0:00

Okay hi welcome everybody to our translational research ethics applied topics talk uh treats are a short 20 to

0:07

40 minute introduction into various topics and research ethics with an open Q&A session at the end these talks are

0:13

held bimonthly and are recorded and uploaded onto our website as a resource for researchers my name is Nicholas

0:18

Oliver and I have the pleasure of introducing today's speaker Andrew O Brightman he is a professor of

0:24

engineering practice in the welding Welden School of biomedical engineering at Purdue University Professor Brightman

0:29

attending North Carolina State University in Raleigh North Carolina where he received a Bachelor of Science degree in botney and plant physiology he

0:36

then went on to receive a PhD in cellular biology and biochemistry at Purdue University he's long been a BAP

0:41

faculty member representing the bioethics and subject advocacy program at Purdue University campus and helping to connect researchers there to the

0:47

resources of the Indiana ctsi today he'll be presenting on the ethics of using medical students as subjects in

0:53

human subjects research thank you Nick that was a great

0:59

introduction um yeah I am happy to be able to participate in uh the Bap uh program and

1:08

uh The Talk today on medical students as research subjects seems particularly

1:13

appropriate as we're wrapping up a semester um here at Purdue and I know in

1:20

in Indianapolis as well the end of the semester is coming and we're all many of us are thinking about students and

1:26

grades and final exams um but uh this question question is about medical students and their role as research

1:34

participants I'm uh going to talk about a little bit of data

1:40

um let's make sure I can change these slides here at the beginning um I'm going to talk a little

1:46

bit about a little bit of data about medical students as research subjects

1:52

participants um what if any special considerations are needed for medical

1:58

students and that's a question I want to be thinking about throughout and I'll give some ethics guidance from a couple

2:04

of sources and then we can have a Q&A at the end I'm going to try to keep this short Nick you sent a set a really um

2:11

great standard on your last talk I appreciated that and I'll try to do the same but I don't think I'll be quite as

2:18

successful um so this was a re really recent study one of I I really it's the

2:24

only one I found that actually looked at um medical students and their the frequency of requests they were

2:32

receiving in their um during their training for um research and evaluation

2:39

um studies so this was a study it happened a large Medical Hospital in New

2:45

Zealand it's a program where the students are in a six-year program of

2:50

training and so this was evaluation of year two and year three of their preclinical studies so not the first

2:57

year students but second and third year of their six years um they had a response rate of about 28% so 167 total

3:06

students in those two cohorts about they have about 300 students per class per

3:11

cohort um and so uh what they found was in one year uh the cohorts received

3:18

42 uh and 34 respectively program evaluation requests and eight and 10

3:25

research uh study requests respectively uh they also uh looked at

3:31

how the students felt about the all the number of requests they were getting and their participation level and and

3:38

generally the students 70% felt they were receiving too many program evaluation requests during the year um

3:45

they thought the 76 said they should be restricted on how many uh they have

3:51

access or how many uh evaluation requests researchers have access to send

3:56

and um 30% indicated that when they received program evaluation requests it

4:02

was a little stressful um here's the data um that

4:08

shows in U both cases year two cohort and year three cohort the evaluation

4:15

requests were coming in um spread throughout the year but heavily at the beginning of their semesters February

4:22

March and um September October um uh the research requests were

4:28

spread a little more evenly and certainly much fewer but still maybe one

4:33

or two a month of for research requests that the students were receiving um the students did view

4:41

research requests quite differently than the program evaluation requests uh they

4:46

were more likely to engage with research studies and that could be academic or clinical research studies

4:53

44% of participation in these uh in these two cohorts and and compared a

5:01

27% participation in the program evaluations um

5:06

23% of the students said they didn't have any interest in engaging with the program evaluations as compared to only

5:14

6% said they didn't have interest in the research requests and that will come up later when we think about how medical

5:21

students perceive um research generally um as said before the students

5:27

received too many their view was they received too many evaluation program evaluation requests which 30 or 40 a

5:34

year seem does seem excessive to me as well um compared to the research requests about one a month or 8 to 10 a

5:43

year the students were much more likely to rate their first reaction to um an

5:49

evaluation request is stressful then compared to a research request 31 to 20%

5:55

uh for research respectively so um do we need special considerations for

6:02

medical students I think there's three things we can talk about one is students are medical students are an accessible

