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I'm Peter Schwartz I'm the director of the bioethics and subject advocacy program at the Indiana CTSI and we are

very pleased to present our next TREATs talk translational research ethics

applied topics talk they were very lucky to have our BSAP faculty member Andrew Brightman Dr.

Brightman is a long-standing malik I can say after a few years in job Purdue

representative on visa and he does a lot of work for us with engineering with

Purdue and other areas to be staff and with thrilled to have him here today he's the associate professor of

engineering practice at the Weldon school of biomedical engineering at Purdue University and he will speak to

us today on a topic I'll let him introduce it's a topic we've talked about within BSAP over the years and

we're happy to have this short introduction shortish introduction to the topic for those who face this

question in our own research Scott when does for example education become research so I'll hand this over now to

Dr. Brightman thanks Andrew thank you Peter and thanks for everybody joining us I wanted to bring up this topic it's

of interest particularly to us in engineering biomedical engineering where

we run a student design projects as a core element of teaching our engineers

about designing new medical devices and I'm hoping that there will be some

crossover relevance to other kinds of projects where students get involved

either as drivers or some form of participation the questions we're going

to address earlier about the student projects themselves and particularly

when students are doing the research on themselves which was an interesting

situation that's come up in discussion to a number of points so let me just get

into a few slides to give you some background here you know the next

generations of medical devices and medical technologies are emerging even

in classrooms today where we're teaching our engineering students how to do the design process but a

number of them take those very same projects on to commercialization the way

that we set up our teaching of medical device design is they start as juniors

in the biomedical engineering program they contact clinical people industry

medical device industry folks and say and what are the problems that are not being addressed or need to be solved and

can that we might be able to address and we try to encourage them and this is just not at Purdue but across the

country and biomedical engineering encouraged them to find real-world problems to attempt to solve granted

that maybe only one or two of those out of each biomedical engineering program

turn out to be something of real use they do pose some ethical challenges and

particularly for this human subjects research so here's an example from the University of Texas at San Antonio the

student teams developing a vein finder technology

I don't know this team specifically but they received a grant funding they

obviously had from NSF they had to put together a proposal there's going to be

a requirement for them to publish and present it certainly even to get to this stage they've probably presented at some

national level regional and national level competitions and it's not click

Euler system but it's very likely that they're testing of the technology was on

other students or even on themselves and more familiar with this team meeting

which is from Purdue it was a team that last year submitted their design project

to the NIH the NIH had a

partnership with an agency venture well that supports biomedical

engineering design of medical devices and so they came up with a solution to a

problem which was getting pediatric sputum samples for measured looking for

pediatric tuberculosis particularly in developing countries and the way they

designed this was a kind of a sampling tube that could the idea is that we pass

through the digestive system but it would be triggered in the stomach and collect some examples that could then

pass to be captured and be tested this

was not tested has not yet been tested on any human subjects but the system

was tested preclinically and they presented both business plan competition

and at this national competition and were first place winners and are taking

this forward into commercialization currently but that that neither of those

projects are particularly focused on invasive technologies we took don't

typically allow the students to do sort of invasive technologies at this stage but they can do proof-of-concept but

some of the issues that come up as they're preparing their projects and imagining what they might be doing and

then as they're actually in their senior year developing the devices and part

of that development is to test the prototypes are some questions that have arisen over the years for example if

they're testing with human subjects and they decide to test them on themselves or their classmates are those students

considered human subjects and is that testing protocol need IRB oversight and

a major part of that is this is in a course in but if they're intending to do

something more public with the data and they're collecting it systematically is

the human subjects testing they're doing really actually fall under research or

is it feasibility is it device testing we'll talk about that issue another

issue that's come up is this are doing it intercourse and in order to get a good grade and to satisfy the

requirements for graduation these seniors often need to collect human

subjects data for their project and then if they're doing it on themselves where's the line around consent with

under coercion because there's clearly some benefits that they might lose if

they didn't collect the data that they needed so we'll talk about that and then

the final piece is maybe less of a bioethics direct principle question but

it certainly plays into making some decisions because the students have a very limited time to work on these

proposals and what we're finding is if they even sense that there might need to

be some IRB protocol approval and they know that those can take months they

just basically abandon that project and say we'll do something else or we'll only do this aspect of it a very limited

component which again limits their ability to test real-world problems in

some cases and so we don't want to delay or even derail projects that could have

real impact so how can we determine early if it's going to need approval

particularly during that previous year in their junior year third year when

they're coming up with the project can we have some way to help them determine that and get a protocol approved for

testing before they go into their senior year and that's up maybe a more a

logistics problem but it does I think speak to the sort of negative side of

that is sometimes protocols are not submitted for review and people decide

that it's not human subjects research because it would be inconvenient to

determine that and so I think that's where this plays from my perspective into the decision-making process in and

