WEBVTT

NOTE duration:"00:49:29" NOTE recognizability:0.651

NOTE language:en-us

NOTE Confidence: 0.49877945

 $00:00:00.000 \longrightarrow 00:00:00.558$ It's a it's

NOTE Confidence: 0.49877945

 $00:00:02.600 \longrightarrow 00:00:06.245$ a pleasure to join with you this morning

NOTE Confidence: 0.49877945

 $00{:}06{:}06{:}245 \dashrightarrow 00{:}00{:}08{.}972$ and and talk to you about the Yale

NOTE Confidence: 0.49877945

 $00:00:08.972 \longrightarrow 00:00:10.676$ Center for Clinical Investigation.

NOTE Confidence: 0.49877945

00:00:10.680 --> 00:00:13.722 I'm thrilled to be back as a member of

NOTE Confidence: 0.49877945

00:00:13.722 --> 00:00:17.995 the Yale community and particularly

NOTE Confidence: 0.49877945

00:00:17.995 --> 00:00:21.880 eager to engage with you this morning

NOTE Confidence: 0.49877945

 $00{:}00{:}21.880 \longrightarrow 00{:}00{:}26.220$ to learn more about how YCCI can

NOTE Confidence: 0.49877945

 $00:00:26.220 \longrightarrow 00:00:29.784$ be more helpful to those of you

NOTE Confidence: 0.49877945

 $00{:}00{:}29.784 \dashrightarrow 00{:}00{:}32.545$ engaged in clinical research related

NOTE Confidence: 0.49877945

 $00{:}00{:}32.545 \dashrightarrow 00{:}00{:}35.720$ to patients with psychiatric and

NOTE Confidence: 0.49877945

 $00:00:35.720 \longrightarrow 00:00:38.718$ other behavioral health disorders.

NOTE Confidence: 0.49877945

00:00:38.718 --> 00:00:41.764 So I will devote,

00:00:41.764 --> 00:00:46.552 I hope a significant part of this

NOTE Confidence: 0.49877945

 $00{:}00{:}46.552 \dashrightarrow 00{:}00{:}49.456$ presentation to what I hope will

NOTE Confidence: 0.49877945

00:00:49.456 --> 00:00:54.015 be open discussion of where our

NOTE Confidence: 0.49877945

 $00:00:54.015 \longrightarrow 00:00:57.355$ opportunities and challenges are.

NOTE Confidence: 0.49877945

 $00:00:57.360 \longrightarrow 00:01:01.560$ So let me try to share my screen.

NOTE Confidence: 0.38370234

 $00:01:05.960 \longrightarrow 00:01:09.560$ Hopefully that is visible.

NOTE Confidence: 0.38370234

 $00{:}01{:}09.560 --> 00{:}01{:}12.154$ There we go. Perfect. OK.

NOTE Confidence: 0.38370234

00:01:12.154 --> 00:01:14.072 Are you seeing the full screen or

NOTE Confidence: 0.38370234

 $00{:}01{:}14.072 \dashrightarrow 00{:}01{:}16.464$ are you seeing the just your slide,

NOTE Confidence: 0.38370234

00:01:16.464 --> 00:01:20.478 just your slide? Oh, OK, good.

NOTE Confidence: 0.38370234

 $00:01:20.480 \longrightarrow 00:01:23.936$ Let me just reverse that now.

NOTE Confidence: 0.38370234

 $00:01:23.936 \longrightarrow 00:01:25.600$ We're good. OK. Nope.

NOTE Confidence: 0.38370234

 $00:01:25.600 \longrightarrow 00:01:27.436$ Back to the way it was.

NOTE Confidence: 0.38370234

 $00:01:27.440 \longrightarrow 00:01:30.956$ Oh, it was the right way.

NOTE Confidence: 0.38370234

 $00:01:30.960 \longrightarrow 00:01:33.764$ All right. There you go.

NOTE Confidence: 0.38370234

 $00:01:33.764 \longrightarrow 00:01:36.100$ It's reversed for me. OK.

 $00:01:36.100 \longrightarrow 00:01:39.355$ So what I hope to cover today is

NOTE Confidence: 0.38370234

 $00{:}01{:}39.355 \dashrightarrow 00{:}01{:}42.463$ to give you a little bit of an

NOTE Confidence: 0.38370234

 $00:01:42.463 \longrightarrow 00:01:45.424$ overview both of our mission and the

NOTE Confidence: 0.38370234

00:01:45.424 --> 00:01:48.400 history of the center to describe

NOTE Confidence: 0.38370234

 $00:01:48.400 \longrightarrow 00:01:50.200$ the administrative organization,

NOTE Confidence: 0.38370234

 $00:01:50.200 \longrightarrow 00:01:53.640$ which is changing very substantially.

NOTE Confidence: 0.38370234

 $00:01:53.640 \longrightarrow 00:01:55.360$ To describe the services

NOTE Confidence: 0.38370234

 $00:01:55.360 \longrightarrow 00:01:57.080$ that we offer briefly.

NOTE Confidence: 0.38370234

 $00:01:57.080 \longrightarrow 00:02:01.394$ And then to have a conversation about

NOTE Confidence: 0.38370234

 $00{:}02{:}01.394 \dashrightarrow 00{:}02{:}05.456$ where our our challenges lie and where

NOTE Confidence: 0.38370234

 $00{:}02{:}05.456 \dashrightarrow 00{:}02{:}07.784$ our opportunities are and how we're

NOTE Confidence: 0.38370234

 $00:02:07.784 \longrightarrow 00:02:10.166$ trying to meet those opportunities

NOTE Confidence: 0.38370234

 $00{:}02{:}10.166 \dashrightarrow 00{:}02{:}12.200$ with an array of new initiatives.

NOTE Confidence: 0.38370234

 $00:02:12.200 \longrightarrow 00:02:16.358$ And then a brief summary I have posed

NOTE Confidence: 0.38370234

 $00:02:16.358 \longrightarrow 00:02:20.045$ as a question that I'd I would very

00:02:20.045 --> 00:02:22.665 much like to discuss with you That

NOTE Confidence: 0.38370234

 $00:02:22.665 \longrightarrow 00:02:24.900$ is how the opportunities specifically

NOTE Confidence: 0.38370234

 $00:02:24.900 \longrightarrow 00:02:27.600$ in research for psychiatry could

NOTE Confidence: 0.38370234

 $00:02:27.600 \longrightarrow 00:02:30.711$ be more effectively served by our

NOTE Confidence: 0.38370234

 $00:02:30.711 \longrightarrow 00:02:33.620$ center and I and I hope to learn from

NOTE Confidence: 0.38370234

 $00{:}02{:}33.620 \longrightarrow 00{:}02{:}35.960$ you in that regard this morning.

NOTE Confidence: 0.38370234

00:02:35.960 --> 00:02:39.370 So the mission of Yale Center

NOTE Confidence: 0.38370234

 $00:02:39.370 \longrightarrow 00:02:40.945$ for Clinical Investigation

NOTE Confidence: 0.38370234

00:02:40.945 --> 00:02:44.070 is to facilitate the the,

NOTE Confidence: 0.38370234

 $00:02:44.070 \longrightarrow 00:02:48.364$ the conduct and the training of members

NOTE Confidence: 0.38370234

 $00{:}02{:}48.364 \dashrightarrow 00{:}02{:}51.071$ of the Yale community in impactful,

NOTE Confidence: 0.38370234 00:02:51.071 --> 00:02:51.662 safe,

NOTE Confidence: 0.38370234

 $00{:}02{:}51.662 \dashrightarrow 00{:}02{:}54.026$ efficient and effective research

NOTE Confidence: 0.38370234

 $00:02:54.026 \longrightarrow 00:02:55.799$ on human subjects.

NOTE Confidence: 0.38370234

00:02:55.800 --> 00:02:59.360 Our our training programs are

NOTE Confidence: 0.38370234

00:02:59.360 --> 00:03:01.910 critically important part of our

 $00:03:01.910 \longrightarrow 00:03:04.976$ mission funded jointly by the CTSA

NOTE Confidence: 0.38370234

00:03:04.976 --> 00:03:08.560 award and by the School of Medicine.

NOTE Confidence: 0.38370234

 $00:03:08.560 \longrightarrow 00:03:11.434$ We're also charged with supporting the

NOTE Confidence: 0.38370234

 $00:03:11.434 \longrightarrow 00:03:14.346$ development of new methods of clinical

NOTE Confidence: 0.38370234

 $00:03:14.346 \longrightarrow 00:03:16.672$ research to improve health outcomes,

NOTE Confidence: 0.38370234

00:03:16.672 --> 00:03:20.004 an area that has taken on added

NOTE Confidence: 0.38370234

00:03:20.004 --> 00:03:22.424 significance given the emphasis of

NOTE Confidence: 0.38370234

 $00{:}03{:}22.424 \dashrightarrow 00{:}03{:}25.320$ N cats in translational science.

NOTE Confidence: 0.38370234

00:03:25.320 --> 00:03:28.520 And then lastly and importantly,

NOTE Confidence: 0.38370234

 $00:03:28.520 \longrightarrow 00:03:30.872$ our mission is to enhance the

NOTE Confidence: 0.38370234

 $00:03:30.872 \longrightarrow 00:03:32.048$ dissemination and implementation

NOTE Confidence: 0.38370234

 $00{:}03{:}32.048 \dashrightarrow 00{:}03{:}34.594$ of research findings to make them

NOTE Confidence: 0.38370234

 $00{:}03{:}34.594 \dashrightarrow 00{:}03{:}36.679$ available for all patient populations.

NOTE Confidence: 0.560577237142857

 $00:03:40.440 \longrightarrow 00:03:44.440$ YCCI is part of a larger clinical research

NOTE Confidence: 0.560577237142857

 $00:03:44.440 \longrightarrow 00:03:47.439$ infrastructure at the School of Medicine.

 $00:03:47.440 \longrightarrow 00:03:51.868$ We are a university wide center,

NOTE Confidence: 0.560577237142857

 $00:03:51.868 \longrightarrow 00:03:55.636$ so we specifically are charged with

NOTE Confidence: 0.560577237142857

00:03:55.636 --> 00:03:58.494 serving faculty throughout Yale University

NOTE Confidence: 0.560577237142857

 $00:03:58.494 \longrightarrow 00:04:01.416$ and particularly those on the medical

NOTE Confidence: 0.560577237142857

00:04:01.416 --> 00:04:04.198 campus from the schools of Nursing,

NOTE Confidence: 0.560577237142857

00:04:04.200 --> 00:04:07.360 Public Health and Medicine.

NOTE Confidence: 0.560577237142857

 $00:04:07.360 \longrightarrow 00:04:09.840$ We also house Administratively House

NOTE Confidence: 0.560577237142857

 $00:04:09.840 \longrightarrow 00:04:13.136$ and and run the Clinical Translational

NOTE Confidence: 0.560577237142857

 $00:04:13.136 \longrightarrow 00:04:17.660$ Science Award and several other large

NOTE Confidence: 0.560577237142857

 $00:04:17.660 \longrightarrow 00:04:21.720$ grants from external agencies devoted

NOTE Confidence: 0.560577237142857

 $00{:}04{:}21.720 \dashrightarrow 00{:}04{:}25.720$ to clinical research methodology.

NOTE Confidence: 0.560577237142857

 $00:04:25.720 \longrightarrow 00:04:26.826$ Sister center,

NOTE Confidence: 0.560577237142857

 $00{:}04{:}26.826 \dashrightarrow 00{:}04{:}30.459$ the Yale Cancer Center has a large

NOTE Confidence: 0.560577237142857

 $00:04:30.459 \longrightarrow 00:04:32.824$ portfolio of services as well

NOTE Confidence: 0.560577237142857

 $00:04:32.824 \longrightarrow 00:04:36.069$ and is similar in many respects

NOTE Confidence: 0.560577237142857

 $00{:}04{:}36.069 \dashrightarrow 00{:}04{:}39.691$ in its mission except that it's

 $00:04:39.691 \longrightarrow 00:04:42.319$ exclusively focused on cancer.

NOTE Confidence: 0.560577237142857

 $00:04:42.320 \longrightarrow 00:04:44.952$ And then there are a variety of

NOTE Confidence: 0.560577237142857

00:04:44.952 --> 00:04:46.540 departmentally based units in

NOTE Confidence: 0.560577237142857

 $00:04:46.540 \longrightarrow 00:04:48.840$ in several large sections and

NOTE Confidence: 0.560577237142857

 $00:04:48.840 \longrightarrow 00:04:50.680$ departments such as cardiology,

NOTE Confidence: 0.560577237142857

00:04:50.680 --> 00:04:53.038 neurology, geriatric psychiatry,

NOTE Confidence: 0.560577237142857

 $00:04:53.038 \longrightarrow 00:04:55.396$ anesthesia and medicine.

NOTE Confidence: 0.560577237142857

 $00{:}04{:}55.400 \dashrightarrow 00{:}04{:}58.844$ And these have evolved over time to

NOTE Confidence: 0.560577237142857

 $00{:}04{:}58.844 \dashrightarrow 00{:}05{:}02.556$ meet some of the unique challenges

NOTE Confidence: 0.560577237142857

 $00:05:02.556 \longrightarrow 00:05:06.096$ that faculty and their respective

NOTE Confidence: 0.560577237142857

 $00{:}05{:}06.096 \mathrel{--}{>} 00{:}05{:}09.159$ content areas or geography or

NOTE Confidence: 0.560577237142857

 $00:05:09.160 \longrightarrow 00:05:13.840$ scientific questions really require.

NOTE Confidence: 0.560577237142857

 $00{:}05{:}13.840 \dashrightarrow 00{:}05{:}16.780$ So it's important to just take note

NOTE Confidence: 0.560577237142857

 $00{:}05{:}16.780 \dashrightarrow 00{:}05{:}19.330$ that we are an important but not

NOTE Confidence: 0.560577237142857

 $00:05:19.330 \longrightarrow 00:05:21.287$ sole provider of clinical research

 $00:05:21.287 \longrightarrow 00:05:23.592$ infrastructure at the Yale School

NOTE Confidence: 0.560577237142857

 $00:05:23.592 \longrightarrow 00:05:24.514$ of Medicine.

NOTE Confidence: 0.8360266

00:05:26.960 --> 00:05:30.532 So over the course of YCCIS history,

NOTE Confidence: 0.8360266

 $00:05:30.532 \longrightarrow 00:05:34.840$ which began back in 2005,

NOTE Confidence: 0.8360266

 $00:05:34.840 \longrightarrow 00:05:38.040$ the center was the primary

NOTE Confidence: 0.48105985

 $00:05:40.640 \longrightarrow 00:05:43.440$ impetus behind this successful

NOTE Confidence: 0.48105985

 $00:05:43.440 \longrightarrow 00:05:46.457$ application for the first cohort

NOTE Confidence: 0.48105985

 $00:05:46.457 \longrightarrow 00:05:48.613$ of Clinical Translational Science

NOTE Confidence: 0.48105985

 $00{:}05{:}48.613 \dashrightarrow 00{:}05{:}52.560$ Awards funded by NIH in 2006.

NOTE Confidence: 0.48105985

 $00{:}05{:}52.560 \dashrightarrow 00{:}05{:}55.592$ The Yale's CTSA has been

NOTE Confidence: 0.48105985

 $00{:}05{:}55.592 \dashrightarrow 00{:}05{:}57.832$ continuously funded since that time,

NOTE Confidence: 0.48105985

 $00:05:57.840 \longrightarrow 00:06:01.520$ a really remarkable achievement.