6:09

convenient human subjects uh research population um as we saw in this at least

6:14

one study students are available easily contacted they are there for a a period

6:22

of time and the um faculty researchers have access to them um second though we

6:30

need to think that students are a vulnerable human subjects research population due to their being in a

6:38

training program due to the faculty student relationships and their professional development we'll talk more

6:43

about that next and then finally I'll come back to this idea that students um

6:49

actually can benefit and uh uh benefit the research and benefit from participation and we'll talk about some

6:55

of the positives uh and potential negatives of therapist partip

7:01

participation so considering medical students as a vulnerable population um

7:07

in the 1998 um publication Beyond consent Seeking Justice there's a big

7:14

section on vulnerable populations and the challenges as research subjects um

7:20

it's necessary sometimes in clinical research because it's complex expensive

7:25

and and highly valued social activity to have a con convenient accessible um

7:31

recruitment population and and a group that you can monitor throughout the course of a study it it simply makes

7:38

clinical research as well as academic research more feasible and certainly academic research that's posed around

7:45

medical training seems to need to evaluate based on the medical students

7:50

but medical students do occupy this middle ground in vulnerability between for example short-term hospitalized

7:57

patients who are constrained by their um hospitalization and um the sort of

8:03

extreme case example of of long-term prisoners and the vulnerability of those

8:09

who are um subject to um limited autonomy and agency because of their

8:16

relationship to the researchers uh among the ways that students do

8:22

differ from General adult population is of course their availability and the greater likelihood that they could be Co

8:28

coerced uh particularly by faculty researchers and manipulated into

8:36

participation so um we also recognize that students

8:42

medical students because of their professional training they have a sense of responsibility to participate in

8:47

research they recognize as part of their training that research underlies a lot of uh Pro progress in medical practice

8:56

um they also understand that uh because of that they're going to be more willing to participate in surveys research

9:03

studies that don't have significant research no more than minimal research risk um but uh because they are first

9:10

and foremost student Learners trainees um there is a consensus that it's

9:16

important to protect their role and their priorities as Learners um and some schools to ensure

9:24

that the students can prioritize their time for coursework um they require an additional review by an associate dean

9:30

of medical education for any protocol seeking to recruit medical students and we'll talk about I'd like to talk come

9:37

back to this is that uh it's it seems only a few schools do this I haven't done a thorough study but um you'll see

9:44

a little data further on that um is this necessary or is it um

9:52

extra so medical students certainly can benefit from participating in research

9:58

they understand research better if they part of participation if they've

10:03

experienced it firsthand um and they understand some of the challenges as well as the role in improving

10:10

medicine um particularly for academic training research um students can

10:17

benefit their own education from going through a study um one uh

10:23

study referenced here Stephenson at all I have the references at the end slide

10:28

was a a study um a endoscopic uh skill and a a

10:34

training Innovation and they used um groups of students and also residents

10:40

and compared them in different um scenarios and found that there was a significant Improvement because of their

10:46

intervention so medical training in that particular field as is done very often

10:52

um for um studies of Medical Practice can really be improved and future

10:59

medical training can be improved if students participate if they don't participate it's harder to judge what

11:05

the impact of that uh intervention might be um it also benefits the students

11:11

understanding of distinctions between clinical research uh biomedical research academic or basic research and academic

11:19

research and they may then choose to participate um differently in the future

11:25

more positively as they've had experiences or support research as they progress professionally into um roles

11:32

where they may have approval or partic participation

11:37

possibilities so certainly a benefit uh for the students um the students um

11:43

actually could benefit the research as well as I mentioned if you're studying academic training practices working with

11:50

students seems essential um but Medical Education and Training um certainly um can uh their

11:58

medical educ and training certainly can increase their uh understanding of the risk or the consent practices in the

12:04

research so they are a more informed uh group of participants they also May

12:10

comply uh have increased compliance with the research protocols because of their medical training and their sense of

12:16

professionalism so those are both benefits to the study however um one of

12:21

the things that came out of the research that's been done on student participation is that participation

12:28

fatigue and general overall stress of the medical students May in fact reduce their compliance or increase even a