I'll just say my role as assistant head for academic errors in our particular program and I

know this is true in other biomedical engineering programs is you know I may be the only one who's paying a lot of

attention to these bioethics human subjects issues the faculty members who

are so focused on innovation can get a little bit of a narrow focus on

technology developing we so we go back and forth about whether something should be considered human subjects research or

not and I think there's a lack of clarity and this is the point of which I

came to back to the t-rex to consult on it a couple years ago to get some

insights and so what I'm presenting is some insights from that consult and

my experience and hopefully it will generate a conversation that I can learn more about this and it could spread to

other sorts of projects so here's a case that I thought would be useful to think about as we're going through some of

these discussions so new wearable sensor

technologies been developed uses acoustical sensors to monitor human

vital signs a college student team proposes to use a tiny acoustic sensor

attached to a thin polymer film that will attach stick to the body and can

stay there the device would have the ability to recognize for example sounds

of heart valves opening closing recording electro Maya Graham's muscles

heart muscles particularly would be able to potentially detect heart murmurs blood clots or any sorts of obstructions

in the flow so there'd be flow recognition and it could even detect

some level of spoken language words because it's recording you know in the

chest and close to the vocal cords so to get the you know the a grade the five

students want to test this device that they're developing with some 24/7

recordings maybe for a week or so or two and they're going to test it on

themselves and then submit that data to a design competition and publish it in a student research

journal so some of the issues that come

up are you know it is this human subjects research are the students

themselves human subjects is a class it's being presented in the design

competition and a student research journal is that generalizable knowledge

is it really research-based so let's go to and then the other issue where other

students consenting under coercion because they're trying to get an A in the course and collecting this data is

really important to proving that they've got a functional device that they've done their engineering well so here's

some ethical things to think about you know that seems the common

rule states you know all researchers have to follow the guidelines CFR 46

part about 45 part 46 seeking protection human subjects studies and that includes

when the researchers themselves are the subjects of the research that does

require IRB pre-approval so it sort of points back to yes the students if they're testing on themselves we have to

determine first is this actual research but if it is then they would likely be considered human subjects it doesn't say

anything about whether this is in a course or not and most of the reading and review I've seen holds doesn't

create a distinction there but later we'll see that some universities do the

Purdue IRB human subjects protection

documents suggest that faculty students and staff any of those that are

involved in any sort of human subjects research are required to comply so equally stating that students are not

outside of this requirement and later will even discuss at the end I'd like to

discuss the fact that maybe as students who are in XP researchers they might require even

higher level of supervision and oversight because of their inexperience generating a higher risk so keep that in

mind so the key definitions from our 46

research is systematic investigation but which includes testing and evaluation

and it's but it's particularly designed to develop or contribute to generalizable knowledge so there's some

key things as most of you are familiar with it the systematic investigation is

what needs to be really understood and the generalizable contribution to generalizable knowledge the second

component is human subject a living individual about whom and investigator

again whether it's a professional student is conducting research so if you

determine it's research and you've got a human subject who's alive and you're collecting data through some sort of

intervention or interaction with the individual or you're collecting identifiable private information so a

couple of things that come up are so they're testing a device in this case a

sensor that's intended to collect human vital signs and information about unions

it potentially could even collect some sort of identifiable private information if it's recording speech or it's

identified who the test subjects are in the data collection but the question is

on some of these cases maybe not this particular one is when is the research

about the device and when it is about the subjects themselves are we

just getting some information that says whether this device is working or not

and how this technology is functioning and that's consider could be considered

generalizable knowledge it can be published and others to build on that information but it's generalizable about

the device and not about the subject how many subjects do you need to test with

the device for it to be generalizable if you only have five students is that general generalizable

population what could you learn from that and then how might the data be

collected in a way that is not attributed in any way to individuals so

for example if the students collected their recordings individually they each wore it and then they wore a device and