NOTE Confidence: 0.48105985

 $00{:}06{:}01.520 \dashrightarrow 00{:}06{:}04.544$ The trainees in the so-called Yale

NOTE Confidence: 0.48105985

 $00:06:04.544 \longrightarrow 00:06:07.520$ Scholars Program of YCCI have involved

NOTE Confidence: 0.48105985

 $00:06:07.520 \longrightarrow 00:06:11.780$ the training of 200 faculty from 24

NOTE Confidence: 0.48105985

 $00:06:11.780 \longrightarrow 00:06:15.128$ departments with a substantial record.

 $00:06:15.128 \longrightarrow 00:06:18.180$ Over the years in grant

NOTE Confidence: 0.48105985

 $00:06:18.180 \longrightarrow 00:06:21.000$ funding and publications,

NOTE Confidence: 0.48105985

00:06:21.000 --> 00:06:26.680 YCCI developed 36 new programs,

NOTE Confidence: 0.48105985

 $00:06:26.680 \longrightarrow 00:06:30.144$ 11 portion of which was one of the

NOTE Confidence: 0.48105985

 $00:06:30.144 \longrightarrow 00:06:31.691$ first bidirectional interfaces

NOTE Confidence: 0.48105985

00:06:31.691 --> 00:06:34.661 between EPIC and the clinical

NOTE Confidence: 0.48105985

00:06:34.661 --> 00:06:37.037 trial management software ENCORE.

NOTE Confidence: 0.69144136

 $00{:}06{:}39.920 \dashrightarrow 00{:}06{:}42.832$ YCCI and the Cancer Center are major

NOTE Confidence: 0.69144136

 $00{:}06{:}42.832 \dashrightarrow 00{:}06{:}45.309$ sources of support for what has been

NOTE Confidence: 0.69144136

 $00:06:45.309 \longrightarrow 00:06:47.840$ a really substantial increase in the

NOTE Confidence: 0.69144136

 $00:06:47.840 \longrightarrow 00:06:50.080$ number of industry funded trials

NOTE Confidence: 0.69144136

 $00:06:52.240 \longrightarrow 00:06:56.000$ as well as those funded

NOTE Confidence: 0.69144136

 $00{:}06{:}56.000 \dashrightarrow 00{:}07{:}00.513$ by NIH when YCCI began.

NOTE Confidence: 0.69144136

00:07:00.513 --> 00:07:05.460 Approximately 1/4 of the RO ones

NOTE Confidence: 0.69144136

00:07:05.460 --> 00:07:07.310 through Yale School of Medicine

00:07:07.310 --> 00:07:09.800 had a human subjects protocol,

NOTE Confidence: 0.69144136

 $00:07:09.800 \longrightarrow 00:07:13.796$ and more recently that number is up over 3/4,

NOTE Confidence: 0.69144136

 $00{:}07{:}13.800 \dashrightarrow 00{:}07{:}16.360$ which reflects a combination of

NOTE Confidence: 0.69144136

 $00:07:16.360 \longrightarrow 00:07:18.840$ changing priorities of funding agencies,

NOTE Confidence: 0.69144136

00:07:18.840 --> 00:07:21.360 but also importantly,

NOTE Confidence: 0.69144136

 $00:07:21.360 \longrightarrow 00:07:23.620$ the interests and infrastructure

NOTE Confidence: 0.69144136

 $00:07:23.620 \longrightarrow 00:07:25.880$ of the Yale faculty.

NOTE Confidence: 0.42645243

 $00:07:28.280 \longrightarrow 00:07:32.226$ The YCCI developed a number of interesting

NOTE Confidence: 0.42645243

 $00{:}07{:}32.226 \dashrightarrow 00{:}07{:}35.356$ community engagement strategies to help

NOTE Confidence: 0.42645243

00:07:35.356 --> 00:07:38.968 us discover program and Yale Cultural

NOTE Confidence: 0.42645243

 $00{:}07{:}38.968 {\:\raisebox{--}{\text{--}}}{\:\raisebox{--}{\text{--}}}{\:\raisebox{--}{\text{--}}} 00{:}07{:}41.848$ Ambassadors Program have been models

NOTE Confidence: 0.42645243

 $00:07:41.848 \longrightarrow 00:07:43.980$ nationally for community engagement

NOTE Confidence: 0.42645243

 $00:07:43.980 \longrightarrow 00:07:46.920$ of research and in particular for

NOTE Confidence: 0.42645243

 $00{:}07{:}46.920 \dashrightarrow 00{:}07{:}51.100$ extending research to relatively

NOTE Confidence: 0.42645243

 $00:07:51.100 \longrightarrow 00:07:54.880$ understudied patient populations.

NOTE Confidence: 0.42645243

 $00{:}07{:}54.880 \dashrightarrow 00{:}07{:}59.017$ We've provided a lot of services over

 $00:07:59.017 \longrightarrow 00:08:04.560$ 7000 and those those services have

NOTE Confidence: 0.42645243

 $00:08:04.560 \longrightarrow 00:08:08.400$ given rise to nearly 5000 publications.

NOTE Confidence: 0.42645243

 $00:08:08.400 \longrightarrow 00:08:10.974$ There's also been a very substantial

NOTE Confidence: 0.42645243

00:08:10.974 --> 00:08:14.190 number of pilot grants and RFA for which

NOTE Confidence: 0.42645243

 $00:08:14.190 \longrightarrow 00:08:16.840$ is about to be distributed once again.

NOTE Confidence: 0.42645243

 $00:08:16.840 \longrightarrow 00:08:21.250$ So there is much to be proud of at

NOTE Confidence: 0.42645243

 $00:08:21.250 \longrightarrow 00:08:24.520$ Yale in its history of clinical

NOTE Confidence: 0.42645243

 $00:08:24.520 \longrightarrow 00:08:27.100$ investigation and YCCI has had an

NOTE Confidence: 0.42645243

 $00:08:27.100 \longrightarrow 00:08:29.080$ important role in that history.

NOTE Confidence: 0.9699061

 $00{:}08{:}31.760 \dashrightarrow 00{:}08{:}35.096$ The numbers of clinical research at

NOTE Confidence: 0.9699061

 $00:08:35.096 \longrightarrow 00:08:37.688$ the School of Medicine reflect the

NOTE Confidence: 0.9699061

 $00:08:37.688 \longrightarrow 00:08:39.517$ generalizations on the previous slide.

NOTE Confidence: 0.9699061

 $00:08:39.520 \longrightarrow 00:08:43.160$ If you tabulate just the number of

NOTE Confidence: 0.9699061

 $00{:}08{:}43.160 \dashrightarrow 00{:}08{:}45.260$ clinical research protocols that

NOTE Confidence: 0.9699061

00:08:45.260 --> 00:08:48.576 are not exempt from IRB approval,

00:08:48.576 --> 00:08:52.832 that is studies that need IRB approval,

NOTE Confidence: 0.9699061

 $00{:}08{:}52.840 \dashrightarrow 00{:}08{:}56.760$ it's roughly doubled since from

NOTE Confidence: 0.9699061

 $00{:}08{:}56.760 \dashrightarrow 00{:}09{:}00{.}940$ 2019 to 2023 from a little over

NOTE Confidence: 0.9699061

 $00:09:00.940 \longrightarrow 00:09:03.600$ 2000 to a little over 4000.

NOTE Confidence: 0.9699061

 $00:09:03.600 \longrightarrow 00:09:05.910$ It is important to note that in

NOTE Confidence: 0.9699061

 $00:09:05.910 \longrightarrow 00:09:09.102$ all of the categories there's been

NOTE Confidence: 0.9699061

 $00:09:09.102 \longrightarrow 00:09:12.084$ substantial increases but the the most

NOTE Confidence: 0.9699061

 $00:09:12.084 \longrightarrow 00:09:14.430$ dramatic increase as I alluded to

NOTE Confidence: 0.9699061

 $00{:}09{:}14.518 \dashrightarrow 00{:}09{:}17.203$ earlier has been industry supported

NOTE Confidence: 0.9699061

00:09:17.203 --> 00:09:20.180 trials going up nearly threefold in

NOTE Confidence: 0.9699061

 $00:09:20.180 \longrightarrow 00:09:24.840$ the five year period since 2019.

NOTE Confidence: 0.9699061

 $00{:}09{:}24.840 \dashrightarrow 00{:}09{:}30.028$ It's also notable that we support a

NOTE Confidence: 0.9699061

 $00{:}09{:}30.028 \rightarrow 00{:}09{:}32.752$ number of unfunded studies at the

NOTE Confidence: 0.9699061

 $00:09:32.752 \longrightarrow 00:09:36.059$ School of Medicine and the we here

NOTE Confidence: 0.9699061

 $00:09:36.059 \longrightarrow 00:09:38.891$ is departments and the Cancer Center

NOTE Confidence: 0.9699061

 $00:09:38.891 \longrightarrow 00:09:43.196$ and the School of Medicine and YCCI.

 $00:09:43.200 \longrightarrow 00:09:46.674$ And these unfunded studies are as

NOTE Confidence: 0.9699061

 $00:09:46.674 \longrightarrow 00:09:50.400$ you would imagine a mix of of studies

NOTE Confidence: 0.9699061

 $00:09:50.400 \longrightarrow 00:09:53.888$ that primarily are focused at

NOTE Confidence: 0.9699061

00:09:53.888 --> 00:09:56.456 generating preliminary data for

NOTE Confidence: 0.9699061

 $00:09:56.456 \longrightarrow 00:09:58.920$ eventual grant submissions.

NOTE Confidence: 0.9699061

 $00:09:58.920 \longrightarrow 00:10:02.546$ So really I think a a impressive

NOTE Confidence: 0.9699061

00:10:02.546 --> 00:10:06.964 and good news story for growth of

NOTE Confidence: 0.9699061

 $00{:}10{:}06.964 \dashrightarrow 00{:}10{:}09.674$ clinical research at the school

NOTE Confidence: 0.9699061

 $00:10:09.680 \longrightarrow 00:10:11.975$ and this obviously reflects the

NOTE Confidence: 0.9699061

 $00:10:11.975 \dashrightarrow 00:10:14.715$ commitment of the leadership of the

NOTE Confidence: 0.9699061

 $00{:}10{:}14.715 \dashrightarrow 00{:}10{:}17.168$ school going back several Deans.

NOTE Confidence: 0.9699061

 $00:10:17.168 \longrightarrow 00:10:21.626$ But a lot of this growth occurred obviously

NOTE Confidence: 0.9699061

 $00:10:21.626 \dashrightarrow 00:10:24.714$ under Dean Alpern and now under Dean Brown.

NOTE Confidence: 0.6658534

 $00:10:27.840 \longrightarrow 00:10:34.412$ An important perspective is on how YCCI is

NOTE Confidence: 0.6658534

 $00{:}10{:}34.412 \dashrightarrow 00{:}10{:}37.370$ supported and I think there's a there's

 $00:10:37.370 \longrightarrow 00:10:39.269$ a couple of really important messages

NOTE Confidence: 0.6658534

 $00:10:39.269 \longrightarrow 00:10:42.286$ here that I want to leave you with #1.

NOTE Confidence: 0.6658534

 $00:10:42.286 \longrightarrow 00:10:45.290$ If you just look at the blue

NOTE Confidence: 0.6658534

00:10:45.290 --> 00:10:47.715 part of this pie chart,

NOTE Confidence: 0.6658534

 $00:10:47.720 \longrightarrow 00:10:51.416$ we are on schedule to receive

NOTE Confidence: 0.6658534

 $00:10:51.416 \longrightarrow 00:10:54.520$ just under \$25 million from the

NOTE Confidence: 0.6658534

 $00:10:54.520 \longrightarrow 00:10:56.440$ combination of the School of Medicine,

NOTE Confidence: 0.6658534

00:10:56.440 --> 00:10:59.275 the Faculty Practice Plan or Yale Medicine

NOTE Confidence: 0.6658534

 $00{:}10{:}59.280 \to 00{:}11{:}03.120$ and Yale New Haven Health System.

NOTE Confidence: 0.6658534

 $00:11:03.120 \longrightarrow 00:11:05.840$ So this represents A remarkable

NOTE Confidence: 0.6658534

 $00{:}11{:}05.840 \to 00{:}11{:}09.920$ contribution in my mind of those 3

NOTE Confidence: 0.6658534

 $00{:}11{:}09.920 \dashrightarrow 00{:}11{:}14.000$ entities in support of clinical research.

NOTE Confidence: 0.6658534

 $00:11:14.000 \longrightarrow 00:11:18.270$ It's also noteworthy that we get just

NOTE Confidence: 0.6658534

 $00{:}11{:}18.270 \dashrightarrow 00{:}11{:}21.450$ under 9,000,000 and the orange slice

NOTE Confidence: 0.6658534

00:11:21.450 --> 00:11:27.280 from our our CTSA in contrast to many

NOTE Confidence: 0.6658534

 $00{:}11{:}27.280 \dashrightarrow 00{:}11{:}31.680$ other academic medical centers are

 $00:11:31.680 \longrightarrow 00:11:35.360$ YCCI infrastructure is relatively

NOTE Confidence: 0.6658534

 $00{:}11{:}35.360 \dashrightarrow 00{:}11{:}38.560$ well supported by the institution

NOTE Confidence: 0.6658534

 $00:11:38.560 \longrightarrow 00:11:42.088$ that in our survey that we've done the

NOTE Confidence: 0.6658534

 $00:11:42.088 \longrightarrow 00:11:44.327$ ratio between institutional support

NOTE Confidence: 0.6658534

00:11:44.327 --> 00:11:48.025 and CTSA range from 1:00 to 1:00

NOTE Confidence: 0.6658534

 $00:11:48.025 \longrightarrow 00:11:52.390$ to to 3:00 to 1:00 and we are in in

NOTE Confidence: 0.6658534

 $00:11:52.390 \longrightarrow 00:11:54.698$ roughly in the three to one ratio.

NOTE Confidence: 0.6658534

00:11:54.698 --> 00:11:57.380 So I I think it is important to to

NOTE Confidence: 0.6658534

 $00:11:57.460 \longrightarrow 00:11:59.755$ celebrate really and certainly to

NOTE Confidence: 0.6658534

 $00{:}11{:}59.755 \dashrightarrow 00{:}12{:}02.495$ acknowledge the fact that the health

NOTE Confidence: 0.6658534

 $00{:}12{:}02.495 \dashrightarrow 00{:}12{:}05.092$ system and the School of Medicine as

NOTE Confidence: 0.6658534

 $00:12:05.092 \longrightarrow 00:12:08.336$ well as the the clinical departments

NOTE Confidence: 0.6658534

 $00{:}12{:}08.336 \dashrightarrow 00{:}12{:}11.456$ are really making a substantial

NOTE Confidence: 0.6658534

 $00:12:11.456 \longrightarrow 00:12:13.560$ contribution to this center and to

NOTE Confidence: 0.6658534

 $00:12:13.560 \longrightarrow 00:12:15.040$ the growth of clinical research.

 $00:12:17.360 \longrightarrow 00:12:20.594$ The the Gray shaded area is

NOTE Confidence: 0.37598565

 $00{:}12{:}20.594 \dashrightarrow 00{:}12{:}22.750$ reflects our projected revenue

NOTE Confidence: 0.37598565

 $00:12:22.850 \longrightarrow 00:12:25.920$ from services that YCCI provides.