12:35

dropout rate from studies they're just too busy too tired or um have other

12:43

priorities so the question that um I'm raising today and I maybe we can talk

12:49

about more at the end but you certainly can interrupt me at any point here I'd love to think do do medical students

12:55

need additional or special protections um over and above what generally IRB

13:01

human subject research um reviews consider for adult general population

13:06

anybody want to chime in with a thought on

13:12

that the study I'm referencing here um from 1985 was an

13:19

interesting report um from Harvard Medical School the the author was um I

13:25

think a seconde medical student representing the student population and they were complaining that the

13:31

protections that Harvard Medical School had had in place for the last something like 25 years were actually harmful to

13:40

the students um even though they were intended to protect them so here's um some of the things that the um the

13:47

students were complaining about uh the early requirements that were in place were so restrictive as to prevent um

13:54

most of the research you know the faculty researches studies from using students so they had to go through

14:00

multiple reviews and other things to um even get access to the students um in

14:06

most cases there was a double review required both by the medical school um

14:11

Administration as well as by the study site Hospital IRB um the students were

14:17

given a policy statement at the beginning of the year about participation which appeared to be quite

14:24

negative about their enrollment or participation um uh another ISS was the

14:29

students health and well-being were considered high priorities in addition to their time constraints to the point

14:36

where some many of the studies required the students to have a special medical exam before they could participate in

14:43

this in any research and then um payment for participation was primarily

14:48

restricted um they felt it was too coercive because of the large debt of most medical

14:54

students so the changes that they were suggesting from the students view was to

15:00

eliminate this perceived paternalistic attitude um from these policies to um

15:07

eliminate the double standard review of protocols and um treat medical students

15:12

as responsible autonomous adults and utilize the same standards for review as with all adult

15:17

populations so that was their perspective that was back in 85 and and certain um changes were implemented at

15:25

that point um and I was curious to know what IU school of medicine was doing

15:32

currently um the guidance that I was able to find about student participation

15:38

was fairly simple there's four points um recruitment of students into a study by

15:44

their structure has the potential to be coercive that's their understanding I

15:50

think agreed upon um and for this reason teachers should not use their own students as subjects of research if it

15:57

can be avoided so use students who are not in your classes um if researchers do wish or need to

16:05

enroll their own students in research uh projects studies the participation and

16:11

participation involves students doing something extracurricular to their activities the researcher is required by

16:17

the school of medicine to obtain permission from the students and additional steps to should be taken to

16:23

prevent students from feeling coerced into participation um and there's not a lot more detail about that but um there are

16:30

two more pieces one is researchers should uh arrange to have permissions um

16:37

and data collection and I think recruitment as well uh done in such a way as they will not know a student if a

16:43

student is participating and will not have access to the data about participation um or outcomes until

16:50

grades have been entered and finally um if course credit is offered in exchange

16:56

for participation and all alternative means an alternate means of

17:02

earning equivalent credit for equal time effort should be made available to all

17:08

the students subjects so these Alternatives must be carefully reviewed to make sure students are not being coerced into being coming subject so a

17:15

lot of emphasis from um this guidance on coercion as the primary problem that um

17:22

students are um subject to extra considerations so question is are these

17:30

protections sufficient to uh for medical students to participate in

17:35

research um anybody want to add a thought here I have a few more tips and

17:42

guidances to come but I'm just curious if anyone's got questions or thoughts at this

17:48

stage if not that's fine I do okay Peter I I will say I think these sound

17:54

reasonable I I know Nick cistus that's interesting that he wrote that paper he was very young then he was I think a

17:59

undergraduate but anyway I'll I'll figure that out it's another time but you know these These are nice

18:05

requirement and I I know you titled your talk students medical students being used in research but as we I think you

18:10

know better than I do being at Purdue not so much having medical students as much as other sorts of student there are

18:16

Fields where student participation in research is very common and often as

18:21

part of course credit and that's where I think some of these concerns are raised about about you know coercion in that

18:28

you know Professor wants you to participate then you kind of have to if you want to do well in the class and

18:33

these seem like reasonable restrictions to try to keep that from being either implied or or reality so I like them

18:40

from starting I'm not crazy about the limits on paying medical students as I've you know we've talked before on

