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talk system our important consults that we've had for T-rex consult service

through the bioethics program and what I'd like to do is talk a little bit

about the three consults and then talk about some broad issues and research in schools so here are our three consults

the first was a diabetes prevention researcher who wanted to recruit adolescent in a high poverty school for

therapists group on potential obesity intervention she was having problems

with parental consent and having kids return consent forms into the school and

had questions about waivers of parental consent in innovative approaches to

confess the second console was an educational research in school researcher in school

Social Work who wanted to examine how educational neuroscience techniques for

operationalized in the classroom educational neuroscience is a hot new area and teaching and with multiple

teacher training programs across the country she has been working with a teacher in one of the Indianapolis area

school and they wanted to see how these played out and realized and then the

third console is from a program evaluator who wanted to administer behavioral surveys before and after an

evidence-based data loss and sex education without consent the purchase again will also Kisan consent so what

I'd like to talk I'd like to talk about three things today from an ethics

perspective in working with schools and the first is engagement with the school community the second will be privacy and

data security and the third is issues around consent or in Pediatrics parental

permission my one caveat is I'm really talking about minimal risk research and school

research that's greater than minimal risk falls in a different category in terms of consent so I'm going to really

I'm going to limit myself here but also minimal risk captures the bulk of school research so schools are really special

cases of community engaged research when I started in adolescent medicine our

pediatric psychology sat me down and said Mary remember this the principal

is the king of the castle and parents are important and it's something that I

carry with me in adolescent medicine in an adolescent ethics but schools are

small communities the principal and administrators are really leaders are

community stakeholders and community leaders and they really we need to think about using community engaged principles

and we work with schools I like to think about the school of the co-investigator bringing them on really early in the

process getting their input on methods how to how when to survey kids how to

survey them how to get consent again is it as a special case of

community engaged research the other piece about school does that research really needs to be grounded in trust

schools go a little bit out on a limb when they work with researchers they make themselves vulnerable and a

trust-building is a really critical part of school engaged research engagement um

the third piece of community engaged research to think about is that you can

harm not just individual children but there can be harnessed to the school communities and community engaged

research typically thinks about marks to the community but as we look at this we need to think about harms to the school

is it really accept what the principals and the administrators view

are what they're you know get their concerns about the research in the next

part sort of key ethics issue a community-engaged research is

providing results back to school because the school's one of the reasons that the

schools generally genuinely want to know what's going on with their students if

you have enough students you can provide the research the data app in a de-identified manner what I typically do

when I work with schools is I'll write up our sort of aggregate report my research report and then I'll really

analyze the data breaking it down by school and then meet with a school and go over what their data were

specifically prior to releasing the larger reports I'll give them sort of like a column with their school and a

column with the entire study and so making them and it's again sort of

applying principles of community engaged research to school and then the last thing is back to my Pediatric Psychology

mentor is like really thinking about how parents how parents should be involved

how parents can be involved parents are really key stakeholders in school communities so schools even where there

are waivers of parental consent schools will often excellent parents I so

thinking about like what types of parental permission how I get parental permission how did you notification is

really important for the second area of

ethics that I recommend that people think about or give me about privacy and data security

so one privacy in school-based research have to do with sort of the knowledge

that the young person is participating and whereas data security really is

sort of their actual data and results of thinking about change security with their results and both of

these are important in important not just in research on sensitive issues like sexuality research but it's

important across the board in the first example it was diabetes prevention study

she was doing research actually with kids he met BMI criteria for for

participation in the focus group so she's working with heavier kids and you know there's stigma associated with

weight so even just participating as an issue they're paying attention to these young people's privacy making sure these

is a data are collected in a way that other students aren't aware of the young person's permission a colleague of mine

and adolescent medicine had did a tobacco cessation intervention in a

school and it was very important to make sure that kids in the but that they had

an equal intervention for non-smokers so that the smokers weren't sort of cool

the school decide and signified so privacy ends up being a concern schools

or public places it's also hard to predict what families will consider sensitive one of my current studies is