then they uploaded it to a anonymous database so that no one including them they could only know their own data and

they didn't know the other four subject data then it would really be a in a sense there's a possibility of creating

anonymous database that could be used to evaluate the technology but not be

generalizable about this subjects so those are some questions that we argue

louder to discuss a couple of other things about private information this is it the point is that includes behaviors

as well as particular functions of the human subject

it's private in the sense that the person is can reasonably expect that

it's not going to be made public or it's not individually identifiable so talking

about the possibility to create databases of information that might be

completely anonymous in then therefore not the individual identifiable in this

case obviously a recording of someone's vital signs the students believe that

it's going to be made public if they have consented to that the question is

you know at what level of identification of themselves with that involve

interestingly other folks have commented differently and so it's that you know

while we're there looking at the common ruler that CFR here's an example the

Society for science and the public which is supporting clear understandings for

students research projects they have a whole section on student research projects they suggested some studies

involving humans are exempt in this case they one of their lists are student designs

inventions prototypes and computer applications or engineering design projects in which the students the

student is the only person testing the invention prototype and the testing does

not propose does not pose any health or safety hazard so they make a distinction

which I actually haven't found that distinction anywhere else but it's interesting it's um a you know published

but I think that that exemption would be more my anecdotal information is that

many biomedical engineering or other engineering programs would sort of take

that position if the students are testing on themselves and it's in a class even if they're going to publish it later it's not really research it's

not enough data to be generalizable even though they're going to publish it

doesn't propose any particular health or safety hazard you know visualizing the vein in someone's arm that's maybe no more

dangerous than taking their picture taking a photograph or recording them on

a video camera while they're speaking wearing a KU Stickle monitor I think

that runs on another step level I mean what if you do in fact detect some heart

murmurs or blood clots or you're recording private information I think

that pumps the level of risk up a little bit even if the device itself is

determined not it's malfunction would not harm anyone it would simply just

fail to record something but we do have devices which in fact if they were to

explode or to short-circuit could potentially not necessarily

short-circuit way to I have an electrical failure some sort could potentially burn the skin or cause a get

up there in the ear or somewhere else could cause a problem so some of the

projects do have health or safety hazards obviously they would not fall under this exemption

interestingly a back to the part 46 minimal risk probability of magnitude of

harm or discomfort anticipated in the research are not greater than any of

themselves that ordinarily encountered in daily life that's the standard definition or in the performance of

routine physical or psychological examinations or tests so we just want to

keep that in mind when we're sort of saying what is minimal risk what is no health or safety hazards and doing risk

assessments is an important piece of the engineering design process we want them to understand both the risk to the

subjects and the risks of failures whatever they do design failure analysis

to see how the device might fail and what could happen interestingly Purdue

IRB does give some examples of research activities and some non research

activities which while their determination of human subjects research

I felt was pretty clear I found this list confusing to some degree so they

are saying some examples of research activities obviously formal investigations and experiments but

including also pilot or feasibility projects exploratory studies student independent studies directed projects or

dissertations and some demonstration activities again I'm not sure how a

demonstration activity becomes research generalizable knowledge they don't explain it that's exactly what they say

and then they also have some non research which include classroom activities that teach research

methodologies or simulate research activities so I think our engineering design courses fall into that realm

their classroom activities their teaching research methodologies they're stimulating research activities some of

them turn out to be actually research and so it's not clear from this

definition where to draw the line I don't know if that's helpful activity is

required for quality assessment or quality improvement not meant to contribute to generalizable knowledge so

sometimes we are determining functionality quality data quality or improving a device and

then the third one raises this question if you're doing interviews of

individuals so collecting individual responses but the questions focus on the

things and not on the people again then it's not considered human subjects

research so I'll keep going through this

but please interrupt me if you want to have questions or dialogue writing it so we can come back to it at the end I guess but I'll keep going through so I'm

some of the ethical issues yes where you just over further under what yes and I

think it's where you get a very blurry line I am imagining and where I've seen

it used in teaching myself and by other faculty members is you would give the

students a set of data that's already been collected everything used and you ask them to do some sort of analysis or

you give them a device that's been tested and use that you collect the data and and you see or you say design one of

the things we do is design an experiment that would help determine the answer to a problem that you you've now learned

about this material property or this device and you want to know something new about it how would you create some

