

WEBVTT

NOTE duration:"00:47:55"

NOTE recognizability:0.826

NOTE language:en-us

NOTE Confidence: 0.5951183475

00:00:00.000 --> 00:00:02.188 They will be Jill.

NOTE Confidence: 0.4886326

00:00:14.650 --> 00:00:19.010 Oh, I think we lost Stephanie.

NOTE Confidence: 0.8948656175

00:00:23.270 --> 00:00:24.880 Let's see. We'll give her

NOTE Confidence: 0.8948656175

00:00:24.880 --> 00:00:27.089 a minute to come back on.

NOTE Confidence: 0.024240106

00:00:40.360 --> 00:00:41.110 Say.

NOTE Confidence: 0.38403532

00:00:53.720 --> 00:00:54.100 Hmm.

NOTE Confidence: 0.911971393

00:01:05.430 --> 00:01:07.026 OK, so you were just introduced

NOTE Confidence: 0.911971393

00:01:07.026 --> 00:01:08.534 and we lost you, right,

NOTE Confidence: 0.911971393

00:01:08.534 --> 00:01:12.910 with Jill and we didn't get her last name in.

NOTE Confidence: 0.911971393

00:01:12.910 --> 00:01:15.340 OK. So anyway, sorry about that.

NOTE Confidence: 0.911971393

00:01:15.340 --> 00:01:19.888 So I'd like to also.

NOTE Confidence: 0.911971393

00:01:19.890 --> 00:01:22.220 OK, so you've lost me really early.

NOTE Confidence: 0.911971393

00:01:22.220 --> 00:01:24.818 OK, that's not good.

NOTE Confidence: 0.911971393

00:01:24.818 --> 00:01:28.420 So names, this is Jill.
NOTE Confidence: 0.911971393

00:01:28.420 --> 00:01:31.199 Luca, who's the director of the Conflict
NOTE Confidence: 0.911971393

00:01:31.199 --> 00:01:33.946 of Interest Office and we have Ed Snyder,
NOTE Confidence: 0.911971393

00:01:33.950 --> 00:01:35.960 who's a professor of laboratory
NOTE Confidence: 0.911971393

00:01:35.960 --> 00:01:37.970 medicine and a long standing
NOTE Confidence: 0.911971393

00:01:37.970 --> 00:01:38.802 member of the committee.
NOTE Confidence: 0.911971393

00:01:38.802 --> 00:01:39.960 So with this, I'll turn it
NOTE Confidence: 0.92079451

00:01:39.970 --> 00:01:42.170 over to the two of you to present.
NOTE Confidence: 0.92079451

00:01:42.170 --> 00:01:43.835 Thank you. Thank you.
NOTE Confidence: 0.92079451

00:01:43.835 --> 00:01:45.665 OK, well, thank you very much.
NOTE Confidence: 0.92079451

00:01:45.670 --> 00:01:48.926 Can you guys hear me? Yes, OK.
NOTE Confidence: 0.92079451

00:01:48.926 --> 00:01:50.256 Well, thank you very much.
NOTE Confidence: 0.92079451

00:01:50.260 --> 00:01:51.898 It's a pleasure to be here.
NOTE Confidence: 0.92079451

00:01:51.900 --> 00:01:53.836 We welcome the opportunity.
NOTE Confidence: 0.92079451

00:01:53.836 --> 00:01:55.288 I'm Ed Snyder.
NOTE Confidence: 0.92079451

00:01:55.290 --> 00:01:57.458 I'm was director of the Blood Bank at

NOTE Confidence: 0.92079451

00:01:57.458 --> 00:01:59.898 Yale for many years and I'm still there,

NOTE Confidence: 0.92079451

00:01:59.900 --> 00:02:01.792 but also currently direct

NOTE Confidence: 0.92079451

00:02:01.792 --> 00:02:04.157 the blood Bank at Bridgeport.

NOTE Confidence: 0.92079451

00:02:04.160 --> 00:02:05.530 And I've been a privilege

NOTE Confidence: 0.92079451

00:02:05.530 --> 00:02:07.620 to be on the COI committee.

NOTE Confidence: 0.92079451

00:02:07.620 --> 00:02:09.556 It's changed quite a bit over the years.

NOTE Confidence: 0.92079451

00:02:09.560 --> 00:02:11.318 And the purpose of this talk

NOTE Confidence: 0.92079451

00:02:11.318 --> 00:02:14.135 is to give you some idea of how

NOTE Confidence: 0.92079451

00:02:14.135 --> 00:02:15.703 this the committee functions.

NOTE Confidence: 0.92079451

00:02:15.710 --> 00:02:17.558 So it's not quite as much of a

NOTE Confidence: 0.92079451

00:02:17.558 --> 00:02:19.360 black box as it might have been.

NOTE Confidence: 0.92079451

00:02:19.360 --> 00:02:20.360 And also at the end,

NOTE Confidence: 0.92079451

00:02:20.360 --> 00:02:22.958 we've got a bunch of vignettes

NOTE Confidence: 0.92079451

00:02:22.958 --> 00:02:25.147 briefly to describe situations that

NOTE Confidence: 0.92079451

00:02:25.147 --> 00:02:27.457 are conflicts of interest or not,

NOTE Confidence: 0.92079451

00:02:27.460 --> 00:02:29.420 that may relate to many of you
NOTE Confidence: 0.92079451

00:02:29.420 --> 00:02:30.260 in the audience,
NOTE Confidence: 0.92079451

00:02:30.260 --> 00:02:32.360 and to sort of engender some discussion,
NOTE Confidence: 0.92079451

00:02:32.360 --> 00:02:34.070 which we're going to leave a
NOTE Confidence: 0.92079451

00:02:34.070 --> 00:02:35.958 bunch of time for at the end.
NOTE Confidence: 0.92079451

00:02:35.960 --> 00:02:38.072 And Jill and I will do A tag
NOTE Confidence: 0.92079451

00:02:38.072 --> 00:02:40.020 team kind of approach to do this.
NOTE Confidence: 0.92079451

00:02:40.020 --> 00:02:41.100 So for disclosures,
NOTE Confidence: 0.92079451

00:02:41.100 --> 00:02:44.239 I do run the three phase three clinical
NOTE Confidence: 0.92079451

00:02:44.239 --> 00:02:46.940 trials for the serious Corporation
NOTE Confidence: 0.92079451

00:02:46.940 --> 00:02:49.873 for Red Cell related issues and
NOTE Confidence: 0.92079451

00:02:49.873 --> 00:02:51.737 I'm also on the Board of Human Ethics,
NOTE Confidence: 0.92079451

00:02:51.740 --> 00:02:53.786 but I don't get it personal
NOTE Confidence: 0.92079451

00:02:53.786 --> 00:02:55.800 on our area or equity.
NOTE Confidence: 0.92079451

00:02:55.800 --> 00:02:57.832 As you'll see that you can't run a
NOTE Confidence: 0.92079451

00:02:57.832 --> 00:02:59.776 clinical trial and get equity from the

NOTE Confidence: 0.92079451

00:02:59.776 --> 00:03:01.730 company that you're doing the trial for,

NOTE Confidence: 0.92079451

00:03:01.730 --> 00:03:04.495 we'll talk about that and Jill has

NOTE Confidence: 0.92079451

00:03:04.495 --> 00:03:06.390 no external financial interest.

NOTE Confidence: 0.92079451

00:03:06.390 --> 00:03:07.581 Next slide please.

NOTE Confidence: 0.92079451

00:03:07.581 --> 00:03:10.360 So the conflict of Interest Committee is

NOTE Confidence: 0.92079451

00:03:10.434 --> 00:03:13.129 appointed by an advisory to the Provost.

NOTE Confidence: 0.92079451

00:03:13.130 --> 00:03:13.895 I've been sharing.

NOTE Confidence: 0.92079451

00:03:13.895 --> 00:03:15.425 I've had the honor of being

NOTE Confidence: 0.92079451

00:03:15.425 --> 00:03:16.368 chair for the last,

NOTE Confidence: 0.92079451

00:03:16.370 --> 00:03:17.810 I guess four or five years,

NOTE Confidence: 0.92079451

00:03:17.810 --> 00:03:19.654 I guess maybe more.

NOTE Confidence: 0.92079451

00:03:19.654 --> 00:03:23.030 We meet once a month every month

NOTE Confidence: 0.92079451

00:03:23.030 --> 00:03:27.118 through the summers and the winters and.

NOTE Confidence: 0.92079451

00:03:27.120 --> 00:03:32.133 We have about 20 two members of the committee

NOTE Confidence: 0.92079451

00:03:32.140 --> 00:03:35.074 and of which 16 are voting 6 or not.

NOTE Confidence: 0.92079451

00:03:35.080 --> 00:03:38.812 There's an equal group of men and women.
NOTE Confidence: 0.92079451

00:03:38.812 --> 00:03:42.294 The majority of the of the members are from
NOTE Confidence: 0.92079451

00:03:42.294 --> 00:03:45.297 the medical school faculty that are voting.
NOTE Confidence: 0.92079451

00:03:45.300 --> 00:03:47.428 We have a couple from the Faculty
NOTE Confidence: 0.92079451

00:03:47.428 --> 00:03:50.061 of Arts and Sciences and we have
NOTE Confidence: 0.92079451

00:03:50.061 --> 00:03:51.713 a variety of administrators,
NOTE Confidence: 0.92079451

00:03:51.720 --> 00:03:53.020 representatives of the Provost
NOTE Confidence: 0.92079451

00:03:53.020 --> 00:03:54.645 office and and so forth.
NOTE Confidence: 0.92079451

00:03:54.650 --> 00:03:56.380 We have quite an eclectic.
NOTE Confidence: 0.92079451

00:03:56.380 --> 00:03:58.084 Group as you'll see in one
NOTE Confidence: 0.92079451

00:03:58.084 --> 00:03:59.750 of the coming up slides,
NOTE Confidence: 0.92079451

00:03:59.750 --> 00:04:00.558 next slide.
NOTE Confidence: 0.92079451

00:04:00.558 --> 00:04:03.386 So the the charge is to advise
NOTE Confidence: 0.92079451

00:04:03.386 --> 00:04:05.884 the university leadership on
NOTE Confidence: 0.92079451

00:04:05.884 --> 00:04:08.548 implementing the COI policy.
NOTE Confidence: 0.92079451

00:04:08.550 --> 00:04:11.286 And this policy is designed to

NOTE Confidence: 0.92079451

00:04:11.286 --> 00:04:14.272 protect the faculty so that as well

NOTE Confidence: 0.92079451

00:04:14.272 --> 00:04:16.438 as is to protect the institution.

NOTE Confidence: 0.92079451

00:04:16.440 --> 00:04:18.715 And that seems to work pretty well.

NOTE Confidence: 0.92079451

00:04:18.720 --> 00:04:20.900 There are sometimes when things

NOTE Confidence: 0.92079451

00:04:20.900 --> 00:04:23.535 get a bit difficult because the

NOTE Confidence: 0.92079451

00:04:23.535 --> 00:04:25.797 faculty at Yale are all very

NOTE Confidence: 0.92079451

00:04:25.797 --> 00:04:28.040 bright and they're very creative,

NOTE Confidence: 0.92079451

00:04:28.040 --> 00:04:30.015 and they're all kinds of

NOTE Confidence: 0.92079451

00:04:30.015 --> 00:04:31.200 relationships that develop.

NOTE Confidence: 0.92079451

00:04:31.200 --> 00:04:33.320 And we try to be nimble to work

NOTE Confidence: 0.92079451

00:04:33.320 --> 00:04:35.837 with the groups and to make sure

NOTE Confidence: 0.92079451

00:04:35.837 --> 00:04:37.757 that university policy is applied,

NOTE Confidence: 0.92079451

00:04:37.760 --> 00:04:39.182 yet the faculty are given the

NOTE Confidence: 0.92079451

00:04:39.182 --> 00:04:40.130 freedom to do what

NOTE Confidence: 0.921681361428571

00:04:40.187 --> 00:04:40.979 they need to do.

NOTE Confidence: 0.921681361428571

00:04:40.980 --> 00:04:42.100 That's why they came here.
NOTE Confidence: 0.921681361428571

00:04:42.100 --> 00:04:43.600 So sometimes it's a little
NOTE Confidence: 0.921681361428571

00:04:43.600 --> 00:04:44.500 easier than others.
NOTE Confidence: 0.921681361428571

00:04:44.500 --> 00:04:46.260 So we just hope that
NOTE Confidence: 0.921681361428571

00:04:46.260 --> 00:04:47.316 everyone understands that.
NOTE Confidence: 0.921681361428571

00:04:47.320 --> 00:04:49.156 Our intention is to be helpful
NOTE Confidence: 0.921681361428571

00:04:49.156 --> 00:04:51.492 to to the faculty as well as
NOTE Confidence: 0.921681361428571

00:04:51.492 --> 00:04:52.880 to protect the institution.
NOTE Confidence: 0.812653034166666

00:04:55.770 --> 00:04:58.122 The review we review faculty requests
NOTE Confidence: 0.812653034166666

00:04:58.122 --> 00:05:00.670 to serve on boards of directors.
NOTE Confidence: 0.812653034166666

00:05:00.670 --> 00:05:02.890 Whether it's for profit or not,
NOTE Confidence: 0.812653034166666

00:05:02.890 --> 00:05:03.922 it doesn't matter.
NOTE Confidence: 0.812653034166666

00:05:03.922 --> 00:05:05.986 We review those all those requests.
NOTE Confidence: 0.812653034166666

00:05:05.990 --> 00:05:09.310 We determine whether significant financial
NOTE Confidence: 0.812653034166666

00:05:09.310 --> 00:05:12.630 interests presented with the disclosure,
NOTE Confidence: 0.812653034166666

00:05:12.630 --> 00:05:15.395 if there is a one existing with

NOTE Confidence: 0.812653034166666

00:05:15.395 --> 00:05:18.029 disclosures that the university faculty

NOTE Confidence: 0.812653034166666

00:05:18.030 --> 00:05:21.679 are required to to submit, and if so,

NOTE Confidence: 0.812653034166666

00:05:21.679 --> 00:05:23.317 how such conflict should be managed,

NOTE Confidence: 0.812653034166666

00:05:23.320 --> 00:05:24.631 reduced or eliminated.

NOTE Confidence: 0.812653034166666

00:05:24.631 --> 00:05:27.690 You can see we left afterward ignored.

NOTE Confidence: 0.812653034166666

00:05:27.690 --> 00:05:28.870 We don't have that option.

NOTE Confidence: 0.812653034166666

00:05:28.870 --> 00:05:30.628 If there's a conflict of interest,

NOTE Confidence: 0.812653034166666

00:05:30.630 --> 00:05:33.736 we need to manage it, to ameliorate it,

NOTE Confidence: 0.812653034166666

00:05:33.736 --> 00:05:35.946 reduce it or eliminate it.

NOTE Confidence: 0.812653034166666

00:05:35.950 --> 00:05:38.210 And there are a variety of ways we do it,

NOTE Confidence: 0.812653034166666

00:05:38.210 --> 00:05:39.594 which we'll talk about.

NOTE Confidence: 0.812653034166666

00:05:39.594 --> 00:05:42.657 We do an activities review to see if

NOTE Confidence: 0.812653034166666

00:05:42.657 --> 00:05:44.485 the significant financial interest.

NOTE Confidence: 0.812653034166666

00:05:44.490 --> 00:05:47.974 Has the potential to affect non research,

NOTE Confidence: 0.812653034166666

00:05:47.974 --> 00:05:50.784 the academic teaching or clinical

NOTE Confidence: 0.812653034166666

00:05:50.784 --> 00:05:52.638 administrative responsibilities and we
NOTE Confidence: 0.812653034166666

00:05:52.638 --> 00:05:54.822 also do order we call transactional
NOTE Confidence: 0.812653034166666

00:05:54.822 --> 00:05:57.073 reviews whether we determine if
NOTE Confidence: 0.812653034166666

00:05:57.073 --> 00:05:59.009 the significant financial interest
NOTE Confidence: 0.812653034166666

00:05:59.009 --> 00:06:01.030 directly and significantly affects.
NOTE Confidence: 0.812653034166666

00:06:01.030 --> 00:06:02.948 And these are the three buzzwords design,
NOTE Confidence: 0.812653034166666

00:06:02.950 --> 00:06:05.158 conduct and reporting.
NOTE Confidence: 0.812653034166666

00:06:05.160 --> 00:06:08.009 Which can relate to whether you get
NOTE Confidence: 0.812653034166666

00:06:08.009 --> 00:06:10.613 consent on something or whether you
NOTE Confidence: 0.812653034166666

00:06:10.613 --> 00:06:13.450 actually evaluate the data, et cetera.
NOTE Confidence: 0.812653034166666

00:06:13.450 --> 00:06:17.480 So it's a pretty broad brush that we use
NOTE Confidence: 0.812653034166666

00:06:17.480 --> 00:06:20.110 and it's not just something we invented.
NOTE Confidence: 0.812653034166666

00:06:20.110 --> 00:06:22.150 These are things that are used by a
NOTE Confidence: 0.812653034166666

00:06:22.150 --> 00:06:25.106 variety of funding agencies, the NIH.
NOTE Confidence: 0.812653034166666

00:06:25.106 --> 00:06:29.444 The National Science Foundation and others.
NOTE Confidence: 0.812653034166666

00:06:29.450 --> 00:06:31.170 And it varies among institutions.