18:46

this group about you know whether paying well is coercive um even for poor

18:51

medical students um I'm I'm sort of on the side that's not coercive to pay well but uh but certainly to withhold grade

18:59

or make it feel like your grade is going to be dependent on doing research um but I'll stop there that's that's just since

19:05

you asked for comment you know you'll never get me you'll never I'll never pass anybody yeah thank you Peter anyone

19:12

else want to chime in I guess this is as a medical student I find this very interesting thinking

19:20

about um I don't feel like outside of like yeah if my grade would be in Jeopardy I don't feel like I need extra

19:26

protection in terms of research I mean quite honestly sometimes it can get annoying if we get a bunch of emails

19:32

about studies but I'm like yeah so what like you're in a setting that's easy to recruit from like it kind of makes sense

19:38

to me um if anything like part of me is like as a researcher what is it going to

19:43

take to like how actually help recruit medical students when you get so many as a

19:50

medical student like get so many request for studies and I think like not only like my brain doesn't even think about

19:57

like how to not be coercive but how to make your study more appealing to medical students to want to participate

20:02

like kind of like the exact opposite of the question that you're mostly raising here but like I'm like I don't feel like

20:08

I need extra protections I don't feel like I'm more vulnerable than somebody else other than the fact like I guess because of grades

20:14

but I don't think I've ever had that concern when seeing a study come through my

20:19

email thank you Clayton thank you yeah I I think there's a couple things that we

20:24

can keep thinking about Peter you raised the question about payment um I didn't find any other research particularly

20:31

around payment so that was an interesting you know back in the 80s I guess there were there were some

20:37

problems with payment issues um but maybe that's been largely resolved and

20:42

this idea that um I think I think the key thing that people are considering is

20:48

um is it just a convenient population or is it the right population to study and it depend you know clearly depends on

20:54

the research Clayton your point of um targeting Medical students because they're the right population and making

21:01

it clear that they should participate because you do if you get 10 requests or

21:06

five requests a year how do you decide which ones to prioritize and if it's just because you're hanging around

21:12

you're available or is it because it may actually um make a big difference to have a medical student participate I

21:19

think are are key ideas and and my participation in irbs and overseeing

21:25

student as subjects those question aren't typically considered at all um

21:31

it's just you know considering students as um potentially coerced and um but

21:38

otherwise as adults so um yeah so uh another um set of guidance though

21:45

recently um I I discovered this this is the University of Pittsburgh medical school um they have eight um points of

21:53

guidance that I wanted to address and some of them are a little more um restrictive so um they recognize the

21:59

heavy curriculum burden on medical students and so they actually have developed specific policy for enrollment

22:06

into research protocols they have a research on medical students Review Committee that gets the pro requires the

22:14

review the protocol before it can be submitted to an IRB so they're doing the double review um their goal additional

22:21

review goal is to balance the needs of the researchers with interest and availability of medical students so maybe they're asking that sort of

22:27

question is is this really about medical students or is it just convenient because you have all their emails or you

22:34

have a way to contact them um their advice or requirement is a medical

22:39

student may not be required to participate in research for course credit so embedding the research into a

22:45

course um and not giving the students an opt out is is not allowed um but if you

22:51

make it optional extra credit um you have to have the comparable non-research

22:56

alternative similar to IU School of medicine um um the the minim to minimize

23:03

that potential for coercion which seems to be the the biggest issue to consider

23:08

um then the alternative to research for credit must be equivalent in time effort

23:14

and fulfillment right you can't say well you can do a research or you can write a 25 page research paper on some topic

23:22

you're unfamiliar with you know the the that's not equivalent time or effort or fulfillment so um

23:29

I think that's the hardest one having done a number of studies with students is to make Alternatives that seem um

23:37

equivalent in terms of time effort requirement fulfillment and student learning right because students learn

23:43

from participation in research can you create something uh uh an alternative that they can equally benefit from

23:50

learning and participation um they emphasize that students must be free to withdraw from

23:57

participation at any point and I think every IRB will um reemphasize this point

24:03

as with any human subject's adult population they have to be able to withdraw from the participation

24:09

particularly if it's a course um without penalty and that means they get full credit for participation even if they um