NOTE Confidence: 0.37598565

 $00:12:25.920 \longrightarrow 00:12:28.220$ Most of that revenue comes

NOTE Confidence: 0.37598565

 $00:12:28.220 \longrightarrow 00:12:29.600$ from research sponsors,

NOTE Confidence: 0.37598565

00:12:29.600 --> 00:12:32.804 NIH and industry and we're projecting

NOTE Confidence: 0.37598565

 $00:12:32.804 \longrightarrow 00:12:35.960$ A substantial increase in that revenue

NOTE Confidence: 0.37598565

 $00:12:35.960 \longrightarrow 00:12:38.756$ as the number of projects grow,

NOTE Confidence: 0.37598565

 $00{:}12{:}38.760 \dashrightarrow 00{:}12{:}41.682$ our services expand and we increase

NOTE Confidence: 0.37598565

 $00:12:41.682 \longrightarrow 00:12:44.520$ the rates for those services.

NOTE Confidence: 0.37598565

 $00:12:44.520 \longrightarrow 00:12:46.596$ And then there are in addition,

NOTE Confidence: 0.37598565

 $00:12:46.600 \longrightarrow 00:12:50.661$ there are grants from Pharma

NOTE Confidence: 0.37598565

 $00{:}12{:}50.661 \dashrightarrow 00{:}12{:}53.496$ Foundation and from FDA that

NOTE Confidence: 0.37598565

 $00:12:53.496 \longrightarrow 00:12:55.593$ provide additional revenue that

NOTE Confidence: 0.37598565

00:12:55.593 --> 00:12:56.958 are managed through the center.

NOTE Confidence: 0.861495

 $00{:}13{:}00.240 \dashrightarrow 00{:}13{:}03.397$ Our training programs are are listed here.

00:13:03.400 --> 00:13:05.682 I know there are a number of

NOTE Confidence: 0.861495

00:13:05.682 --> 00:13:07.852 faculty from the Department of

NOTE Confidence: 0.861495

 $00:13:07.852 \longrightarrow 00:13:10.076$ Psychiatry who have participated

NOTE Confidence: 0.861495

 $00:13:10.080 \longrightarrow 00:13:12.960$ in both the T and the K programs.

NOTE Confidence: 0.861495

 $00:13:12.960 \longrightarrow 00:13:16.915$ These are both of these programs are

NOTE Confidence: 0.861495

00:13:16.915 --> 00:13:21.960 funded about 60% by the CTSA award and

NOTE Confidence: 0.861495

 $00:13:21.960 \longrightarrow 00:13:27.440$ about 40% by the School of Medicine.

NOTE Confidence: 0.861495

 $00:13:27.440 \longrightarrow 00:13:30.808$ We also offer a number of other services

NOTE Confidence: 0.861495

00:13:30.808 --> 00:13:35.344 for trainees and faculty in grant writing,

NOTE Confidence: 0.861495

 $00:13:35.344 \longrightarrow 00:13:39.740$ a summer Rokats program focused on developing

NOTE Confidence: 0.861495

00:13:39.740 --> 00:13:42.840 skills in interdisciplinary team science,

NOTE Confidence: 0.861495

 $00{:}13{:}42.840 \dashrightarrow 00{:}13{:}47.072$ several both individual and group

NOTE Confidence: 0.861495

 $00{:}13{:}47.072 \dashrightarrow 00{:}13{:}49.305$ meetings to discuss research.

NOTE Confidence: 0.861495

 $00{:}13{:}49.305 \dashrightarrow 00{:}13{:}52.920$ We also try to facilitate and select

NOTE Confidence: 0.861495

 $00:13:52.920 \longrightarrow 00:13:54.600$ candidates for supplementary awards,

 $00:13:54.600 \longrightarrow 00:13:56.484$ particularly diversity supplements.

NOTE Confidence: 0.861495

 $00{:}13{:}56.484 \dashrightarrow 00{:}14{:}01.850$ And we do house at least part of the support

NOTE Confidence: 0.861495

 $00:14:01.850 \longrightarrow 00:14:04.084$ for the Investigative Medicine Program,

NOTE Confidence: 0.861495

 $00:14:04.084 \longrightarrow 00:14:07.080$ which as you probably know is the

NOTE Confidence: 0.861495

 $00:14:07.080 \longrightarrow 00:14:11.052$ MD to PhD program that is offered

NOTE Confidence: 0.861495

 $00:14:11.052 \longrightarrow 00:14:12.756$ by the Graduate School.

NOTE Confidence: 0.9499234

 $00:14:14.960 \longrightarrow 00:14:18.400$ Our services that we offer are listed here.

NOTE Confidence: 0.9499234

 $00:14:18.400 \longrightarrow 00:14:20.680$ These are in various states of

NOTE Confidence: 0.9499234

 $00{:}14{:}20.680 \dashrightarrow 00{:}14{:}23.600$ expansion and in some cases contraction.

NOTE Confidence: 0.7381935

 $00:14:25.920 \longrightarrow 00:14:27.780$ When we ask faculty where

NOTE Confidence: 0.7381935

 $00:14:27.780 \longrightarrow 00:14:29.640$ we can improve the most,

NOTE Confidence: 0.7381935

 $00:14:29.640 \longrightarrow 00:14:32.240$ what we hear is on the first line

NOTE Confidence: 0.7381935

 $00:14:32.240 \longrightarrow 00:14:34.608$ Biostatistics and study design.

NOTE Confidence: 0.7381935

 $00:14:34.608 \longrightarrow 00:14:38.160$ There is a tremendous interest in

NOTE Confidence: 0.7381935

 $00:14:38.259 \longrightarrow 00:14:41.880$ expanding these services so that faculty

NOTE Confidence: 0.7381935

 $00{:}14{:}41.880 \dashrightarrow 00{:}14{:}46.518$ have greater access to those services.

00:14:46.520 --> 00:14:49.376 But in addition, these services,

NOTE Confidence: 0.7381935

00:14:49.376 --> 00:14:51.392 I won't read them all to you,

NOTE Confidence: 0.7381935

 $00:14:51.400 \longrightarrow 00:14:54.440$ but just to convey the,

NOTE Confidence: 0.7381935

00:14:54.440 --> 00:14:58.320 the sense that there's a very broad range of

NOTE Confidence: 0.7381935

 $00:14:58.320 \longrightarrow 00:15:01.320$ services related to the conceptualization,

NOTE Confidence: 0.7381935

 $00:15:01.320 \longrightarrow 00:15:05.520$ activation, execution and then completion

NOTE Confidence: 0.7381935

 $00:15:05.520 \longrightarrow 00:15:08.880$ of clinical research protocols.

NOTE Confidence: 0.7381935

 $00:15:08.880 \longrightarrow 00:15:13.060$ The one area that we are contracting is in,

NOTE Confidence: 0.7381935

 $00{:}15{:}13.060 \dashrightarrow 00{:}15{:}16.160$ well may be there's two areas.

NOTE Confidence: 0.7381935

00:15:16.160 --> 00:15:18.320 One is in sample management.

NOTE Confidence: 0.7381935

 $00:15:18.320 \longrightarrow 00:15:23.370$ We are we have been one of the several homes

NOTE Confidence: 0.7381935

 $00:15:23.490 \longrightarrow 00:15:27.836$ of bio repository mostly a blood samples.

NOTE Confidence: 0.7381935

 $00{:}15{:}27.840 \to 00{:}15{:}30.222$ We are continuing to store those

NOTE Confidence: 0.7381935

 $00:15:30.222 \longrightarrow 00:15:32.920$ but we are beginning to advise

NOTE Confidence: 0.7381935

 $00:15:32.920 \longrightarrow 00:15:37.251$ investigators to use the central

 $00:15:37.251 \longrightarrow 00:15:42.117$ repository in pathology and lab medicine.

NOTE Confidence: 0.7381935

 $00{:}15{:}42.120 \dashrightarrow 00{:}15{:}45.900$ We are also getting largely out

NOTE Confidence: 0.7381935

 $00:15:45.900 \longrightarrow 00:15:48.000$ of the data management business.

NOTE Confidence: 0.7381935

 $00:15:48.000 \longrightarrow 00:15:49.444$ We will do some.

NOTE Confidence: 0.7381935

 $00:15:49.444 \longrightarrow 00:15:52.087$ We will be the business owner of

NOTE Confidence: 0.7381935

00:15:52.087 --> 00:15:54.379 several data management platforms,

NOTE Confidence: 0.7381935

 $00:15:54.379 \longrightarrow 00:15:57.795$ but the new section of biomedical

NOTE Confidence: 0.7381935

 $00:15:57.795 \longrightarrow 00:16:00.825$ informatics and data science is taking

NOTE Confidence: 0.7381935

 $00{:}16{:}00.825 \dashrightarrow 00{:}16{:}03.938$ over these functions and bringing

NOTE Confidence: 0.7381935

 $00:16:03.938 \longrightarrow 00:16:07.811$ frankly tremendous expertise to this area,

NOTE Confidence: 0.7381935

 $00{:}16{:}07.811 \dashrightarrow 00{:}16{:}10.982$ which has been historically pretty

NOTE Confidence: 0.7381935

 $00:16:10.982 \longrightarrow 00:16:13.150$ widely distributed in several

NOTE Confidence: 0.7381935

 $00:16:13.150 \longrightarrow 00:16:15.318$ different centers including YCCI.

NOTE Confidence: 0.7381935

 $00{:}16{:}15.320 \dashrightarrow 00{:}16{:}18.323$ So this is largely being excised out

NOTE Confidence: 0.7381935

00:16:18.323 --> 00:16:21.059 of YCCI and migrating administratively

NOTE Confidence: 0.7381935

00:16:21.059 --> 00:16:25.133 under this new section directed by

 $00:16:25.133 \longrightarrow 00:16:28.268$ Doctor Lucilla Onomachado and we're

NOTE Confidence: 0.7381935

 $00{:}16{:}28.268 \dashrightarrow 00{:}16{:}30.238$ very excited about that partnership.

NOTE Confidence: 0.7747299

 $00:16:35.120 \longrightarrow 00:16:40.449$ So it wouldn't be a reasonable

NOTE Confidence: 0.7747299

00:16:40.449 --> 00:16:43.094 presentation frankly to not discuss

NOTE Confidence: 0.7747299

 $00:16:43.094 \longrightarrow 00:16:45.844$ where some of our challenges

NOTE Confidence: 0.7747299

 $00:16:45.844 \longrightarrow 00:16:48.599$ are and they are substantial.

NOTE Confidence: 0.7747299

 $00:16:48.600 \longrightarrow 00:16:50.760$ They they reflect I think

NOTE Confidence: 0.7747299

 $00:16:50.760 \longrightarrow 00:16:52.920$ the ambition of the faculty,

NOTE Confidence: 0.7747299

 $00{:}16{:}52.920 \dashrightarrow 00{:}16{:}55.660$ the opportunities in clinical

NOTE Confidence: 0.7747299

 $00:16:55.660 \longrightarrow 00:16:58.400$ research and evolving methodologies.

NOTE Confidence: 0.7747299

 $00:16:58.400 \longrightarrow 00:17:03.560$ But they also reflect I think some

NOTE Confidence: 0.7747299

 $00{:}17{:}03.560 \dashrightarrow 00{:}17{:}05.736$ operational challenges that we

NOTE Confidence: 0.7747299

00:17:05.736 --> 00:17:09.544 have as a center have been somewhat

NOTE Confidence: 0.7747299

 $00{:}17{:}09.544 \dashrightarrow 00{:}17{:}12.808$ slow to address in part confounded

NOTE Confidence: 0.7747299

 $00:17:12.808 \longrightarrow 00:17:16.319$ frankly by the the challenges that

 $00:17:16.320 \longrightarrow 00:17:19.320$ so many centers and departments

NOTE Confidence: 0.7747299

 $00{:}17{:}19.320 \dashrightarrow 00{:}17{:}22.320$ face through the COVID pandemic.

NOTE Confidence: 0.7747299

 $00{:}17{:}22.320 \dashrightarrow 00{:}17{:}24.460$ So I've listed our challenges

NOTE Confidence: 0.7747299

 $00:17:24.460 \longrightarrow 00:17:26.600$ here in three different buckets.

NOTE Confidence: 0.7747299

 $00:17:26.600 \longrightarrow 00:17:29.113$ I do want to go through these

NOTE Confidence: 0.7747299

00:17:29.113 --> 00:17:31.230 because they they are important

NOTE Confidence: 0.7747299

 $00{:}17{:}31.230 \dashrightarrow 00{:}17{:}33.635$ in informing the initiatives and

NOTE Confidence: 0.7747299

 $00:17:33.635 \longrightarrow 00:17:35.999$ future growth of the center.

NOTE Confidence: 0.7747299

 $00{:}17{:}36.000 \mathrel{--}{>} 00{:}17{:}39.630$ So strategically one of our our

NOTE Confidence: 0.7747299

 $00:17:39.630 \longrightarrow 00:17:43.879$ challenges is that we largely support

NOTE Confidence: 0.7747299

 $00{:}17{:}43.880 \mathrel{--}{>} 00{:}17{:}46.772$ interventional clinical trials and

NOTE Confidence: 0.7747299

 $00:17:46.772 \longrightarrow 00:17:50.387$ pathophysiology studies like one would

NOTE Confidence: 0.7747299

 $00:17:50.387 \longrightarrow 00:17:54.131$ do in a typical supervised either

NOTE Confidence: 0.7747299

 $00:17:54.131 \longrightarrow 00:17:58.517$ ambulatory or hospital based research unit.

NOTE Confidence: 0.7747299

 $00:17:58.520 \longrightarrow 00:18:01.873$ We are relatively light in our support

NOTE Confidence: 0.7747299

 $00:18:01.873 \longrightarrow 00:18:04.148$ of other research methodologies

 $00:18:04.148 \longrightarrow 00:18:07.156$ such as observational studies,

NOTE Confidence: 0.7747299

 $00:18:07.160 \longrightarrow 00:18:09.968$ case control studies,

NOTE Confidence: 0.7747299

00:18:09.968 --> 00:18:11.840 epidemiologic studies,

NOTE Confidence: 0.7747299

 $00:18:11.840 \longrightarrow 00:18:13.480$ health services.

NOTE Confidence: 0.7747299

 $00{:}18{:}13.480 \dashrightarrow 00{:}18{:}18.182$ And I I think you know my own view and

NOTE Confidence: 0.7747299

 $00{:}18{:}18.182 \dashrightarrow 00{:}18{:}20.479$ this is just a personal view is that

NOTE Confidence: 0.95718986

 $00:18:23.080 \longrightarrow 00:18:27.000$ the center needs to have a broader range

NOTE Confidence: 0.95718986

00:18:27.000 --> 00:18:29.785 of infrastructure to leverage those

NOTE Confidence: 0.95718986

 $00:18:29.785 \longrightarrow 00:18:32.640$ other forms of research methodology.

NOTE Confidence: 0.95718986

00:18:32.640 --> 00:18:34.915 We have certainly have plenty of very,

NOTE Confidence: 0.95718986

 $00:18:34.920 \longrightarrow 00:18:38.280$ very distinguished faculty in those areas,

NOTE Confidence: 0.95718986

 $00:18:38.280 \longrightarrow 00:18:40.786$ but they don't benefit in the same

NOTE Confidence: 0.95718986

 $00:18:40.786 \longrightarrow 00:18:44.174$ way and with the same magnitude that

NOTE Confidence: 0.95718986

 $00:18:44.174 \longrightarrow 00:18:48.444$ investigators who use either the

NOTE Confidence: 0.95718986

 $00:18:48.444 \longrightarrow 00:18:53.684$ GCRC or HRU or use do interventional

 $00:18:53.684 \longrightarrow 00:18:56.594$ clinical trials currently benefit from.

