themselves.

**I: Okay.**

R: So really we are, you know, having said earlier that that perhaps in an ideal world we would only require one or the other, our role is in making sure that the database registration is managed and that way if, because obviously, you know, we’re conscious that not everything can get published and particularly negative results that quite often journals simply aren’t interested in publishing negative results.

**I: Yeah.**

R: So, what we ensure is that there’s this backstop that things are published on the databases and then beyond that publication lies with the academics and with their faculty management.

**I: Great yeah and so you, even though there’s no sort of like, you know, equivalent EU requirement to post things like there’s no UK at the moment requirement to post things on the ISRCTN you, you guys take that step as part of your routine process anyway?**

R: Yes, that is an organisational requirement.

**I: Great and then so a few follow ups here, so can you talk about you don’t have to get into excruciating detail here but just generally, like what is your process, your monitoring process look like, like how are you checking in to make sure people are doing this right and how does the pestering work, how do you know who to pester and when, things like that?**

R: So for the CTIMPs because it’s a small number they’re, they’re very much managed independ-, you know, individually.

**I: Yeah.**

R: So, we will see that a CTIMPs has closed set a date that we then know this is the date in which that needs to be published and will arrange checks in advance of that date to individually go to those teams so that would be scheduled into the individual whose role that is, [they] would schedule that into her diary and make sure [they go] to those teams individually and checks those and she also has regular checks on EudraCT itself so as well as checking with individual studies also checking that where when we’ve sent corrections to EudraCT, where we’ve asked for things to be amended [they’ll] have kind of regular check-ins to that to make sure that that’s the case.

And then with the other systems, again it’s, it’s regularly scheduled that it’s essentially an audit a number of times a year so that’s individual or somebody within the team will on a regular basis check our records on ISRCTN and on ClincialTrials.gov. Although, as I say, obviously that’s less available to us but still it is possible to run searches and find things that are registered with [our institution] so regularly scheduled times throughout the year a check is done on all of the trials that we’re essentially expecting to be on there; see if they’re registered and then those where we have end dates for them, we know that they should have also registered results, again to check those and then the individual teams will be contacted if there are things outstanding.

**I: Great and then the last question I wanted to ask since you guys handle, even though it’s a relatively small amount, you’re working with CTIMPs, how has you know, the forthcoming Brexit, sort of losing access to the EMA and the EUCTR, how have you guys planned or, you know, are prepared for that?**

R: So in some ways it’s, it helps us to give impetus to individual studies so we have one study currently that has actually closed quite a long time ago and have been chasing the teams for that for a good long time now to update the results on EudraCT and to be able to say, “You have until the end of December, this has to be done right now” has actually in some ways been of benefit to us. So we’ve also because we’re registered on CESP (Common European Submission Platform) and on the MRHAs planned systems for starting the 1st of January.

We have also been in communication so I’m part of a sort of informal network of University sponsors of clinical research and so there have been communications through that and we have actually had confirmation it was forwarded just this week actually from another university who had been informed that we will still have access to EudraCT beyond the end of the year that where we have studies on there we will still be able to maintain that data.

**I: Yeah.**

R: To be honest we didn’t tell the researchers that.

**I: [laughs]**

R: It means that we still have that, that access so we’re now confident that while we want to make this push and get everything as up to date as we can by the end of the year we are conscious that we’ll, we’ll still be able to maintain those beyond and, as I say, we’ve registered with the appropriate services for starting next year for new studies.

**I: Great and so in all these processes obviously you’re the head of the team and you have these people under you so just what level sort of you, do you consider yourself involved in the implementation of these processes, like do you have a portfolio or are you mainly overseeing the people below you who have a portfolio or are you doing any of these audits or sort of like how are you involved on a day to day basis on this process?**

R: It’s members of my staff who conduct the audits so at the time that they are conducted they would show me their findings essentially so at the time of the audits they’ll take me through the findings, they’ll take me though any concerns. I would typically only be directly involved if there were significant problems with an investigator.