new information and when you get to that point if they're creating new information and they're testing

collecting that from individuals in human subjects you really have to ask okay when does it become when does the

data you collect get to a publish of quality are they going to generate figures and graphs and put it in their

report yes are they're going to put it into public knowledge and say this is going to be accepted by peer review

maybe not we've had several cases where the courses that are stimulating

research actually they publish a paper from the course and it goes into a peer-reviewed journal we're going to have

going up John Bowman it's going to comment there's actually no

address both have some hard questions about generalizability yes and about the idea of systematic

investigation I like to post on the end finish and I think you really want to go down John they really want to ask these hard questions that are

changing out their common rule I think too although it'll be a good guide to pull for us and for people watching and

he's got a great but I noticed I mean I find interesting the notion of simulate research activities so I've been

involved in the IRB review of studies of physicians and medical students to test

knowledge gaining through the use of a of a simulated body and so forth however

we did get one time they wanted to test the quality of the simulate

simulated entity assembly not of the purse not of the operators learning

skills techniques and we said that's not human research because Isaac pointed out

before the data being collected is not about the human okay and so I mean that

fits in there a lot and I think that might be something we'll come back to a lot when we go and ask about a specific

activity is it a simulated research activity on the simulator in a versus on

the learning or experience of using it we're staying also with other

indications for all the vice testing whether research is on the device it's not on the people wearing devices he

does that come into play in deciding whether the I be involved with teams of users at all and that's much broader

than just a question person who does testing devices located I'd love to hear more John why do we do that the end is

okay there of course right off center great thank you yeah so I want to go back we talked

about sort of the first two are they considered human subjects students testing on themselves in a class setting

I think yes the question is is it research if it is then they would be

considered human subjects the the third one is are they consenting under

coercion here and I know less about this I would say that a recent paper came out

in the Asian bioethics review was a study of medical students participating

in research and it was a partial meta-analysis cross-sectional that wasn't man analysis

sorry that was a different one but it was a cross-section they interviewed hundreds of medical students and they determined that a large number were by

the concern the form that was determined

that used to measure coercion that a large number a third of them would be

considered to participate under coercion because their medical school professor

or a significant person conducting the research was requiring them to do so and

they did it against their own choice so the general requirements for informed

consent are pretty cool it are very clear legally effective informed consent includes sufficient opportunity to

consider whether or not to participate and minimize the possibility of coercion

or undue influence and then a further component the statement that

participation is voluntary and that refusal to participate without no penalty or loss of benefits to which

subjects is otherwise entitled and so both of these have to be true the subject may discontinue participation at

any time without penalty or loss of benefits one way we get around this with student

projects is we say if you don't want to collect the data on yourself then you have to find a willing participant

somewhere else who will consent and likely that would be someone who's not

in the class so they don't aren't influenced by the grade the opportunity to do that the numbers of students or

other people who are willing to participate and this goes way down and so then they're in a sense if they're

going to collect the data they have a very limited number of participants that they can recruit I'm laughing yeah so

you have to coerce them so they have to coerce someone else right into another way this issue of coercion is

interesting because you not only need sort of say you need to have a situation

where a person like a reasonable person might otherwise just that would

otherwise decide not to do it you know and and and so there has to be some type of like images

they need to be some type of negative consequence to it like you know it's it's so like the first one where you're

looking for the vein like you know it's um you know there's like no it's

yeah there's no harm to it it's not something that like a rational person

would not with otherwise choose not to do you know the the listening device is

sort of interesting because if it can pick a voice and you're wearing it continuously you may not want to have

people pick up your private conversations um so you know you have particular heart issues yeah may not

want other people to know that yeah sort of make you some privacy a you know benefited so I don't know like a bit so

thinking about like with these really minimal risk studies I always like to push back a little bit about this idea

of coercion because it has to be a situation but this is sort of like I mean the vein thing is sort of like yeah

why not I mean there's not a lot of risks there's not a lot of benefit yeah I mean it you know

so is it and I do think that one of the question is in one of the disputes are

very highly motivated internally together and it does that overrule the

sense of coercion because they wanted they've signed up for this course they've had they've chosen to be a

biomedical engineer this is a huge benefit to that so up next to a minimal

risk next yeah if you're looking at something that's really minimal RIF there's no loss of privacy I mean you

know you could talk about maybe it's undue influence maybe not but if they need to do it we could you sit right so