NOTE Confidence: 0.95718986

00:18:56.600 --> 00:19:00.849 And this is common I think in

NOTE Confidence: 0.95718986

 $00:19:00.849 \longrightarrow 00:19:04.135$ historically rooted in the priorities

NOTE Confidence: 0.95718986

00:19:04.135 --> 00:19:07.360 of Ncats with the CTSA awards and

NOTE Confidence: 0.95718986

 $00:19:07.360 \longrightarrow 00:19:09.240$ that is changing very rapidly.

NOTE Confidence: 0.95718986

 $00:19:09.240 \longrightarrow 00:19:13.520$ And I think our center needs to to

NOTE Confidence: 0.95718986

 $00:19:13.520 \longrightarrow 00:19:15.810$ help generate A strategic discussion

NOTE Confidence: 0.95718986

 $00:19:15.810 \longrightarrow 00:19:18.590$ with the faculty and the leadership

NOTE Confidence: 0.95718986

 $00:19:18.590 \longrightarrow 00:19:21.038$ of the school in this area.

NOTE Confidence: 0.95718986

 $00:19:21.040 \longrightarrow 00:19:26.638$ We like all clinical investigators have

NOTE Confidence: 0.95718986

 $00:19:26.640 \longrightarrow 00:19:30.066$ a real moral and practical imperative

NOTE Confidence: 0.95718986

 $00:19:30.066 \longrightarrow 00:19:33.412$ to conduct generalizable studies and

NOTE Confidence: 0.95718986

00:19:33.412 --> 00:19:36.704 we unfortunately do not reach all

NOTE Confidence: 0.95718986

 $00{:}19{:}36.704 \dashrightarrow 00{:}19{:}39.084$ relevant patient populations that we

NOTE Confidence: 0.95718986

 $00:19:39.084 \longrightarrow 00:19:42.358$ have an obligation to serve clinically

NOTE Confidence: 0.95718986

 $00{:}19{:}42.360 \dashrightarrow 00{:}19{:}44.320$ in our clinical research protocols.

 $00:19:44.320 \longrightarrow 00:19:44.880$ So

NOTE Confidence: 0.7194853

 $00:19:47.200 \longrightarrow 00:19:51.880$ designing new methods to enfranchise

NOTE Confidence: 0.7194853

00:19:51.880 --> 00:19:55.184 populations who have historically

NOTE Confidence: 0.7194853

 $00:19:55.184 \longrightarrow 00:19:58.139$ been disenfranchised to engage in

NOTE Confidence: 0.7194853

 $00{:}19{:}58.139 \dashrightarrow 00{:}20{:}00.737$ clinical research is an area that's

NOTE Confidence: 0.7194853

 $00:20:00.737 \longrightarrow 00:20:03.239$ particularly compelling and that we have.

NOTE Confidence: 0.7194853

00:20:03.240 --> 00:20:08.040 A lot of interest and a lot of leadership in,

NOTE Confidence: 0.7194853

 $00:20:08.040 \longrightarrow 00:20:10.623$ but it would not be correct to say that

NOTE Confidence: 0.7194853

 $00:20:10.623 \longrightarrow 00:20:15.119$ we are where we want to be in that area.

NOTE Confidence: 0.7194853

 $00:20:15.120 \longrightarrow 00:20:20.400$ Ncats, the NIH sponsor of the Ctsas is

NOTE Confidence: 0.7194853

00:20:20.400 --> 00:20:23.200 moving very aggressively towards community

NOTE Confidence: 0.7194853

 $00:20:23.200 \longrightarrow 00:20:26.479$ based research and translational science.

NOTE Confidence: 0.7194853

 $00:20:26.480 \longrightarrow 00:20:30.320$ The days of them supporting clinical

NOTE Confidence: 0.7194853

 $00:20:30.320 \longrightarrow 00:20:33.080$ research infrastructure say in A

NOTE Confidence: 0.7194853

 $00:20:33.080 \longrightarrow 00:20:35.900$ in a traditional hospital research

00:20:35.900 --> 00:20:38.720 unit or ambulatory research unit,

NOTE Confidence: 0.7194853

 $00:20:38.720 \longrightarrow 00:20:42.128$ I think those days are either

NOTE Confidence: 0.7194853

 $00:20:42.128 \longrightarrow 00:20:43.832$ ending or ended.

NOTE Confidence: 0.7194853

 $00:20:43.840 \longrightarrow 00:20:46.504$ They they have really changed their

NOTE Confidence: 0.7194853

00:20:46.504 --> 00:20:49.988 focus in a important way and and

NOTE Confidence: 0.7194853

 $00{:}20{:}49.988 \to 00{:}20{:}53.770$ and I think in ways that are a

NOTE Confidence: 0.7194853

 $00{:}20{:}53.770 \dashrightarrow 00{:}20{:}56.320$ bit precipitous for some of us.

NOTE Confidence: 0.7194853

 $00:20:56.320 \longrightarrow 00:21:00.073$ But I think have a have a distinct rationale.

NOTE Confidence: 0.96471393

 $00:21:02.400 \longrightarrow 00:21:05.080$ One of our challenges strategically

NOTE Confidence: 0.96471393

 $00:21:05.080 \longrightarrow 00:21:08.374$ in the center is that we,

NOTE Confidence: 0.96471393

 $00{:}21{:}08.374 \dashrightarrow 00{:}21{:}12.672$ we have leadership at the associate and

NOTE Confidence: 0.96471393

 $00:21:12.672 \longrightarrow 00:21:16.071$ Deputy director level of faculty and

NOTE Confidence: 0.96471393

00:21:16.071 --> 00:21:18.808 many of them are in positions where

NOTE Confidence: 0.96471393

 $00:21:18.808 \longrightarrow 00:21:21.852$ they're not exactly sure what their

NOTE Confidence: 0.96471393

 $00:21:21.852 \longrightarrow 00:21:24.036$ authority and responsibility are.

NOTE Confidence: 0.96471393

 $00:21:24.040 \longrightarrow 00:21:26.236$ And that's not the faculty's fault,

 $00:21:26.240 \longrightarrow 00:21:27.320$ that's our fault.

NOTE Confidence: 0.96471393

 $00:21:27.320 \longrightarrow 00:21:30.193$ We haven't done a good job of of

NOTE Confidence: 0.96471393

00:21:30.193 --> 00:21:32.280 conveying that and organizing it. And

NOTE Confidence: 0.43199226

 $00:21:34.320 \longrightarrow 00:21:36.460$ we also have been concerned

NOTE Confidence: 0.43199226

 $00:21:36.460 \longrightarrow 00:21:39.410$ that we don't have a sufficient

NOTE Confidence: 0.43199226

00:21:39.410 --> 00:21:43.000 faculty voice historically in YCCI

NOTE Confidence: 0.43199226

 $00:21:45.040 \longrightarrow 00:21:48.880$ and that's an obvious and significant

NOTE Confidence: 0.43199226

 $00:21:48.880 \longrightarrow 00:21:51.560$ missed opportunity for the

NOTE Confidence: 0.43199226

 $00:21:51.560 \longrightarrow 00:21:54.320$ center on the operational side.

NOTE Confidence: 0.43199226

 $00:21:54.320 \longrightarrow 00:21:56.900$ I would say that partly

NOTE Confidence: 0.43199226

00:21:56.900 --> 00:21:59.400 because YCCI grew so rapidly,

NOTE Confidence: 0.43199226

 $00:21:59.400 \longrightarrow 00:22:03.376$ many of the work flows and operational

NOTE Confidence: 0.43199226

 $00{:}22{:}03.376 \dashrightarrow 00{:}22{:}07.920$ changes were made in response to a crisis.

NOTE Confidence: 0.43199226

 $00:22:07.920 \longrightarrow 00:22:11.292$ And it has a bit of a, at least

NOTE Confidence: 0.43199226

 $00:22:11.292 \longrightarrow 00:22:13.714$ looking back over the last many years,

 $00:22:13.720 \longrightarrow 00:22:16.240$ a bit of an ad hoc feel to it.

NOTE Confidence: 0.43199226

 $00:22:16.240 \longrightarrow 00:22:21.060$ And so we're really trying to take

NOTE Confidence: 0.43199226

 $00:22:21.060 \longrightarrow 00:22:23.610$ apart and understand our work flows

NOTE Confidence: 0.43199226

 $00:22:23.686 \longrightarrow 00:22:27.104$ because they are too complicated,

NOTE Confidence: 0.43199226

 $00:22:27.104 \longrightarrow 00:22:30.440$ they're relatively inefficient

NOTE Confidence: 0.43199226

 $00:22:30.440 \longrightarrow 00:22:32.480$ and most importantly,

NOTE Confidence: 0.43199226

 $00:22:32.480 \longrightarrow 00:22:36.579$ they don't really consistently provide

NOTE Confidence: 0.43199226

 $00:22:36.579 \longrightarrow 00:22:42.278$ customer service that our faculty deserve.

NOTE Confidence: 0.43199226

 $00{:}22{:}42.280 \dashrightarrow 00{:}22{:}45.115$ We have a broader problem and this

NOTE Confidence: 0.43199226

 $00{:}22{:}45.115 \dashrightarrow 00{:}22{:}47.908$ is AI think a issue across clinical

NOTE Confidence: 0.43199226

 $00:22:47.908 \longrightarrow 00:22:50.478$ research and that is that we have

NOTE Confidence: 0.43199226

 $00:22:50.480 \longrightarrow 00:22:53.480$ relatively low accrual rates of

NOTE Confidence: 0.43199226

 $00:22:53.480 \longrightarrow 00:22:56.416$ research participants and we have a

NOTE Confidence: 0.43199226

00:22:56.416 --> 00:22:58.586 number of studies that unfortunately

NOTE Confidence: 0.43199226

00:22:58.586 --> 00:23:01.182 don't reach their their target

NOTE Confidence: 0.43199226

 $00{:}23{:}01.182 \dashrightarrow 00{:}23{:}04.848$ accruals and therefore are impaired in

 $00:23:04.848 \longrightarrow 00:23:07.932$ their ability to answer the question

NOTE Confidence: 0.43199226

 $00{:}23{:}07.932 \dashrightarrow 00{:}23{:}11.600$ that they originally set out to do.

NOTE Confidence: 0.43199226

 $00{:}23{:}11.600 \dashrightarrow 00{:}23{:}14.526$ Of great concern is that if we

NOTE Confidence: 0.43199226

 $00:23:14.526 \longrightarrow 00:23:16.492$ are asking research participants

NOTE Confidence: 0.43199226

 $00:23:16.492 \longrightarrow 00:23:20.280$ to consent to a study protocol,

NOTE Confidence: 0.43199226

 $00:23:20.280 \longrightarrow 00:23:22.592$ we would all like to be able to

NOTE Confidence: 0.43199226

 $00:23:22.592 \longrightarrow 00:23:25.045$ have a high degree of confidence

NOTE Confidence: 0.43199226

 $00:23:25.045 \longrightarrow 00:23:27.739$ that that study protocol would be

NOTE Confidence: 0.43199226

00:23:27.816 --> 00:23:30.328 successfully completed to fulfill

NOTE Confidence: 0.43199226

 $00:23:30.328 \longrightarrow 00:23:32.840$ that obligation to participants.

NOTE Confidence: 0.43199226

 $00:23:32.840 \longrightarrow 00:23:36.900$ That's aside from all of the financial

NOTE Confidence: 0.43199226

 $00:23:36.900 \longrightarrow 00:23:39.635$ and really dispiriting aspects there are

NOTE Confidence: 0.43199226

 $00{:}23{:}39.635 \dashrightarrow 00{:}23{:}42.518$ when a study doesn't achieve its goals.

NOTE Confidence: 0.551098135

 $00:23:45.360 \longrightarrow 00:23:48.482$ As I indicated, YCCI is only one

NOTE Confidence: 0.551098135

 $00:23:48.482 \longrightarrow 00:23:51.559$ of several forms of infrastructure.

00:23:51.560 --> 00:23:55.880 And so we have a kind of a federalized

NOTE Confidence: 0.551098135

 $00:23:55.880 \longrightarrow 00:23:58.015$ set of Research Services and then

NOTE Confidence: 0.551098135

 $00:23:58.015 \longrightarrow 00:24:00.800$ we have more of a states rights,

NOTE Confidence: 0.551098135

 $00:24:00.800 \longrightarrow 00:24:02.928$ decentralized form of services.

NOTE Confidence: 0.551098135

00:24:02.928 --> 00:24:07.491 And I think one of the benefits of having

NOTE Confidence: 0.551098135

00:24:07.491 --> 00:24:10.690 both and that is having a decentralized

NOTE Confidence: 0.551098135

 $00{:}24{:}10.768 \dashrightarrow 00{:}24{:}13.596$ service component is that individual

NOTE Confidence: 0.551098135

00:24:13.596 --> 00:24:17.010 units and departments have been able

NOTE Confidence: 0.551098135

 $00:24:17.099 \longrightarrow 00:24:19.066$ to craft research infrastructure in

NOTE Confidence: 0.551098135

 $00:24:19.066 \longrightarrow 00:24:22.020$ a way that meets their unique needs

NOTE Confidence: 0.551098135

 $00{:}24{:}22.095 \dashrightarrow 00{:}24{:}24.549$ and addresses the questions that are

NOTE Confidence: 0.551098135

 $00:24:24.549 \longrightarrow 00:24:26.800$ most important to their faculty.

NOTE Confidence: 0.551098135

 $00:24:26.800 \longrightarrow 00:24:31.533$ The downside is particularly on the in

NOTE Confidence: 0.551098135

 $00:24:31.533 \longrightarrow 00:24:34.424$ the areas of of the financial practices

NOTE Confidence: 0.551098135

 $00:24:34.424 \longrightarrow 00:24:37.600$ in those decentralized center centers

NOTE Confidence: 0.551098135

 $00:24:37.600 \longrightarrow 00:24:43.168$ and the compliance and regulatory issues

00:24:43.168 --> 00:24:46.080 there are potentially significant.

NOTE Confidence: 0.551098135

 $00:24:46.080 \longrightarrow 00:24:49.279$ So one of the conversations that we

NOTE Confidence: 0.551098135

 $00:24:49.279 \longrightarrow 00:24:52.568$ will be having as a as a organization

NOTE Confidence: 0.551098135

00:24:52.568 --> 00:24:55.786 is how how can we create flexibility

NOTE Confidence: 0.551098135

 $00:24:55.786 \longrightarrow 00:24:58.558$ at the department level,

NOTE Confidence: 0.551098135

 $00:24:58.560 \longrightarrow 00:25:01.760$ not fix what's not broken,

NOTE Confidence: 0.551098135

 $00:25:01.760 \longrightarrow 00:25:05.585$ but also ensure that there's financial

NOTE Confidence: 0.551098135

 $00:25:05.585 \longrightarrow 00:25:08.405$ and regulatory integrity throughout

NOTE Confidence: 0.551098135

 $00:25:08.405 \longrightarrow 00:25:11.400$ our clinical research portfolio.

NOTE Confidence: 0.5677144

 $00:25:15.000 \longrightarrow 00:25:18.130$ We also have significant staff

NOTE Confidence: 0.5677144

00:25:18.130 --> 00:25:20.634 recruitment and retention issues

NOTE Confidence: 0.5677144

 $00{:}25{:}20.634 \dashrightarrow 00{:}25{:}24.824$ that that YCCI has multiple PhD

NOTE Confidence: 0.5677144

 $00{:}25{:}24.824 \dashrightarrow 00{:}25{:}27.060$ level research administrators

NOTE Confidence: 0.5677144

00:25:27.060 --> 00:25:31.440 who frankly teach me every day,

NOTE Confidence: 0.5677144

 $00:25:31.440 \longrightarrow 00:25:34.056$ but it's hard to find them and hard

 $00:25:34.056 \longrightarrow 00:25:36.344$ to recruit them And we we've been

NOTE Confidence: 0.5677144

 $00:25:36.344 \longrightarrow 00:25:38.640$ able to do so largely because we've

NOTE Confidence: 0.5677144

 $00:25:38.708 \longrightarrow 00:25:41.318$ offered a hybrid workplace environment.