24:16

enroll and only complete part of the study um which is sometimes hard for

24:22

investigators to uh deal with um U recruitment must be designed to minimize

24:29

possibility of undue influence so um recruiting from a broad base of individuals rather than from your own

24:35

class or from partic or personal solicitation of specific students those are um generally seen as um um more

24:44

coercive and finally um investigators should not enroll students from their own classes when the research involves

24:51

greater than minimal risk uh particularly without the prospect of direct benefit to those students so

24:57

that's University of Pittsburgh medical school there eight special requirements

25:02

for enrolling their medical students um an additional set of 12

25:09

recommendations that I think are similar but useful to consider this was a 2018

25:15

paper from Canada on medical uh student enrollment in in primarily um academic

25:23

research projects um because that it seems to be the majority of where students are enrolled um and I think

25:31

these are some good tips to keep in mind if you ever want to do a study um with students is first determine if the study

25:37

is a program evaluation or an actual research project because the um oversight requirements the consent

25:43

requirements are are different um the difference there if it's human subjects

25:49

research that's typically generalizable data that is required to be

25:54

generalizable da data that's going to be um published in a widespread um

26:00

dissemination whereas a program evaluation is for local use only and the data is specific to the scenario of of

26:08

the study of the program um it's important to verify if you're going to

26:13

use um secondary data uh secondary use of data that's already been collected

26:19

verify if you need to get consent from the students so um if you collected some data in a course already and you want to

26:25

do a research project on it in most most cases if the if it's deidentified or

26:31

anonymized um consent is not needed but um sometimes furpa requirements because

26:38

it's um in an educational setting the family education rights and Privacy Act

26:43

requires instructors to get consent um for student data to be used um but that

26:49

needs to be verified um you certainly want to inform the students of all the

26:55

privacy and consent measures that your research involves you want them to understand um what you're doing to

27:01

reduce any potential for coercion and also for biased responses you you

27:07

certainly don't want your data to be impacted by students who are just telling you what you want to hear

27:12

because they think you'll give them a good grade um that kind of ruins the point of the study so uh uh detailed

27:21

information informed consent uh about privacy about um consent practices um

27:27

and that involves typically consent by an independent team member rather than the faculty them member themsel even U

27:35

if it's not your class specifically if you're a faculty member um a standard of

27:40

practices defined a third party to do recruitment um and consent um so there's less conflict of

27:47

interest in coercion um there's even a project um research project uh

27:53

recruitment management um for um participants software programs that will do this

27:59

electronically uh separate from um um the the researchers uh that that a

28:06

member of the research team can run I I actually haven't worked with any of that I don't know if anybody knows any good

28:12

programs but you want to have a a a wellestablished and verified program if

28:18

you're going to use one of those but that's a a good tip for um making

28:23

independent Recruitment and consent practice um tip five is uh ensure the

28:30

participation remains confidential throughout the study so particularly if it's longitudinal studies if the cohort

28:37

starts to decrease uh and they're becoming more professionally trained um or advancing

28:45

in your program in the training it may get harder and harder to keep the data

28:50

deidentified or Anonymous so you have to think about that for particularly for

28:55

long longitudinal studies um in any case you want to limit personal data

29:01

collection to the minimum required for the study uh anonymize the data if

29:07

possible uh and um or de identify it um if you still need to have it linked to a

29:14

code uh before it's released to the research team and and to keep it that

29:19

way again with third-party um deidentification if possible um this is

29:26

important as um you're dealing with different kinds of data but protect against any possible reidentification of

29:32

data so again with smaller cohorts strict inclusion criteria uh it may

29:39

become possible once that data is is ready for publication for someone to trace back um based on gender or based

29:47

on um the training site if that's included in there and the cohort size in the year then it may be become possible

29:54

to re-identify certain um participants individuals and um you want to protect

30:00

against possible unauthorized access so data security particularly Digital Data that's being

30:06

collected um data breaches uh really erode trust in research not just in the

30:12

individual researcher but in the whole research uh Paradigm and and process so

30:18

that you get less participation if people don't feel their data can be protected um the last four are avoid

30:26

making any research study part of mandatory training so this sort of is um

30:33

if you implement an intervention that's mandatory before you and then you do the study on it you're sort of avoiding any

30:40

you are avoiding full consent and it actually may prove to be a harmful intervention to some who don't have the