**I: Okay.**

R: If they were trying to get an investigator to engage and to update data and they, they met barriers. It doesn’t happen, it hasn’t happened yet. There haven’t been the occasion. There have been, you know, a couple of occasions where maybe I was copied into an email just to add that that extra sort of weight of concern but it’s not yet been the case that I’ve been directly involved. It’s more that I’m kept informed of those process as and where we’re up to those those audits and and obviously on a case-by-case basis for the CTIMPs.

**I: Great so is it fair to say that you’re sort of more involved in, so you’re both the management level of your team and at the like policy and procedural level, is that, are you also involved in sort of setting your institutional policies and procedures along for, you know, these areas for the governance?**

R: That is part of my role. These are actual policies were in place having only been in the role for eighteen months, these were, have been in place for a couple of years now.

**I: Right.**

R: So, I didn’t set these polices but obviously if they need to be updated if there are changes that are required to be made to the policies then that would be part of my role.

**I: So, has since you’ve entered the role, has anything sort of, have you changed or updated or advanced anything about any of the way this all managed at the University?**

R: No no there had been a very significant overhaul of the processes and an increased formalisation of the processes shortly before I arrived.

**I: Okay.**

R: So we had been 2016 or 17, so the processes that we have now were brought in in response to as I said the POS-note enquiry, specific enquiries from people in a similar role to you, so from Ben Goldacre’s group and others and I can’t remember his name but essentially there had been, my predecessor had really worked on this with a number of people who were interested in the field and [shared] barriers to this, about processes and had set this processes in place so beyond obviously the requirement for reporting through the MHRA in January, there haven’t been any significant changes because we had robust processes in place.

**I: Great yeah so just to clarify for the POST-note enquiry, is that from the the parliamentary science technology committee hearings?**

R: Yes.

**I: Okay just making sure, great.**

R: Yes, sorry that’s the shorthand that my colleagues at the University had at the time.

**I: Yeah, no problem so in sounds like you’ve taken to these processes pretty well in the position so and this is, might also draw a little bit on your past experience but what has worked well, like what has really stuck out to you as working well in the way your institution manages this, these processes?**

R: I think the biggest things is early discussion and early notification around the expectations of this with researchers and I think historic problems with this a larger part of historic problems with this have been with organisations essentially having to having to retrospectively try to manage this data with research teams that have been disbanded you know, once, once the project had finished with large amounts of data having to be managed all at once. So certainly, in in previous organisations that I’ve seen where there was a push to get data on EudraCT obviously when the EU, now it’s not the clinical trials register, it’s the sort of public tracking side of that, it’s making public. At that point, organisations who hadn’t really had to engage with this previously who hadn’t been aware of the scale of the issue had to very rapidly manage this and without any significant expertise without staff in place, so trying to do it en masse is the biggest challenge. So what we do is to make sure that it’s part of discussions with researchers very early on regarding specific projects.

In my, in my former role as a GCP trainer it was absolutely part of the training, it was something that we made people aware of that there were these requirements around reporting, EudraCT for CTIMPs, other databases for other types of research that some basic requirements of ethics committees but that’s, you know, that’s a small element of an in-depth training course around a lot of other things so what we absolutely do at [my institution] is to discuss this, to make sure that it’s clear to individual researchers about their specific project, “This is the way we work. This our expectation,” and it means that that by large, those expectations are met and where they’re not we’re dealing with individual cases where we’re, we’re having to chase where we’re having to update things.

**I: Great and we touched on this a little bit earlier but just to draw it out a little bit so is there anything that you’re looking towards improving or implementing, you know, I know you mentioned staffing is a little light at the moment but is there anything that like sort of on your wish list or on your priority list moving forward that you’d like to implement or see changed?**

R: Being still in a sense comparatively new in the role my, my focus certainly around this, is on assessing the existing system seeing how it works in practice. The change in process in January will be a good opportunity to review that as we’re having to work on a, on a new system but currently our management around the non-CTIMPs type things around IRCTN and ClinicalTrials.gov there’s not a systemic change that I’m looking to make those in areas.