NOTE Confidence: 0.5677144

 $00:25:41.320 \longrightarrow 00:25:45.360$ In some cases we've offered work play remote.

NOTE Confidence: 0.5677144

 $00:25:45.360 \longrightarrow 00:25:49.520$ So we are as a center and every

NOTE Confidence: 0.5677144

 $00:25:49.520 \longrightarrow 00:25:53.192$ time I say this I I'm stunned by it.

NOTE Confidence: 0.5677144

 $00:25:53.192 \longrightarrow 00:25:57.000$ 30% of our staff reside outside Connecticut.

NOTE Confidence: 0.5677144

 $00:25:57.000 \longrightarrow 00:25:58.599$ So it's a

NOTE Confidence: 0.69704217

 $00{:}26{:}02.000 \dashrightarrow 00{:}26{:}05.488$ the good news is that we have some

NOTE Confidence: 0.69704217

00:26:05.488 --> 00:26:08.027 extraordinary people and we're able to

NOTE Confidence: 0.69704217

 $00{:}26{:}08.027 \dashrightarrow 00{:}26{:}11.004$ expand the pool of of applicants for

NOTE Confidence: 0.69704217

 $00:26:11.004 \longrightarrow 00:26:14.050$ positions that that the the challenge

NOTE Confidence: 0.69704217

00:26:14.050 --> 00:26:16.896 is that it creates real practical

NOTE Confidence: 0.69704217

00:26:16.896 --> 00:26:19.752 issues as we try to create community

NOTE Confidence: 0.69704217

00:26:19.752 --> 00:26:23.408 and connectedness not only within YCCI

NOTE Confidence: 0.69704217

 $00:26:23.408 \longrightarrow 00:26:26.720$ but between YCCI and our faculty.

00:26:26.720 --> 00:26:29.142 It's not unique to our center obviously

NOTE Confidence: 0.69704217

 $00{:}26{:}29.142 \dashrightarrow 00{:}26{:}32.012$ this is we're seeing this in just about

NOTE Confidence: 0.69704217

 $00:26:32.012 \longrightarrow 00:26:34.740$ every part of academics and just about

NOTE Confidence: 0.69704217

 $00:26:34.740 \longrightarrow 00:26:36.755$ every employer group and industry.

NOTE Confidence: 0.69704217

 $00:26:36.760 \longrightarrow 00:26:38.608$ But it is, it is nonetheless

NOTE Confidence: 0.69704217

 $00:26:38.608 \longrightarrow 00:26:39.840$ a challenge for us

NOTE Confidence: 0.4395778

 $00:26:41.920 \longrightarrow 00:26:44.560$ on the financial side. The

NOTE Confidence: 0.4395778

 $00{:}26{:}46.600 \dashrightarrow 00{:}26{:}48.928$ the biggest challenge we have is

NOTE Confidence: 0.4395778

 $00:26:48.928 \longrightarrow 00:26:51.000$ that that institutional subsidy

NOTE Confidence: 0.4395778

 $00:26:51.000 \longrightarrow 00:26:54.222$ that nearly \$25 million that I

NOTE Confidence: 0.4395778

 $00{:}26{:}54.222 \dashrightarrow 00{:}26{:}56.677$ referenced earlier has grown very,

NOTE Confidence: 0.4395778

 $00:26:56.680 \longrightarrow 00:26:59.790$ very substantially over the last

NOTE Confidence: 0.4395778

 $00:26:59.790 \longrightarrow 00:27:02.900$ five years and it's grown at a

NOTE Confidence: 0.4395778

 $00:27:02.900 \longrightarrow 00:27:04.760$ rate that is not sustainable.

NOTE Confidence: 0.4395778

 $00:27:04.760 \longrightarrow 00:27:07.120$ So the good news is we've expanded clinic,

 $00:27:07.120 \longrightarrow 00:27:08.602$ expanded clinical research.

NOTE Confidence: 0.4395778

00:27:08.602 --> 00:27:12.551 The the not so good news is that

NOTE Confidence: 0.4395778

 $00:27:12.551 \longrightarrow 00:27:15.316$ we've done so at at really high

NOTE Confidence: 0.4395778

 $00:27:15.316 \longrightarrow 00:27:18.719$ cost to our supporting institutions.

NOTE Confidence: 0.4395778

 $00:27:18.720 \longrightarrow 00:27:22.160$ And as the fiscal climate changes

NOTE Confidence: 0.4395778

 $00:27:22.160 \longrightarrow 00:27:24.080$ and their costs go up,

NOTE Confidence: 0.4395778

 $00:27:24.080 \longrightarrow 00:27:26.385$ it's increased going to be

NOTE Confidence: 0.4395778

 $00:27:26.385 \longrightarrow 00:27:28.229$ increasingly difficult for the

NOTE Confidence: 0.4395778

 $00{:}27{:}28.229 \dashrightarrow 00{:}27{:}30.569$ health system and the school to

NOTE Confidence: 0.4395778

 $00{:}27{:}30.569 \to 00{:}27{:}32.880$ support us at the current level.

NOTE Confidence: 0.4395778

 $00{:}27{:}32.880 \longrightarrow 00{:}27{:}37.026$ Our cost recovery for the services

NOTE Confidence: 0.4395778

 $00:27:37.026 \longrightarrow 00:27:40.845$ is quite inconsistent and and

NOTE Confidence: 0.4395778

 $00{:}27{:}40.845 \dashrightarrow 00{:}27{:}44.595$ really way below what our peer

NOTE Confidence: 0.4395778

 $00:27:44.595 \longrightarrow 00:27:47.720$ organizations both charge and recover.

NOTE Confidence: 0.4395778

 $00:27:47.720 \longrightarrow 00:27:51.240$ So we're taking steps to to change that.

NOTE Confidence: 0.4395778

00:27:51.240 --> 00:27:54.204 We will always want to support

 $00:27:54.204 \longrightarrow 00:27:56.824$ unfunded studies but the question

NOTE Confidence: 0.4395778

 $00:27:56.824 \longrightarrow 00:28:00.960$ is I think we we have had it nearly

NOTE Confidence: 0.4395778

 $00:28:00.960 \longrightarrow 00:28:04.600$ just say yes policy and the question

NOTE Confidence: 0.4395778

00:28:04.600 --> 00:28:08.504 is should we put processes in place

NOTE Confidence: 0.4395778

 $00:28:08.504 \longrightarrow 00:28:12.345$ that filter out the least promising

NOTE Confidence: 0.4395778

 $00:28:12.345 \longrightarrow 00:28:15.920$ studies for that free support.

NOTE Confidence: 0.4395778

00:28:15.920 --> 00:28:18.824 And then lastly and not surprisingly

NOTE Confidence: 0.4395778

 $00{:}28{:}18.824 \dashrightarrow 00{:}28{:}21.756$ Ncats and the regulatory agencies have

NOTE Confidence: 0.4395778

 $00:28:21.756 \longrightarrow 00:28:24.708$ a growing number of unfunded mandates

NOTE Confidence: 0.4395778

 $00{:}28{:}24.708 \dashrightarrow 00{:}28{:}27.972$ that that creates a lot of pressure

NOTE Confidence: 0.4395778

 $00{:}28{:}27.972 \dashrightarrow 00{:}28{:}30.182$ on the on clinical investigators

NOTE Confidence: 0.4395778

 $00{:}28{:}30.182 \dashrightarrow 00{:}28{:}32.237$ in general and certainly YCCI.

NOTE Confidence: 0.7458629

 $00:28:34.480 \longrightarrow 00:28:37.518$ So what are we doing about it?

NOTE Confidence: 0.7458629

 $00:28:37.520 \longrightarrow 00:28:40.040$ I'll just run through these quickly.

NOTE Confidence: 0.7458629

 $00:28:40.040 \longrightarrow 00:28:43.127$ We have a series of faculty advisory

00:28:43.127 --> 00:28:44.865 committees and thankfully there's

NOTE Confidence: 0.7458629

00:28:44.865 --> 00:28:47.998 a number of faculty from psychiatry

NOTE Confidence: 0.7458629

 $00{:}28{:}47.998 \dashrightarrow 00{:}28{:}51.665$ on these committees and we are

NOTE Confidence: 0.7458629

 $00:28:51.665 \longrightarrow 00:28:54.240$ restructuring the faculty director roles.

NOTE Confidence: 0.7458629

 $00:28:54.240 \longrightarrow 00:28:57.579$ So we are really trying hard to

NOTE Confidence: 0.7458629

00:28:57.579 --> 00:29:00.760 increase the faculty voice within YCCI.

NOTE Confidence: 0.7458629

 $00{:}29{:}00.760 \dashrightarrow 00{:}29{:}02.690$ And these advisory committees have

NOTE Confidence: 0.7458629

 $00:29:02.690 \longrightarrow 00:29:05.980$ been meeting for about four months now

NOTE Confidence: 0.7458629

 $00{:}29{:}05.980 \to 00{:}29{:}09.598$ and they've been a remarkable source

NOTE Confidence: 0.7458629

 $00:29:09.598 \longrightarrow 00:29:13.355$ of advice and input that's really

NOTE Confidence: 0.7458629

 $00{:}29{:}13.355 \dashrightarrow 00{:}29{:}16.480$ helped materially shape our thinking.

NOTE Confidence: 0.7458629

 $00:29:16.480 \longrightarrow 00:29:19.672$ We are working hard to integrate

NOTE Confidence: 0.7458629

 $00:29:19.672 \longrightarrow 00:29:21.800$ and expand community engagement.

NOTE Confidence: 0.7458629

 $00:29:21.800 \longrightarrow 00:29:23.920$ We have, we were fortunately,

NOTE Confidence: 0.7458629

 $00:29:23.920 \longrightarrow 00:29:26.920$ we have two national leaders in this area,

NOTE Confidence: 0.7458629

00:29:26.920 --> 00:29:28.576 Marcella Nunez Smith,

00:29:28.576 --> 00:29:31.888 who's the Deputy Director for Community

NOTE Confidence: 0.7458629

 $00{:}29{:}31.888 \dashrightarrow 00{:}29{:}33.892$ Engagement and Administrative

NOTE Confidence: 0.7458629

00:29:33.892 --> 00:29:36.796 Leadership from Tisha Johnson,

NOTE Confidence: 0.7458629

 $00:29:36.800 \longrightarrow 00:29:39.476$ who's in a newly created role

NOTE Confidence: 0.7458629

 $00:29:39.476 \longrightarrow 00:29:42.440$ focused on our external partnerships.

NOTE Confidence: 0.7458629

00:29:42.440 --> 00:29:44.855 And we're working very diligently

NOTE Confidence: 0.7458629

00:29:44.855 --> 00:29:47.911 to try to expand local partnerships

NOTE Confidence: 0.7458629

00:29:47.911 --> 00:29:50.968 as well as national collaborations,

NOTE Confidence: 0.7458629

 $00{:}29{:}50.968 \dashrightarrow 00{:}29{:}54.360$ particularly with other Ctsas.

NOTE Confidence: 0.7458629

 $00{:}29{:}54.360 \dashrightarrow 00{:}29{:}58.595$ And then as you know from some

NOTE Confidence: 0.7458629

 $00:29:58.595 \longrightarrow 00:30:00.159$ of the e-mail traffic,

NOTE Confidence: 0.7458629

 $00{:}30{:}00.160 \dashrightarrow 00{:}30{:}02.500$ there's been a very important

NOTE Confidence: 0.7458629

 $00{:}30{:}02.500 \dashrightarrow 00{:}30{:}04.190$ series of strategic conversations

NOTE Confidence: 0.7458629

 $00:30:04.190 \longrightarrow 00:30:06.815$ between the school and the the all

NOTE Confidence: 0.7458629

 $00:30:06.815 \longrightarrow 00:30:09.560$ New Haven health system to expand

 $00:30:09.560 \longrightarrow 00:30:11.880$ clinical and translational research.

NOTE Confidence: 0.7458629

 $00:30:11.880 \longrightarrow 00:30:15.480$ There will be a webinar or a town hall,

NOTE Confidence: 0.7458629

 $00:30:15.480 \longrightarrow 00:30:21.440$ I guess more correctly led by Dean Brown

NOTE Confidence: 0.7458629

 $00:30:21.440 \longrightarrow 00:30:25.952$ and and CEO O'Connor next Thursday at 11.

NOTE Confidence: 0.7458629

 $00:30:25.952 \longrightarrow 00:30:28.400$ I encourage you to tune into that.

NOTE Confidence: 0.7458629

 $00:30:28.400 \longrightarrow 00:30:29.576$ If you can't,

NOTE Confidence: 0.7458629

 $00:30:29.576 \longrightarrow 00:30:32.696$ there's a a document that's been

NOTE Confidence: 0.7458629

00:30:32.696 --> 00:30:37.660 produced that has a very thoughtful and

NOTE Confidence: 0.7458629

00:30:37.660 --> 00:30:40.022 carefully crafted strategic planning

NOTE Confidence: 0.7458629

 $00{:}30{:}40.022 \dashrightarrow 00{:}30{:}43.630$ document that came as a result of a

NOTE Confidence: 0.7458629

 $00:30:43.715 \dashrightarrow 00:30:46.019$ strategic planning committee chaired

NOTE Confidence: 0.7458629

 $00:30:46.019 \dashrightarrow 00:30:49.475$ by Brian Smith and Peg McGovern.

NOTE Confidence: 0.7458629

00:30:49.480 --> 00:30:53.600 So I encourage you to look into

NOTE Confidence: 0.7458629

 $00:30:53.600 \longrightarrow 00:30:57.080$ that On the operational side,

NOTE Confidence: 0.7458629

 $00:30:57.080 \longrightarrow 00:30:59.555$ this is where where we're

NOTE Confidence: 0.7458629

 $00:30:59.555 \longrightarrow 00:31:01.040$ really working feverishly.

 $00:31:01.040 \longrightarrow 00:31:04.451$ I think you know we have ambitions to expand

NOTE Confidence: 0.7458629

 $00{:}31{:}04.451 \dashrightarrow 00{:}31{:}07.758$ our footprint of research methodologies,

NOTE Confidence: 0.7458629

00:31:07.760 --> 00:31:09.530 but I think we're our enthusiasm

NOTE Confidence: 0.7458629

 $00:31:09.530 \longrightarrow 00:31:11.863$ to do that is tempered a bit by

NOTE Confidence: 0.7458629

 $00:31:11.863 \longrightarrow 00:31:14.299$ the fact that we have to get our

NOTE Confidence: 0.7458629

 $00:31:14.299 \longrightarrow 00:31:15.799$ operational house in order.

NOTE Confidence: 0.7458629

00:31:15.800 --> 00:31:17.579 So we're reorganizing

NOTE Confidence: 0.7458629

 $00:31:17.579 \longrightarrow 00:31:19.358$ the center significantly.

NOTE Confidence: 0.7458629

 $00{:}31{:}19.360 \dashrightarrow 00{:}31{:}23.080$ I'll show you snapshots of that

NOTE Confidence: 0.7458629

 $00:31:23.080 \longrightarrow 00:31:25.918$ designed really around this theme of

NOTE Confidence: 0.7458629

00:31:25.918 --> 00:31:29.004 customer service and and to enhance

NOTE Confidence: 0.7458629

 $00{:}31{:}29.004 \dashrightarrow 00{:}31{:}31.182$ the investigator services available

NOTE Confidence: 0.7458629

 $00{:}31{:}31.182 \dashrightarrow 00{:}31{:}34.194$ to our faculty and our trainees.