an evaluation of a teen pregnancy prevention program in a rural school and

our community collaborator was less worried about asking about sexual

behavior and more worried about asking about family in their community family

income was a very sensitive issue and you know with the sex education programming knew we would ask about sex

that they didn't feel that it was our right to ask about families so it was in it was only in sort of working with the

school as you know thinking about a community engaged approach that we pulled this out and sort of thinking to

them what's private what's important what do we need to be concerned about

HIPAA is something that all of us who work in or around health organization

concerned about it deals with data security and when we do school-based

research we need to be very careful hires and study numbers is who has

access to the keys which have the kids theme and their study number is it

something that's held at the school that something that's held at the research office these are just things to consider

before starting and then very practical matters or like chains of data security

but usually I mean when we're doing research in clinics a young person is at a clinic they're in a private room we

get the information oftentimes it's uploaded directly into a web-based portal but when you're in a classroom

with our sex education researchers surveyed 23 kids he's going to have

paper surveys those paper surveys are going to be numbers they're going to need to have identifiers separated from

them they're going to need to be collected they're going to need to be reviewed to make sure all the questions

are answered once they're collected they're going to need to be get to the place where they're going to be stored

in these pieces there's just more chaos and full there are more steps in the

process of getting data collected in schools to the place where the data will be stored and entered so chains of data

security end up being important in seeking and again it's sort of one of these like sort of points to consider

ahead of time making sure a lot of

researchers will be there with laptops or tablets or phones and just we

typically think about password protecting and encrypting laptop but we don't always think about password

protecting and encrypting our tablets and our phones at schools or public places and making just make sure all of

our electronic devices our password person and encrypted and then thinking

about data data storage and data security that weren't a firewalled and

if you're in the health field HIPAA compliant way to store data so privacy

and data security these perfect sort of our main risks and maintenance and again sort of you really working

through them from the front end is going to be is going to save you on the back end so I was talking about hip hop and

the last slide then it turns out like education research is doubly difficult

because you have two sets of regulations you not just have not you do not know if

but you have FERPA so surface the Family Educational Rights and Privacy Act and

FERPA is a federal law that deals with the release of and access to educational

records all institutions receive institutions that receive federal education dollars which is really almost

all schools even private and charter schools receive federal dollars in some

way shape or form are required to follow for her requirements and a key piece of

FERPA is that private records of young people are not released without the written consent of their parents if

they're a minor Burpo deals with unlike HIPPA deals with

health records and we have our seventeen identifiers with your name and medical record number and date of birth and age

if you're over 85 years of age well FERPA it deals with educational records

and so it's also helpful to know what records are considered records for FERPA

one of them is class rosters so a class roster is considered protected

information grades exams and transcripts are considered protected information

health records if there's school at they're owned by the school so immunization records things like that

discipline records student schedules and then any thing that teachers or school

have that's written about students so notes they could be handwritten notes

they could be computer files they could be email these are all protected by FERPA so so a school based researcher

needs to consider these other protected areas so for instance our

researcher looking at educational neuroscience was thinking about like class list as a way to recruit but all

of a sudden you're thinking about using a type of information to recruit and so

and you you know technically should get parental consent before recruiting for that so she came up with an alternative

strategy in collaboration with the teacher because class worker consider protected FERPA does have exceptions one

of the exceptions is developing validating in administering predictive

tests so for organizations that are doing this would be sort of like our

Indiana state exams these might be like Isaac's for private schools

administering student aid programs or improving instruction and the researcher

must have a written agreement from the school about like essentially a contract

or memorandum of understanding for this to concede to count as an exception and

these are really end up being things that schools these are organizations that schools contract with to provide

essential services for families so

parental permission going back to my child psychologist colleague who said

you know the parents are in school so parental permission in general is not

really consent which is why I deliberately use the word permission the form of surrogate decision making it's

the base of the ethical assumption that parents usually make decisions in the best interest of their children