**I: Okay and how would you describe how sort of like top level, higher level than you support for your work in, you know, the research governance and this registration reporting looks like at your institution?**

R: I’d say there’s, there’s an understanding of the significance of it. It is, the responsibility of research governance to manage this in practice, so we’re supported in the sense that that we are generally supported in all of our role. The responsibility for oversight lies largely so within professional services so that’s the area in which my team sits. Certainly I know that if I needed support I could go to my management, I could go to the Executive Director of our Directorate and they would assist and they would lend their support if we, if we needed that with investigators but that’s not, not really been the case that we’ve, we’ve needed that. And on the academic side of things obviously, on the academic side of things there’s, there’s always an almost instinctive resistance to bureaucracy and administrative process but in truth on, on this particular subject, I haven’t met any, any significant resistance.

There is an understanding that this is important. There’s an understanding that this ultimately kind of backs up the validity of the of not just our data but clinical research data generally and it supports people in decision making and in the design of future research. So there is support at an academic level in that sense that where they are able to, where they have the appropriate administrative support, they will take their time and they will do what’s required of them to make sure that this is managed appropriately.

**I: Great and one other follow-up to this broad section of questions that -- so you mentioned that you’re sort of chasing some results, some long outstanding results down at the moment, is that, has that been a priority in terms of, you know, reporting to the EUCTR or, you know, EudraCT and the EUTCR, has addressing, you know, past unreported trials, they may have bene reported elsewhere but specifically reporting to the registry, has that been like a priority or something you’ve worked on.**

R: It’s, it’s a priority for the member of staff who takes responsibility for that so the member of staff on the, on the CTIMPS side of things. Obviously it’s, one of many priorities.

**I: Yes.**

R: But it is something that is a regular thing on [their] to do list, it’s something that [they check] in on, on a sort of regular basis as I said she has the sort of scheduled times for review and she’ll have it sort of scheduled into her calendar to check on certain things so yes it is something that [they are] very conscious is a significant element of [their] role and is something that [they] manage routinely.

**I: Great so talking about when you were talking about things that worked well, you mentioned a lot of, you know, how these lines of communications and with the investigators and the study teams is a real positive, so I’m wondering what is the level of sort of training, like what is the way that you train people to be aware of these, how does that look at [your institution]?**

R: So that is an area in which we are currently developing.

**I: Okay.**

R: So in accordance with the concordat to support research integrity we are in the process of well prior to the current situation, we were in the process of taking on additional staff and looking to expand to have a, to have an integrity team and to actually conduct integrity training. So it’s something that is, is ongoing within the University. So within my team it, it’s an intention to develop integrity training. Currently we have training programmes for individual courses essentially so it tends to be sort of taught postgraduate courses that are going to be working in clinical research.

We provide training to them on ethics and integrity, on all of, the sort of principles and then the processes and so database registration is an element of that but it’s obviously, it’s part of a larger programme. Really, the specific requirements around this are managed on an individual trial basis so it’s at the point that we’re setting up and working with individual Chief Investigators making sure that they’re aware of the requirements. There is also within the University, there’s a [group] so that’s led by the, the [lead for research improvement] so a large part of their role is looking at development, academic development and training and progression and tying research quality concerns including things like transparency, including really all of the sort of broader research integrity concerns, the longer term aim is to ensure that that’s integrated into promotion and progress at the University.

So, a lot of these are works in progress and they’re works that have been delayed over the past [few] months just because of obviously the shift in in resource focus essentially in order to manage immediate concerns. So there are programmes, there are programmes targeted to individual early career researchers and to students within the University and to first time supervisors as well.

**I: Mm okay.**

R: So those who are going to be acting as a supervisor on a research course, on a, you know, a sort of research qualification. So there’s training that’s available for for all of those groups on as I say, all areas of ethics and integrity and this a an element of that.