NOTE Confidence: 0.812653034166666
00:06:31.170 --> 00:06:32.900 Some institutions are much stricter
NOTE Confidence: 0.812653034166666
00:06:32.900 --> 00:06:35.274 than Yale might be, for example.
NOTE Confidence: 0.812653034166666
00:06:35.274 --> 00:06:37.734 Others might be more LAX.
NOTE Confidence: 0.812653034166666
00:06:37.740 --> 00:06:39.791 So we are concerned about whether it
NOTE Confidence: 0.812653034166666
00:06:39.791 --> 00:06:41.810 affects directly and significantly design,
NOTE Confidence: 0.812653034166666
00:06:41.810 --> 00:06:43.946 conduct and reporting or or could
NOTE Confidence: 0.812653034166666
00:06:43.946 --> 00:06:46.268 the research have a direct and
NOTE Confidence: 0.812653034166666
00:06:46.268 --> 00:06:48.323 significant effect on the objectivity
NOTE Confidence: 0.812653034166666
00:06:48.323 --> 00:06:52.078 of the investigator's next slide?
NOTE Confidence: 0.812653034166666
00:06:52.080 --> 00:06:54.384 So the university policy states a
NOTE Confidence: 0.812653034166666
00:06:54.384 --> 00:06:56.519 conflicts exists when an individual
NOTE Confidence: 0.812653034166666
00:06:56.519 --> 00:06:59.169 has a significant financial interest.
NOTE Confidence: 0.812653034166666
00:06:59.170 --> 00:07:00.680 That's what SFI stands for.
NOTE Confidence: 0.812653034166666
00:07:00.680 --> 00:07:02.972 Should I didn't define that that
NOTE Confidence: 0.812653034166666
00:07:02.972 --> 00:07:05.082 could directly or significantly affect
NOTE Confidence: 0.812653034166666

00:07:05.082 --> 00:07:07.138 his university activities generally,
NOTE Confidence: 0.812653034166666

00:07:07.140 --> 00:07:09.436 this is when the external interest has
NOTE Confidence: 0.812653034166666

00:07:09.436 --> 00:07:12.099 incentive to our to the individuals conduct,
NOTE Confidence: 0.812653034166666

00:07:12.100 --> 00:07:13.804 his or her conduct,
NOTE Confidence: 0.812653034166666

00:07:13.804 --> 00:07:15.934 and whether there's an opportunity,
NOTE Confidence: 0.812653034166666

00:07:15.940 --> 00:07:17.740 which you'll see in a couple of slides.
NOTE Confidence: 0.812653034166666

00:07:17.740 --> 00:07:19.836 We'll show you how we put that into
NOTE Confidence: 0.812653034166666

00:07:19.836 --> 00:07:22.490 into effect. Next slide, please.
NOTE Confidence: 0.812653034166666

00:07:22.490 --> 00:07:25.515 So if you the,
NOTE Confidence: 0.812653034166666

00:07:25.515 --> 00:07:27.645 the concern for conflict of interest
NOTE Confidence: 0.812653034166666

00:07:27.645 --> 00:07:29.908 heightens in the medical school when
NOTE Confidence: 0.812653034166666

00:07:29.908 --> 00:07:31.748 there are human subjects involved
NOTE Confidence: 0.812653034166666

00:07:31.809 --> 00:07:32.790 in the research.
NOTE Confidence: 0.812653034166666

00:07:32.790 --> 00:07:33.906 So if you're,
NOTE Confidence: 0.812653034166666

00:07:33.906 --> 00:07:34.650 you know,
NOTE Confidence: 0.812653034166666

00:07:34.650 --> 00:07:36.612 in the Department of Anthropology and

NOTE Confidence: 0.812653034166666

00:07:36.612 --> 00:07:38.880 they want to give you a large amount

NOTE Confidence: 0.812653034166666

00:07:38.880 --> 00:07:41.559 of money to go on a trip or to do

NOTE Confidence: 0.812653034166666

00:07:41.559 --> 00:07:43.134 some lecturing that's different than

NOTE Confidence: 0.812653034166666

00:07:43.134 --> 00:07:44.728 it would be in the medical school.

NOTE Confidence: 0.812653034166666

00:07:44.730 --> 00:07:46.874 If you're asked to do a study and

NOTE Confidence: 0.812653034166666

00:07:46.874 --> 00:07:48.582 you're involved in recruiting patients

NOTE Confidence: 0.812653034166666

00:07:48.582 --> 00:07:50.808 and putting them into clinical trials,

NOTE Confidence: 0.812653034166666

00:07:50.810 --> 00:07:52.650 very, very different.

NOTE Confidence: 0.812653034166666

00:07:52.650 --> 00:07:55.818 What we have is a general.

NOTE Confidence: 0.812653034166666

00:07:55.820 --> 00:07:57.906 It's not an official policy but it's

NOTE Confidence: 0.812653034166666

00:07:57.906 --> 00:08:00.538 sort of the guidelines we follow that

NOTE Confidence: 0.812653034166666

00:08:00.538 --> 00:08:03.040 if you are getting personal remuneration.

NOTE Confidence: 0.812653034166666

00:08:03.040 --> 00:08:05.064 Personal remuneration excess of

NOTE Confidence: 0.812653034166666

00:08:05.064 --> 00:08:09.090 \$10,000 that we do not allow you to

NOTE Confidence: 0.812653034166666

00:08:09.090 --> 00:08:11.808 do clinical trials for that company.

NOTE Confidence: 0.812653034166666

00:08:11.810 --> 00:08:12.232 Now,
NOTE Confidence: 0.812653034166666
00:08:12.232 --> 00:08:13.920 there are mitigating circumstances
NOTE Confidence: 0.812653034166666
00:08:13.920 --> 00:08:15.608 which you're seeing here.
NOTE Confidence: 0.812653034166666
00:08:15.610 --> 00:08:18.490 And why was \$10,000 chosen?
NOTE Confidence: 0.774387945
00:08:18.490 --> 00:08:19.948 They had to be drawn somewhere.
NOTE Confidence: 0.774387945
00:08:19.950 --> 00:08:22.690 Some places have 5000 NIH,
NOTE Confidence: 0.774387945
00:08:22.690 --> 00:08:24.310 you need to report it 5000.
NOTE Confidence: 0.774387945
00:08:24.310 --> 00:08:25.770 Other places have larger amounts.
NOTE Confidence: 0.774387945
00:08:25.770 --> 00:08:28.670 Them institutions don't allow any
NOTE Confidence: 0.774387945
00:08:28.670 --> 00:08:32.270 financial personal remuneration.
NOTE Confidence: 0.774387945
00:08:32.270 --> 00:08:34.424 So there's a we have 10,000
NOTE Confidence: 0.774387945
00:08:34.424 --> 00:08:36.340 and if that's the case,
NOTE Confidence: 0.774387945
00:08:36.340 --> 00:08:37.996 if you're getting over \$10,000 and
NOTE Confidence: 0.774387945
00:08:37.996 --> 00:08:39.719 you are involved in the design,
NOTE Confidence: 0.774387945
00:08:39.720 --> 00:08:41.328 conduct or reporting of
NOTE Confidence: 0.774387945
00:08:41.328 --> 00:08:42.936 research that you will,

NOTE Confidence: 0.774387945

00:08:42.940 --> 00:08:44.938 you have a management plan that

NOTE Confidence: 0.774387945

00:08:44.938 --> 00:08:47.267 usually gives you a choice of capping

NOTE Confidence: 0.774387945

00:08:47.267 --> 00:08:49.813 at 10K for that year or giving up.

NOTE Confidence: 0.774387945

00:08:49.813 --> 00:08:52.130 The research and faculty that I have

NOTE Confidence: 0.774387945

00:08:52.200 --> 00:08:54.377 talked to do both depending on who

NOTE Confidence: 0.774387945

00:08:54.377 --> 00:08:56.838 they are and what the situation is.

NOTE Confidence: 0.774387945

00:08:56.840 --> 00:08:59.025 And the conflict of interest

NOTE Confidence: 0.774387945

00:08:59.025 --> 00:08:59.899 involves yourself,

NOTE Confidence: 0.774387945

00:08:59.900 --> 00:09:02.288 your spouse and any dependent children.

NOTE Confidence: 0.774387945

00:09:02.290 --> 00:09:04.770 So if you are working for a company

NOTE Confidence: 0.774387945

00:09:04.770 --> 00:09:06.950 doing research and your wife works for

NOTE Confidence: 0.774387945

00:09:06.950 --> 00:09:09.187 that company and gets or your husband

NOTE Confidence: 0.774387945

00:09:09.187 --> 00:09:11.668 works for that company and gets \$30,000,

NOTE Confidence: 0.774387945

00:09:11.668 --> 00:09:14.236 that has an impact on your

NOTE Confidence: 0.774387945

00:09:14.236 --> 00:09:16.370 conflict of interest reporting.

NOTE Confidence: 0.774387945

00:09:16.370 --> 00:09:18.127 So we'll make some of this clear.
NOTE Confidence: 0.774387945

00:09:18.130 --> 00:09:20.104 The the IT seems kind of Byzantine,
NOTE Confidence: 0.774387945

00:09:20.110 --> 00:09:22.060 but we're here to help and
NOTE Confidence: 0.774387945

00:09:22.060 --> 00:09:24.110 to to try to explain.
NOTE Confidence: 0.774387945

00:09:24.110 --> 00:09:26.574 So what you see here are a bunch
NOTE Confidence: 0.774387945

00:09:26.574 --> 00:09:28.078 of mitigating factors including
NOTE Confidence: 0.774387945

00:09:28.078 --> 00:09:30.538 if it's a multi centered study,
NOTE Confidence: 0.774387945

00:09:30.540 --> 00:09:32.640 remember we talked about the design conduct.
NOTE Confidence: 0.774387945

00:09:32.640 --> 00:09:33.032 Reporting.
NOTE Confidence: 0.774387945

00:09:33.032 --> 00:09:36.168 So what is the opportunity that someone has?
NOTE Confidence: 0.774387945

00:09:36.170 --> 00:09:37.964 If you're doing a study that
NOTE Confidence: 0.774387945

00:09:37.964 --> 00:09:40.295 has 50 patients in it and 40 of
NOTE Confidence: 0.774387945

00:09:40.295 --> 00:09:41.897 them are from Yale and you're
NOTE Confidence: 0.774387945

00:09:41.966 --> 00:09:43.936 getting money from the company,
NOTE Confidence: 0.774387945

00:09:43.940 --> 00:09:46.173 that's much more likely you'll have an
NOTE Confidence: 0.774387945

00:09:46.173 --> 00:09:48.895 impact on that than if it's a multicenter

NOTE Confidence: 0.774387945

00:09:48.895 --> 00:09:51.928 study being conducted at 75 institutions,

NOTE Confidence: 0.774387945

00:09:51.928 --> 00:09:55.466 multinational multi nationally and you're

NOTE Confidence: 0.774387945

00:09:55.466 --> 00:09:58.488 recruiting for patients that even if you

NOTE Confidence: 0.774387945

00:09:58.488 --> 00:10:00.690 completely were doing the wrong thing,

NOTE Confidence: 0.774387945

00:10:00.690 --> 00:10:01.790 you still probably wouldn't

NOTE Confidence: 0.774387945

00:10:01.790 --> 00:10:02.890 be able to affect.

NOTE Confidence: 0.774387945

00:10:02.890 --> 00:10:03.940 The outcome of the study,

NOTE Confidence: 0.774387945

00:10:03.940 --> 00:10:05.506 because it's such a minimal impact.

NOTE Confidence: 0.774387945

00:10:05.510 --> 00:10:08.003 So we look at whether it's a multi centered.

NOTE Confidence: 0.774387945

00:10:08.010 --> 00:10:09.642 We did look at whether Yale

NOTE Confidence: 0.774387945

00:10:09.642 --> 00:10:10.730 is a coordinating site,

NOTE Confidence: 0.774387945

00:10:10.730 --> 00:10:12.210 if there's less percent 5,

NOTE Confidence: 0.774387945

00:10:12.210 --> 00:10:14.508 less than 5% enrollment, if you're,

NOTE Confidence: 0.774387945

00:10:14.510 --> 00:10:16.190 if there's involvement in study design,

NOTE Confidence: 0.774387945

00:10:16.190 --> 00:10:17.531 collection, reporting consent,

NOTE Confidence: 0.774387945

00:10:17.531 --> 00:10:19.766 if there's an independent DSMB.
NOTE Confidence: 0.774387945

00:10:19.770 --> 00:10:21.324 All of these things go into the
NOTE Confidence: 0.774387945

00:10:21.330 --> 00:10:22.978 committee's evaluation of whether
NOTE Confidence: 0.774387945

00:10:22.978 --> 00:10:25.038 there's a conflict of interest.
NOTE Confidence: 0.774387945

00:10:25.040 --> 00:10:27.504 So it's not just black and white,
NOTE Confidence: 0.774387945

00:10:27.510 --> 00:10:29.757 there's lots of Shades of Grey that
NOTE Confidence: 0.774387945

00:10:29.757 --> 00:10:31.696 we consider and other factors as
NOTE Confidence: 0.774387945

00:10:31.696 --> 00:10:33.852 well such as if the individuals.
NOTE Confidence: 0.774387945

00:10:33.852 --> 00:10:36.750 Expertise is unique and there's a good
NOTE Confidence: 0.774387945

00:10:36.827 --> 00:10:39.899 reason why certain situations should occur.
NOTE Confidence: 0.774387945

00:10:39.900 --> 00:10:42.420 If the research is in an early stage,
NOTE Confidence: 0.774387945

00:10:42.420 --> 00:10:45.316 if it's in the best interest of patients
NOTE Confidence: 0.774387945

00:10:45.320 --> 00:10:47.336 who would directly benefit from involvement,
NOTE Confidence: 0.774387945

00:10:47.340 --> 00:10:49.158 all of these things we consider.
NOTE Confidence: 0.774387945

00:10:49.160 --> 00:10:51.200 We really do try to to look at
NOTE Confidence: 0.774387945

00:10:51.200 --> 00:10:52.900 all possible mitigating factors.

NOTE Confidence: 0.774387945

00:10:52.900 --> 00:10:53.974 Next slide, please.

NOTE Confidence: 0.774387945

00:10:53.974 --> 00:10:56.480 And there are other things we consider.

NOTE Confidence: 0.774387945

00:10:56.480 --> 00:10:57.740 If there are increased risks,

NOTE Confidence: 0.774387945

00:10:57.740 --> 00:11:01.800 if the research compares or value enhances

NOTE Confidence: 0.774387945

00:11:01.800 --> 00:11:03.540 investigators intellectual property,

NOTE Confidence: 0.774387945

00:11:03.540 --> 00:11:05.430 there's the opportunity for conflict.

NOTE Confidence: 0.774387945

00:11:05.430 --> 00:11:07.205 At least the appearance and

NOTE Confidence: 0.774387945

00:11:07.205 --> 00:11:08.270 optics are critical.

NOTE Confidence: 0.774387945

00:11:08.270 --> 00:11:10.178 We don't want anyone in the

NOTE Confidence: 0.774387945

00:11:10.178 --> 00:11:12.297 faculty to be the poster child

NOTE Confidence: 0.774387945

00:11:12.297 --> 00:11:14.625 on the Yale Daily News someday.

NOTE Confidence: 0.774387945

00:11:14.630 --> 00:11:15.440 We are.

NOTE Confidence: 0.774387945

00:11:15.440 --> 00:11:17.870 We try to work with individuals

NOTE Confidence: 0.9050190222222222

00:11:17.870 --> 00:11:19.725 to ensure that they're complying

NOTE Confidence: 0.9050190222222222

00:11:19.725 --> 00:11:21.209 with the university policy,

NOTE Confidence: 0.9050190222222222

00:11:21.210 --> 00:11:23.025 and we understand what what
NOTE Confidence: 0.9050190222222222

00:11:23.025 --> 00:11:24.477 the investigators needs are.
NOTE Confidence: 0.9050190222222222

00:11:24.480 --> 00:11:27.144 If there are multiple SF's with the entity,
NOTE Confidence: 0.9050190222222222

00:11:27.150 --> 00:11:29.260 if the investigator has intellectual
NOTE Confidence: 0.9050190222222222

00:11:29.260 --> 00:11:31.370 property license to the sponsor,
NOTE Confidence: 0.9050190222222222

00:11:31.370 --> 00:11:33.806 if their students or trainees involved,
NOTE Confidence: 0.9050190222222222

00:11:33.810 --> 00:11:35.868 we've had some situations where faculty.
NOTE Confidence: 0.9050190222222222

00:11:35.870 --> 00:11:37.800 Have been.
NOTE Confidence: 0.9050190222222222

00:11:37.800 --> 00:11:39.738 Having students work on their projects,
NOTE Confidence: 0.9050190222222222

00:11:39.740 --> 00:11:41.510 they're getting some money from
NOTE Confidence: 0.9050190222222222

00:11:41.510 --> 00:11:43.280 companies and the faculty members
NOTE Confidence: 0.9050190222222222

00:11:43.340 --> 00:11:45.140 on the students Thesis committee.
NOTE Confidence: 0.9050190222222222

00:11:45.140 --> 00:11:48.997 All of these things are are Byzantine.
NOTE Confidence: 0.9050190222222222

00:11:49.000 --> 00:11:51.262 Issues that need to be addressed
NOTE Confidence: 0.9050190222222222

00:11:51.262 --> 00:11:54.421 and we have ways of of of addressing
NOTE Confidence: 0.9050190222222222

00:11:54.421 --> 00:11:56.386 them and and and pursuing.

NOTE Confidence: 0.9050190222222222

00:11:56.390 --> 00:11:58.203 How we can protect the student and

NOTE Confidence: 0.9050190222222222

00:11:58.203 --> 00:11:59.869 the faculty and the institution.

NOTE Confidence: 0.9050190222222222

00:11:59.870 --> 00:12:01.440 And there are various management

NOTE Confidence: 0.9050190222222222

00:12:01.440 --> 00:12:02.068 plan techniques.