however issues can arise and challenge this ethical assumption when there's a

conflict of interest between the parents and child when parental permission

introduces some type of risk to the child or parental permission is a

barrier such that to research or changes data specialists not after it and some

of these issues have came up with our three consults so for instance the study

doing focus groups with children for diabetes prevention I had a lot of

defeated King from communities that had

high levels of poverty there was a lot of family chaos and they just had a

really low return of parental permission slips and the kids that returned the

parental permission lists were different than the kids that didn't return them and this is a population that has

extraordinarily high rates of obesity and type 2 diabetes with some very

population the very kids that would be the target of the intervention were the

kids that were unable to return the permission slips because of family chaos and so there so there may be

situations for parental permission active parental permission would be

something that would influence the researcher in a way that would in this case make it less accurate the

study on sex education had a survey about adolescent sexual behaviors and

these are things that young people typically consent to on their own information about sexuality typically

protected information kids would typically be able to give their own consent for this type of information at

a high school level so again there's sometimes there are conflicts that come up so this is sort of what I've talked

about on the last slide typically what's been sort of topic council permission can compromise science so we talked about diabetes with

the last one this is a published study that was a natural experiment they had a group in a Children's

Hospital of validating the craft screen which is a drug risk drug used risk

screening did you use drugs or alcohol in a car views them to the last to use them alone from the friends

have your friends told you to stop I've ever gotten into trouble for using drugs and alcohol in the first study they got

a waiver of parental permission and they adapted their scale and then they did it

however the institution the medical school where they worked had a change in policy and they changed their parental

consent policy and they were as they gave a waiver for the first round they didn't give a waiver for the second and

what they found is that participant from the first study had a different ethnic makeup they were more able to recruit

ethnic minority and also had kids that scored higher on the craft score so kids

with higher risk for substance use when there was a waiver of parental consent it was the same population same clinic

the parental the parental consent changed their results so it's this sort of natural experiment that really

demonstrated the importance of attending to issues around consent and thinking

about how it would play out in terms of data quality the other question that

sometimes comes up of consensus are the young people able to consent because a

key piece of parental consent that is the protection it gives like an extra

consent or for to assure that the valid consent in pediatric research

people oftentimes question about question whether the child has the capacity to consent Dutch Children's

Hospital group had did a study that essentially that that provided some key

data on this they took every child participating in a clinical trial and a

large Children's Hospital these clinical trials cross the specialties and types

of trials so they have people kids and Gi and oncology

other types of trials and then they took an adult capacity assessment tool to MacArthur confidence assessment school

for clinical research adapted and administered it to the young people and

what the map cap does is that it looks at whether young people can understand the results it looks at whether on young

people can reason can weigh risks and benefits whether they appreciate how the

research might affect them themselves and it assesses whether they can do make

a voluntary choice and what this dutch group found was in kids under nine and a

half competences unlikely in kids over eleven competence was probable and the

Ultem optimal cutoff statistically speaking was about ten and a half years of age I mean so what they're saying is

that by about you know at least eleven um by ten and a half to eleven young

people can understand reason I

appreciate how the research would affect them themselves to make a voluntary choice and we're taught not talking

about optimal decision making but we're talking about our sort of threshold decision making can they make decisions

per se and if you translate this to schools what you're looking at is middle

school high school because if you think about you know kids are ten going into eleven fifth grade so sixth grade on we

can feel comfortable that in many situations young people who have the capacity to consent

so waivers of parental permission so waivers are allowed in medical research

the two big regulatory guidelines known as the United States are subpart B in

the common rule which provides waivers for abused or neglected children and

then the National commission's report on research involving children 1973 and

what the National commission's report talks about conditions for which adolescence may obtain treatment without parental

permission so sexuality research research would call here research with

mature minors which possess not more than minimal risk and then the last two

cases parents were illegally or functionally incompetent or bored to the court you might waive parental permission that you would have to have a

some type of substitute consent process in its place but it's the first two that

really are relevant to school based research number two is sort of loose

mature minors minimal risk but it's really spelled out later on because we

I'm going to go one more more because we

allow waivers of parental permission when we allow waivers of adults written informed consent and these are cases