**I: Right so you, we’ve talked a bit about some barriers, you know, you’ve mentioned the pandemic and the staffing concerns that’s for you been sort of one issue. You’ve mentioned sort of one issue, you’ve mentioned sort of, you know, sort of not a universal but at times you meet some resistance to, you know, the bureaucracy of all this sort of work when you’re working with the academic side of things. Are there any other sort of barriers that you regularly encounter in the registration and reporting space that you’d like to elaborate on?**

R: Yes there are two really significant barriers. The first is technical and I’m sure you’ve heard this before.

**I: Mhm.**

R: The first is a significant difficulty especially with EudraCT. It is a very difficult system to engage with particularly where there are non-standard occurrences where perhaps a study has closed early, where a study has perhaps even closed without ever recruiting things like that. Actually, reporting null results, reporting something that hasn’t just followed the standard as, the sort of processes expected. This system is very difficult. Actually, again with the group of academic sponsors have have shared, you know, had to kind of share guidance notes to say this is something that we’ve tried and after much consultation with the MRHA this is a way that we were able to actually change things on there. So, the way in which we interact with, with the system ourselves is very difficult and very clunky.

Beyond that, then if there are things on there, if there are things on EudraCT that are incorrect, if there are things that have perhaps been corrected on EudraCT but not on the EU clinical trials register we then have no, no way of reaching them at all, all we can do is email the MHRA.

There have been occasions, in fact there is at least one that it’s still outstanding where my colleague has, you know, as as part of those kind of regularly scheduled check-ins [they] got to the point where [they were] emailing them monthly to say, “This is still wrong, please correct this.”

And obviously I get it, I understand the MHRA are also under significant pressure and don’t necessarily have the resource so it’s, it’s a question of difficult systems and then a lack of resources for the, the management of it.

Which really comes onto the second significant issue for academic research particularly which is the fact that the research is grant funded so what we have is funding to pay for staff for the duration of the study. They’re all on contracts and once the study, once we’ve done at the end of trial submission, all of those staff move onto their next contract

**I: Right.**

R: and so, we still have contact with the Chief Investigator, but the Chief Investigator often isn’t the expert on these kind of systems, doesn’t have the time, is very busy, you know, clinician, academic. We don’t then have administrative support on the investigator team side to manage that. Occasionally, you know, we get very lucky and actually there’s somebody whose next job is in the same office and they’re still around and they’ll do the work but, you know, maybe they’re doing the work weekend and evenings because that’s the only way to get it done. It’s, it’s something that isn’t addressed in funding applications. It’s something that I’ve, you know, I have in the past seen resistance from funders to funding that would meet this need that would meet research governance needs, administrative needs, all of the additional work that’s created by doing a study.

So yeah that’s really the significant difficulty is that you no longer have administrative staff, you no longer have a team that you can go to assist with this. You have the Chief Investigator and if the Chief Investigator retires or moves onto another organisation at that point it becomes even more difficult.

R: We have also instituted a process for, a leaver’s process so that at the point that an academic leaves the University, there’s a process that we have sort of requested HR to conduct to say, “Does this person have ongoing clinical research, they have ongoing CTIMPs, have they been reported?” and yeah to make sure that we can do what we can to capture those if somebody’s leaving but that’s not always possible and, you know, you certainly you have the occasional circumstance where a researcher passes away and then and then it’s, you know, a question of people trying to piece together the sufficient records. So I’d say really that is the, that’s the biggest barrier from an academic point of view is that there aren’t consistent teams who have direct access to the data of a study and have responsibility for it’s reporting. We’re established through, through core funding. We exist in an ongoing way to oversee the process and to make sure that things are being submitted appropriately to make sure that things are being updated and published but obviously as sponsor is not appropriate that we necessarily have direct access to, you know, certainly not any identifiable data but it’s not our role to have access to the direct data and to publish in that way. It’s reliant on teams who are not funded in that continuous manner.

**I: Right, this is just one short follow-up that I thought of in line with this. So when it actually comes time to, you know, to put the summary data on the EUCTR and that that is being done, is that a member of your team who, you know, receives that and does that or are they supporting someone on the actual study team to be doing the actual, you know, real typing into the system and uploading those results.**

R: They’re supporting somebody on the study team because they have the understanding of the data.