NOTE Confidence: 0.9050190222222222

00:12:02.070 --> 00:12:03.925 Those of you who have received management

NOTE Confidence: 0.9050190222222222

00:12:03.925 --> 00:12:05.569 plans disclosed in the collaborators,

NOTE Confidence: 0.9050190222222222

00:12:05.570 --> 00:12:06.746 publications, research,

NOTE Confidence: 0.9050190222222222

00:12:06.746 --> 00:12:08.510 you know well.

NOTE Confidence: 0.9050190222222222

00:12:08.510 --> 00:12:10.610 For example, having a disclosure slide.

NOTE Confidence: 0.9050190222222222

00:12:10.610 --> 00:12:12.618 I spoke to 1 faculty member who told

NOTE Confidence: 0.9050190222222222

00:12:12.618 --> 00:12:14.985 me that he couldn't use a disclosure

NOTE Confidence: 0.9050190222222222

00:12:14.985 --> 00:12:16.785 slide on his abstract presentation

NOTE Confidence: 0.9050190222222222

00:12:16.847 --> 00:12:19.247 because he only had 15 minutes to present.

NOTE Confidence: 0.9050190222222222

00:12:19.250 --> 00:12:21.280 Those of you who do this work,

NOTE Confidence: 0.9050190222222222

00:12:21.280 --> 00:12:22.910 you know it takes about.

NOTE Confidence: 0.9050190222222222

00:12:22.910 --> 00:12:25.078 3 nanoseconds to show that slide and to
NOTE Confidence: 0.9050190222222222

00:12:25.078 --> 00:12:27.008 discuss whether you have a conflict or not.
NOTE Confidence: 0.9050190222222222

00:12:27.010 --> 00:12:29.530 So we do have some hard and fast rules
NOTE Confidence: 0.9050190222222222

00:12:29.530 --> 00:12:31.960 that we require and but we try to be
NOTE Confidence: 0.9050190222222222

00:12:31.960 --> 00:12:34.509 fair and very collegial as best we can.
NOTE Confidence: 0.9050190222222222

00:12:34.510 --> 00:12:36.556 So next slide,
NOTE Confidence: 0.9050190222222222

00:12:36.556 --> 00:12:37.238 please.
NOTE Confidence: 0.9050190222222222

00:12:37.240 --> 00:12:38.716 All of these things are considered,
NOTE Confidence: 0.9050190222222222

00:12:38.720 --> 00:12:39.812 and as I mentioned,
NOTE Confidence: 0.9050190222222222

00:12:39.812 --> 00:12:41.836 we have a lot of interactions on
NOTE Confidence: 0.9050190222222222

00:12:41.836 --> 00:12:43.780 the committee are people from the
NOTE Confidence: 0.9050190222222222

00:12:43.780 --> 00:12:45.310 Office of Cooperative Research,
NOTE Confidence: 0.9050190222222222

00:12:45.310 --> 00:12:49.000 which is now the University Yale.
NOTE Confidence: 0.9050190222222222

00:12:49.000 --> 00:12:52.318 I figure what the V stands for.
NOTE Confidence: 0.9050190222222222

00:12:52.320 --> 00:12:54.084 Cheers. Thank you, university.
NOTE Confidence: 0.9050190222222222

00:12:54.084 --> 00:12:56.250 Yale Ventures, you only have one hospital,

NOTE Confidence: 0.9050190222222222
00:12:56.250 --> 00:12:57.630 has a seat at the table.
NOTE Confidence: 0.9050190222222222
00:12:57.630 --> 00:12:58.418 Yale Medicine,
NOTE Confidence: 0.9050190222222222
00:12:58.418 --> 00:13:00.388 the office of sponsored projects,
NOTE Confidence: 0.9050190222222222
00:13:00.390 --> 00:13:02.502 the institutional conflict of
NOTE Confidence: 0.9050190222222222
00:13:02.502 --> 00:13:05.142 interest where the institution has
NOTE Confidence: 0.9050190222222222
00:13:05.150 --> 00:13:08.198 either a royalties or they get
NOTE Confidence: 0.9050190222222222
00:13:08.198 --> 00:13:10.926 the intellectual property as an
NOTE Confidence: 0.9050190222222222
00:13:10.926 --> 00:13:12.565 institution involving human subjects.
NOTE Confidence: 0.9050190222222222
00:13:12.565 --> 00:13:14.635 There's a separate committee that meets
NOTE Confidence: 0.9050190222222222
00:13:14.635 --> 00:13:16.878 the discuss that at the provincial level,
NOTE Confidence: 0.9050190222222222
00:13:16.880 --> 00:13:20.247 the IRB, the Purchasing office of purchases,
NOTE Confidence: 0.9050190222222222
00:13:20.250 --> 00:13:22.540 the Purchasing Office is involved.
NOTE Confidence: 0.9050190222222222
00:13:22.540 --> 00:13:24.616 Office of General Counsel and the
NOTE Confidence: 0.9050190222222222
00:13:24.616 --> 00:13:26.000 conflict of Interest leadership,
NOTE Confidence: 0.9050190222222222
00:13:26.000 --> 00:13:27.790 which really involves the Provost,
NOTE Confidence: 0.9050190222222222

00:13:27.790 --> 00:13:28.414 Provost Office,
NOTE Confidence: 0.9050190222222222

00:13:28.414 --> 00:13:30.286 and many of the other people
NOTE Confidence: 0.9050190222222222

00:13:30.286 --> 00:13:32.159 present at at separate meetings,
NOTE Confidence: 0.9050190222222222

00:13:32.160 --> 00:13:33.900 all have input into the COI.
NOTE Confidence: 0.9050190222222222

00:13:33.900 --> 00:13:35.670 And as you can see their arrows at both ends.
NOTE Confidence: 0.9050190222222222

00:13:35.670 --> 00:13:37.780 It's a pulsating Venn diagram,
NOTE Confidence: 0.9050190222222222

00:13:37.780 --> 00:13:40.454 if you will, which can be quite.
NOTE Confidence: 0.9050190222222222

00:13:40.460 --> 00:13:41.540 It's good to get all this,
NOTE Confidence: 0.9050190222222222

00:13:41.540 --> 00:13:42.840 all this input that's needed.
NOTE Confidence: 0.9050190222222222

00:13:42.840 --> 00:13:44.332 Next slide,
NOTE Confidence: 0.9050190222222222

00:13:44.332 --> 00:13:45.078 please.
NOTE Confidence: 0.9050190222222222

00:13:45.080 --> 00:13:47.145 So in the responsible conduct
NOTE Confidence: 0.9050190222222222

00:13:47.145 --> 00:13:48.797 of research we give,
NOTE Confidence: 0.9050190222222222

00:13:48.800 --> 00:13:50.780 we try to have educational outreach
NOTE Confidence: 0.9050190222222222

00:13:50.780 --> 00:13:53.816 and this is a good example this this
NOTE Confidence: 0.9050190222222222

00:13:53.816 --> 00:13:55.871 particular grand rounds we give

NOTE Confidence: 0.9050190222222222
00:13:55.871 --> 00:13:57.667 yearly lectures to postdoctoral
NOTE Confidence: 0.9050190222222222
00:13:57.667 --> 00:13:59.857 appointees on COI and COCC.
NOTE Confidence: 0.9050190222222222
00:13:59.860 --> 00:14:01.468 We also have been asked to
NOTE Confidence: 0.9050190222222222
00:14:01.468 --> 00:14:03.459 talk to the MD PhD students,
NOTE Confidence: 0.9050190222222222
00:14:03.460 --> 00:14:05.156 which we'll be doing in a few months.
NOTE Confidence: 0.9050190222222222
00:14:05.160 --> 00:14:07.960 We've had talks at the Himont group lab,
NOTE Confidence: 0.9050190222222222
00:14:07.960 --> 00:14:10.640 medicine surgery and we have a couple of
NOTE Confidence: 0.9050190222222222
00:14:10.640 --> 00:14:12.639 other departments to to discuss as well,
NOTE Confidence: 0.9050190222222222
00:14:12.640 --> 00:14:16.069 also the FAS that we've talked to the chairs.
NOTE Confidence: 0.9050190222222222
00:14:16.070 --> 00:14:16.892 And other groups,
NOTE Confidence: 0.9050190222222222
00:14:16.892 --> 00:14:18.810 you know as as we have been
NOTE Confidence: 0.826188776363637
00:14:18.879 --> 00:14:21.146 requested. So if after this is over,
NOTE Confidence: 0.826188776363637
00:14:21.150 --> 00:14:22.830 you know another group that might
NOTE Confidence: 0.826188776363637
00:14:22.830 --> 00:14:24.610 benefit from our wonderful presentation,
NOTE Confidence: 0.826188776363637
00:14:24.610 --> 00:14:26.610 let us know, we'd be more than happy
NOTE Confidence: 0.826188776363637

00:14:26.610 --> 00:14:28.610 to discuss the opportunity to do that.
NOTE Confidence: 0.826188776363637

00:14:28.610 --> 00:14:30.570 I believe there's another slide.
NOTE Confidence: 0.826188776363637

00:14:30.570 --> 00:14:32.432 OK. So I'm going to turn this
NOTE Confidence: 0.826188776363637

00:14:32.432 --> 00:14:34.268 over now to to Jill Peluca,
NOTE Confidence: 0.826188776363637

00:14:34.270 --> 00:14:36.405 who's going to give us more information
NOTE Confidence: 0.826188776363637

00:14:36.405 --> 00:14:38.728 on the what the COI office does and
NOTE Confidence: 0.826188776363637

00:14:38.728 --> 00:14:41.260 then at the end we'll have some of the
NOTE Confidence: 0.826188776363637

00:14:41.260 --> 00:14:43.704 vignettes and then leave it up for questions.
NOTE Confidence: 0.826188776363637

00:14:43.704 --> 00:14:45.589 So Jill, it's all yours.
NOTE Confidence: 0.847216279310345

00:14:45.730 --> 00:14:48.068 Thank you, Ed. So the conflict of
NOTE Confidence: 0.847216279310345

00:14:48.068 --> 00:14:49.530 Interest Office administers and
NOTE Confidence: 0.847216279310345

00:14:49.530 --> 00:14:51.150 implements the universities conflict
NOTE Confidence: 0.847216279310345

00:14:51.150 --> 00:14:53.175 of interest policy procedures and
NOTE Confidence: 0.847216279310345

00:14:53.232 --> 00:14:55.392 we ensure compliance with conflict
NOTE Confidence: 0.847216279310345

00:14:55.392 --> 00:14:57.120 of interest regulatory requirements.
NOTE Confidence: 0.847216279310345

00:14:57.120 --> 00:14:59.172 Our activities include overseeing

NOTE Confidence: 0.847216279310345
00:14:59.172 --> 00:15:01.224 the external interest disclosure
NOTE Confidence: 0.847216279310345
00:15:01.224 --> 00:15:03.611 process for faculty and individuals
NOTE Confidence: 0.847216279310345
00:15:03.611 --> 00:15:06.197 who are responsible for the design,
NOTE Confidence: 0.847216279310345
00:15:06.200 --> 00:15:08.320 conduct or reporting of research.
NOTE Confidence: 0.847216279310345
00:15:08.320 --> 00:15:10.342 We provide advice to and support
NOTE Confidence: 0.847216279310345
00:15:10.342 --> 00:15:12.814 the activities of the COI committee
NOTE Confidence: 0.847216279310345
00:15:12.814 --> 00:15:14.934 and identifying and inappropriately
NOTE Confidence: 0.847216279310345
00:15:14.934 --> 00:15:15.994 managing reducing.
NOTE Confidence: 0.847216279310345
00:15:16.000 --> 00:15:18.280 Or eliminating conflicts and we work
NOTE Confidence: 0.847216279310345
00:15:18.280 --> 00:15:20.428 to ensure that committee determinations
NOTE Confidence: 0.847216279310345
00:15:20.428 --> 00:15:23.258 comport with regulatory and institutional
NOTE Confidence: 0.847216279310345
00:15:23.258 --> 00:15:25.522 conflict of interest requirements.
NOTE Confidence: 0.847216279310345
00:15:25.530 --> 00:15:28.495 We also make sure that there is equity
NOTE Confidence: 0.847216279310345
00:15:28.495 --> 00:15:31.165 in how those decisions are made.
NOTE Confidence: 0.847216279310345
00:15:31.170 --> 00:15:33.250 We assess the external interest
NOTE Confidence: 0.847216279310345

00:15:33.250 --> 00:15:34.914 disclosures submitted to determine
NOTE Confidence: 0.847216279310345

00:15:34.914 --> 00:15:36.901 if outside significant financial
NOTE Confidence: 0.847216279310345

00:15:36.901 --> 00:15:39.406 interest present conflicts of interest
NOTE Confidence: 0.847216279310345

00:15:39.406 --> 00:15:41.559 with sponsored research projects.
NOTE Confidence: 0.847216279310345

00:15:41.560 --> 00:15:42.724 As Ed described,
NOTE Confidence: 0.847216279310345

00:15:42.724 --> 00:15:44.276 those are called transactional
NOTE Confidence: 0.847216279310345

00:15:44.276 --> 00:15:46.490 reviews or with the individuals.
NOTE Confidence: 0.847216279310345

00:15:46.490 --> 00:15:48.593 Other institutional responsibilities,
NOTE Confidence: 0.847216279310345

00:15:48.593 --> 00:15:52.340 the activities review side of our House,
NOTE Confidence: 0.847216279310345

00:15:52.340 --> 00:15:53.570 if you will.
NOTE Confidence: 0.847216279310345

00:15:53.570 --> 00:15:55.838 But we also communicate and monitor
NOTE Confidence: 0.847216279310345

00:15:55.838 --> 00:15:57.750 conflict of interest management plans.
NOTE Confidence: 0.847216279310345

00:15:57.750 --> 00:15:59.649 We spend quite a bit of time doing that.
NOTE Confidence: 0.847216279310345

00:15:59.650 --> 00:16:02.914 We educate and advise faculty and
NOTE Confidence: 0.847216279310345

00:16:02.914 --> 00:16:05.540 other Yale community members who
NOTE Confidence: 0.847216279310345

00:16:05.540 --> 00:16:08.240 are affected by and dependent on

NOTE Confidence: 0.847216279310345
00:16:08.240 --> 00:16:10.460 COI requirements and processes.
NOTE Confidence: 0.847216279310345
00:16:10.460 --> 00:16:10.921 Again,
NOTE Confidence: 0.847216279310345
00:16:10.921 --> 00:16:13.687 advice to COI leadership Group and
NOTE Confidence: 0.847216279310345
00:16:13.687 --> 00:16:16.270 the institutional conflict of Interest
NOTE Confidence: 0.847216279310345
00:16:16.270 --> 00:16:18.522 Committee senior leadership regarding
NOTE Confidence: 0.847216279310345
00:16:18.522 --> 00:16:20.774 management approaches to mitigate
NOTE Confidence: 0.847216279310345
00:16:20.847 --> 00:16:23.625 risks and exposures we inform university.
NOTE Confidence: 0.847216279310345
00:16:23.630 --> 00:16:25.420 Letters of areas of concern
NOTE Confidence: 0.847216279310345
00:16:25.420 --> 00:16:26.494 and emerging issues.
NOTE Confidence: 0.847216279310345
00:16:26.500 --> 00:16:27.436 Of course.
NOTE Confidence: 0.847216279310345
00:16:27.436 --> 00:16:29.776 We submit the required financial
NOTE Confidence: 0.847216279310345
00:16:29.776 --> 00:16:32.720 conflict of interest reports to sponsors.
NOTE Confidence: 0.847216279310345
00:16:32.720 --> 00:16:35.228 We respond to public requests for
NOTE Confidence: 0.847216279310345
00:16:35.228 --> 00:16:36.482 information concerning financial
NOTE Confidence: 0.847216279310345
00:16:36.482 --> 00:16:37.619 conflicts of interest.
NOTE Confidence: 0.847216279310345

00:16:37.620 --> 00:16:41.780 The NIH regulations require that we do so,
NOTE Confidence: 0.847216279310345

00:16:41.780 --> 00:16:44.480 and we network with peer institutions
NOTE Confidence: 0.847216279310345

00:16:44.480 --> 00:16:47.123 and national organizations to see where
NOTE Confidence: 0.847216279310345

00:16:47.123 --> 00:16:49.839 Yale stands with some of our requirements,
NOTE Confidence: 0.847216279310345

00:16:49.840 --> 00:16:53.960 processes, etc.
NOTE Confidence: 0.847216279310345

00:16:53.960 --> 00:16:57.800 A little bit about the.
NOTE Confidence: 0.847216279310345

00:16:57.800 --> 00:16:59.960 External interest disclosure requirements.
NOTE Confidence: 0.847216279310345

00:16:59.960 --> 00:17:04.480 At Yale, I'll start off with who
NOTE Confidence: 0.847216279310345

00:17:04.480 --> 00:17:07.288 the requirements apply to faculty
NOTE Confidence: 0.847216279310345

00:17:07.288 --> 00:17:10.154 with a greater than 50% appointment,
NOTE Confidence: 0.847216279310345

00:17:10.154 --> 00:17:14.026 as well as any faculty or non faculty
NOTE Confidence: 0.847216279310345

00:17:14.026 --> 00:17:16.540 personnel who are the magic words.
NOTE Confidence: 0.847216279310345

00:17:16.540 --> 00:17:17.988 Again responsible for design,
NOTE Confidence: 0.847216279310345

00:17:17.988 --> 00:17:19.798 conduct or reporting of research.
NOTE Confidence: 0.847216279310345

00:17:19.800 --> 00:17:21.785 So that's regardless of percentage
NOTE Confidence: 0.847216279310345