I like to raise this question with the faculty or running the senior project to

to just be aware that a student choosing for some reason or for any reason could

not participate should be considered and not penalized for this yeah yeah I think

that's where we draw the sort of draw the attention and that there might be an

issue that they don't know about and thinking about like I guess the contextual pieces

of what's the project and right is it involved and I think we also have to be

careful that just because there's ethical issues just because there's risk just because they're safety that doesn't

make it an IRB is you acted yeah and and there are other organizations and agencies that either exist within the

university or that may be created on an ad-hoc basis to address those rather

than inappropriately in my opinion mission creep the IRB into those other

safety and risk factors I agree John and and we'll talk about it

in a minute but the the idea that there could be safety issues that are not

human subjects research issues we do have laboratory safety controls the students or have to be checked out we do

determine what the risk is of danger to themselves even if it's not human subjects research so we've got another

system in place that protects the scales from their own yeah enthusiasm and and inexperience but one

other piece that comes into this coercion is when the project the students working on has originated in a

TI's lab and they have federal funding and they're trying to meet a deadline

and they've involved the students project as part of collecting their own data we crossed into a zone where I feel

like that faculty then are at some risk of unintentional or intentional coercion

and they have to be made aware of when the students because if they don't

include those students as human subjects they can't use that data right so then they have to make sure they have full

consent on their own IRB approved protocol right because then the student project becomes part of their research I

mean faculty conduct a research among their students is a norm not not not

unusual and there are not any number of standard processes in order to do or that that it occurs in a way that is

both ethically and regulatory sound but if they're the PII and they've not

identified perhaps that they're also the senior design project faculty and

they're using some of the students that they have approved for students but some of those students are in a class now that are being graded I think we have to

navigate that as an extra level of concern the other issue is about

expedited review some folks say well this is just expedited review its

student projects the language is that research activity so if we

determine this is research and attune and subject but their research activities that present no more than

minimal risk involves only procedures in these I think there are seven categories

it doesn't have an age or student exemption there but the one that seemed

to it seems to be called on is this collection of data through non-invasive procedures which is what we're often

doing in these from human subjects but these are procedures routinely employed

in clinical practice and medical devices that are already cleared and approved

for marketing so these are not investigational devices these are not newly developed with devices so the

caveat there that studies intended to evaluate the safety and effectiveness of medical device are not generally

eligible for expedited review so this gets back to this idea can we get through the IRB review quickly with an

expedited review I think our general responses if it's determined to be human subjects research it's not a expedited

review so yes it depends on the device somehow to screen you right if it's a

student design device and it's being used in a research setting I think this would argue that it can't

be expedited review they've got to look at the full ethical proof of the safety

the the risk to the students the FDA has separate regulations for

devices I'd rather set yeah yeah they have a separate review as well and just

is there like 21 are yes right 812 it

yeah yeah it doesn't differ from this or does it not differ from there are some

differences and I can't tell you you have to dot my traumatic well first thing is specifically for medical there

are some differences specifical specific to medical devices and there's there whether they're in investigational

device exemption or whether they're in a clearance protocol for that sort of

approval or clearance or if they're full invest you know new device of pre-market

approval so at this stage you know we're not doing the level of data collection

that would be used in a in an fda submission so none of this data could be

used in an FDA submission but if they go to the next step and they want to collect that data in that way then they

they have other requirements in terms of how the data is collected so the FDA regulations wouldn't apply at this

really preliminary not typically not at this stage because FDA is mostly looking

at post research evaluation right so you've completed your research you said

it you said it designed now you're going to develop a product so it's in the clinical study sometimes preclinical but

at that point you've got a device that you've determined from this sort of

research that it does this that and the other thing and now you're going into plug I've been suspicious of John

so I've been spot let's you with a term of art I suspect so the student with the acoustic sensor who is just not sure

they're worse for wearing it for five days is that not if you decided watching

the compass research for other reasons we'll get back to that but it was and you want to know what they do for expedited this seems to indicate because

one of the be assessing will be that whether it hurts he's a hippie and whether it actually record the

the sounds I guess that could be counted as fiction if I sum this on the other hand you might say those terms

evaluating safety and effectiveness would apply over to a more formal study involving the real stopping rules and

medicine effectiveness for us and that's the important outcome or do you think Jonathan's men they don't know our