NOTE Confidence: 0.7458629

 $00:31:34.200 \longrightarrow 00:31:37.965$ We're alpha testing currently a

NOTE Confidence: 0.7458629

 $00:31:37.965 \longrightarrow 00:31:40.160$ feasibility protocol review process

 $00:31:40.160 \longrightarrow 00:31:44.798$ that we hope will enable us to

NOTE Confidence: 0.7458629

 $00{:}31{:}44.800 \dashrightarrow 00{:}31{:}49.540$ determine whether studies that we're

NOTE Confidence: 0.7458629

 $00{:}31{:}49.540 \dashrightarrow 00{:}31{:}53.223$ supporting are ones that have a

NOTE Confidence: 0.7458629

 $00:31:53.223 \longrightarrow 00:31:55.235$ reasonable likelihood of reaching

NOTE Confidence: 0.7458629

 $00:31:55.235 \longrightarrow 00:31:57.750$ their accrual targets and have

NOTE Confidence: 0.7458629

00:31:57.826 --> 00:31:59.958 a reasonable financial plan.

NOTE Confidence: 0.7458629

 $00:31:59.960 \longrightarrow 00:32:03.215$ And really to try to convert this

NOTE Confidence: 0.7458629

 $00:32:03.215 \longrightarrow 00:32:05.677$ feasibility review process into an

NOTE Confidence: 0.7458629

 $00{:}32{:}05.677 \dashrightarrow 00{:}32{:}08.132$ educational process where we can

NOTE Confidence: 0.7458629

00:32:08.132 --> 00:32:10.674 offer additional ideas and hopefully

NOTE Confidence: 0.7458629

 $00{:}32{:}10.674 \dashrightarrow 00{:}32{:}12.746$ helpful tools to investigators

NOTE Confidence: 0.7458629

 $00:32:12.746 \longrightarrow 00:32:15.616$ to increase the likelihood that

NOTE Confidence: 0.7458629

 $00{:}32{:}15.616 \dashrightarrow 00{:}32{:}18.076$ their protocols are successful.

NOTE Confidence: 0.7458629

 $00:32:18.080 \longrightarrow 00:32:21.880$ We've modified the monitoring and

NOTE Confidence: 0.7458629

 $00:32:21.880 \longrightarrow 00:32:25.424$ project management plans of investigator

NOTE Confidence: 0.7458629

 $00:32:25.424 \longrightarrow 00:32:26.936$ initiated trials particularly

 $00:32:26.936 \longrightarrow 00:32:30.320$ those in which Yale holds the Ind.

NOTE Confidence: 0.7458629

 $00{:}32{:}30.320 \dashrightarrow 00{:}32{:}34.066$ We've had a one-size-fits-all and that

NOTE Confidence: 0.7458629

00:32:34.066 --> 00:32:37.822 one size has been very expensive and

NOTE Confidence: 0.7458629

 $00:32:37.822 \longrightarrow 00:32:41.838$ and presume that all studies are high risk.

NOTE Confidence: 0.7458629

 $00:32:41.840 \longrightarrow 00:32:46.280$ We've now changed that approach.

NOTE Confidence: 0.7458629

 $00:32:46.280 \longrightarrow 00:32:48.920$ We have a group that's going to be

NOTE Confidence: 0.7458629

 $00:32:48.920 \longrightarrow 00:32:51.415$ meeting the end of this month to

NOTE Confidence: 0.7458629

00:32:51.415 --> 00:32:54.090 make some recommendations on how

NOTE Confidence: 0.7458629

 $00{:}32{:}54.090 \dashrightarrow 00{:}32{:}57.828$ we can adopt best practices for

NOTE Confidence: 0.7458629

 $00:32:57.828 \longrightarrow 00:33:00.496$ more effectively recruiting and

NOTE Confidence: 0.7458629

00:33:00.496 --> 00:33:01.830 retaining research

NOTE Confidence: 0.96495473

 $00{:}33{:}01.923 \dashrightarrow 00{:}33{:}05.704$ participants. And then we're also

NOTE Confidence: 0.96495473

 $00{:}33{:}05.704 \dashrightarrow 00{:}33{:}08.984$ looking at the feasibility and

NOTE Confidence: 0.96495473

 $00:33:08.984 \longrightarrow 00:33:11.792$ advisability of mandating use of

NOTE Confidence: 0.96495473

 $00{:}33{:}11.792 \dashrightarrow 00{:}33{:}13.944$ clinical trial management software

 $00:33:13.944 \longrightarrow 00:33:16.119$ and electronic data capture,

NOTE Confidence: 0.96495473

 $00{:}33{:}16.120 {\: -->\:} 00{:}33{:}18.295$ particularly under circumstances

NOTE Confidence: 0.96495473

00:33:18.295 --> 00:33:21.920 where studies are subject to

NOTE Confidence: 0.96495473

 $00:33:21.920 \longrightarrow 00:33:25.080$ invoicing and and financial

NOTE Confidence: 0.96495473

 $00:33:25.080 \longrightarrow 00:33:27.960$ scrutiny as well as compliance risk.

NOTE Confidence: 0.96495473

 $00:33:27.960 \longrightarrow 00:33:29.796$ Right now it's advised but not

NOTE Confidence: 0.96495473

 $00:33:29.796 \longrightarrow 00:33:32.459$ required and and we have run into some

NOTE Confidence: 0.96495473

00:33:32.459 --> 00:33:34.517 problems when it's not used properly.

NOTE Confidence: 0.86095977

 $00{:}33{:}36.840 \dashrightarrow 00{:}33{:}39.756$ On the financial side, we have

NOTE Confidence: 0.86095977

 $00:33:39.760 \longrightarrow 00:33:42.400$ increased our rates for our services.

NOTE Confidence: 0.86095977

 $00:33:42.400 \longrightarrow 00:33:44.750$ They were set at historically

NOTE Confidence: 0.86095977

 $00:33:44.750 \longrightarrow 00:33:47.100$ low levels and hadn't been

NOTE Confidence: 0.86095977

00:33:47.193 --> 00:33:49.798 increased for about five years.

NOTE Confidence: 0.88511187

 $00:33:52.000 \longrightarrow 00:33:56.904$ Even the rates that they were increased to

NOTE Confidence: 0.88511187

 $00:33:56.904 \longrightarrow 00:34:00.716$ has not come close to covering our costs.

NOTE Confidence: 0.88511187

 $00:34:00.720 \longrightarrow 00:34:04.040$ So we're projecting that that

 $00:34:04.040 \longrightarrow 00:34:06.075$ \$5,000,000 in service revenue that

NOTE Confidence: 0.88511187

 $00{:}34{:}06.075 \dashrightarrow 00{:}34{:}09.275$ I showed you in the pie chart will

NOTE Confidence: 0.88511187

 $00:34:09.275 \longrightarrow 00:34:12.760$ will grow to about 10 or \$11 million

NOTE Confidence: 0.88511187

 $00:34:12.760 \longrightarrow 00:34:17.236$ within about four or five years.

NOTE Confidence: 0.88511187

 $00{:}34{:}17.240 \dashrightarrow 00{:}34{:}19.634$ Those rates that we're increasing our

NOTE Confidence: 0.88511187

00:34:19.634 --> 00:34:22.079 our prospective that is they're not,

NOTE Confidence: 0.88511187

00:34:22.080 --> 00:34:26.598 they're they don't impact existing trials.

NOTE Confidence: 0.88511187

00:34:26.600 --> 00:34:29.155 We're trying to work internally

NOTE Confidence: 0.88511187

00:34:29.155 --> 00:34:31.199 to have more transparency.

NOTE Confidence: 0.88511187

 $00{:}34{:}31.200 \dashrightarrow 00{:}34{:}33.240$ We're giving our associate directors

NOTE Confidence: 0.88511187

 $00:34:33.240 \longrightarrow 00:34:36.064$ their budgets to manage that surprisingly

NOTE Confidence: 0.88511187

00:34:36.064 --> 00:34:39.200 hadn't been done previously.

NOTE Confidence: 0.88511187

 $00{:}34{:}39.200 \dashrightarrow 00{:}34{:}43.120$ The school is about to announce an increase

NOTE Confidence: 0.88511187

 $00:34:43.120 \longrightarrow 00:34:47.400$ in the rate charged to industry sponsors

NOTE Confidence: 0.88511187

 $00:34:47.400 \longrightarrow 00:34:51.972$ for indirect costs on industry trials.

 $00:34:51.972 \longrightarrow 00:34:55.880$ And then coming on the heels of

NOTE Confidence: 0.88511187

 $00:34:55.880 \longrightarrow 00:34:57.680$ those two pieces of bad news,

NOTE Confidence: 0.88511187

 $00{:}34{:}57.680 \dashrightarrow 00{:}34{:}59.680$ namely the rates for services

NOTE Confidence: 0.88511187

 $00:34:59.680 \longrightarrow 00:35:02.176$ and the indirect rate we are,

NOTE Confidence: 0.88511187

 $00:35:02.176 \longrightarrow 00:35:05.312$ we have a draft proposal that we're

NOTE Confidence: 0.88511187

 $00:35:05.312 \dashrightarrow 00:35:08.395$ getting input on to provide a voucher

NOTE Confidence: 0.88511187

 $00:35:08.400 \longrightarrow 00:35:11.736$ to offset a portion or in some cases

NOTE Confidence: 0.88511187

 $00:35:11.736 \longrightarrow 00:35:15.199$ all of the cost of YCCI services.

NOTE Confidence: 0.88511187

 $00{:}35{:}15.200 \dashrightarrow 00{:}35{:}16.400$ And I'll show you more about

NOTE Confidence: 0.88511187

 $00:35:16.400 \longrightarrow 00:35:17.200$ that in a second.

NOTE Confidence: 0.51797265

 $00:35:20.960 \longrightarrow 00:35:24.560$ So our structure is shown

NOTE Confidence: 0.51797265

 $00:35:24.560 \longrightarrow 00:35:26.720$ here administrative structure.

NOTE Confidence: 0.51797265

 $00{:}35{:}26.720 \dashrightarrow 00{:}35{:}30.720$ Brian Smith and John Crystal

NOTE Confidence: 0.51797265

 $00:35:30.720 \longrightarrow 00:35:34.000$ serve as our Co Pis for the CTSA.

NOTE Confidence: 0.51797265

 $00:35:34.000 \longrightarrow 00:35:38.960$ And John as you know Focus is

NOTE Confidence: 0.51797265

 $00:35:38.960 \longrightarrow 00:35:42.320$ also the Co Director of YCCI.

 $00:35:42.320 \longrightarrow 00:35:47.203$ We have a a new role for Tisha Johnson

NOTE Confidence: 0.51797265

 $00{:}35{:}47.203 \dashrightarrow 00{:}35{:}49.648$ who was formerly our Chief Operating

NOTE Confidence: 0.51797265

 $00:35:49.648 \longrightarrow 00:35:52.721$ Officer as I mentioned and Brian Severe

NOTE Confidence: 0.51797265

00:35:52.796 --> 00:35:55.400 is our new Chief Operating Officer.

NOTE Confidence: 0.51797265

 $00:35:55.400 \longrightarrow 00:35:58.640$ And I want to just expand on this area

NOTE Confidence: 0.51797265

00:35:58.640 --> 00:36:01.408 on the right just to to highlight

NOTE Confidence: 0.51797265

 $00:36:01.408 \longrightarrow 00:36:03.812$ what I hope will be important

NOTE Confidence: 0.51797265

 $00{:}36{:}03.812 \dashrightarrow 00{:}36{:}07.256$ benefits for our faculty and that is

NOTE Confidence: 0.51797265

 $00:36:07.256 \longrightarrow 00:36:09.479$ this investigator services group,

NOTE Confidence: 0.51797265

 $00:36:09.480 \longrightarrow 00:36:12.765$ which is really where most

NOTE Confidence: 0.51797265

 $00:36:12.765 \longrightarrow 00:36:15.393$ faculty interface with YCCI.

NOTE Confidence: 0.51797265

 $00:36:15.400 \longrightarrow 00:36:18.879$ So we're creating 2 new organizational units.

NOTE Confidence: 0.51797265

 $00{:}36{:}18.880 \dashrightarrow 00{:}36{:}21.036$ The first one is called protocol design,

NOTE Confidence: 0.51797265

 $00:36:21.040 \longrightarrow 00:36:22.381$ development and feasibility.

NOTE Confidence: 0.51797265

00:36:22.381 --> 00:36:25.960 There will be a single portal of entry

 $00:36:25.960 \dashrightarrow 00:36:29.248$ electronically into YCCI and then a

NOTE Confidence: 0.51797265

 $00{:}36{:}29.248 \dashrightarrow 00{:}36{:}32.774$ range of services that we'll provide

NOTE Confidence: 0.51797265

 $00:36:32.774 \longrightarrow 00:36:35.874$ to aid in the conceptualization,

NOTE Confidence: 0.51797265

 $00:36:35.880 \longrightarrow 00:36:38.320$ design and ultimately development

NOTE Confidence: 0.51797265

 $00:36:38.320 \longrightarrow 00:36:40.760$ of clinical research protocols.

NOTE Confidence: 0.51797265

 $00:36:40.760 \longrightarrow 00:36:44.715$ Investigators can choose one or all of

NOTE Confidence: 0.51797265

 $00{:}36{:}44.715 \dashrightarrow 00{:}36{:}48.440$ these services at this initial stage.

NOTE Confidence: 0.51797265

 $00:36:48.440 \longrightarrow 00:36:52.581$ Then once they're ready for activation,

NOTE Confidence: 0.51797265

 $00{:}36{:}52.581 \dashrightarrow 00{:}36{:}54.968$ they'll go to the second unit from

NOTE Confidence: 0.51797265

 $00:36:54.968 \longrightarrow 00:36:57.120$ the left called protocol activation

NOTE Confidence: 0.51797265

 $00:36:57.120 \longrightarrow 00:36:58.996$ and life cycle management.

NOTE Confidence: 0.51797265

 $00:36:59.000 \longrightarrow 00:37:02.090$ These services that are listed here

NOTE Confidence: 0.51797265

 $00:37:02.090 \longrightarrow 00:37:04.082$ are scattered organizationally in

NOTE Confidence: 0.51797265

 $00:37:04.082 \longrightarrow 00:37:06.968$ ways that make it difficult to

NOTE Confidence: 0.51797265

 $00:37:06.968 \longrightarrow 00:37:08.720$ both track the work,

NOTE Confidence: 0.51797265

 $00:37:08.720 \longrightarrow 00:37:10.840$ hold ourselves accountable and importantly,

 $00:37:10.840 \longrightarrow 00:37:12.990$ inform faculty of the status

NOTE Confidence: 0.51797265

 $00:37:12.990 \longrightarrow 00:37:14.280$ of their protocols.

NOTE Confidence: 0.51797265

00:37:14.280 --> 00:37:18.678 We also have a prohibitively long

NOTE Confidence: 0.51797265

 $00{:}37{:}18.680 \dashrightarrow 00{:}37{:}22.080$ protocol activation time that not

NOTE Confidence: 0.51797265

 $00:37:22.080 \dashrightarrow 00:37:25.060$ only and very importantly frustrates

NOTE Confidence: 0.51797265

00:37:25.060 --> 00:37:28.840 the daylights out of faculty but is

NOTE Confidence: 0.51797265

 $00:37:28.926 \longrightarrow 00:37:30.853$ really discrediting with research

NOTE Confidence: 0.51797265

 $00:37:30.853 \dashrightarrow 00:37:33.679$ sponsors because they they often have

NOTE Confidence: 0.51797265

 $00:37:33.679 \longrightarrow 00:37:36.507$ very aggressive timelines and we just

NOTE Confidence: 0.51797265

 $00:37:36.507 \longrightarrow 00:37:38.792$ simply don't meet those timelines.