00:17:21.785 --> 00:17:23.332 of appointment, rank,

NOTE Confidence: 0.847216279310345
00:17:23.332 --> 00:17:25.588 title if you're.
NOTE Confidence: 0.847216279310345
00:17:25.588 --> 00:17:27.420 On responsible for design
NOTE Confidence: 0.847216279310345
00:17:27.420 --> 00:17:28.860 comment reporting of research,
NOTE Confidence: 0.847216279310345
00:17:28.860 --> 00:17:31.518 you made the disclosure requirement criteria.
NOTE Confidence: 0.847216279310345
00:17:31.520 --> 00:17:33.893 We have faculty who hold administrative roles
NOTE Confidence: 0.847216279310345
00:17:33.893 --> 00:17:36.780 who also are required to submit disclosures,
NOTE Confidence: 0.847216279310345
00:17:36.780 --> 00:17:39.905 and also members of research
NOTE Confidence: 0.847216279310345
00:17:39.905 --> 00:17:41.155 compliance committees.
NOTE Confidence: 0.847216279310345
00:17:41.160 --> 00:17:44.525 The requirement is to disclose
NOTE Confidence: 0.847216279310345
00:17:44.525 --> 00:17:46.544 significant financial interests.
NOTE Confidence: 0.847216279310345
00:17:46.550 --> 00:17:48.800 A pause for a second to note that you
NOTE Confidence: 0.847216279310345
00:17:48.800 --> 00:17:50.950 are disclosing financial interest.
NOTE Confidence: 0.847216279310345
00:17:50.950 --> 00:17:52.570 You are not disclosing conflicts.
NOTE Confidence: 0.847216279310345
00:17:52.570 --> 00:17:54.811 I have a number of faculty who will say
NOTE Confidence: 0.847216279310345
00:17:54.811 --> 00:17:57.366 I don't have any conflicts to disclose.
NOTE Confidence: 0.847216279310345

00:17:57.370 --> 00:17:59.605 And so you're not disclosing
NOTE Confidence: 0.847216279310345

00:17:59.605 --> 00:18:00.499 conflicts necessarily.
NOTE Confidence: 0.847216279310345

00:18:00.500 --> 00:18:02.378 You're disclosing significant
NOTE Confidence: 0.847216279310345

00:18:02.378 --> 00:18:05.376 financial interests as defined by
NOTE Confidence: 0.847216279310345

00:18:05.376 --> 00:18:07.704 your particular funding sources.
NOTE Confidence: 0.847216279310345

00:18:07.710 --> 00:18:10.286 And if you follow along the disclosure form,
NOTE Confidence: 0.847216279310345

00:18:10.290 --> 00:18:12.410 you don't need to.
NOTE Confidence: 0.847216279310345

00:18:12.410 --> 00:18:14.930 Remember what disclosure thresholds are?
NOTE Confidence: 0.847216279310345

00:18:14.930 --> 00:18:16.650 The disclosure form itself will
NOTE Confidence: 0.847216279310345

00:18:16.650 --> 00:18:18.026 lead you through that.
NOTE Confidence: 0.847216279310345

00:18:18.030 --> 00:18:21.190 Fiduciary roles for outside entities
NOTE Confidence: 0.847216279310345

00:18:21.190 --> 00:18:23.180 qualify for disclosure and whether
NOTE Confidence: 0.847216279310345

00:18:23.180 --> 00:18:25.170 that's for profit or nonprofit.
NOTE Confidence: 0.847216279310345

00:18:25.170 --> 00:18:26.592 So that includes,
NOTE Confidence: 0.847216279310345

00:18:26.592 --> 00:18:28.488 as as Ed mentioned,
NOTE Confidence: 0.847216279310345

00:18:28.490 --> 00:18:31.858 a seat on the Board of Directors or

NOTE Confidence: 0.847216279310345
00:18:31.858 --> 00:18:35.014 any other type of fiduciary responsibility,
NOTE Confidence: 0.847216279310345
00:18:35.014 --> 00:18:36.886 officer type roles,
NOTE Confidence: 0.847216279310345
00:18:36.886 --> 00:18:40.006 intellectual property rights are disclosed
NOTE Confidence: 0.745532663333333
00:18:40.010 --> 00:18:43.058 and in terms of the timing.
NOTE Confidence: 0.745532663333333
00:18:43.060 --> 00:18:44.760 It's at least annually,
NOTE Confidence: 0.745532663333333
00:18:44.760 --> 00:18:47.310 and then the requirement is to
NOTE Confidence: 0.745532663333333
00:18:47.390 --> 00:18:50.696 update within 30 days of acquiring
NOTE Confidence: 0.745532663333333
00:18:50.696 --> 00:18:52.900 new significant financial interest,
NOTE Confidence: 0.745532663333333
00:18:52.900 --> 00:18:56.716 or if there's a material change to one's
NOTE Confidence: 0.745532663333333
00:18:56.720 --> 00:19:00.488 Yale responsibilities, for example.
NOTE Confidence: 0.745532663333333
00:19:00.490 --> 00:19:02.210 Appointment as a department chair,
NOTE Confidence: 0.745532663333333
00:19:02.210 --> 00:19:03.908 that's that would represent a change.
NOTE Confidence: 0.745532663333333
00:19:03.910 --> 00:19:06.830 That is a material change.
NOTE Confidence: 0.745532663333333
00:19:06.830 --> 00:19:09.898 And it's extremely important
NOTE Confidence: 0.745532663333333
00:19:09.898 --> 00:19:12.966 to keep disclosures up-to-date.
NOTE Confidence: 0.745532663333333

00:19:12.970 --> 00:19:17.785 We have to perform retrospective
NOTE Confidence: 0.7455326633333333

00:19:17.785 --> 00:19:20.894 reviews for specifically for NIH
NOTE Confidence: 0.7455326633333333

00:19:20.894 --> 00:19:23.574 funding sources and other agencies
NOTE Confidence: 0.7455326633333333

00:19:23.574 --> 00:19:26.753 that are sponsors that apply the
NOTE Confidence: 0.7455326633333333

00:19:26.753 --> 00:19:29.308 PHS requirements to their awards.
NOTE Confidence: 0.7455326633333333

00:19:29.310 --> 00:19:30.818 There are negative consequences
NOTE Confidence: 0.7455326633333333

00:19:30.818 --> 00:19:32.703 for failing to disclose timely,
NOTE Confidence: 0.7455326633333333

00:19:32.710 --> 00:19:37.520 which include retrospective reviews, which.
NOTE Confidence: 0.7455326633333333

00:19:37.520 --> 00:19:39.056 Create a lot of extra work
NOTE Confidence: 0.7455326633333333

00:19:39.056 --> 00:19:40.080 for the faculty member.
NOTE Confidence: 0.7455326633333333

00:19:40.080 --> 00:19:42.087 We have to go back and ask a series
NOTE Confidence: 0.7455326633333333

00:19:42.087 --> 00:19:43.937 of questions about the financial
NOTE Confidence: 0.7455326633333333

00:19:43.937 --> 00:19:45.892 interest when it was acquired,
NOTE Confidence: 0.7455326633333333

00:19:45.900 --> 00:19:48.756 the impact on the research and.
NOTE Confidence: 0.7455326633333333

00:19:48.760 --> 00:19:50.794 It can be a very time-consuming
NOTE Confidence: 0.7455326633333333

00:19:50.794 --> 00:19:52.150 process for everyone involved.

NOTE Confidence: 0.7917208644444444

00:19:54.530 --> 00:19:57.785 To help faculty ensure that

NOTE Confidence: 0.7917208644444444

00:19:57.785 --> 00:20:00.389 their disclosures don't expire,

NOTE Confidence: 0.7917208644444444

00:20:00.390 --> 00:20:03.810 we have a multi tier.

NOTE Confidence: 0.7917208644444444

00:20:03.810 --> 00:20:05.460 We have multi tiered mechanisms,

NOTE Confidence: 0.7917208644444444

00:20:05.460 --> 00:20:08.184 and some of them include automated

NOTE Confidence: 0.7917208644444444

00:20:08.184 --> 00:20:11.009 reminders that come from the systems,

NOTE Confidence: 0.7917208644444444

00:20:11.010 --> 00:20:13.605 either from the training management

NOTE Confidence: 0.7917208644444444

00:20:13.605 --> 00:20:16.200 system or from the conflict

NOTE Confidence: 0.7917208644444444

00:20:16.286 --> 00:20:18.430 of interest system itself.

NOTE Confidence: 0.7917208644444444

00:20:18.430 --> 00:20:21.070 We pair that with manual reminders

NOTE Confidence: 0.7917208644444444

00:20:21.070 --> 00:20:23.670 that come from the conflict.

NOTE Confidence: 0.7917208644444444

00:20:23.670 --> 00:20:24.520 Interest office,

NOTE Confidence: 0.7917208644444444

00:20:24.520 --> 00:20:27.495 we do have a small population of

NOTE Confidence: 0.7917208644444444

00:20:27.495 --> 00:20:29.394 individuals who are responsible

NOTE Confidence: 0.7917208644444444

00:20:29.394 --> 00:20:31.262 personnel on sponsored projects

NOTE Confidence: 0.7917208644444444

00:20:31.262 --> 00:20:33.458 where they have disclosures that
NOTE Confidence: 0.7917208644444444

00:20:33.458 --> 00:20:35.630 have expired and so we reach
NOTE Confidence: 0.7917208644444444

00:20:35.630 --> 00:20:40.509 out to those individuals to.
NOTE Confidence: 0.7917208644444444

00:20:40.510 --> 00:20:42.856 The CIA office directly reaches out
NOTE Confidence: 0.7917208644444444

00:20:42.856 --> 00:20:46.139 to them to get them into compliance.
NOTE Confidence: 0.7917208644444444

00:20:46.140 --> 00:20:48.150 We have partners in gatekeeping
NOTE Confidence: 0.7917208644444444

00:20:48.150 --> 00:20:50.680 to ensure that the conflict of
NOTE Confidence: 0.7917208644444444

00:20:50.680 --> 00:20:52.480 interest requirements are met.
NOTE Confidence: 0.7917208644444444

00:20:52.480 --> 00:20:54.260 The office of Sponsored Projects,
NOTE Confidence: 0.7917208644444444

00:20:54.260 --> 00:20:55.428 for example,
NOTE Confidence: 0.7917208644444444

00:20:55.428 --> 00:20:57.764 confirms that all responsible
NOTE Confidence: 0.7917208644444444

00:20:57.764 --> 00:21:00.724 personnel have non expired and
NOTE Confidence: 0.7917208644444444

00:21:00.724 --> 00:21:03.389 the appropriate type disclosure on
NOTE Confidence: 0.7917208644444444

00:21:03.389 --> 00:21:06.460 file prior to submitting proposals.
NOTE Confidence: 0.7917208644444444

00:21:06.460 --> 00:21:09.010 And that's not a something Yale
NOTE Confidence: 0.7917208644444444

00:21:09.010 --> 00:21:11.694 made-up or the conflict of Interest

NOTE Confidence: 0.7917208644444444
00:21:11.694 --> 00:21:13.954 office decided to strong arm.
NOTE Confidence: 0.7917208644444444
00:21:13.960 --> 00:21:17.430 It's it's a requirement for.
NOTE Confidence: 0.7917208644444444
00:21:17.430 --> 00:21:22.418 NIH and NSF proposals office of
NOTE Confidence: 0.7917208644444444
00:21:22.418 --> 00:21:25.742 sponsored projects also does the same
NOTE Confidence: 0.7917208644444444
00:21:25.742 --> 00:21:28.450 gatekeeping before setting up awards,
NOTE Confidence: 0.7917208644444444
00:21:28.450 --> 00:21:30.610 and that's regardless of funding source.
NOTE Confidence: 0.7917208644444444
00:21:30.610 --> 00:21:33.240 And if non expired disclosures
NOTE Confidence: 0.7917208644444444
00:21:33.240 --> 00:21:35.344 are not on file,
NOTE Confidence: 0.7917208644444444
00:21:35.350 --> 00:21:39.166 that can lead to delays in award setup.
NOTE Confidence: 0.7917208644444444
00:21:39.170 --> 00:21:42.250 The HRPP confirms that investigators
NOTE Confidence: 0.7917208644444444
00:21:42.250 --> 00:21:45.992 on IRB protocols also have non
NOTE Confidence: 0.7917208644444444
00:21:45.992 --> 00:21:48.777 expired disclosures on file with
NOTE Confidence: 0.7917208644444444
00:21:48.777 --> 00:21:52.638 the COI office prior to reviewing
NOTE Confidence: 0.7917208644444444
00:21:52.638 --> 00:21:54.927 IRB protocol applications.
NOTE Confidence: 0.7917208644444444
00:21:54.930 --> 00:21:58.026 And we do have a tool that's available
NOTE Confidence: 0.7917208644444444

00:21:58.026 --> 00:22:00.070 to Department Business Office.
NOTE Confidence: 0.7917208644444444

00:22:00.070 --> 00:22:01.842 So individual departments have
NOTE Confidence: 0.7917208644444444

00:22:01.842 --> 00:22:05.048 access to a case status report or
NOTE Confidence: 0.7917208644444444

00:22:05.048 --> 00:22:07.408 they can proactively track and
NOTE Confidence: 0.7917208644444444

00:22:07.408 --> 00:22:09.296 monitor disclosure dates types.
NOTE Confidence: 0.7917208644444444

00:22:09.300 --> 00:22:10.310 And stacks.
NOTE Confidence: 0.856556981

00:22:15.190 --> 00:22:17.146 I'll talk a little bit about
NOTE Confidence: 0.856556981

00:22:17.146 --> 00:22:18.450 the disclosure landscaping Yale,
NOTE Confidence: 0.856556981

00:22:18.450 --> 00:22:20.500 since there are some different
NOTE Confidence: 0.856556981

00:22:20.500 --> 00:22:23.045 disclosure requirements and I know some
NOTE Confidence: 0.856556981

00:22:23.045 --> 00:22:26.048 of that can become confusing and some
NOTE Confidence: 0.856556981

00:22:26.048 --> 00:22:27.991 individuals participating on the present
NOTE Confidence: 0.856556981

00:22:27.991 --> 00:22:30.031 in the presentation today may meet
NOTE Confidence: 0.856556981

00:22:30.031 --> 00:22:32.168 more than one disclosure requirement.
NOTE Confidence: 0.856556981

00:22:32.168 --> 00:22:34.403 We have a senior administrative
NOTE Confidence: 0.856556981

00:22:34.403 --> 00:22:35.630 disclosure requirement,

NOTE Confidence: 0.856556981

00:22:35.630 --> 00:22:37.835 which is administered by the Office of

NOTE Confidence: 0.856556981

00:22:37.835 --> 00:22:39.889 the Vice President and General Counsel

NOTE Confidence: 0.856556981

00:22:39.890 --> 00:22:42.530 and they reach out to employees who make.

NOTE Confidence: 0.856556981

00:22:42.530 --> 00:22:44.920 Or influence decisions regarding auditing,

NOTE Confidence: 0.856556981

00:22:44.920 --> 00:22:46.260 purchasing, contracting,

NOTE Confidence: 0.856556981

00:22:46.260 --> 00:22:48.940 admissions, financial aid terms,

NOTE Confidence: 0.856556981

00:22:48.940 --> 00:22:50.524 and conditions of employment,

NOTE Confidence: 0.856556981

00:22:50.524 --> 00:22:52.384 fundraising, or grants administration

NOTE Confidence: 0.856556981

00:22:52.384 --> 00:22:55.800 so they reach out to those individuals.

NOTE Confidence: 0.856556981

00:22:55.800 --> 00:22:56.526 For example,

NOTE Confidence: 0.856556981

00:22:56.526 --> 00:22:59.430 a Dean of the medical school has to

NOTE Confidence: 0.856556981

00:22:59.505 --> 00:23:02.499 submit a disclosure that is reviewed

NOTE Confidence: 0.856556981

00:23:02.499 --> 00:23:04.495 through the General Counsel's

NOTE Confidence: 0.856556981

00:23:04.572 --> 00:23:06.837 office and the Vice president.

NOTE Confidence: 0.856556981

00:23:06.840 --> 00:23:08.520 I submitted disclosure through

NOTE Confidence: 0.856556981

00:23:08.520 --> 00:23:10.200 that process as well.
NOTE Confidence: 0.856556981

00:23:10.200 --> 00:23:12.540 There is a separate disclosure.
NOTE Confidence: 0.856556981

00:23:12.540 --> 00:23:15.347 Process for Yale New Haven health system.
NOTE Confidence: 0.856556981

00:23:15.350 --> 00:23:17.860 They have a separate systems
NOTE Confidence: 0.856556981

00:23:17.860 --> 00:23:19.366 Compliance operations office,
NOTE Confidence: 0.856556981

00:23:19.370 --> 00:23:21.776 and the requirement applies to their
NOTE Confidence: 0.856556981

00:23:21.776 --> 00:23:24.010 covered individuals such as officers,
NOTE Confidence: 0.856556981

00:23:24.010 --> 00:23:24.475 directors,
NOTE Confidence: 0.856556981

00:23:24.475 --> 00:23:26.800 certain key employees and medical
NOTE Confidence: 0.856556981

00:23:26.800 --> 00:23:27.730 staff members.
NOTE Confidence: 0.834756986923077

00:23:31.130 --> 00:23:34.714 We have a conflict of interest leadership
NOTE Confidence: 0.834756986923077

00:23:34.714 --> 00:23:37.874 Group and spoke to on the Nice visual
NOTE Confidence: 0.834756986923077

00:23:37.874 --> 00:23:40.408 that he had all of the different
NOTE Confidence: 0.834756986923077

00:23:40.408 --> 00:23:42.049 interactions it takes a village.
NOTE Confidence: 0.834756986923077

00:23:42.050 --> 00:23:44.870 So the COI leadership group is
NOTE Confidence: 0.834756986923077

00:23:44.870 --> 00:23:47.589 lives in the village with us.