English it is many more like any use of that divide I say the devil's of the

details on that but there are many turqu not many there are note there are frequent it's not

infrequent that we have a study that really is minimal risk but it doesn't

fit any of the minimal risk categories so it has to go to a convening it goes to convene committee for initial

approval and then they at that same meeting determine it now meets expedited

category 9 which means a study that was originally reviewed by full committee but in the future can be reviewed by

expedited but it but the admit webbing we it's minimal risk but it doesn't fit

a category back and I don't know I can't answer right now whether the new common rule changes that or not sufficiently

thank you um so one of the things at

that last point was can we get an early sort of review to determine if it's

human subjects research and are there some ways to do that early in the design process when the students are thinking

about a project so our Purdue human subjects protection research protection

has a form it's the determination of human subjects

research it's a short form comes from the University of Washington materials

developed a little bit Purdue but it basically asks you go through the steps

of this systematic data collection is it an investigation is contributing to

generalizable knowledge so it determines first in research then it determines human subjects you know the people who

you're collecting from humans are you are they alive is it identifiable data is a private information etc. so you go

through these category is it includes Mary the FDA

categories on there for devices that have been cleared or approved and so they want to know that as well so we ask

the students to use that as a first step when they're planning their testing so

they in this in the spring of their junior year when they're thinking about a project they're planning their testing

which we ask them to think about it ahead of course they don't even have a device or know what the device is sometimes at that point so they just

have a problem they're trying to solve with some projected solutions so it's hard to come up with actual you know what are we going to actually do as a

test but we ask them to do this and then the other thing we use is sort of an in

course a quick check that they can use at any particular point because

sometimes they get down the road they say oh we need to test this on a human and they haven't gotten an approval approval so we ask seven okay if you're

going to test it on human the answer to one is yes will the data be collected directly about the person so this is

that question of visit about the device or about the person we ask them to try to determine that clearly are you going

to use this data in some sort of tables figures graphs are you going to publish this or present it you're going to take

it on to other than your report for the course is it going to go into the student research journal or into a

larger journal you know peer-reviewed journal not that the student research the student research journals are peer

reviewed as well but the standard research journal are you going to take it to a design competition and publish

it publicly and then and then the fifth and perhaps critical piece is is there

any risk of harm to anyone what's your harm risk assessment here including

physical psychological relational privacy that's perfect so this is what is not official but it's just a quick

check that we ask the students to alert us and alert the faculty member and then

it can ultimately bump up to me or and we can bump it up to the IRB and say you

know here's the answers we have do you think we need to submit this as a protocol because we're not trying to

make extra work for people but we also don't want to put the students or the project at risk so the last piece

are just here's a few published articles and interestingly there's some very

different opinions in the literature right now about how to handle this everything from some very specific

details pritchards work on what actually is generalizable knowledge and when can you

say that this is data that you're collecting just as feasibility and it's

not really needs the human subjects research categorization then there's the

folks like Doyle and Wilkinson who or Edwards I guess who who argued back and

forth like student projects most likely don't result in generalizable knowledge

so it's sort of a waste of everyone's time to put it through a full review we

should get a student review board that would specifically review student

project and then they can recommend if it goes to the next level or not so it's sort of a pre-screening whereas Edwards

says no look these are inexperienced researchers if this is research even if it doesn't result in the outcomes that

you want because they did it made mistakes there's still a risk there's human it's intended to generalize to

develop generalizable knowledge and so it's putting human subjects at risk and it should be reviewed even with even

more scrutiny so you know and then and

then I think the last one the point is that maybe a little bit cynical bit sort

of like we don't expect students to publish anything of any value so we shouldn't even let them do human

subjects research we shouldn't call it that we shouldn't let them do it we should give them you know so I don't

know that many people and I may be over generalizing that particular view but I don't think many people would would take

a stance where we shouldn't let students have the experience of learning this is how they get there and and you know

there's not a big difference between our students or seniors and a few months later who are working at a company actually doing this work

life and and if they don't haven't had a chance to make some mistakes along the way we think we've not turned out well

preparing for the higher fee requirement would I agree what you would not be required in that company it would not be reviewed it right but we want them to

understand what that process is and what human service do we don't want them to

understand what the IRB process is or do we want them to understand responsible conduct of research and the ethical

processes which are not necessarily the same thing yeah yeah okay we have a

million questions they're all holding onto so who wants to go first

well us or up so um I'm this cute back of one slide EP so with the data

collected be directly about the persons in any way this is actually the big a big question for me so first if I'm a

student I want to avoid having worry about the IRB I don't want to avoid the grants for

research I want to sort of solve the problem if I make my data D identified I

collected it you know I wear the five of us with a sensor when I put that in the computer I do not assign any

individualized data to it it's just it's person a b c and d e is no even key to

go back to do a a b c and d newest i don't care it's just my class i did it for you know a week