30:46

option to uh um to um withdraw or to not

30:52

participate um this is an important one I thought considering um using breaks in

30:58

mandatory training schedule so if you're working with medical students and you find out their training schedule and they have a two week off break and you

31:04

can give them a chance to participate in some study at that point um it certainly

31:10

reduces their stress and increases their possibility of participation so that could be an efficient way to um run a

31:17

study if it's possible to do it on that time frame um certainly avoiding course

31:22

credit for participation is a general practice uh that um is best practice it

31:29

offering course credit complicates consent coercion and selection bias the thing that I think Reacher researchers

31:36

don't think about is oh I'm going to offer this extra credit well often then the cohort that decides to do it are

31:43

either those who really are struggling and need the extra credit or those who um uh are just looking for a good grade

31:51

and not really interested in the research so you could get some selection bias there and finally um a review by an

31:58

educational research committee um even though those committees seem to be rare now um one study

32:05

recently of um the top medical four top medical um education journals indicated

32:13

that only 5% of research studies had been reviewed by an education research

32:19

committee these are academic research versus clinical research um but those kinds of reviews could supplement what's

32:26

being done by an IRB who irbs often um expedite educational research and don't

32:33

um do the deeper dive on human subjects research um considering these

32:38

constraints of medical students so that's the data that I have um pretty

32:45

close to 30 minutes how's that Peter um uh I but I want to open it up just to

32:50

see if people have any more thoughts about um thinking about special considerations for medical students or

32:57

any students um as we've looked at as research participants do do we need

33:03

special considerations yes no maybe irbs okay Nick go ahead sure uh this was

33:11

actually just on your previous slide you said that only five% of these studies were reviewed by an academic review

33:16

board and that the irbs usually just expedite this are you saying that IRB should sensibly take a closer look at

33:22

these studies or are somehow failing the subjects in some way

33:28

I wouldn't say they're failing the subjects um and I have very limited IRB review but I've participated in IRB

33:36

review of Education these are I'm talking about academic research on with

33:41

students and student populations um I do think that um medical students

33:49

or I would say any students who are in a specific cohort training program um may have some special

33:58

considerations um versus a study that looks at all University students or is

34:03

open to you know all students who are in a you know liberal arts uh

34:10

program um and I don't think I haven't

34:15

seen IRB review um asking questions about that kind of um coersion other

34:22

than just the standard is the student in your classroom kind of how are you protecting the research is from knowing

34:28

who's participating so I'm not accusing the IRB of of um undo

34:35

um uh limited review but a lot of those studies do get expedited review and

34:41

maybe are missing some things just wanted to be provocative got it thank

34:56

you yes go ahead um Clayton I think no it's Colin sorry oh

35:04

uh so thank you for your talk it was really interesting uh I'm really interested in uh especially the boundary

35:11

between the kind of Qi like uh course Improvement type projects which I do

35:18

every year with all of my uh teaching um but have no intention of publishing um

35:23

but the thing that I'm really interested in uh that's kind of my questions SL comment for you uh is about privacy

35:31

which I was happy to hear you bring up and I think it's also related to what you were just saying about the distinction between kind of more

35:38

specialized training uh levels of training and then these really broad uh schoolwide studies when I was in grad

35:46

school uh I participated in a study and I will say it wasn't coercive but the money was 100% the reason that I was

35:53

willing to do it uh and it was just an interview study with some soci sociologists on campus um but they asked

36:00

pretty pointed questions about our experience as a cohort and it was all

36:06

about networking um and then my cohort was 11 people they were doing it at a few

36:12

different sites but there were all sites that were equally small cohorts um and for me it completely

36:20

prevented me from saying a lot of things that I would say because I knew that there was no way they'd actually be able to anonymize it um

36:28

they like consistently reassured me that they would but then as soon as their first publication came out the very

36:33

first quote uh was from someone I forget exactly how they

36:39

disclosed it but it was they even said something like I think they even said which campus it was from they said that

36:44

the participant was a male um and the quote was something about uh playing DND

36:50

D with friends over the internet and I'm like well that can be only one person in my cohort you know and and then they

36:57

gave a pseudonym and so then you could just track every single thing this person said throughout the entire paper