NOTE Confidence: 0.834756986923077

00:23:47.590 --> 00:23:50.130 The membership consists of senior

NOTE Confidence: 0.834756986923077

00:23:50.130 --> 00:23:52.670 leadership from the Provost Office,

NOTE Confidence: 0.834756986923077

00:23:52.670 --> 00:23:55.030 representative from the General Counsel,

NOTE Confidence: 0.834756986923077

00:23:55.030 --> 00:23:58.705 myself and Ed's Office of

NOTE Confidence: 0.834756986923077

00:23:58.705 --> 00:24:00.175 Research Administration.

NOTE Confidence: 0.834756986923077

00:24:00.180 --> 00:24:03.280 And Office of Research Compliance.

NOTE Confidence: 0.834756986923077

00:24:03.280 --> 00:24:04.740 The leadership group is

NOTE Confidence: 0.834756986923077

00:24:04.740 --> 00:24:06.200 advisory to the Provost,

NOTE Confidence: 0.834756986923077

00:24:06.200 --> 00:24:08.972 and they do review cases that

NOTE Confidence: 0.834756986923077

00:24:08.972 --> 00:24:10.820 require provincial approval per

NOTE Confidence: 0.834756986923077

00:24:10.904 --> 00:24:13.178 faculty handbook requirements,

NOTE Confidence: 0.834756986923077

00:24:13.180 --> 00:24:14.004 for example,

NOTE Confidence: 0.834756986923077

00:24:14.004 --> 00:24:17.300 a request to serve on the Board of

NOTE Confidence: 0.834756986923077

00:24:17.391 --> 00:24:20.547 Directors or an exception to policy.

NOTE Confidence: 0.834756986923077

00:24:20.550 --> 00:24:23.100 They also are engaged in policy

NOTE Confidence: 0.834756986923077

00:24:23.100 --> 00:24:25.305 review and development and sometimes
NOTE Confidence: 0.834756986923077

00:24:25.305 --> 00:24:27.855 we have some very challenging cases
NOTE Confidence: 0.834756986923077

00:24:27.855 --> 00:24:30.529 that the COI Committee reviews,
NOTE Confidence: 0.834756986923077

00:24:30.530 --> 00:24:33.645 which we can escalate to or refer
NOTE Confidence: 0.834756986923077

00:24:33.645 --> 00:24:36.810 to the COI leadership group.
NOTE Confidence: 0.834756986923077

00:24:36.810 --> 00:24:39.894 There is also an institutional conflict
NOTE Confidence: 0.834756986923077

00:24:39.894 --> 00:24:42.455 of Interest committee appointed by
NOTE Confidence: 0.834756986923077

00:24:42.455 --> 00:24:44.570 the President of the University.
NOTE Confidence: 0.834756986923077

00:24:44.570 --> 00:24:48.350 And the purpose of that committee is
NOTE Confidence: 0.834756986923077

00:24:48.350 --> 00:24:51.087 to assess institutional significant
NOTE Confidence: 0.834756986923077

00:24:51.087 --> 00:24:53.864 external relationships of the
NOTE Confidence: 0.834756986923077

00:24:53.864 --> 00:24:55.699 university or and or university
NOTE Confidence: 0.834756986923077

00:24:55.699 --> 00:24:58.080 leaders to determine whether they pose
NOTE Confidence: 0.834756986923077

00:24:58.080 --> 00:25:00.100 the risk of creating institutional
NOTE Confidence: 0.834756986923077

00:25:00.100 --> 00:25:02.261 conflicts of interest in relation
NOTE Confidence: 0.834756986923077

00:25:02.261 --> 00:25:03.969 to human subjects research.

NOTE Confidence: 0.834756986923077
00:25:03.970 --> 00:25:06.300 So it's a limited scope.
NOTE Confidence: 0.834756986923077
00:25:06.300 --> 00:25:09.180 But policy and procedure directly
NOTE Confidence: 0.834756986923077
00:25:09.180 --> 00:25:12.703 related to financial interest that are
NOTE Confidence: 0.834756986923077
00:25:12.703 --> 00:25:15.458 related to human subjects research,
NOTE Confidence: 0.834756986923077
00:25:15.460 --> 00:25:17.295 and the committee decides on
NOTE Confidence: 0.834756986923077
00:25:17.295 --> 00:25:19.685 actions to eliminate or manage the
NOTE Confidence: 0.834756986923077
00:25:19.685 --> 00:25:21.629 institutional conflict of interest.
NOTE Confidence: 0.832765821333333
00:25:25.720 --> 00:25:28.666 A topic that dovetails with conflict
NOTE Confidence: 0.832765821333333
00:25:28.666 --> 00:25:31.860 of interest is conflict of commitment.
NOTE Confidence: 0.832765821333333
00:25:31.860 --> 00:25:34.500 There is a specific policy
NOTE Confidence: 0.832765821333333
00:25:34.500 --> 00:25:36.612 on conflict of commitment.
NOTE Confidence: 0.832765821333333
00:25:36.620 --> 00:25:39.903 It is Appendix D of the university
NOTE Confidence: 0.832765821333333
00:25:39.903 --> 00:25:42.857 policy on conflicts of interest and
NOTE Confidence: 0.832765821333333
00:25:42.857 --> 00:25:45.287 a conflict of commitment occurs
NOTE Confidence: 0.832765821333333
00:25:45.287 --> 00:25:48.397 when the commitment to external
NOTE Confidence: 0.832765821333333

00:25:48.397 --> 00:25:51.125 activities adversely affects the
NOTE Confidence: 0.832765821333333

00:25:51.130 --> 00:25:53.622 individual's capacity to meet
NOTE Confidence: 0.832765821333333

00:25:53.622 --> 00:25:54.868 university responsibilities.
NOTE Confidence: 0.832765821333333

00:25:54.870 --> 00:25:57.030 And the responsibility for reviewing,
NOTE Confidence: 0.832765821333333

00:25:57.030 --> 00:25:59.190 identifying and addressing conflicts
NOTE Confidence: 0.832765821333333

00:25:59.190 --> 00:26:02.430 of commitment is with the Dean
NOTE Confidence: 0.832765821333333

00:26:02.515 --> 00:26:04.367 and the relevant chair.
NOTE Confidence: 0.832765821333333

00:26:04.370 --> 00:26:06.915 The Faculty handbook allows outside
NOTE Confidence: 0.832765821333333

00:26:06.915 --> 00:26:08.951 consulting for full-time faculty
NOTE Confidence: 0.832765821333333

00:26:08.951 --> 00:26:11.764 one day and seven since conflict of
NOTE Confidence: 0.832765821333333

00:26:11.764 --> 00:26:14.392 commitment is not always a formulaic.
NOTE Confidence: 0.7298438214

00:26:17.470 --> 00:26:19.590 Determination. It's it really.
NOTE Confidence: 0.7298438214

00:26:19.590 --> 00:26:22.770 We rely heavily on department chairs.
NOTE Confidence: 0.7298438214

00:26:22.770 --> 00:26:24.576 You know, you can have maybe five
NOTE Confidence: 0.7298438214

00:26:24.576 --> 00:26:26.255 days a year, and if those are the
NOTE Confidence: 0.7298438214

00:26:26.255 --> 00:26:27.700 five days a year that you're in

NOTE Confidence: 0.7298438214

00:26:27.700 --> 00:26:29.176 clinic or meeting classes and not

NOTE Confidence: 0.7298438214

00:26:29.176 --> 00:26:30.450 meeting those responsibilities,

NOTE Confidence: 0.7298438214

00:26:30.450 --> 00:26:32.452 you could still have a conflict of

NOTE Confidence: 0.7298438214

00:26:32.452 --> 00:26:34.228 commitment even though the number of

NOTE Confidence: 0.7298438214

00:26:34.228 --> 00:26:35.962 days is below the allowable threshold.

NOTE Confidence: 0.7298438214

00:26:35.970 --> 00:26:39.546 And we we are in the process of

NOTE Confidence: 0.7298438214

00:26:39.546 --> 00:26:41.950 developing reporting for Deans and

NOTE Confidence: 0.7298438214

00:26:41.950 --> 00:26:44.315 department chairs so that they

NOTE Confidence: 0.7298438214

00:26:44.315 --> 00:26:47.327 can become more involved with and.

NOTE Confidence: 0.7298438214

00:26:47.330 --> 00:26:49.390 Engage with their faculty about

NOTE Confidence: 0.7298438214

00:26:49.390 --> 00:26:51.038 conflict of commitment issues.

NOTE Confidence: 0.850998830833333

00:26:53.450 --> 00:26:58.466 On the horizon, we have the enhancement of

NOTE Confidence: 0.850998830833333

00:26:58.466 --> 00:27:01.618 disclosure requirements and what's under

NOTE Confidence: 0.850998830833333

00:27:01.618 --> 00:27:04.613 consideration is the possible expansion

NOTE Confidence: 0.850998830833333

00:27:04.613 --> 00:27:08.947 of the population required to disclose,

NOTE Confidence: 0.850998830833333

00:27:08.950 --> 00:27:12.205 for example, all faculty as opposed to
NOTE Confidence: 0.850998830833333

00:27:12.205 --> 00:27:15.672 faculty with a greater and 50% appointment,
NOTE Confidence: 0.850998830833333

00:27:15.672 --> 00:27:18.320 lowering the threshold for
NOTE Confidence: 0.850998830833333

00:27:18.320 --> 00:27:22.310 disclosure sort of across the board.
NOTE Confidence: 0.850998830833333

00:27:22.310 --> 00:27:25.538 So disclosure is. Level playing field.
NOTE Confidence: 0.850998830833333

00:27:25.540 --> 00:27:29.236 Currently, the thresholds are tied to the
NOTE Confidence: 0.850998830833333

00:27:29.236 --> 00:27:32.559 funding sources and their requirements.
NOTE Confidence: 0.850998830833333

00:27:32.560 --> 00:27:35.120 There will be additional elements
NOTE Confidence: 0.850998830833333

00:27:35.120 --> 00:27:37.168 related to external activities.
NOTE Confidence: 0.850998830833333

00:27:37.170 --> 00:27:40.295 Unfortunately, we are looking at
NOTE Confidence: 0.850998830833333

00:27:40.295 --> 00:27:42.795 a more comprehensive disclosure.
NOTE Confidence: 0.850998830833333

00:27:42.800 --> 00:27:45.110 We're looking at more comprehensive
NOTE Confidence: 0.850998830833333

00:27:45.110 --> 00:27:46.958 disclosure requirements so that
NOTE Confidence: 0.850998830833333

00:27:46.958 --> 00:27:49.694 we can be responsive to changes
NOTE Confidence: 0.850998830833333

00:27:49.694 --> 00:27:51.454 in federal agency requirements.
NOTE Confidence: 0.850998830833333

00:27:51.460 --> 00:27:55.240 So there will be some additional elements,

NOTE Confidence: 0.850998830833333
00:27:55.240 --> 00:27:58.481 for example in kind support to be
NOTE Confidence: 0.850998830833333
00:27:58.481 --> 00:28:00.673 disclosed and additional travel
NOTE Confidence: 0.850998830833333
00:28:00.673 --> 00:28:02.830 disclosure requirements that.
NOTE Confidence: 0.850998830833333
00:28:02.830 --> 00:28:05.644 At present are are not in effect.
NOTE Confidence: 0.03615448
00:28:09.720 --> 00:28:14.740 And. Future enhancements, we would like
NOTE Confidence: 0.03615448
00:28:14.740 --> 00:28:17.260 to explore harmonizing university and
NOTE Confidence: 0.03615448
00:28:17.330 --> 00:28:19.778 the hospital disclosure mechanisms,
NOTE Confidence: 0.03615448
00:28:19.780 --> 00:28:22.498 1 disclosure versus 2 separate disclosures.
NOTE Confidence: 0.03615448
00:28:22.500 --> 00:28:24.342 It sounds simple,
NOTE Confidence: 0.03615448
00:28:24.342 --> 00:28:28.026 but it's really a very challenging.
NOTE Confidence: 0.03615448
00:28:28.030 --> 00:28:29.578 Initiative the hospital
NOTE Confidence: 0.03615448
00:28:29.578 --> 00:28:31.126 has different requirements,
NOTE Confidence: 0.03615448
00:28:31.130 --> 00:28:32.726 different disclosure thresholds
NOTE Confidence: 0.03615448
00:28:32.726 --> 00:28:35.386 we don't want to impose.
NOTE Confidence: 0.03615448
00:28:35.390 --> 00:28:38.030 Requirements that we don't have to.
NOTE Confidence: 0.03615448

00:28:38.030 --> 00:28:41.246 So there's some tension with that.
NOTE Confidence: 0.03615448

00:28:41.250 --> 00:28:42.576 So for now,
NOTE Confidence: 0.03615448

00:28:42.576 --> 00:28:44.786 there are separate disclosure requirements.
NOTE Confidence: 0.03615448

00:28:44.790 --> 00:28:47.098 Another consideration is the
NOTE Confidence: 0.03615448

00:28:47.098 --> 00:28:49.983 possibility of publicly posting on
NOTE Confidence: 0.03615448

00:28:49.983 --> 00:28:52.174 Yale websites financial interests.
NOTE Confidence: 0.03615448

00:28:52.174 --> 00:28:54.706 Not so much value in amount,
NOTE Confidence: 0.03615448

00:28:54.710 --> 00:28:57.368 but the fact that these outside
NOTE Confidence: 0.03615448

00:28:57.368 --> 00:28:58.697 professional relationships exist.
NOTE Confidence: 0.786341309

00:29:00.910 --> 00:29:03.916 And we will at the end of the presentation.
NOTE Confidence: 0.786341309

00:29:03.920 --> 00:29:06.181 You know there might be some suggestions
NOTE Confidence: 0.786341309

00:29:06.181 --> 00:29:09.069 that come out of the talk that we gave today.
NOTE Confidence: 0.786341309

00:29:09.070 --> 00:29:12.234 So I called jotting those down and
NOTE Confidence: 0.786341309

00:29:12.234 --> 00:29:14.958 and listing that for future as well.
NOTE Confidence: 0.526701956

00:29:18.100 --> 00:29:20.960 So that since time permits,
NOTE Confidence: 0.526701956

00:29:20.960 --> 00:29:23.102 I think that we can delve into

NOTE Confidence: 0.526701956
00:29:23.102 --> 00:29:25.512 a little more detail and we can
NOTE Confidence: 0.526701956
00:29:25.512 --> 00:29:27.642 talk about the types of financial
NOTE Confidence: 0.526701956
00:29:27.712 --> 00:29:29.692 interests that are disclosed and
NOTE Confidence: 0.526701956
00:29:29.692 --> 00:29:32.063 that we review of course honoraria,
NOTE Confidence: 0.526701956
00:29:32.063 --> 00:29:33.978 consulting fees and any other
NOTE Confidence: 0.526701956
00:29:33.978 --> 00:29:36.434 fees for serving on for example
NOTE Confidence: 0.526701956
00:29:36.434 --> 00:29:38.138 a scientific Advisory Board,
NOTE Confidence: 0.526701956
00:29:38.140 --> 00:29:39.664 expert witness activities,
NOTE Confidence: 0.526701956
00:29:39.664 --> 00:29:41.696 financial interest can include
NOTE Confidence: 0.526701956
00:29:41.696 --> 00:29:43.220 patents and licenses,
NOTE Confidence: 0.526701956
00:29:43.220 --> 00:29:45.236 intellectual property equity
NOTE Confidence: 0.526701956
00:29:45.236 --> 00:29:48.596 and also as we discussed.
NOTE Confidence: 0.526701956
00:29:48.600 --> 00:29:50.163 Earlier fiduciary responsibilities,
NOTE Confidence: 0.526701956
00:29:50.163 --> 00:29:52.768 so things like board seats,
NOTE Confidence: 0.526701956
00:29:52.770 --> 00:29:57.196 officer roles, etcetera. And Umm,
NOTE Confidence: 0.526701956

00:29:57.196 --> 00:30:00.472 considerations are if there is a greater
NOTE Confidence: 0.526701956

00:30:00.472 --> 00:30:03.204 than \$5000 significant financial interest.
NOTE Confidence: 0.526701956

00:30:03.204 --> 00:30:04.919 Again, that's the PHS,
NOTE Confidence: 0.526701956

00:30:04.919 --> 00:30:07.600 or NIH threshold for what is defined
NOTE Confidence: 0.526701956

00:30:07.682 --> 00:30:10.337 as a significant financial interest,
NOTE Confidence: 0.526701956

00:30:10.340 --> 00:30:11.724 or \$10,000.
NOTE Confidence: 0.526701956

00:30:11.724 --> 00:30:15.876 If it's non PHS NIH funding,
NOTE Confidence: 0.526701956

00:30:15.880 --> 00:30:17.872 or if there are other significant
NOTE Confidence: 0.526701956

00:30:17.872 --> 00:30:19.200 financial interests such as
NOTE Confidence: 0.526701956

00:30:19.256 --> 00:30:20.776 equity in a startup company,
NOTE Confidence: 0.526701956

00:30:20.780 --> 00:30:23.426 the individuals disclosure is labeled with
NOTE Confidence: 0.526701956

00:30:23.426 --> 00:30:26.180 a transaction labeled as transactional.
NOTE Confidence: 0.526701956

00:30:26.180 --> 00:30:29.183 Give you required and we need to
NOTE Confidence: 0.526701956

00:30:29.183 --> 00:30:31.071 evaluate each sponsored project
NOTE Confidence: 0.526701956

00:30:31.071 --> 00:30:34.185 or new award against the outside
NOTE Confidence: 0.526701956

00:30:34.185 --> 00:30:35.223 financial interests.