where the research is minimal risk it won't affect the rights and welfare of the adolescent it could not practically

be carried out of other lives and it's appropriate adolescents who provided with additional pertinent information at

participation and plainly restore the research can be FDA regulated so this is

our diabetes prevention studies clearly minimal risk it won't affect their rights and welfare they're not even

being asked about their own particular behaviors during it being asked more broadly on how they feel about

interventions and to talk about what I'd be effective for the groups of children

similar to them and it's certainly the researcher has demonstrated that it couldn't practically be carried out

without a waiver I'm going to go back to and think about two slides and talk about our sexuality or searching example

so the regulatory definition of children isn't under 18 it actually is has to do

with whether young people have attained the legal age for consent to treatments or procedures involved in the research

and the legal age is dependent on the applicable law of the jurisdiction in

which the research will be conducted so for a situation we're looking at STV

research young people can consent for STDs so young people aren't children with

respect to STD research and some Part D doesn't apply this is purely a regulatory argument but

you know if you look at how children are defined you know we can when we think

about like what our parental consent requirements are from a regulatory active in certain areas like STD

research that our children and subpart D

may not be required deployments maybe I don't well but it's just a reminder how you go

direct with our but I love the medicine so I didn't really know that adolescents could get treatment with that kind of

consent for anything so is there a cut up in the age when you can start getting treated for STDs without print of the

pentagram at 70 they are sort of like functional cutoff so there's no cutoff

in the law and the consent law but but other laws require us to involve parents

so for instance if we know that a very young child is involved in sexual

activity we need to report it as child abuse so the seven-year-old I would you

know would involve families also away from in our tisha nurse judgment when it

crosses over from young person probably engaging in voluntary know there's laws

around that a budget report yeah bikes our sort of reporting requirements are all specified in law so they're

reporting rope laws it is also sort of the ethics of it so I mean if you think of to the hind result like you know I

would feel very comfortable having a fourteen-year-old consent based on her results I would feel much less

comfortable looking at a seven-year-old provide consent

and so your question as to loss here are some of our Indiana laws so our age of

majority is 18 the exceptions would be

emancipated minors who would be treated as if they were adults to be emancipated

by court order by living apart or by being married and by being active duty

military service we also have waivers

based on diagnosis so STDs would be one of those waivers substance use treatment

young people can donate blood yes their blood together well there are there

there are those are three things that are in the law examples of three examples that are in the law yeah so

this is these this is our broader context but now we're going to go back because I started the talk by talking

about schools as being sort of this microcosm of community engaged research and thinking about schools as

communities and administrators as stakeholders and parents as important stakeholders so we so that brings us is

sort of you know opting in and opting out one additional thing I would like to say about minimal risk for anyone who's

looking at this if you need to know what's minimal risk for school children in health care they're actually

guidelines on press best practices like Bright Futures and Academy of Pediatrics

and CC and you know US Preventive Services Task Force recommendation so if

you are doing health research and want to know sort of what standard look so

for instance for our diabetes prevention research if she wanted to add on a hemoglobin a1c it still could

potentially be minimal risk because that's a standard part of health care for young people it's a screening

recommended screening so the last thing I want to talk about it opt out is that and this is really important for schools

because schools really like off parental consent and the reason why they

like it is because it involves parents that it also recognizes the need that

adolescents might you might want to waive concerns for practicability reasons you might want to wait consent

because it's a parental consent because it's a sensitive issue my ethics

colleagues never fail to remind me that opt-out consent is not really consent

because you haven't closed the circle like you what happens without consent is

you inform parents about what's going to happen in the school so with the sex education program I in fact just

recently got an email from my 12 year olds class that they were going to have their sex education program next week so