37:04

um and I wanted to flag that both because I think it's important for uh

37:10

for the participants like this person didn't care luckily uh that their

37:15

comments were so identifiable but you could certainly imagine that that could be a problem um they did go on to say

37:20

that like talk about being depressed and stuff like that kind of sensitive stuff um but on the other hand like on the my

37:27

side of the story uh how damaging it can be to the data that you're collecting um

37:33

even if you're trying to make these guarantees um at that kind of a level um and the the way that that plays into the

37:40

hierarchy of of educational settings Colin thank you for raising

37:45

that uh I I wish I could have found more um actual research on that topic because

37:51

I've seen it in my own research and um what the only comment that I saw the

37:57

papers I was reading was that um that was re reaffirming that students often

38:04

consider some of their information as more personal sensitive or embarrassing

38:11

uh than the researchers might you know so maybe somebody doesn't want other people to know they play D and D right

38:17

with their friends or maybe they're in a professional training program and they don't want people to know other issues

38:23

about them that you know maybe are publicly acceptable but not in that context so um this idea of anonymizing

38:30

or de identifying is is problematic uh um I've and several of my research teams

38:37

when we're collecting um smaller student cohorts you know something that's closer

38:43

to 25 or 30 um even if they're drawn from different uh groups as you said you

38:49

know maybe multiple sites how do we de identify and yet if it particularly if it's a qualitative study how do we then

38:56

present the data so it's not re-identifiable so things like uh mixing

39:02

genders mixing names not using names because sometimes names are we've started using um um pseudonyms that are

39:11

not identifiable male or female gender names um in the population because

39:19

sometimes we have you know in engineering but we may have a cohort with we try to get equal genders but

39:24

we're often skewed very heavily in one way um as you might imagine so and then

39:30

not identifying which cohort they're in certainly as you said not identifying a campus or a class or a group that

39:36

they're from because reidentification becomes so much more easy particularly

39:41

for students who are participating in that and so the data gets skewed if they don't know that you've done all your

39:48

homework to protect them and protect their responses so you're you're absolutely right it's it's both the

39:54

human subjects protection but you you want to look at how that both selection bias on the front end and then response

40:01

bias is going to be impacted by your ability to anonymize the data and

40:08

anonymize the recruitment participation so it I don't see enough research on

40:14

that so maybe maybe that's a a project that you know more about um maybe you

40:19

are doing some research in that area I don't know Colin but I'd love to see more

40:25

there may may I uh thank you first of all very much indeed for the this the

40:31

presentation uh going back to the University of Pittsburgh this this sort of oversight committee uh that

40:38

supposedly protects the students um based on the commitments they have and so on and so forth and it sort of also

40:46

touches sort of inversely on the as we all know everyone's right to withdraw uh

40:52

from a study for whatever reason without prejudice and so on but one thing occur

40:57

to me perhaps this oversight committee if it has a gatekeeper responsibility perhaps it actually discriminates

41:03

against individual students who might want to participate in the study even

41:08

though the committee decides that overall for example it's too demanding of time but we all know everyone is

41:14

different and some students may say look I can do this I'd like to do this but the committee isn't allowing me to do

41:23

this indeed um that I think was the argument that um the the 1985 paper the students

41:31

at Harvard Medical School were saying you you can't lump us all together into one group as medical students we have

41:38

very different um life circumstances experience capabilities um and it does seem overly

41:47

controlling paternalistic gatekeeping um for an additional review with such

41:53

stringent requirements at the same time um I might argue that an educational

42:00

Review Committee um might think of the students in some ways that a standard

42:06

clinical IRB would not and um so there if it I think you want to find a balance

42:12

between those two and not go in the direction you're mentioning I agree of of being overly restrictive so that

42:18

students who would gain a great deal and the research would gain a great deal from their participation yeah thank you

42:26

yeah thank you but what's interesting Andrew um is also

42:34

you know this this general question right of balancing the protection of subjects against the advance of Science

42:39

and and I think these these issues come up here like like you were saying about the medical streams how much protection do they need versus how much paternalism

42:46

can we stand right um I I I appreciate that that balance there you even brought

42:51

it up also in terms of whether should be an additional review of you know potentially minimal risk research which

42:58

maybe would be a appreciated source of income for a medical student you know and say well no this isn't a very good