NOTE Confidence: 0.526701956
00:30:35.230 --> 00:30:36.763 As Ed mentioned,
NOTE Confidence: 0.526701956
00:30:36.763 --> 00:30:38.807 there are special considerations
NOTE Confidence: 0.526701956
00:30:38.807 --> 00:30:41.100 for human subjects research,
NOTE Confidence: 0.526701956
00:30:41.100 --> 00:30:44.280 which may include limiting income to
NOTE Confidence: 0.526701956
00:30:44.280 --> 00:30:47.469 no more than \$10,000 per calendar
NOTE Confidence: 0.526701956
00:30:47.469 --> 00:30:50.667 year if the number of mitigating
NOTE Confidence: 0.526701956
00:30:50.670 --> 00:30:56.277 circumstances do not exist and we know.
NOTE Confidence: 0.526701956
00:30:56.280 --> 00:30:59.844 That often we have individuals who
NOTE Confidence: 0.526701956
00:30:59.844 --> 00:31:02.220 have significant financial interests
NOTE Confidence: 0.526701956
00:31:02.313 --> 00:31:04.908 with with multiple entities so.
NOTE Confidence: 0.526701956
00:31:04.910 --> 00:31:07.250 Some of our faculty are prolific
NOTE Confidence: 0.526701956
00:31:07.250 --> 00:31:08.810 in their consulting engagements.
NOTE Confidence: 0.526701956
00:31:08.810 --> 00:31:12.563 And they're adhering to the one day in seven,
NOTE Confidence: 0.526701956
00:31:12.570 --> 00:31:16.425 but still have significant numbers
NOTE Confidence: 0.526701956
00:31:16.425 --> 00:31:20.280 of consulting or outside engagements.
NOTE Confidence: 0.526701956

00:31:20.280 --> 00:31:23.770 Intellectual property is not considered
NOTE Confidence: 0.526701956

00:31:23.770 --> 00:31:27.260 to be a significant financial
NOTE Confidence: 0.526701956

00:31:27.364 --> 00:31:30.395 interest by PHS or by the NSF,
NOTE Confidence: 0.526701956

00:31:30.400 --> 00:31:31.960 provided the royalties come
NOTE Confidence: 0.526701956

00:31:31.960 --> 00:31:33.520 through the home institution.
NOTE Confidence: 0.526701956

00:31:33.520 --> 00:31:36.248 And the reason for that carve out is
NOTE Confidence: 0.526701956

00:31:36.248 --> 00:31:39.410 that by dole act that encouraged the
NOTE Confidence: 0.526701956

00:31:39.410 --> 00:31:42.440 translation of new discoveries to market.
NOTE Confidence: 0.526701956

00:31:42.440 --> 00:31:45.090 So it's an inherent conflict
NOTE Confidence: 0.526701956

00:31:45.090 --> 00:31:46.680 of interest that.
NOTE Confidence: 0.526701956

00:31:46.680 --> 00:31:51.300 PHS and NSF recognize uh nevertheless.
NOTE Confidence: 0.7033914125

00:31:53.840 --> 00:31:55.620 Yale's conflict of Interest
NOTE Confidence: 0.7033914125

00:31:55.620 --> 00:31:57.400 Committee and the IRB.
NOTE Confidence: 0.7033914125

00:31:57.400 --> 00:32:00.166 Thus, our disclosure form asks for
NOTE Confidence: 0.7033914125

00:32:00.166 --> 00:32:02.010 information about intellectual property
NOTE Confidence: 0.7033914125

00:32:02.082 --> 00:32:04.202 rights may take into consideration

NOTE Confidence: 0.7033914125

00:32:04.202 --> 00:32:06.322 the existence of the intellectual

NOTE Confidence: 0.7033914125

00:32:06.389 --> 00:32:08.313 property rights when evaluating

NOTE Confidence: 0.7033914125

00:32:08.313 --> 00:32:11.098 conflicts of interest, for example,

NOTE Confidence: 0.7033914125

00:32:11.098 --> 00:32:14.443 if the research evaluates the

NOTE Confidence: 0.7033914125

00:32:14.443 --> 00:32:16.450 investigators intellectual property.

NOTE Confidence: 0.7033914125

00:32:16.450 --> 00:32:19.250 And human subjects research that

NOTE Confidence: 0.7033914125

00:32:19.250 --> 00:32:22.050 is testing or evaluating comparing

NOTE Confidence: 0.7033914125

00:32:22.050 --> 00:32:24.435 the investigator's own IP can

NOTE Confidence: 0.7033914125

00:32:24.435 --> 00:32:26.343 be especially worrisome and

NOTE Confidence: 0.7033914125

00:32:26.343 --> 00:32:28.732 generally avoided unless they're a

NOTE Confidence: 0.7033914125

00:32:28.732 --> 00:32:31.027 strong management plans in place.

NOTE Confidence: 0.7033914125

00:32:31.030 --> 00:32:33.207 And we do have some of those

NOTE Confidence: 0.7033914125

00:32:33.207 --> 00:32:33.829 ongoing examples.

NOTE Confidence: 0.839079786

00:32:36.030 --> 00:32:40.670 Another topic is startup companies.

NOTE Confidence: 0.839079786

00:32:40.670 --> 00:32:43.230 Faculty can and may hold equity interest in

NOTE Confidence: 0.839079786

00:32:43.230 --> 00:32:45.609 startups that license intellectual property.

NOTE Confidence: 0.839079786

00:32:45.610 --> 00:32:48.460 As a founder, you are entitled

NOTE Confidence: 0.839079786

00:32:48.460 --> 00:32:50.360 to your Founders equity.

NOTE Confidence: 0.839079786

00:32:50.360 --> 00:32:52.118 Any equity interest in the startup

NOTE Confidence: 0.839079786

00:32:52.118 --> 00:32:54.055 company is considered to be a

NOTE Confidence: 0.839079786

00:32:54.055 --> 00:32:55.126 significant financial interest.

NOTE Confidence: 0.839079786

00:32:55.130 --> 00:32:58.550 That is according to federal

NOTE Confidence: 0.839079786

00:32:58.550 --> 00:33:01.286 regulations and Yale policy.

NOTE Confidence: 0.839079786

00:33:01.290 --> 00:33:03.630 Therefore, it must be disclosed

NOTE Confidence: 0.839079786

00:33:03.630 --> 00:33:05.970 even if the options are.

NOTE Confidence: 0.839079786

00:33:05.970 --> 00:33:08.250 Founder shares are only worth the

NOTE Confidence: 0.839079786

00:33:08.250 --> 00:33:10.360 paper upon which they're written.

NOTE Confidence: 0.839079786

00:33:10.360 --> 00:33:12.496 They are still considered to be

NOTE Confidence: 0.839079786

00:33:12.496 --> 00:33:13.920 a significant financial interest

NOTE Confidence: 0.839079786

00:33:13.920 --> 00:33:17.320 and equity in startup companies.

NOTE Confidence: 0.839079786

00:33:17.320 --> 00:33:19.715 Investigators should be aware that

NOTE Confidence: 0.839079786

00:33:19.715 --> 00:33:22.110 their ability to conduct research

NOTE Confidence: 0.839079786

00:33:22.185 --> 00:33:24.370 sponsored by that same company.

NOTE Confidence: 0.839079786

00:33:24.370 --> 00:33:26.092 Especially human subjects

NOTE Confidence: 0.839079786

00:33:26.092 --> 00:33:28.388 research may be restricted.

NOTE Confidence: 0.839079786

00:33:28.390 --> 00:33:30.214 We have been able to in a number

NOTE Confidence: 0.839079786

00:33:30.214 --> 00:33:32.096 of cases to put in place management

NOTE Confidence: 0.839079786

00:33:32.096 --> 00:33:33.740 plans or as Ed pointed out,

NOTE Confidence: 0.839079786

00:33:33.740 --> 00:33:36.428 there are a number of mitigating factors

NOTE Confidence: 0.839079786

00:33:36.428 --> 00:33:39.513 that allowed us to go forward with the

NOTE Confidence: 0.839079786

00:33:39.513 --> 00:33:41.868 research with a management plan often.

NOTE Confidence: 0.839079786

00:33:41.868 --> 00:33:45.354 When it comes to basic science research,

NOTE Confidence: 0.839079786

00:33:45.360 --> 00:33:46.182 bench research,

NOTE Confidence: 0.839079786

00:33:46.182 --> 00:33:48.237 we do have faculty investigators

NOTE Confidence: 0.839079786

00:33:48.237 --> 00:33:50.478 who have equity and startup

NOTE Confidence: 0.839079786

00:33:50.478 --> 00:33:52.354 companies and research sponsored

NOTE Confidence: 0.839079786

00:33:52.354 --> 00:33:54.620 research agreements from the same,
NOTE Confidence: 0.839079786

00:33:54.620 --> 00:33:56.256 from the same entity,
NOTE Confidence: 0.839079786

00:33:56.256 --> 00:33:58.710 but again with a very strong
NOTE Confidence: 0.839079786

00:33:58.801 --> 00:34:00.849 management plan in place.
NOTE Confidence: 0.839079786

00:34:00.850 --> 00:34:03.112 Board of directors service must be
NOTE Confidence: 0.839079786

00:34:03.112 --> 00:34:05.470 improved and it must be approved
NOTE Confidence: 0.839079786

00:34:05.470 --> 00:34:07.786 in advance by the Provost Office.
NOTE Confidence: 0.839079786

00:34:07.790 --> 00:34:09.450 Because of the fiduciary obligation
NOTE Confidence: 0.839079786

00:34:09.450 --> 00:34:11.770 that comes along with the board seat,
NOTE Confidence: 0.839079786

00:34:11.770 --> 00:34:14.238 those obligations can conflict
NOTE Confidence: 0.839079786

00:34:14.238 --> 00:34:16.089 with the individuals.
NOTE Confidence: 0.839079786

00:34:16.090 --> 00:34:16.557 Yeah,
NOTE Confidence: 0.839079786

00:34:16.557 --> 00:34:17.024 responsibilities.
NOTE Confidence: 0.839079786

00:34:17.024 --> 00:34:20.760 The one tip I have is to discuss
NOTE Confidence: 0.839079786

00:34:20.847 --> 00:34:23.597 prospective board seats with startup
NOTE Confidence: 0.839079786

00:34:23.597 --> 00:34:27.190 companies or other for profit ventures.

NOTE Confidence: 0.839079786

00:34:27.190 --> 00:34:29.092 Very early on with the conflict

NOTE Confidence: 0.839079786

00:34:29.092 --> 00:34:30.043 of interest office.

NOTE Confidence: 0.839079786

00:34:30.050 --> 00:34:31.615 The approval process can take

NOTE Confidence: 0.839079786

00:34:31.615 --> 00:34:32.867 a number of weeks.

NOTE Confidence: 0.839079786

00:34:32.870 --> 00:34:36.884 I've had one that took close to two months.

NOTE Confidence: 0.839079786

00:34:36.890 --> 00:34:37.894 So it all depends.

NOTE Confidence: 0.839079786

00:34:37.894 --> 00:34:39.930 Some of them can go very quickly,

NOTE Confidence: 0.839079786

00:34:39.930 --> 00:34:42.870 some of them are more complicated.

NOTE Confidence: 0.839079786

00:34:42.870 --> 00:34:44.952 So allow plan early and allow

NOTE Confidence: 0.839079786

00:34:44.952 --> 00:34:45.993 for enough time.

NOTE Confidence: 0.864518509583333

00:34:48.490 --> 00:34:50.875 Gales startup policy states that

NOTE Confidence: 0.864518509583333

00:34:50.875 --> 00:34:53.708 a faculty member cannot serve as

NOTE Confidence: 0.864518509583333

00:34:53.708 --> 00:34:56.242 an officer of a startup or any

NOTE Confidence: 0.864518509583333

00:34:56.242 --> 00:34:58.510 other company while not on leave,

NOTE Confidence: 0.864518509583333

00:34:58.510 --> 00:35:02.830 and except for rare and compelling

NOTE Confidence: 0.864518509583333

00:35:02.830 --> 00:35:06.780 circumstances, that policy is is a.
NOTE Confidence: 0.873018834285714

00:35:09.300 --> 00:35:12.052 We also have what we call high value
NOTE Confidence: 0.873018834285714

00:35:12.052 --> 00:35:13.160 significant financial interests
NOTE Confidence: 0.873018834285714

00:35:13.160 --> 00:35:15.026 and that Yale, those interests
NOTE Confidence: 0.873018834285714

00:35:15.026 --> 00:35:17.068 are those that exceed \$100,000.
NOTE Confidence: 0.873018834285714

00:35:17.068 --> 00:35:19.308 And they typically will prompt
NOTE Confidence: 0.873018834285714

00:35:19.308 --> 00:35:21.100 additional questions or asking
NOTE Confidence: 0.873018834285714

00:35:21.166 --> 00:35:23.058 for more detailed information,
NOTE Confidence: 0.873018834285714

00:35:23.060 --> 00:35:25.620 information regarding the activity,
NOTE Confidence: 0.873018834285714

00:35:25.620 --> 00:35:28.112 the entity, the individuals research
NOTE Confidence: 0.873018834285714

00:35:28.112 --> 00:35:31.542 at Yale and perhaps if they have an
NOTE Confidence: 0.873018834285714

00:35:31.542 --> 00:35:34.197 institutional or academic leadership role,
NOTE Confidence: 0.873018834285714

00:35:34.200 --> 00:35:36.740 if those high value significant
NOTE Confidence: 0.873018834285714

00:35:36.740 --> 00:35:38.772 financial interests could influence.
NOTE Confidence: 0.873018834285714

00:35:38.780 --> 00:35:41.600 Decisions that are made in that
NOTE Confidence: 0.873018834285714

00:35:41.600 --> 00:35:44.115 capacity and the reason for that

NOTE Confidence: 0.873018834285714

00:35:44.115 --> 00:35:46.650 is that there's some belief that,

NOTE Confidence: 0.873018834285714

00:35:46.650 --> 00:35:49.530 you know, the higher the value,

NOTE Confidence: 0.873018834285714

00:35:49.530 --> 00:35:52.066 the higher the incentive.

NOTE Confidence: 0.873018834285714

00:35:52.066 --> 00:35:55.852 So there are also philosophical

NOTE Confidence: 0.873018834285714

00:35:55.852 --> 00:35:57.428 conversations around,

NOTE Confidence: 0.873018834285714

00:35:57.430 --> 00:35:59.550 you know, high value,

NOTE Confidence: 0.873018834285714

00:35:59.550 --> 00:36:01.140 significant financial interest

NOTE Confidence: 0.873018834285714

00:36:01.140 --> 00:36:03.100 can sometimes exceed ones

NOTE Confidence: 0.873018834285714

00:36:03.100 --> 00:36:05.764 institutional employment value.

NOTE Confidence: 0.873018834285714

00:36:05.764 --> 00:36:09.944 So you know, we don't.

NOTE Confidence: 0.873018834285714

00:36:09.944 --> 00:36:11.458 Have a.

NOTE Confidence: 0.873018834285714

00:36:11.460 --> 00:36:15.328 Restriction on the amount,

NOTE Confidence: 0.873018834285714

00:36:15.330 --> 00:36:17.530 but we do look at the amount differently

NOTE Confidence: 0.873018834285714

00:36:17.530 --> 00:36:19.350 and may impose instructions if

NOTE Confidence: 0.873018834285714

00:36:19.350 --> 00:36:21.360 there is human subjects research.

NOTE Confidence: 0.390568405

00:36:26.350 --> 00:36:32.196 So Umm. And I think that I will turn this,

NOTE Confidence: 0.390568405

00:36:32.200 --> 00:36:33.968 the rest of the presentation back to you.

NOTE Confidence: 0.901058214615385

00:36:34.030 --> 00:36:35.983 OK. Thank you. One of the things

NOTE Confidence: 0.901058214615385

00:36:35.983 --> 00:36:37.639 that you should keep in mind,

NOTE Confidence: 0.901058214615385

00:36:37.640 --> 00:36:39.230 you're mentioned about the time

NOTE Confidence: 0.901058214615385

00:36:39.230 --> 00:36:41.437 it takes for board seats to be

NOTE Confidence: 0.901058214615385

00:36:41.437 --> 00:36:42.817 reviewed and some go slowly,

NOTE Confidence: 0.901058214615385

00:36:42.820 --> 00:36:44.801 some go quickly and it must be

NOTE Confidence: 0.901058214615385

00:36:44.801 --> 00:36:46.638 mentioned and some don't go at all.

NOTE Confidence: 0.901058214615385

00:36:46.640 --> 00:36:49.230 We have had faculty members.

NOTE Confidence: 0.901058214615385

00:36:49.230 --> 00:36:50.693 Come to us with a request for

NOTE Confidence: 0.901058214615385

00:36:50.693 --> 00:36:52.319 a board of director approval,

NOTE Confidence: 0.901058214615385

00:36:52.320 --> 00:36:54.624 seat seat approval for a seat as if

NOTE Confidence: 0.901058214615385

00:36:54.624 --> 00:36:57.256 it was a given that it would happen.