II just did it for a week so with that as far as you know that helped or hurt

the question of it is directly about the person anyway the data was collected from a person so that's what it's about

the person there is a heart-racing for me for the week but i have no way of

readily going back to me so it's not really about me at all that's that's the

small question what is the identification that is the bigger question thing I think I must John to help me on I think what Slaton Rd

identified work is over some other work so you know when you interview a warden

at a prison to find out how the prison runs at start research study where

you're collecting information by prison that's not human service research because it's not about the warden giving you information

you quit satan is a direct analogy there with the device but you're using a device to measure heart rates but it's

not about the heart rates we're not trying to see whether we can diagnose a fib in facial defib we actually want to

see if as much as you work today is that that I'm doing human subjects issues here but when it seems of a three

surgeries it's just it is unit that was raised if you are collecting data about people with devices strapped to their

body and Peter you're overthinking this to say that's not you know it's like in

a duel warden like absolute then I'm going I mean I think we're I think any

they're going to buy you might not be collecting these particularly information about them but you are engaged in an intervention and having

them do something different than they normally would do so that that might be that might be learned in horses a lot

the warning is on the phone he was normally on the phone no that's a bit

different okay that's a bit different I type thing because it's it's it's not quite the same

I mean the new common rule also makes a very big deal that about journalism about about oral history literary and an

equal legal research are not in the subjects research and I think that they're trying to do is sort of redirect

our attention a little bit not just specifically about those things but in terms of what we think about in terms of

your first question we tend not to like it when there's the selfie identification when the person

collecting the data is also doing the D identification and then doing the analysis of that same de-identified data

whether what you described would be an exception to Arjun we're not liking that

may or may not be the case if what was saying if I did that that will get me feel submit as an exempt so this human

that was research because I am a trapping consensus people it was saying that general gets more for the people on

the phone as well if you went with this later about do I have to worry don't think you're going to get out of this

demon just in the basis that the R is done another person but if it is adequately

de-identified maybe you get an exam but staff but I would do something else I would argue with this really a systematic investigation so good I don't

think you have taken five people that you know constitutes a systematic

investigation if the research unless the research question is about my friends or

other people or some such very I mean but then it's not even a research place and unless we go back to it's a research

question about the device and if we're saying this acoustic sensor functioned

with this spectrum of efficiency with five different people and we can generalize that the skin of those values

place all at the same point the skin of five people is generally the same we can

say the device is able to measure through the skin this level of voice

detection this level of electro Maia Graham this level of heart murmur right and then we could publish that as data

about the device but we wouldn't be able to publish this necessarily about data about any of those individual around or

about people so given what he said John are you saying you still might be able to argue like a detailed della movie in

detail we study all is not a systematic investigation to have such a such a

early study so simple and of design that it's not actually research it's just a a

event Wow as was pointed out it is the presentation itself there is no

exception for pilot studies is the regulation so a pilot study would would

require so I remember one time getting a study in which there is going to be a subject population about five it was for

it was a subject population about five but they were but they submitted the

this IRB submission sort of as a as a model grant application that they hope

to submit after II they do the pilot study and and they had very broad aims

and the IRB rejected it because the design would not answer the question so

again the question it might be that that it constitutes human subjects research

and it needs IRB review but the methodology and the aims have to match

and if the methodology is five people and the aims are grandiose it will get

it won't hit an IRB booth easy what if

the answer is simple as just to show that it works in some people is that getting close to systematic and

generalizable enough I mean enjoy Las Vegas was there but systematic enough where that is an IRB call it would be an