I could go to parents night next week so they have informed me about it and then

I read through the email and they say if I don't want my young person to participate in this they'll provide an alternate activity they could fit at the

school in with the school secretary and work on extra math homework or something like that and so and if I would like

that option I can call the school on avail myself of that option if I don't

call this goal than my 12 year old will participate in the sex education program

so that's an example of opt-out parental consent so not really consent because you

haven't assessed I mean for consent is a process by which you impart information

and you assess the person for understanding and so no one has assessed

whether I ever received the information because like sometimes I get I read these emails weeks after the event has

occurred and now I've assessed whether I understood what's going on with it so

it's not truly consent but it is a process that demonstrates respect for

parents and respect the dignity of parents because it goes it informs them

and gives them an opportunity to decide about their kids participation so it's

not really we're not really consenting the parents but it's this important piece of

respect and involvement the only time you can use all you can use opt out

infant but when you use it as you use it when you meet criteria for a wage or a parental consent and if you meet

criteria for that way or you go ahead request the labor from the IRB and then

you propose a process where you inform parents of the research and give them that opportunity to go so opt-out

consent is really like sort of a subgroup of waivers where parents are given extra information it is you know

perhaps even more rigorous than regular waivers of consent because there is some

involvement because we you know we involve parents in it and this is for

the diabetes prevention study this was the approach that they talked they took

an opt-out prova they requested a waiver with giving parents the opportunity to

opt out for the sex education evaluation they did similarly the parents were

already going to be informed about the educational program they just added on

information about the survey and evaluation and gave them the opportunity to opt out so so both conditions that

would have met waivers but both in which the researchers off the top down so you

know just sort of keeping in mind without consent again not consent but also it's often has a nice way to

demonstrate sort of respect for the parents and their whole in school now

that's it for school-based research I'm open for questions respecting goes live

our future software and have an email to the email in that question from the

email questions out for questions

anybody in the room of the question so a

little bit more detail so what about

yeah that would be considered data

and you know there's probably are ways to do it but it would be it would

require careful work with a school and with the IRB I have a question

looking at the exceptions a that any

sort of for example without the this

particular contact people about finance about financial information is a FERPA

applies not just at elementary and middle school limit applies to universities so if you look at our I you

IRB SOP on the issue it's really all about doing research with undergraduate

and consent for research with undergraduates and there's less information on our SOP about doing

research in primary and secondary schools which is why we ended up doing

this as a treat yeah well that's probably yeah

my name is ladies our questions can always consult the VFC program or

married yes I was in file for questions so let's say you we're going to track absenteeism before an accident I'm an

invention say so can they provide us data and it's the identified way yeah so

I'm sure that there's no put that wouldn't be a problem the problem would be like tacking it to individuals and

getting like Sally bluefin attendance

records before and after and whether she had participated in it so you could get aggregate data then asking them to track

individual students with some kind of ID or something and signing what else in our cards right it's my fear that our

timing anyways once the school is doing that they're actually handle exudes data for research purposes you could take it

and be identified individual data I assume that's not gonna be an easy answer at all either so yeah that's not

I don't actually know it's the school personnel where the people that have a code making it and so and the other

piece that you get into is just sort of like their role in the school and star like that but it just but it is I mean

there are times when that that those types of approaches hasn't used like

people doing research in prisons or juvenile prisons and having like the prison facility have someone on their

side doing some of the manipulation so that what you actually I wonder if it is a whole offense so if you have a

school-based school people in the school

yeah and they can have that internal linking also in store based clinics

I would also you'd have to look at the structure of the school-based clinics because some school-based clinics really

do does is provide in the space but the actual records medical records

treatments etc are all kept as health via their health records that might be

through the economic system or Marion County Health Department or Health Net or whatever st. Vincent's whatever

health organization so there's also sort of thinking about

where you know where the information your and then your information like two sources school attendance records and

clinic records yeah that's how they

initially ever

I know there are waivers or record permission there we are this

corridor until Colonel changes we really said as long as not just double virgin

there are under specific circumstances that are permissible from a regulatory

and ethical standpoint the dairy get their energy businesses the idea of

somehow intervention if you want to mention there some images stop through deception see ISM that intervention