NOTE Confidence: 0.901058214615385

00:36:57.260 --> 00:36:59.990 And it turns out that some of

NOTE Confidence: 0.901058214615385

00:36:59.990 --> 00:37:02.030 them were so involved in the

NOTE Confidence: 0.901058214615385
00:37:02.030 --> 00:37:04.060 companies work and the work of the
NOTE Confidence: 0.901058214615385
00:37:04.123 --> 00:37:06.385 company was so involved in their
NOTE Confidence: 0.901058214615385
00:37:06.385 --> 00:37:07.893 hot their university activities.
NOTE Confidence: 0.901058214615385
00:37:07.900 --> 00:37:09.748 It would they were just not
NOTE Confidence: 0.901058214615385
00:37:09.748 --> 00:37:11.560 possible for them to coexist.
NOTE Confidence: 0.901058214615385
00:37:11.560 --> 00:37:12.960 And they were denied the
NOTE Confidence: 0.901058214615385
00:37:12.960 --> 00:37:14.360 ability to join the board,
NOTE Confidence: 0.901058214615385
00:37:14.360 --> 00:37:16.202 which was awkward because sometimes they
NOTE Confidence: 0.901058214615385
00:37:16.202 --> 00:37:17.805 had already made plane reservations
NOTE Confidence: 0.901058214615385
00:37:17.805 --> 00:37:19.430 for the next board meeting.
NOTE Confidence: 0.901058214615385
00:37:19.430 --> 00:37:21.257 Where they were going to be presented
NOTE Confidence: 0.901058214615385
00:37:21.257 --> 00:37:22.978 with great fanfare, so please.
NOTE Confidence: 0.901058214615385
00:37:22.978 --> 00:37:25.792 Listen closely about contacting us as
NOTE Confidence: 0.901058214615385
00:37:25.792 --> 00:37:29.420 soon as possible and don't expect that,
NOTE Confidence: 0.901058214615385
00:37:29.420 --> 00:37:31.408 because we have to work with multiple
NOTE Confidence: 0.901058214615385

00:37:31.408 --> 00:37:33.112 agencies and although we may be
NOTE Confidence: 0.901058214615385

00:37:33.112 --> 00:37:34.714 interested in moving it forward quickly,
NOTE Confidence: 0.901058214615385

00:37:34.720 --> 00:37:36.659 other agencies may not be so moved.
NOTE Confidence: 0.901058214615385

00:37:36.660 --> 00:37:39.150 So we try to help you and be your advocate.
NOTE Confidence: 0.901058214615385

00:37:39.150 --> 00:37:41.131 But with that we do have some
NOTE Confidence: 0.901058214615385

00:37:41.131 --> 00:37:42.638 constraints for human subjects.
NOTE Confidence: 0.901058214615385

00:37:42.638 --> 00:37:43.856 There's special considerations,
NOTE Confidence: 0.901058214615385

00:37:43.860 --> 00:37:46.272 the degree of risk some people
NOTE Confidence: 0.901058214615385

00:37:46.272 --> 00:37:49.118 would be more than happy to have.
NOTE Confidence: 0.901058214615385

00:37:49.120 --> 00:37:50.608 Special research done on them all.
NOTE Confidence: 0.901058214615385

00:37:50.610 --> 00:37:53.263 My doctor knows all about the special
NOTE Confidence: 0.901058214615385

00:37:53.263 --> 00:37:55.150 research activities and I'm getting
NOTE Confidence: 0.901058214615385

00:37:55.150 --> 00:37:56.050 state-of-the-art cutting edge.
NOTE Confidence: 0.901058214615385

00:37:56.050 --> 00:37:57.499 Others may say, are you kidding?
NOTE Confidence: 0.901058214615385

00:37:57.499 --> 00:37:58.414 I'm just a Guinea pig.
NOTE Confidence: 0.901058214615385

00:37:58.420 --> 00:37:59.545 There's no way you're coming

NOTE Confidence: 0.901058214615385
00:37:59.545 --> 00:38:01.010 with me unless it's been proven.
NOTE Confidence: 0.901058214615385
00:38:01.010 --> 00:38:02.571 So there are all kinds of things
NOTE Confidence: 0.901058214615385
00:38:02.571 --> 00:38:04.309 that have to be considered to protect
NOTE Confidence: 0.901058214615385
00:38:04.309 --> 00:38:06.330 the faculty as well as the subjects.
NOTE Confidence: 0.901058214615385
00:38:06.330 --> 00:38:08.118 Then the hospital doesn't get involved
NOTE Confidence: 0.901058214615385
00:38:08.118 --> 00:38:10.890 in some of these issues as the jail medicine.
NOTE Confidence: 0.901058214615385
00:38:10.890 --> 00:38:12.010 The phase of the trial,
NOTE Confidence: 0.901058214615385
00:38:12.010 --> 00:38:14.154 if it's phase one or two safety and
NOTE Confidence: 0.901058214615385
00:38:14.154 --> 00:38:15.629 efficacy versus the phase three
NOTE Confidence: 0.901058214615385
00:38:15.629 --> 00:38:17.104 clinical trial or phase four,
NOTE Confidence: 0.901058214615385
00:38:17.110 --> 00:38:21.246 which would be you know a a marketing
NOTE Confidence: 0.901058214615385
00:38:21.246 --> 00:38:24.926 evaluation of post approval of the FDA,
NOTE Confidence: 0.901058214615385
00:38:24.930 --> 00:38:28.196 whether it's a single or multiple site study,
NOTE Confidence: 0.901058214615385
00:38:28.196 --> 00:38:31.892 expected proportion of subjects to be
NOTE Confidence: 0.901058214615385
00:38:31.892 --> 00:38:34.214 accrued which goes to the ability of
NOTE Confidence: 0.901058214615385

00:38:34.214 --> 00:38:36.369 a single investigator to influence results.
NOTE Confidence: 0.901058214615385

00:38:36.370 --> 00:38:38.210 Is the randomization or blinding?
NOTE Confidence: 0.901058214615385

00:38:38.210 --> 00:38:40.450 Is there a data safety monitoring board?
NOTE Confidence: 0.901058214615385

00:38:40.450 --> 00:38:41.794 And should be conflicted
NOTE Confidence: 0.901058214615385

00:38:41.794 --> 00:38:43.138 investigator be involved in,
NOTE Confidence: 0.901058214615385

00:38:43.140 --> 00:38:44.736 you know, the activities.
NOTE Confidence: 0.901058214615385

00:38:44.736 --> 00:38:47.582 So next slide gives us the the
NOTE Confidence: 0.901058214615385

00:38:47.582 --> 00:38:49.820 start of the the case studies.
NOTE Confidence: 0.901058214615385

00:38:49.820 --> 00:38:51.780 What I'm going to do is just
NOTE Confidence: 0.901058214615385

00:38:51.780 --> 00:38:53.986 mention these in in an attempt to
NOTE Confidence: 0.901058214615385

00:38:53.986 --> 00:38:55.606 stimulate the interest that some
NOTE Confidence: 0.901058214615385

00:38:55.606 --> 00:38:57.676 of you may have for questions.
NOTE Confidence: 0.901058214615385

00:38:57.680 --> 00:38:59.548 So here's a situation.
NOTE Confidence: 0.901058214615385

00:38:59.548 --> 00:39:02.288 An MD PhD researcher receives 100,000
NOTE Confidence: 0.901058214615385

00:39:02.288 --> 00:39:04.676 in consulting fees from Mark Tag.
NOTE Confidence: 0.901058214615385

00:39:04.680 --> 00:39:06.201 The researcher prescribes

NOTE Confidence: 0.901058214615385
00:39:06.201 --> 00:39:08.736 martec drugs to their patient,
NOTE Confidence: 0.901058214615385
00:39:08.740 --> 00:39:10.956 and the researcher qualifies.
NOTE Confidence: 0.901058214615385
00:39:10.956 --> 00:39:13.726 Patients for the clinical trial
NOTE Confidence: 0.901058214615385
00:39:13.726 --> 00:39:16.428 using the drug as a comparison.
NOTE Confidence: 0.901058214615385
00:39:16.430 --> 00:39:18.600 And compared to other drugs,
NOTE Confidence: 0.901058214615385
00:39:18.600 --> 00:39:20.040 if you thought this was not
NOTE Confidence: 0.901058214615385
00:39:20.040 --> 00:39:21.000 a conflict of interest,
NOTE Confidence: 0.901058214615385
00:39:21.000 --> 00:39:23.562 you have not been listening because
NOTE Confidence: 0.901058214615385
00:39:23.562 --> 00:39:25.772 this is certainly a consideration
NOTE Confidence: 0.901058214615385
00:39:25.772 --> 00:39:27.540 for a conflict that
NOTE Confidence: 0.881216427222222
00:39:27.612 --> 00:39:30.398 would have to be evaluated thoroughly by
NOTE Confidence: 0.881216427222222
00:39:30.398 --> 00:39:32.798 the by the conflict of Interest committee.
NOTE Confidence: 0.881216427222222
00:39:32.800 --> 00:39:36.660 Next slide. Case two, an assistant professor,
NOTE Confidence: 0.881216427222222
00:39:36.660 --> 00:39:39.612 receives 4000 consulting fees
NOTE Confidence: 0.881216427222222
00:39:39.612 --> 00:39:41.473 from Armageddon Pharmaceuticals.
NOTE Confidence: 0.881216427222222

00:39:41.473 --> 00:39:43.771 The assistant professors also the Pi
NOTE Confidence: 0.881216427222222

00:39:43.771 --> 00:39:46.513 in a stage two clinical trial involving
NOTE Confidence: 0.881216427222222

00:39:46.513 --> 00:39:49.290 Armageddon where she is involved in design,
NOTE Confidence: 0.881216427222222

00:39:49.290 --> 00:39:51.828 conduct and reporting.
NOTE Confidence: 0.881216427222222

00:39:51.830 --> 00:39:54.694 This is not a conflict of interest because
NOTE Confidence: 0.881216427222222

00:39:54.694 --> 00:39:57.657 it's only \$4000 looking at it on its face.
NOTE Confidence: 0.881216427222222

00:39:57.660 --> 00:39:59.230 There may be other extenuating
NOTE Confidence: 0.881216427222222

00:39:59.230 --> 00:40:01.269 circumstances we would need to look at,
NOTE Confidence: 0.881216427222222

00:40:01.270 --> 00:40:03.439 but as far as the whether it's a considered
NOTE Confidence: 0.881216427222222

00:40:03.439 --> 00:40:05.408 a significant financial interest,
NOTE Confidence: 0.881216427222222

00:40:05.410 --> 00:40:06.810 the answer would be no.
NOTE Confidence: 0.881216427222222

00:40:06.810 --> 00:40:10.458 Why? 9999 makes you,
NOTE Confidence: 0.881216427222222

00:40:10.458 --> 00:40:12.299 you know, relatively pure and
NOTE Confidence: 0.892938207142857

00:40:14.390 --> 00:40:15.670 \$10,001.57 means that you've
NOTE Confidence: 0.892938207142857

00:40:15.670 --> 00:40:17.350 crossed the line. I'm sorry,
NOTE Confidence: 0.892938207142857

00:40:17.350 --> 00:40:19.870 the line needed to be drawn somewhere.

NOTE Confidence: 0.892938207142857
00:40:19.870 --> 00:40:21.330 That's why we have mitigating.
NOTE Confidence: 0.892938207142857
00:40:21.330 --> 00:40:23.484 Circumstances that come to play so
NOTE Confidence: 0.892938207142857
00:40:23.484 --> 00:40:26.186 we can try to be as this passionate
NOTE Confidence: 0.892938207142857
00:40:26.186 --> 00:40:28.634 and in the deciding and again
NOTE Confidence: 0.892938207142857
00:40:28.634 --> 00:40:31.418 we are advisory to the Provost.
NOTE Confidence: 0.892938207142857
00:40:31.420 --> 00:40:33.300 What we do is we say yes or no and
NOTE Confidence: 0.892938207142857
00:40:33.359 --> 00:40:35.214 it goes to the Provost and that
NOTE Confidence: 0.892938207142857
00:40:35.214 --> 00:40:36.960 office makes the final decisions.
NOTE Confidence: 0.892938207142857
00:40:36.960 --> 00:40:38.920 They usually want up to hear what
NOTE Confidence: 0.892938207142857
00:40:38.920 --> 00:40:41.284 our our points of view are and we
NOTE Confidence: 0.892938207142857
00:40:41.284 --> 00:40:43.047 always have guidelines but this case
NOTE Confidence: 0.892938207142857
00:40:43.047 --> 00:40:44.784 would not be if this was \$114,000.
NOTE Confidence: 0.892938207142857
00:40:44.784 --> 00:40:46.772 Then we're back to slide one which
NOTE Confidence: 0.892938207142857
00:40:46.772 --> 00:40:49.109 I just I just talked about but it's
NOTE Confidence: 0.892938207142857
00:40:49.109 --> 00:40:50.700 4K would be considered kosher.
NOTE Confidence: 0.892938207142857

00:40:50.700 --> 00:40:53.368 That's OK. Next slide.
NOTE Confidence: 0.892938207142857

00:40:53.370 --> 00:40:56.212 Of professors of founder of a new
NOTE Confidence: 0.892938207142857

00:40:56.212 --> 00:40:59.404 biotech she owns 5% or he owns 5%.
NOTE Confidence: 0.892938207142857

00:40:59.404 --> 00:41:01.128 Founders equity in stock.
NOTE Confidence: 0.892938207142857

00:41:01.130 --> 00:41:02.890 The professor also has several
NOTE Confidence: 0.892938207142857

00:41:02.890 --> 00:41:05.020 graduate students working in her lab
NOTE Confidence: 0.892938207142857

00:41:05.020 --> 00:41:06.886 on projects related to the startup.
NOTE Confidence: 0.892938207142857

00:41:06.890 --> 00:41:09.475 This is encumbered with conflicts
NOTE Confidence: 0.892938207142857

00:41:09.475 --> 00:41:10.509 of interest.
NOTE Confidence: 0.892938207142857

00:41:10.510 --> 00:41:13.288 It's a startup, there's equity involved,
NOTE Confidence: 0.892938207142857

00:41:13.290 --> 00:41:14.010 stock, and options.
NOTE Confidence: 0.892938207142857

00:41:14.010 --> 00:41:15.690 If the company is new and it's
NOTE Confidence: 0.892938207142857

00:41:15.741 --> 00:41:16.986 not on the Stock Exchange,
NOTE Confidence: 0.892938207142857

00:41:16.990 --> 00:41:19.359 we have no way of knowing what the what
NOTE Confidence: 0.892938207142857

00:41:19.359 --> 00:41:21.662 the stock may be worth because it's
NOTE Confidence: 0.892938207142857

00:41:21.662 --> 00:41:24.317 not listed and they're graduate students.

NOTE Confidence: 0.892938207142857
00:41:24.320 --> 00:41:26.180 Involved, which raises all kinds of
NOTE Confidence: 0.892938207142857
00:41:26.180 --> 00:41:28.140 red flags to protect the student.
NOTE Confidence: 0.892938207142857
00:41:28.140 --> 00:41:29.120 So you some may say,
NOTE Confidence: 0.892938207142857
00:41:29.120 --> 00:41:29.497 well,
NOTE Confidence: 0.892938207142857
00:41:29.497 --> 00:41:32.513 the student is working on this area is
NOTE Confidence: 0.892938207142857
00:41:32.513 --> 00:41:34.775 wonderful to help his or her career.
NOTE Confidence: 0.892938207142857
00:41:34.780 --> 00:41:37.138 They'll have a great inroad into
NOTE Confidence: 0.892938207142857
00:41:37.138 --> 00:41:38.710 an academic environment that's
NOTE Confidence: 0.892938207142857
00:41:38.774 --> 00:41:40.210 great for that student.
NOTE Confidence: 0.892938207142857
00:41:40.210 --> 00:41:42.121 What about the other two or three
NOTE Confidence: 0.892938207142857
00:41:42.121 --> 00:41:44.137 students in the in the same lab
NOTE Confidence: 0.892938207142857
00:41:44.137 --> 00:41:45.557 that aren't working as closely
NOTE Confidence: 0.892938207142857
00:41:45.557 --> 00:41:47.323 with the faculty member on the
NOTE Confidence: 0.892938207142857
00:41:47.323 --> 00:41:49.110 project who may feel that they're
NOTE Confidence: 0.892938207142857
00:41:49.110 --> 00:41:51.270 being excluded or the other persons
NOTE Confidence: 0.892938207142857

00:41:51.270 --> 00:41:52.940 being given preferential treatment?
NOTE Confidence: 0.892938207142857

00:41:52.940 --> 00:41:54.430 Double edged swords are alive.
NOTE Confidence: 0.892938207142857

00:41:54.430 --> 00:41:54.662 Well,
NOTE Confidence: 0.892938207142857

00:41:54.662 --> 00:41:56.054 in the conflict of interest world
NOTE Confidence: 0.892938207142857

00:41:56.054 --> 00:41:57.887 and we have to consider all of that,
NOTE Confidence: 0.892938207142857

00:41:57.890 --> 00:42:00.074 we often may have a an honest broker
NOTE Confidence: 0.892938207142857

00:42:00.074 --> 00:42:02.381 or a third party person that the
NOTE Confidence: 0.892938207142857

00:42:02.381 --> 00:42:04.880 students could go to to ask whether
NOTE Confidence: 0.892938207142857

00:42:04.880 --> 00:42:07.808 there's a concern and and and raise issues.
NOTE Confidence: 0.892938207142857

00:42:07.810 --> 00:42:09.770 So we work with people on that
NOTE Confidence: 0.892938207142857

00:42:09.770 --> 00:42:11.170 in that regard as well,
NOTE Confidence: 0.892938207142857

00:42:11.170 --> 00:42:12.362 protecting again the student,
NOTE Confidence: 0.892938207142857

00:42:12.362 --> 00:42:14.485 the faculty member and and the other
NOTE Confidence: 0.892938207142857

00:42:14.485 --> 00:42:16.147 students who may not be involved.
NOTE Confidence: 0.892938207142857

00:42:16.150 --> 00:42:18.208 So here's a little lightning round and
NOTE Confidence: 0.892938207142857

00:42:18.208 --> 00:42:20.237 then we'll open it up for questions.