NOTE Confidence: 0.51797265

 $00:37:38.800 \longrightarrow 00:37:42.280$ So those functions are being reorganized

NOTE Confidence: 0.51797265

 $00:37:42.280 \longrightarrow 00:37:45.740$ and and the workflow is being re

NOTE Confidence: 0.51797265

 $00:37:45.740 \longrightarrow 00:37:49.497$ crafted to make it easier to track and

NOTE Confidence: 0.51797265

 $00:37:49.497 \longrightarrow 00:37:52.339$ hopefully more timely and efficient.

NOTE Confidence: 0.51797265

 $00:37:52.339 \longrightarrow 00:37:55.728$ We will be putting all of our

 $00:37:55.728 \longrightarrow 00:37:57.588$ workflow on a Salesforce platform

NOTE Confidence: 0.51797265

 $00:37:57.588 \longrightarrow 00:37:59.717$ in early next calendar year,

NOTE Confidence: 0.51797265

00:37:59.720 --> 00:38:04.162 so faculty can access Salesforce,

NOTE Confidence: 0.51797265

 $00:38:04.162 \longrightarrow 00:38:07.530$ find out the status of their protocol and

NOTE Confidence: 0.51797265

 $00:38:07.608 \longrightarrow 00:38:10.275$ who to contact if they have questions.

NOTE Confidence: 0.51797265

 $00:38:10.280 \dashrightarrow 00:38:14.066$ So we're trying very hard to make these

NOTE Confidence: 0.51797265

 $00{:}38{:}14.066 \dashrightarrow 00{:}38{:}17.996$ processes more responsive and timely.

NOTE Confidence: 0.51797265

 $00{:}38{:}18.000 \dashrightarrow 00{:}38{:}19.840$ The clinical research operations where

NOTE Confidence: 0.51797265

 $00:38:19.840 \longrightarrow 00:38:22.360$ a lot of our services are housed

NOTE Confidence: 0.51797265

 $00:38:22.360 \longrightarrow 00:38:26.280$ is largely unchanged and similarly

NOTE Confidence: 0.51797265

 $00{:}38{:}26.280 \dashrightarrow 00{:}38{:}29.992$ regulatory and compliance affairs.

NOTE Confidence: 0.51797265

 $00:38:29.992 \longrightarrow 00:38:32.780$ So really important reorgs from

NOTE Confidence: 0.51797265

 $00:38:32.780 \longrightarrow 00:38:34.640$ our point of view.

NOTE Confidence: 0.51797265

 $00:38:34.640 \longrightarrow 00:38:36.772$ The protocol design development

NOTE Confidence: 0.51797265

 $00:38:36.772 \longrightarrow 00:38:39.437$ and feasibility will have protocol

NOTE Confidence: 0.51797265

 $00:38:39.440 \longrightarrow 00:38:43.320$ development pods with project managers,

 $00:38:43.320 \longrightarrow 00:38:46.398$ a data management and biostats core.

NOTE Confidence: 0.51797265

 $00{:}38{:}46.400 \mathrel{--}{>} 00{:}38{:}51.138$ We will be taking moving a substantial

NOTE Confidence: 0.51797265

 $00:38:51.138 \longrightarrow 00:38:54.083$ portion of the biostats functionality

NOTE Confidence: 0.51797265

00:38:54.083 --> 00:38:57.939 out of Wycas and moving it under

NOTE Confidence: 0.51797265

 $00{:}38{:}57.939 \dashrightarrow 00{:}39{:}00.720$ YCCI to facilitate the connections

NOTE Confidence: 0.51797265

 $00:39:00.720 \longrightarrow 00:39:02.640$ with our faculty.

NOTE Confidence: 0.51797265

 $00:39:02.640 \longrightarrow 00:39:05.070$ And then we'll have this feasibility

NOTE Confidence: 0.51797265

 $00:39:05.070 \longrightarrow 00:39:07.400$ and intake process managed separately

NOTE Confidence: 0.8807152

 $00{:}39{:}09.760 \dashrightarrow 00{:}39{:}11.232$ and the protocol activation

NOTE Confidence: 0.8807152

 $00{:}39{:}11.232 \dashrightarrow 00{:}39{:}14.010$ right now we we have it separated

NOTE Confidence: 0.8807152

 $00{:}39{:}14.010 \dashrightarrow 00{:}39{:}16.475$ into non oncology and oncology.

NOTE Confidence: 0.8807152

00:39:16.480 --> 00:39:18.736 We still do their the budgeting

NOTE Confidence: 0.8807152

 $00:39:18.736 \longrightarrow 00:39:21.005$ for the Cancer Center that is

NOTE Confidence: 0.8807152

00:39:21.005 --> 00:39:23.087 going to migrate to the Cancer

NOTE Confidence: 0.8807152

 $00:39:23.087 \longrightarrow 00:39:25.558$ Center and we will do the financial

00:39:25.560 --> 00:39:29.920 work on non oncology studies,

NOTE Confidence: 0.7313033

 $00{:}39{:}33.240 \dashrightarrow 00{:}39{:}37.460$ this risk based approach to Yale

NOTE Confidence: 0.7313033

 $00:39:37.460 \longrightarrow 00:39:39.440$ sponsor investigative studies.

NOTE Confidence: 0.7313033

 $00:39:39.440 \longrightarrow 00:39:42.080$ I'll just summarize briefly.

NOTE Confidence: 0.7313033

 $00:39:42.080 \longrightarrow 00:39:44.510$ I don't know if you have a tradition to of

NOTE Confidence: 0.7313033

00:39:44.571 --> 00:39:47.119 making your slides available to the faculty,

NOTE Confidence: 0.7313033

 $00{:}39{:}47.120 \dashrightarrow 00{:}39{:}50.198$ but I can certainly forward these

NOTE Confidence: 0.7313033

 $00:39:50.200 \longrightarrow 00:39:52.877$ these slides to Stephanie and you're

NOTE Confidence: 0.7313033

 $00{:}39{:}52.877 \dashrightarrow 00{:}39{:}54.816$ welcome to hang on to them and

NOTE Confidence: 0.7313033

00:39:54.816 --> 00:39:56.597 look through them at your leisure.

NOTE Confidence: 0.7313033

 $00:39:56.600 \longrightarrow 00:39:59.640$ Basically what we've done is said not all,

NOTE Confidence: 0.7313033

 $00:39:59.640 \longrightarrow 00:40:02.034$ not all protocols have the same risk.

NOTE Confidence: 0.7313033

 $00:40:02.040 \longrightarrow 00:40:04.595$ So let's divide them into two subsets,

NOTE Confidence: 0.7313033

 $00{:}40{:}04.600 \dashrightarrow 00{:}40{:}07.428$ high risk studies where we'll do the

NOTE Confidence: 0.7313033

 $00:40:07.428 \longrightarrow 00:40:09.992$ full throated monitoring and low risk

NOTE Confidence: 0.7313033

 $00:40:09.992 \longrightarrow 00:40:12.620$ studies where we'll modify the monitoring

 $00{:}40{:}12.692 \to 00{:}40{:}15.116$ plan commensurate with the low risk.

NOTE Confidence: 0.7313033

 $00:40:15.120 \longrightarrow 00:40:17.668$ The the benefit here is that it's

NOTE Confidence: 0.7313033

00:40:17.668 --> 00:40:20.341 a lot less expensive in people

NOTE Confidence: 0.7313033

 $00:40:20.341 \longrightarrow 00:40:23.640$ time for the low risk monitoring.

NOTE Confidence: 0.7313033

 $00:40:23.640 \longrightarrow 00:40:25.540$ And it's also possible that

NOTE Confidence: 0.7313033

 $00:40:25.540 \longrightarrow 00:40:27.440$ investigators can do their own

NOTE Confidence: 0.7313033

 $00:40:27.507 \longrightarrow 00:40:29.553$ monitoring under certain conditions.

NOTE Confidence: 0.7313033

 $00{:}40{:}29.553 \dashrightarrow 00{:}40{:}31.918$ So this is being implemented.

NOTE Confidence: 0.7313033

00:40:31.920 --> 00:40:35.357 It's awaiting very final approval from HRPP,

NOTE Confidence: 0.7313033

 $00:40:35.360 \longrightarrow 00:40:37.856$ but we are already starting to

NOTE Confidence: 0.7313033

 $00{:}40{:}37.856 \dashrightarrow 00{:}40{:}39.520$ engage investigators in this,

NOTE Confidence: 0.5472333

 $00:40:41.880 \longrightarrow 00:40:44.760$ the rate site for our services.

NOTE Confidence: 0.5472333

 $00:40:44.760 \longrightarrow 00:40:46.860$ I mentioned earlier we've

NOTE Confidence: 0.5472333

 $00:40:46.860 \longrightarrow 00:40:48.960$ communicated these in emails,

NOTE Confidence: 0.5472333

 $00:40:48.960 \longrightarrow 00:40:52.480$ but just the highlights,

 $00:40:52.480 \longrightarrow 00:40:56.152$ we we never really had a system where

NOTE Confidence: 0.5472333

 $00{:}40{:}56.152 \dashrightarrow 00{:}40{:}58.640$ we pegged our rates to our costs.

NOTE Confidence: 0.5472333

 $00:40:58.640 \longrightarrow 00:41:01.979$ So part of the reason our institutional

NOTE Confidence: 0.5472333

 $00:41:01.979 \longrightarrow 00:41:05.892$ supplement is so high is that we are,

NOTE Confidence: 0.5472333

 $00:41:05.892 \longrightarrow 00:41:10.879$ we are basically subsidizing the sponsors

NOTE Confidence: 0.5472333

 $00{:}41{:}10.879 \dashrightarrow 00{:}41{:}13.115$ by providing institutional resources

NOTE Confidence: 0.5472333

 $00:41:13.115 \longrightarrow 00:41:17.079$ to offset the cost of our services.

NOTE Confidence: 0.5472333

00:41:17.080 --> 00:41:19.565 And while you know I think most

NOTE Confidence: 0.5472333

00:41:19.565 --> 00:41:21.948 of us we are enthusiastic about

NOTE Confidence: 0.5472333

00:41:21.948 --> 00:41:24.170 doing so for internally funded

NOTE Confidence: 0.5472333

 $00{:}41{:}24.170 \dashrightarrow 00{:}41{:}26.595$ grants and federally funded grants,

NOTE Confidence: 0.5472333

 $00:41:26.600 \longrightarrow 00:41:29.270$ We are not enthusiastic about doing

NOTE Confidence: 0.5472333

 $00:41:29.270 \longrightarrow 00:41:32.720$ so for industry sponsored grants which

NOTE Confidence: 0.5472333

 $00:41:32.720 \longrightarrow 00:41:36.220$ in in which we have this untenable

NOTE Confidence: 0.5472333

00:41:36.220 --> 00:41:39.960 situation potentially of of being a non

NOTE Confidence: 0.5472333

 $00:41:39.960 \longrightarrow 00:41:43.200$ profit but supporting for profit entities.

 $00:41:43.200 \longrightarrow 00:41:47.362$ So because of the increase in cost and

NOTE Confidence: 0.5472333

 $00:41:47.362 \longrightarrow 00:41:51.016$ because our last rates were never pegged

NOTE Confidence: 0.5472333

00:41:51.016 --> 00:41:54.388 to costs or changed for multiple years,

NOTE Confidence: 0.5472333

 $00:41:54.388 \longrightarrow 00:41:58.879$ we have a big jump in our our rates

NOTE Confidence: 0.5472333

 $00:41:58.880 \longrightarrow 00:42:01.995$ in some cases as much as twofold.

NOTE Confidence: 0.5472333

 $00:42:02.000 \longrightarrow 00:42:05.018$ And those rates are being implemented

NOTE Confidence: 0.5472333

00:42:05.018 --> 00:42:08.507 only in a prospective manner namely on

NOTE Confidence: 0.5472333

 $00:42:08.507 \longrightarrow 00:42:11.370$ grants that are being budgeted now.

NOTE Confidence: 0.5472333

00:42:11.370 --> 00:42:12.380 Going forward,

NOTE Confidence: 0.5472333

 $00:42:12.380 \longrightarrow 00:42:15.410$ the old rates will be retained

NOTE Confidence: 0.5472333

 $00:42:15.503 \longrightarrow 00:42:16.888$ for existing rates.

NOTE Confidence: 0.5472333

 $00:42:16.888 \longrightarrow 00:42:20.836$ We were quite concerned that the higher

NOTE Confidence: 0.5472333

 $00:42:20.836 \longrightarrow 00:42:23.816$ rates if instituted across the board,

NOTE Confidence: 0.5472333

00:42:23.816 --> 00:42:26.486 while it would be financially

NOTE Confidence: 0.5472333

 $00:42:26.486 \longrightarrow 00:42:29.048$ beneficial for YCCI and our

00:42:29.048 --> 00:42:31.040 sponsors sponsor institutions,

NOTE Confidence: 0.5472333

 $00:42:31.040 \longrightarrow 00:42:33.660$ it would be very detrimental

NOTE Confidence: 0.5472333

 $00:42:33.660 \longrightarrow 00:42:35.756$ to existing research studies.

NOTE Confidence: 0.5472333

 $00:42:35.760 \longrightarrow 00:42:38.504$ So we're holding off on that and

NOTE Confidence: 0.5472333

 $00:42:38.504 \longrightarrow 00:42:41.904$ the school has been very generous in

NOTE Confidence: 0.5472333

00:42:41.904 --> 00:42:43.840 supporting a more delayed timeline

NOTE Confidence: 0.5472333

 $00:42:43.840 \longrightarrow 00:42:46.220$ so that we don't disrupt clinical

NOTE Confidence: 0.5472333

 $00:42:46.220 \longrightarrow 00:42:47.200$ research protocols.

NOTE Confidence: 0.6469004

 $00{:}42{:}50.640 \dashrightarrow 00{:}42{:}54.984$ So this is going in effect as of

NOTE Confidence: 0.6469004

 $00:42:54.984 \longrightarrow 00:42:58.199$ budgets formulated from 10:30 forward.

NOTE Confidence: 0.6469004

 $00{:}42{:}58.200 \dashrightarrow 00{:}43{:}01.960$ The formula is that we're applying

NOTE Confidence: 0.6469004

 $00:43:01.960 \longrightarrow 00:43:04.864$ rates that are reflect 200% of

NOTE Confidence: 0.6469004

 $00:43:04.864 \longrightarrow 00:43:07.624$ our costs for industry sponsored

NOTE Confidence: 0.6469004

 $00:43:07.624 \longrightarrow 00:43:12.288$ trials and 90% of our costs for

NOTE Confidence: 0.6469004

 $00:43:12.288 \longrightarrow 00:43:14.576$ individual investigator initiated

NOTE Confidence: 0.6469004

 $00{:}43{:}14.576 \dashrightarrow 00{:}43{:}18.416$ studies and NIH and foundation

 $00:43:18.416 \longrightarrow 00:43:21.360$ and internally studied sources.

NOTE Confidence: 0.79298246

00:43:24.400 --> 00:43:26.608 We're also as I mentioned piloting

NOTE Confidence: 0.79298246

 $00:43:26.608 \longrightarrow 00:43:28.080$ this feasibility review process.

NOTE Confidence: 0.79298246

 $00:43:28.080 \longrightarrow 00:43:30.080$ I won't go through it in in detail.