**I: Right great so the last little couple of questions here. I just wanted to follow up so you mentioned that you’re sort of part of this informal, you know, group of academic sponsors where you chat about the job is there are there any other groups that you’re sort of a part of, professional groups or informal groups that are related to the job as it were?**

R: So obviously [my institution] being a member of The Russell Group, I’m a member of the Russell Group Integrity forum so and obviously other members of the university are members of relevant elements of that so there’s particularly on this issue that is something that’s managed by the integrity forum or, you know, is discussed by the integrity forum and then obviously we’re members of UK Research Integrity Office or we’re subscribers to the UK Research Integrity Office and ARMA [Association of Research Managers and Administrators] and other sort of more senior members of the Research and Enterprise Division are members of Praxis and the sort of various professional organisations, yeah.

**I: So, when something sort of changes in this space you know, you were mentioning the continued access to EudraCT but like sort if a development happens in this space or if there’s knowledge sharing like what is the primary mechanism by which you would hear about that?**

R: So actually, that’s really going to be more from the National bodies.

**I: Okay.**

R: So, I obviously subscribe to all the various updates from the MHRA, from the HRA, from NIHR. So, it would tend to be more at a national level and UKRI obviously. It’s not always perfect and, you know, sometimes when actually you should have heard from UKRI about changes in, you know, funding contracts and and their kind of ethical requirements around that for example, all we actually hear is from our contracts team at first when they see it and update and say, “Are we okay with this? Is this, is this something we do?” So so yeah, we are, we’re engaged with all of the sources of information to be kept informed about that and, you know, we tend MRHA, HMSC conferences and, you know, obviously at the moment around changes because of Brexit. So that’s all from a research governance point of view, primarily my role is to keep an eye on all of those things but other members of the team are also subscribed to newsletters so we share information internally and then obviously with things like the integrity forum and University Sponsors Association we would share information at the sort of formal visits of those but also there are just, you know, email circulars of the sort of things that come up, problems that people are having or information received.

**I: Great so I think that pretty much wraps up my planned questions so if you have any final thoughts or you’d like to expand on anything else we talked about or if there’s something you think I should have asked but didn’t? I just like to give people that opportunity.**

R: Yeah, I I think the the one other thing I would like to mention. In terms of pressure on staffing, in terms of time of people, you know, who have what is only a relatively, you know, what is only a proportionate of their overall job is managing registration is that as an organisation we spend quite a lot of time responding to freedom of information requests regarding this so since, certainly since the post note enquiry and well since *Bad Pharma* really there’s been an increase in freedom of information requests from different organisations and, you know, obviously they are beneficial and relevant but they’re extremely time consuming for the organisation, and then for us within the team to actually respond with information and, you know, each one is slightly different. It isn’t not there can just be a standard response. The response needs to be tailored to each request and sometimes involves discussions with HR or other organisations if it’s about staffing. So I think it’s a, it is a problem for us and it’s something that that sometimes takes away time from actually doing the work and managing these things and making sure they are updated. From my point of view it would be better if there were one single source for this. If there were somewhere that they could be and, you know, obviously they aren’t going to answers on some of the professional FOI sites, like WhatDoTheyKnow. If rather than managing individual requests there was some way in which this could simply be in a sort of managed way generally available to people.

**I: Right.**

R: I think that would be, would free us up to have more time to actually, you know, kind of chase academics and manage the specifics of it.

**I: Okay great so that’s that’s pretty much it unless there’s anything else? So the one thing at the end of the studies I just want, I always like to offer if you [um] so you mentioned earlier during the consent that you’d like to receive, you know, any outputs from this. Also like, I’m happy to share the transcript with you once I’ve got it transcribed and anonymised if you have any interest in reviewing that?**

R: Yes that would be, that would be interesting.

**I: That might not be, that might be a few months in the future after the holidays.**

R: No, I appreciate it takes time.

**I: But I will make sure I follow up with about that. Let me just note. Excellent that’s it.**