IRB call the whole sort of a temperature reading of the institution and the culture the question is so this dude is

you have put up with a lot of student projects you're so early even they're not it is possible to say this however

this is a take-home point possibly is posthumous up and please tell me if I to get it wrong John student projects maybe

at an early enough stage and be simple enough as beginning tasks to be judged

by a reasonable IRB as being not a systematic investigation and therefore

not research at all instead we also need to define students or we do approach it differently for graduate students and we

do undergraduate this is really to give yeah what about wait but but because a classroom activity is generally not

considered human subjects research a honours thesis a capstone project what

because of the quality of the study that it becomes to look more and more systematic and like research where as an

undergraduate project and having written under got good thesis and I'm aware right having resume be wasn't even

research is one of the stab we had it wasn't even research that known a systematic investigation we philosophers

have an argument over is a child mental radio he died that by tying a string to

a rock is that not a radio this is a really bad way

because the Ruth Milliken and now it's been recorded okay right and and I mean

one way that teams sometimes do this is

we are doing this as a pilot we don't intend to publish just at all we want to see if this works and if we get

something that we believe is now a device is not working we will generate a protocol we will collect the data and

system systematically we will have a adequate study that has the right aims

and the right experimental method and we'll submit that well but be careful

also the idea of whether you're going to publish or not publish your sort has a lot of false positives and false negatives delays built in to be on top I

mean if you can you can do you could do Qi yeah and publish it as Qi are you

telling us we did this at my institution and we changed the way we did X and it

resulted in in y plus three is and how completely and I'm not making I'm not

saying that it will do the same thing at your institution but you might want to look at right Marriott it giving the

truth lots of summer on quality improvement we have been shooting on

that one yeah when your body through become research and what exactly doesn't your home doctor I have one more bit I

want to go big deep in genetics and I do think is really fascinating because again we're care so much about what the

regulations are we need you be but also some ethics questions around this especially I love what you said about

how so much students will graduate and go on to companies will not be subject to common rule or view because you do

want to teach them the ethics doing meets a certain way even it's not I are be but and of course what we think here

at be SAP thinking about ethics building is that the fascinating idea these diseases fact about planning to publish

and about systematicity the risks to the subjects you know are

the same whether or not there are five or ten of them and

there is just nagging obstacles research or not they're still strapping on a sensor which has the same risk and so is

a funny thing that we tweet these activities so differently 10 of them is

systemic then each subject has to consent and their risk set be assessed by an independent board but it's only

five of them and it's not yet enough they're facing the same risks but now nobody reviewed it

I guess that again I guess the conclusion is that you just dip the precepts of doing treating people fairly

and nicely and protecting that well their health and their and their safety is important with an audio and rarity

review but the fact of IRB review is a little I will call it arbitrary because

it has to do with the thoughts in the mind of the person conducting it rather than the actual risk that's the

definition is intended to contribute right yes so it doesn't matter if it's

not it doesn't matter if if it does if it's not a real contribution if you intended to do so it is and then the

other works the other way as well right but more hundred closing thought

maybe us all right I think sort of building on what's shown on the entries that is I've been thinking about the Sri

Xiu Qi versus IRB it really is quite striking because in the IRB pickasee I

mean my realm of research is Morris the behavioral research so if it's determined to be Qi or student project

not vision then there's like no requirement whatsoever and it is determined to be IRB they have a consent

form it's the same model consent that you use for like infusing poisonous

chemotherapy into someone's wrinkled spinal fluid and so you have this sort of the bed bed when you think about the

ethics on it really like the ethics or issues around consent is the person that what they're doing are they aware the

procedures and they aware of any possible risks which in behavioral research might be embarrassment or

issues around privacy and so thinking about like you know even if it's something that's not in the

IRB purview in terms of where the new common role fall you know one of the

obligations investigator in terms of making sure people are informed making

sure people understand that they can refuse this making sure that they know sort of like what might potentially

happen even if it's nothing at all like you know what they're looking at the main thing but you know you know like

you know the best thing that you're wearing it might record your conversations mm-hmm you know when your girlfriend breaks up

with you or you know it's yeah but so

what's so thinking about like what do we teach people what sort of standards do we have for ourselves for when things

end up is qi and research and non research I mean I loved your little like

five questions and I almost think that's like a whole class session where you sort of like here's our five questions

but how do we work through one of these five questions things post will post the recording

of this and the five question forum you time your slides will post as well and

actually John you had some forms you said you might have on assessing ethics of faculty conducting research to

involve students and some guys that I was going to say are just such things we will update and post as well on the BSAP TREATs page