NOTE Confidence: 0.79298246

 $00{:}43{:}30.080 \dashrightarrow 00{:}43{:}33.014$ A number of departments and perhaps

NOTE Confidence: 0.79298246

 $00{:}43{:}33.014 \dashrightarrow 00{:}43{:}34.970$ even psychiatry have experience

NOTE Confidence: 0.79298246

00:43:35.052 --> 00:43:37.191 with some of this and I I already

NOTE Confidence: 0.79298246

 $00{:}43{:}37.191 \dashrightarrow 00{:}43{:}38.746$ summarized kind of the general

NOTE Confidence: 0.79298246

 $00{:}43{:}38.746 \dashrightarrow 00{:}43{:}40.280$ approach and rationale for this.

NOTE Confidence: 0.82234824

 $00:43:42.800 \longrightarrow 00:43:44.355$ What we haven't rolled out

NOTE Confidence: 0.82234824

 $00{:}43{:}44.355 \dashrightarrow 00{:}43{:}45.599$ yet for broad comment,

NOTE Confidence: 0.82234824

00:43:45.600 --> 00:43:47.120 although our faculty advisory

NOTE Confidence: 0.82234824

 $00{:}43{:}47.120 \dashrightarrow 00{:}43{:}49.400$ committees have is a voucher program.

NOTE Confidence: 0.82234824

 $00:43:49.400 \longrightarrow 00:43:53.820$ And the idea here is that there are

NOTE Confidence: 0.82234824

 $00:43:53.820 \longrightarrow 00:43:56.830$ groups of people and perhaps types of

 $00:43:56.830 \longrightarrow 00:43:59.854$ studies that we want to contribute to

NOTE Confidence: 0.82234824

 $00:43:59.854 \longrightarrow 00:44:03.856$ offsetting the cost of executing those

NOTE Confidence: 0.82234824

 $00:44:03.856 \longrightarrow 00:44:07.128$ studies to to help those individuals

NOTE Confidence: 0.82234824

 $00:44:07.128 \longrightarrow 00:44:09.912$ or those studies take flight.

NOTE Confidence: 0.82234824

 $00:44:09.912 \longrightarrow 00:44:13.368$ So we've developed some eligibility proposed

NOTE Confidence: 0.82234824

 $00{:}44{:}13.368 \dashrightarrow 00{:}44{:}16.077$ eligibility criteria that are shown here.

NOTE Confidence: 0.82234824

 $00:44:16.080 \longrightarrow 00:44:22.560$ It's basically everyone on the campus with

NOTE Confidence: 0.82234824

00:44:22.560 --> 00:44:26.080 a Yale appointment is potentially eligible

NOTE Confidence: 0.8893716

 $00:44:28.200 \longrightarrow 00:44:30.786$ and the only ones that we're

NOTE Confidence: 0.8893716

 $00:44:30.786 \longrightarrow 00:44:32.510$ excluding are individual projects

NOTE Confidence: 0.8893716

 $00{:}44{:}32.583 \dashrightarrow 00{:}44{:}34.599$ funded by commercial sources.

NOTE Confidence: 0.8893716

00:44:36.960 --> 00:44:39.396 So the approach that we're suggesting,

NOTE Confidence: 0.8893716

 $00:44:39.400 \longrightarrow 00:44:42.640$ again, this is still in very early stage.

NOTE Confidence: 0.8893716

 $00:44:42.640 \longrightarrow 00:44:44.194$ So this is the first departmental

NOTE Confidence: 0.8893716

 $00:44:44.194 \longrightarrow 00:44:46.000$ meeting I've kind of shared it with.

NOTE Confidence: 0.8893716

 $00:44:46.000 \longrightarrow 00:44:48.916$ So please take it with a grain of salt.

 $00:44:48.920 \longrightarrow 00:44:52.280$ We we have a lot more refinement to do here.

NOTE Confidence: 0.8893716

 $00:44:52.280 \longrightarrow 00:44:55.097$ The idea would be that there would be a

NOTE Confidence: 0.8893716

 $00:44:55.097 \longrightarrow 00:44:57.820$ sliding scale of financial support for

NOTE Confidence: 0.8893716

00:44:57.820 --> 00:45:01.240 these vouchers that YCCI would fund,

NOTE Confidence: 0.8893716

 $00{:}45{:}01.240 \dashrightarrow 00{:}45{:}05.034$ depending on the person and the circumstance,

NOTE Confidence: 0.8893716

 $00:45:05.040 \longrightarrow 00:45:11.051$ anywhere from 25 to 100% of the voucher cost.

NOTE Confidence: 0.8893716

 $00:45:11.051 \longrightarrow 00:45:12.644$ The department, center,

NOTE Confidence: 0.8893716

00:45:12.644 --> 00:45:15.560 school or section would provide

NOTE Confidence: 0.8893716

 $00:45:15.560 \longrightarrow 00:45:19.330$ the balance 0 to 75% depending

NOTE Confidence: 0.8893716

 $00:45:19.330 \longrightarrow 00:45:22.720$ on the awardee or the project.

NOTE Confidence: 0.8893716

 $00:45:22.720 \longrightarrow 00:45:25.275$ Because we don't know exactly

NOTE Confidence: 0.8893716

 $00:45:25.275 \longrightarrow 00:45:27.319$ what this would cost,

NOTE Confidence: 0.8893716

 $00{:}45{:}27.320 \dashrightarrow 00{:}45{:}30.520$ we're proposing to set a cap of

NOTE Confidence: 0.81307488

 $00:45:35.320 \longrightarrow 00:45:38.120$ \$500,000 in the first year.

NOTE Confidence: 0.81307488

 $00:45:38.120 \longrightarrow 00:45:40.504$ And this, this is just a back of

 $00:45:40.504 \longrightarrow 00:45:42.480$ the envelope calculation based on

NOTE Confidence: 0.81307488

 $00{:}45{:}42.480 \dashrightarrow 00{:}45{:}44.665$ the rationale that our services

NOTE Confidence: 0.81307488

 $00:45:44.665 \longrightarrow 00:45:46.684$ are projected this year to

NOTE Confidence: 0.81307488

00:45:46.684 --> 00:45:50.439 generate about 5 million dollars,

NOTE Confidence: 0.81307488

 $00{:}45{:}50.440 --> 00{:}45{:}53.317$ 10% of that seems like a reasonable

NOTE Confidence: 0.81307488

 $00{:}45{:}53.317 \dashrightarrow 00{:}45{:}55.000$ percentage to commit to a,

NOTE Confidence: 0.81307488

 $00:45:55.000 \longrightarrow 00:45:59.040$ a voucher program at least at first pass.

NOTE Confidence: 0.81307488

 $00:45:59.040 \longrightarrow 00:46:02.136$ We would then take 10% of that 5 million

NOTE Confidence: 0.81307488

 $00:46:02.136 \longrightarrow 00:46:05.266$ or 500,000 and make it available on

NOTE Confidence: 0.81307488

 $00:46:05.266 \longrightarrow 00:46:08.224$ a quarterly basis so that we could

NOTE Confidence: 0.81307488

00:46:08.224 --> 00:46:11.008 distribute that 500,000 / 4 quarters

NOTE Confidence: 0.81307488

 $00{:}46{:}11.008 \dashrightarrow 00{:}46{:}14.639$ of an academic year that set a cap

NOTE Confidence: 0.81307488

 $00:46:14.640 \longrightarrow 00:46:17.680$ of \$10,000 either per investigator,

NOTE Confidence: 0.81307488

 $00:46:17.680 \longrightarrow 00:46:21.720$ per year or per project.

NOTE Confidence: 0.81307488

 $00:46:21.720 \longrightarrow 00:46:24.330$ We have a lot of work to do on

NOTE Confidence: 0.81307488

 $00:46:24.330 \longrightarrow 00:46:27.984$ how to execute the voucher credit.

 $00:46:27.984 \longrightarrow 00:46:30.958$ That's at this point all to be determined.

NOTE Confidence: 0.48275673

 $00{:}46{:}35.120 \dashrightarrow 00{:}46{:}38.630$ So in summary, I want to leave you with

NOTE Confidence: 0.48275673

 $00:46:38.630 \longrightarrow 00:46:42.256$ the notion that I hope that YCCI is an

NOTE Confidence: 0.48275673

 $00:46:42.256 \longrightarrow 00:46:44.329$ important source of clinical research

NOTE Confidence: 0.48275673

00:46:44.329 --> 00:46:46.641 infrastructure and training across

NOTE Confidence: 0.48275673

 $00:46:46.641 \longrightarrow 00:46:50.160$ the university and the health system.

NOTE Confidence: 0.48275673

 $00:46:50.160 \longrightarrow 00:46:53.544$ That all forms of clinical research

NOTE Confidence: 0.48275673

 $00{:}46{:}53.544 \dashrightarrow 00{:}46{:}55.236$ and particularly infrastructure

NOTE Confidence: 0.48275673

 $00{:}46{:}55.240 {\:{\circ}{\circ}{\circ}}>00{:}46{:}58.438$ really requires a much higher level

NOTE Confidence: 0.48275673

 $00{:}46{:}58.438 \dashrightarrow 00{:}47{:}01.648$ of discipline and and commitment to

NOTE Confidence: 0.48275673

 $00:47:01.648 \longrightarrow 00:47:04.328$ operating that infrastructure in a

NOTE Confidence: 0.48275673

 $00:47:04.328 \longrightarrow 00:47:08.080$ in an efficient and effective way.

NOTE Confidence: 0.48275673

 $00{:}47{:}08.080 \dashrightarrow 00{:}47{:}11.578$ All design with the goal of of helping

NOTE Confidence: 0.48275673

 $00:47:11.578 \longrightarrow 00:47:13.534$ people successfully complete protocols

NOTE Confidence: 0.48275673

 $00:47:13.534 \longrightarrow 00:47:17.891$ and to do so in a way that's safe for

00:47:17.891 --> 00:47:20.662 human subjects and meets all of the

NOTE Confidence: 0.48275673

 $00{:}47{:}20.662 \dashrightarrow 00{:}47{:}22.466$ applicable regulatory requirements and

NOTE Confidence: 0.48275673

 $00:47:22.466 \longrightarrow 00:47:28.480$ also has a path of financial sustainability.

NOTE Confidence: 0.48275673

00:47:28.480 --> 00:47:33.028 And I think what it what it really says,

NOTE Confidence: 0.48275673

 $00:47:33.028 \longrightarrow 00:47:36.190$ I think strategically is centers like

NOTE Confidence: 0.48275673

00:47:36.289 --> 00:47:39.064 YCCI have to really professionalize

NOTE Confidence: 0.48275673

 $00{:}47{:}39.064 \dashrightarrow 00{:}47{:}43.132$ all of these services and really take

NOTE Confidence: 0.48275673

 $00:47:43.132 \longrightarrow 00:47:46.303$ seriously the the opportunities to

NOTE Confidence: 0.48275673

 $00{:}47{:}46.303 \dashrightarrow 00{:}47{:}49.218$ discover new approaches to treatment

NOTE Confidence: 0.48275673

 $00:47:49.218 \longrightarrow 00:47:52.263$ of individual patients and and

NOTE Confidence: 0.48275673

00:47:52.263 --> 00:47:54.120 populations of patients.

NOTE Confidence: 0.48275673

00:47:54.120 --> 00:47:56.920 I hope I've shared with you what

NOTE Confidence: 0.48275673

 $00:47:56.920 \longrightarrow 00:47:58.655$ is been a very,

NOTE Confidence: 0.48275673

 $00:47:58.655 \longrightarrow 00:48:01.508$ very active several months of of changing

NOTE Confidence: 0.48275673

 $00:48:01.508 \longrightarrow 00:48:03.706$ our policies and our procedures to be

NOTE Confidence: 0.48275673

 $00:48:03.706 \longrightarrow 00:48:06.239$ more responsive to the research community.

 $00:48:06.240 \longrightarrow 00:48:09.397$ We are not where we want to be yet,

NOTE Confidence: 0.48275673

 $00{:}48{:}09.397 \dashrightarrow 00{:}48{:}12.176$ but we're very hopeful that over the

NOTE Confidence: 0.48275673

 $00:48:12.176 \longrightarrow 00:48:15.273$ next many months our services will begin

NOTE Confidence: 0.48275673

 $00:48:15.273 \longrightarrow 00:48:18.623$ to improve and we're going to rely on

NOTE Confidence: 0.48275673

 $00:48:18.623 \longrightarrow 00:48:21.415$ the feedback of faculty to tell us how

NOTE Confidence: 0.48275673

 $00:48:21.415 \longrightarrow 00:48:23.760$ we're doing and where we can improve.

NOTE Confidence: 0.48275673

00:48:23.760 --> 00:48:27.365 So I hope you will feel very comfortable

NOTE Confidence: 0.48275673

 $00:48:27.365 \longrightarrow 00:48:31.548$ sharing that feedback with us and then

NOTE Confidence: 0.48275673

 $00{:}48{:}31.548 \dashrightarrow 00{:}48{:}34.296$ you know hopefully we will continue to

NOTE Confidence: 0.48275673

 $00:48:34.296 \longrightarrow 00:48:36.963$ have regular meetings of the leadership

NOTE Confidence: 0.48275673

 $00{:}48{:}36.963 \dashrightarrow 00{:}48{:}40.460$ of a center and and to get

NOTE Confidence: 0.48275673

 $00{:}48{:}40.460 \dashrightarrow 00{:}48{:}43.188$ iterative feedback and and disseminate

NOTE Confidence: 0.48275673

 $00{:}48{:}43.188 \to 00{:}48{:}45.558$ information to the research community.

NOTE Confidence: 0.48275673

 $00:48:45.560 \longrightarrow 00:48:48.234$ So there's a lot of work ahead.

NOTE Confidence: 0.48275673

 $00:48:48.240 \longrightarrow 00:48:51.381$ I I do hope I've left you with the

 $00:48:51.381 \longrightarrow 00:48:54.168$ notion that there is an extraordinary

NOTE Confidence: 0.48275673

00:48:54.168 --> 00:48:57.903 opportunity if we do this well to

NOTE Confidence: 0.48275673

 $00:48:57.903 \longrightarrow 00:49:00.411$ leverage discovery on this campus.

NOTE Confidence: 0.48275673

 $00:49:00.411 \longrightarrow 00:49:02.079$ And for me personally,

NOTE Confidence: 0.48275673

 $00:49:02.080 \longrightarrow 00:49:05.216$ coming back as a member of the Yale

NOTE Confidence: 0.48275673

00:49:05.216 --> 00:49:09.176 community after 16 years in in Boston,

NOTE Confidence: 0.48275673

 $00:49:09.176 \longrightarrow 00:49:11.672$ as Doctor O'Malley indicated has really

NOTE Confidence: 0.48275673

00:49:11.672 --> 00:49:14.871 been a a wonderful reminder of the

NOTE Confidence: 0.48275673

 $00{:}49{:}14.871 \dashrightarrow 00{:}49{:}17.211$ creativity and and the aspirations

NOTE Confidence: 0.48275673

 $00:49:17.211 \longrightarrow 00:49:19.838$ of of our faculty and trainees.

NOTE Confidence: 0.48275673

 $00:49:19.840 \longrightarrow 00:49:21.320$ So it's been a,

NOTE Confidence: 0.48275673

 $00:49:21.320 \longrightarrow 00:49:24.160$ it's been a real privileged time for me.

NOTE Confidence: 0.48275673

 $00:49:24.160 \longrightarrow 00:49:25.318$ So thank you.

NOTE Confidence: 0.7958927

 $00{:}49{:}27.560 \dashrightarrow 00{:}49{:}29.000$ Thank you so much.