43:04

study or something or like Colin was saying you know we do lots of you know classroom evaluation which which it

43:10

would be it seems very I'm GNA say it seems whiny on my part for the medical students to say we don't like being

43:16

asked if our classes are good like well I don't really care if you like it it's really not about research it's about

43:22

improving your curriculum maybe maybe it'll be published so it's research maybe it's not so I just I I really love the these topics that you've raised I

43:28

love how you did it can I ask a question zil so you said you have done research with your students so are you talking to

43:34

because I those who don't know Andrew he he does device research so he's talking about implanting defibrillators in his

43:40

students I assume it wasn't that I assume it was some kind like like like temperature gauge on their skin or something what sort of research are we

43:46

talking and and what sort of issues did you face if you don't mind my asking yeah so um my research team um in the

43:56

last decade or so has focused on um how to teach ethics to Engineers so

44:03

we've not actually used any devices um that said uh I also review and consult

44:11

for our uh senior hapstone design projects where um the students are

44:18

designing their own medical Technologies and then testing them either on themselves or on their uh colleagues and

44:24

so I do do some um Consulting and some advising around you know is that does

44:30

that study need um an IRB review of your protocol or is it simply device uh

44:37

testing so in the device world you're right um similar to quality improvement

44:44

of programs something that's focused on non-generalizable data it's local when

44:50

the students are trying to determine if a if a new device is working properly they need to test it on a

44:57

um they're not trying to collect generalizable data here they're just trying to see does this actually work or

45:04

does it work how does it work and can we make it better most of those are not considered research and but the research

45:12

that I do in the classroom is often um it's been NSF National Science

45:17

Foundation funded research to try to develop generalizable U protocols and and

45:24

pedagogy for better teaching models um particularly around ethics ethics of

45:29

engineering medical Technologies because we're trying to train um biomedical engineers and those who develop medical

45:36

Technologies to think about them in better in more ethical ways does that

45:41

help answer your question oh yeah no no I didn't mean to accuse you of using device research but I guess I guess it does sort of put a point on it right

45:48

like um well first of all I would say the Colin kind of rais this too I I mean we are not the we we as ethicists and we

45:55

get called by the bioethics program of the ctsi we're not IRB so so the ethics questions may still be there

46:02

right if a let's say a faculty member is you know has some intellectual property he's just doing local trialing on his

46:09

students I would think the same ethics issues would arise if they you know

46:15

coers their students into letting him strap that thermometer on their arm even

46:20

though it's not officially researched so the IRB is not involved do those issues come up for you do you ever feel like

46:26

you have to give an ethic advice which is not around IRB

46:32

um rarely um but it is always a concern um just for that I would say one of the

46:40

most important things for any engineering department but particularly biomedical engineering department is to

46:46

have a very um Co comprehensive culture

46:51

of safety and so um we do a lot of training the student students complain

46:57

like you said they whine we have them through all kinds of

47:03

training staff go through all kinds of training faculty go through training you know what's safe to

47:09

do what's safe to use um we as a department I I'm just

47:16

giving you some details indemnification because we are reviewed by radiological Environmental Management and OSHA and so

47:23

all these safety constraints are in place in all of our laborat iies and our classrooms um and we know that all it

47:32

takes is one student to get harmed in some experiment and guess what the

47:37

research is GNA stop um so I think the general attitude is if you think it's

47:45

going to be too risky don't do it and um and and find a way to to do it that's

47:51

safe and um so so I it's not a it's never been a problem in our school uh

47:57

it's always a consideration and a concern that needs to be addressed and and you point out rightly that those are

48:03

ethical issues safety issues um that influence research but not at the it's

48:10

usually in the development stage before it becomes a research protocol and goes to the IRB great answer Andrew thank you

48:16

beautiful yeah thanks everyone I have um the the

48:22

references to the the citations they're listed at the end of my slides and also

48:28

again U citing um the center for bioethics and the Bap program if you

48:34

have additional questions about this and you want consultation contact Nick um

48:40

and he'll direct it to the right person to give feedback or consultations this

48:46

is a great service to any researchers um that um will help you I will make your slides and

48:53

references available on our website when we upload this recording okay thank

49:00

you thanks again Andrew great take care everyone thanks for the questions

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