itself would be minimal risk yeah wouldn't comprise some people yeah there

are you totally we are not going to get a waiver for FERPA are there any equivalent waivers for Bertha yeah that was purple you know I'm

not going to be yeah I mean it is a good question I don't know in would this sort of peace about

signing having a contractual the other

thing is if are you going you know like how would you be able to get active parental consent like could you fund a

little other things that kids need for consent if you did it at the front end of the school year they're like clinic utilization she use

the clinic they need a parental consent form can you bundle your study consent form with that consent form so that they

would be signing the both if it is you know like because is it you know because it but the parents would get them both

at the same time so that it would be sort of a single point because the issue with schools and parental consent

usually is not parents objecting to it it's things being done without their

knowing it so it's that issue at school and it just makes you have access you know it's my reading email from the

school three weeks late for the events of the third so I do yeah yeah Judy I'm invited by my wife

that I did so that you raised ish about

bias like yeah the people who are going to consent I'm going to be a subsection

of population and positivism study describe or a subsection which is less representative of problems you're trying

to address yeah the question is today different ways that would be relevant to the research that you're doing

oh the educational neuroscience one is looking at active frontal consent because they were part of their study

we're going to interview kids about their experiences in the classroom so

they were getting active insurance but it was one of these things where it's really like what you were interested in with the teacher-student interaction

that would be driven by the teacher not whether or not the parent then it can

sense what you know so there may be situations where it may be less of an influence so I mean the drug and alcohol

screening study it was parental knowledge of participation with a big

issue this issue for consent no matter what yes any clinical data tables yeah

um that's also so she's one of your waivers but because think about it to my

hand if I saw the capacious I meant like how the story time of the behavioral neuroscience right so what's intervention which is um low-risk is a

sort of thing which is not a thing you normally consent for so isn't that one

also we did a waiver for Spanish because the interventions minimal risk very top

you know I'm talking to intervention at a minimal risk but something gave me the category yeah we don't have to worry

until permission is you going to get a waiver any I was my companion and again it sort of you get into situational

issues this is a fifth grade classroom so the kids are sort of right at this cup what they're going to understand it

or and then thinking about community and school to the special cases search like

even I really am quite liberal and what my kids participate in would want to

know if someone were interviewing my fifth grader about teacher techniques in the classroom yeah so you know so

it's also there are contextual pieces about it that you would want to make

sure like in this particular case just having parental consent for that component for other components her first

study was going to be a classroom observation and so she was going to get a waiver for the classroom observation

and then do active parental consent for the actual interviews who's driving her

to the ex-president Stephanie which is not actually common rule subpart D once

it applies to children but actually this concern of house so the fact I live in

Memorial FERPA that you're doing research in school with kids that are me

perfect doesn't happen right so the IRB would approve it ldiot would befall well

that our IRB would actually take kirpan into consideration okay

but in my interviews with if i perfectly the interviews if the data being shared

child is giving you this speaking to you if you're not getting school data from

the school I'm going to try to say oh yeah like this is a picture of the problem with your purpose

or regulations written or data collected

as part of the survey in there secondarily applied research in school

say so the regulations weren't actually the regulations are about getting access to great

attendance record family shop and I've got other types of identify I'm so doing

what they might assert that it is sort of encompasses as a piece of it this sort of research in the classroom but it

wasn't primarily written for research in the classroom and because it wasn't primarily written for that purpose it

turns out that it's sort of like an imperfect fit when you're applying it it's like even applying 45 CFR 46 or

subpart B regulations were written at a time when people were thinking about biomedical research and randomized

control trials and children they weren't thinking about comparative effectiveness research they weren't thinking about

other vital banking they weren't to me about long longitudinal studies they

were thinking about you know get the new insulin and see if it could get better into launching it so it so it's a case

again like CERCLA is like that some of our other regulations it's a case where the regulations weren't specifically

designed for the contact so there's some interpretation if the mark on time here

42 minutes by the clock thank you