NOTE Confidence: 0.892938207142857
00:42:20.240 --> 00:42:22.335 35% of an assistant professor
NOTE Confidence: 0.892938207142857
00:42:22.335 --> 00:42:24.430 salary by the Garbanzo Corporation.
NOTE Confidence: 0.892938207142857
00:42:24.430 --> 00:42:26.518 Is sent to the Yale Department for a
NOTE Confidence: 0.892938207142857
00:42:26.518 --> 00:42:28.168 phase three randomized clinical trial
NOTE Confidence: 0.892938207142857
00:42:28.168 --> 00:42:30.900 for which the assistant professor is the Pi.
NOTE Confidence: 0.892938207142857
00:42:30.900 --> 00:42:33.388 So none of the money goes as personal
NOTE Confidence: 0.892938207142857
00:42:33.388 --> 00:42:35.499 on Auraria to the faculty member.
NOTE Confidence: 0.892938207142857
00:42:35.500 --> 00:42:37.320 It goes to the university,
NOTE Confidence: 0.892938207142857
00:42:37.320 --> 00:42:40.722 the Dean takes the 30% or so
NOTE Confidence: 0.892938207142857
00:42:40.722 --> 00:42:41.664 indirect charges,
NOTE Confidence: 0.892938207142857
00:42:41.664 --> 00:42:44.490 and the and the grant is
NOTE Confidence: 0.892938207142857
00:42:44.593 --> 00:42:47.537 administered through the Yale.
NOTE Confidence: 0.892938207142857
00:42:47.540 --> 00:42:50.777 And let's say the it's \$300,000
NOTE Confidence: 0.892938207142857
00:42:50.777 --> 00:42:51.578 that they're supplying.
NOTE Confidence: 0.892938207142857
00:42:51.578 --> 00:42:53.550 That is not a conflict of interest
NOTE Confidence: 0.892938207142857

00:42:53.550 --> 00:42:55.446 because it goes through the university.

NOTE Confidence: 0.892938207142857

00:42:55.450 --> 00:42:57.826 If it's not going as personal on area,

NOTE Confidence: 0.892938207142857

00:42:57.830 --> 00:42:58.770 that's fine.

NOTE Confidence: 0.892938207142857

00:42:58.770 --> 00:43:01.590 If it's going through the university,

NOTE Confidence: 0.892938207142857

00:43:01.590 --> 00:43:02.006 so this,

NOTE Confidence: 0.892938207142857

00:43:02.006 --> 00:43:03.046 although you might think there's

NOTE Confidence: 0.892938207142857

00:43:03.046 --> 00:43:03.670 a lot of

NOTE Confidence: 0.870455045454546

00:43:03.719 --> 00:43:06.610 money, it's over 10,000, maybe over 100,000.

NOTE Confidence: 0.870455045454546

00:43:06.610 --> 00:43:08.210 If it's through the university,

NOTE Confidence: 0.870455045454546

00:43:08.210 --> 00:43:10.418 it's acceptable. It's not a considered

NOTE Confidence: 0.870455045454546

00:43:10.418 --> 00:43:12.530 a conflict again on its face.

NOTE Confidence: 0.870455045454546

00:43:12.530 --> 00:43:14.280 The faculty member asked to sit in

NOTE Confidence: 0.870455045454546

00:43:14.280 --> 00:43:16.882 a not-for-profit board of a of a

NOTE Confidence: 0.870455045454546

00:43:16.882 --> 00:43:18.688 senior care and not-for-profit. Still,

NOTE Confidence: 0.870455045454546

00:43:18.688 --> 00:43:20.830 a conflict of interest has to be looked at.

NOTE Confidence: 0.870455045454546

00:43:20.830 --> 00:43:22.790 It usually requires very little

NOTE Confidence: 0.870455045454546

00:43:22.790 --> 00:43:24.750 discussion by the Committee of

NOTE Confidence: 0.870455045454546

00:43:24.820 --> 00:43:26.910 they're not probing for problems,

NOTE Confidence: 0.870455045454546

00:43:26.910 --> 00:43:29.066 but it does need to be brought

NOTE Confidence: 0.870455045454546

00:43:29.066 --> 00:43:31.069 up and approved by the Provost.

NOTE Confidence: 0.870455045454546

00:43:31.070 --> 00:43:32.470 Obviously the next one,

NOTE Confidence: 0.870455045454546

00:43:32.470 --> 00:43:34.570 whether it's a pharma giant joining

NOTE Confidence: 0.870455045454546

00:43:34.636 --> 00:43:36.360 the board, we would need to know,

NOTE Confidence: 0.870455045454546

00:43:36.360 --> 00:43:39.306 you know, what is the faculty

NOTE Confidence: 0.870455045454546

00:43:39.306 --> 00:43:40.779 members administrative activities?

NOTE Confidence: 0.870455045454546

00:43:40.780 --> 00:43:43.746 Are they in the middle of everyone

NOTE Confidence: 0.870455045454546

00:43:43.746 --> 00:43:46.689 who reports to them is working on

NOTE Confidence: 0.870455045454546

00:43:46.689 --> 00:43:48.447 a product made by that company?

NOTE Confidence: 0.870455045454546

00:43:48.450 --> 00:43:51.738 And here are the person who's the center.

NOTE Confidence: 0.870455045454546

00:43:51.740 --> 00:43:54.380 Node for all of this content

NOTE Confidence: 0.870455045454546

00:43:54.380 --> 00:43:57.260 or the faculty member.

NOTE Confidence: 0.870455045454546

00:43:57.260 --> 00:43:58.945 Reporting this to this person
NOTE Confidence: 0.870455045454546

00:43:58.945 --> 00:44:00.955 who now was sitting wants to
NOTE Confidence: 0.870455045454546

00:44:00.955 --> 00:44:02.775 sit on the board of this giant.
NOTE Confidence: 0.870455045454546

00:44:02.780 --> 00:44:04.990 That's a problem that needs
NOTE Confidence: 0.870455045454546

00:44:04.990 --> 00:44:06.316 to be adjudicated.
NOTE Confidence: 0.870455045454546

00:44:06.320 --> 00:44:09.976 Faculty is invited to join a speakers Bureau.
NOTE Confidence: 0.870455045454546

00:44:09.980 --> 00:44:14.100 Speakers Bureau has become anathema at Yale.
NOTE Confidence: 0.870455045454546

00:44:14.100 --> 00:44:18.160 The Yale New Haven Hospital has extensive
NOTE Confidence: 0.870455045454546

00:44:18.160 --> 00:44:20.016 retraining on speakers bureaus,
NOTE Confidence: 0.870455045454546

00:44:20.016 --> 00:44:22.336 and that was speakers Bureau.
NOTE Confidence: 0.870455045454546

00:44:22.340 --> 00:44:24.300 Doesn't mean that you're giving
NOTE Confidence: 0.870455045454546

00:44:24.300 --> 00:44:26.532 a clinical talk involving a
NOTE Confidence: 0.870455045454546

00:44:26.532 --> 00:44:27.584 company's activities.
NOTE Confidence: 0.870455045454546

00:44:27.584 --> 00:44:29.688 At a national meeting,
NOTE Confidence: 0.870455045454546

00:44:29.690 --> 00:44:32.497 it's when you have these little cozy
NOTE Confidence: 0.870455045454546

00:44:32.497 --> 00:44:35.232 dinners at well very high-priced

NOTE Confidence: 0.870455045454546
00:44:35.232 --> 00:44:37.995 restaurants where you're given slides
NOTE Confidence: 0.870455045454546
00:44:37.995 --> 00:44:40.959 by the company and you're basically.
NOTE Confidence: 0.870455045454546
00:44:40.960 --> 00:44:44.164 Trying to advertise for the companies
NOTE Confidence: 0.870455045454546
00:44:44.164 --> 00:44:46.480 product, those are the speakers bureaus.
NOTE Confidence: 0.870455045454546
00:44:46.480 --> 00:44:48.083 So you have to define what it
NOTE Confidence: 0.870455045454546
00:44:48.083 --> 00:44:49.499 is that you're referring to.
NOTE Confidence: 0.870455045454546
00:44:49.500 --> 00:44:51.075 And this is not just at Yale,
NOTE Confidence: 0.870455045454546
00:44:51.080 --> 00:44:51.788 this is nationally.
NOTE Confidence: 0.870455045454546
00:44:51.788 --> 00:44:52.260 In fact,
NOTE Confidence: 0.870455045454546
00:44:52.260 --> 00:44:54.236 Yale is trying to catch up to what
NOTE Confidence: 0.870455045454546
00:44:54.236 --> 00:44:56.277 many other institutions in my opinion,
NOTE Confidence: 0.870455045454546
00:44:56.280 --> 00:44:59.920 have already gone beyond.
NOTE Confidence: 0.870455045454546
00:44:59.920 --> 00:45:02.296 As far as the Speakers Bureau
NOTE Confidence: 0.870455045454546
00:45:02.296 --> 00:45:03.880 is not being acceptable,
NOTE Confidence: 0.870455045454546
00:45:03.880 --> 00:45:05.882 how about the faculty in the Department
NOTE Confidence: 0.870455045454546

00:45:05.882 --> 00:45:07.693 of Music or offered half \$1,000,000
NOTE Confidence: 0.870455045454546

00:45:07.693 --> 00:45:09.772 to write a score for a movie?
NOTE Confidence: 0.870455045454546

00:45:09.780 --> 00:45:11.180 Not a conflict of interest.
NOTE Confidence: 0.870455045454546

00:45:11.180 --> 00:45:13.070 There's no human subjects involved.
NOTE Confidence: 0.870455045454546

00:45:13.070 --> 00:45:15.260 They do need to disclose.
NOTE Confidence: 0.870455045454546

00:45:15.260 --> 00:45:17.493 They need to disclose the 500,000,
NOTE Confidence: 0.870455045454546

00:45:17.493 --> 00:45:18.359 but congratulations.
NOTE Confidence: 0.870455045454546

00:45:18.359 --> 00:45:21.532 I hope it's a great movie and it's
NOTE Confidence: 0.870455045454546

00:45:21.532 --> 00:45:23.248 up to the department chair to
NOTE Confidence: 0.870455045454546

00:45:23.248 --> 00:45:25.235 determine if the amount of time that
NOTE Confidence: 0.870455045454546

00:45:25.235 --> 00:45:27.331 he or her spends writing the score
NOTE Confidence: 0.870455045454546

00:45:27.331 --> 00:45:29.056 becomes a conflict of commitment.
NOTE Confidence: 0.870455045454546

00:45:29.060 --> 00:45:29.400 But.
NOTE Confidence: 0.870455045454546

00:45:29.400 --> 00:45:31.440 It's not a conflict of interest,
NOTE Confidence: 0.870455045454546

00:45:31.440 --> 00:45:33.048 they just need to disclose it.
NOTE Confidence: 0.870455045454546

00:45:33.050 --> 00:45:35.200 And because human subjects aren't

NOTE Confidence: 0.870455045454546
00:45:35.200 --> 00:45:37.040 involved that that puts it into
NOTE Confidence: 0.870455045454546
00:45:37.040 --> 00:45:38.450 a different category but does
NOTE Confidence: 0.870455045454546
00:45:38.509 --> 00:45:39.649 need to be disclosed.
NOTE Confidence: 0.870455045454546
00:45:39.650 --> 00:45:41.848 And if a faculty member spends 50%
NOTE Confidence: 0.870455045454546
00:45:41.850 --> 00:45:43.607 of her time as an expert witness,
NOTE Confidence: 0.870455045454546
00:45:43.610 --> 00:45:45.612 this is conflict of commitment which the
NOTE Confidence: 0.870455045454546
00:45:45.612 --> 00:45:47.248 department chair would get involved in.
NOTE Confidence: 0.870455045454546
00:45:47.250 --> 00:45:49.140 And we don't make those adjudications
NOTE Confidence: 0.870455045454546
00:45:49.140 --> 00:45:51.509 and the conflict of interest committee,
NOTE Confidence: 0.870455045454546
00:45:51.510 --> 00:45:54.443 but we are getting more involved in
NOTE Confidence: 0.870455045454546
00:45:54.443 --> 00:45:57.438 assuring that that is looked at
NOTE Confidence: 0.870455045454546
00:45:57.438 --> 00:45:59.508 by appropriate personnel in the.
NOTE Confidence: 0.870455045454546
00:45:59.510 --> 00:46:00.482 To the institution.
NOTE Confidence: 0.870455045454546
00:46:00.482 --> 00:46:03.180 So I think that was there another slide?
NOTE Confidence: 0.870455045454546
00:46:03.180 --> 00:46:04.750 I think there may be one more, yes.
NOTE Confidence: 0.870455045454546

00:46:04.750 --> 00:46:07.400 So COI is a situation,
NOTE Confidence: 0.870455045454546

00:46:07.400 --> 00:46:09.278 not a behavior nor an indictment.
NOTE Confidence: 0.881317984583333

00:46:09.280 --> 00:46:11.440 You do not need to walk around with a
NOTE Confidence: 0.881317984583333

00:46:11.440 --> 00:46:13.667 sandwich board saying I have a conflict of
NOTE Confidence: 0.881317984583333

00:46:13.667 --> 00:46:15.599 interest and people throw stones at you.
NOTE Confidence: 0.881317984583333

00:46:15.600 --> 00:46:16.980 Everyone to some degree
NOTE Confidence: 0.881317984583333

00:46:16.980 --> 00:46:18.360 may have an involvement.
NOTE Confidence: 0.881317984583333

00:46:18.360 --> 00:46:20.439 It's our job to work with you,
NOTE Confidence: 0.881317984583333

00:46:20.440 --> 00:46:22.638 to protect you, to protect the institution.
NOTE Confidence: 0.881317984583333

00:46:22.640 --> 00:46:24.780 I've said this multiple times,
NOTE Confidence: 0.881317984583333

00:46:24.780 --> 00:46:27.384 it is not an indictment and some
NOTE Confidence: 0.881317984583333

00:46:27.384 --> 00:46:28.776 people may not even be aware.
NOTE Confidence: 0.881317984583333

00:46:28.780 --> 00:46:30.756 It's an issue that's we're here to help.
NOTE Confidence: 0.881317984583333

00:46:30.760 --> 00:46:32.636 Transparency is the name of the game,
NOTE Confidence: 0.881317984583333

00:46:32.640 --> 00:46:34.520 no matter how many times you say it,
NOTE Confidence: 0.881317984583333

00:46:34.520 --> 00:46:37.800 disclosure is is the key and that's

NOTE Confidence: 0.881317984583333

00:46:37.800 --> 00:46:39.500 critical and certainly give us

NOTE Confidence: 0.881317984583333

00:46:39.500 --> 00:46:41.618 enough time to to work with you.

NOTE Confidence: 0.881317984583333

00:46:41.620 --> 00:46:43.028 Again, don't come to us at the last

NOTE Confidence: 0.881317984583333

00:46:43.028 --> 00:46:44.418 minute and expect we're going to say,

NOTE Confidence: 0.881317984583333

00:46:44.420 --> 00:46:47.255 oh, sure, no problem, glad to help.

NOTE Confidence: 0.881317984583333

00:46:47.260 --> 00:46:48.440 It may be the case,

NOTE Confidence: 0.881317984583333

00:46:48.440 --> 00:46:50.040 but you don't want to risk it if

NOTE Confidence: 0.881317984583333

00:46:50.040 --> 00:46:51.350 it's really an important issue.

NOTE Confidence: 0.881317984583333

00:46:51.350 --> 00:46:52.931 Disclosure of mitigation,

NOTE Confidence: 0.881317984583333

00:46:52.931 --> 00:46:55.039 management and elimination are

NOTE Confidence: 0.881317984583333

00:46:55.039 --> 00:46:57.198 the various management plans which

NOTE Confidence: 0.881317984583333

00:46:57.198 --> 00:46:59.394 can be fairly involved and we

NOTE Confidence: 0.881317984583333

00:46:59.394 --> 00:47:01.286 do work with you on that.

NOTE Confidence: 0.881317984583333

00:47:01.290 --> 00:47:02.320 If it's a big problem,

NOTE Confidence: 0.881317984583333

00:47:02.320 --> 00:47:04.609 I often call the faculty member in

NOTE Confidence: 0.881317984583333

00:47:04.609 --> 00:47:07.332 advance rather than have a some kind of a
NOTE Confidence: 0.881317984583333

00:47:07.332 --> 00:47:09.419 disturbing e-mail pop up in their inbox.
NOTE Confidence: 0.881317984583333

00:47:09.420 --> 00:47:11.499 We try to be as as helpful as we
NOTE Confidence: 0.881317984583333

00:47:11.499 --> 00:47:14.110 can and professional in our in our
NOTE Confidence: 0.881317984583333

00:47:14.110 --> 00:47:16.409 interactions with the faculty and please
NOTE Confidence: 0.881317984583333

00:47:16.409 --> 00:47:18.810 contact us if in one questions arise,
NOTE Confidence: 0.881317984583333

00:47:18.810 --> 00:47:20.182 the earlier the better.
NOTE Confidence: 0.881317984583333

00:47:20.182 --> 00:47:22.772 Jill and her staff are superb and we
NOTE Confidence: 0.881317984583333

00:47:22.772 --> 00:47:24.960 we try to be as helpful as we can,
NOTE Confidence: 0.881317984583333

00:47:24.960 --> 00:47:27.280 so I'll stop there if we have questions,
NOTE Confidence: 0.881317984583333

00:47:27.280 --> 00:47:28.680 hopefully from you folks,
NOTE Confidence: 0.881317984583333

00:47:28.680 --> 00:47:30.780 so we'll be more than happy
NOTE Confidence: 0.881317984583333

00:47:30.854 --> 00:47:32.309 to try to answer them.
NOTE Confidence: 0.881317984583333

00:47:32.310 --> 00:47:33.310 Thank you for your attention.
NOTE Confidence: 0.899819355

00:47:36.040 --> 00:47:37.012 Thank you very much.
NOTE Confidence: 0.899819355

00:47:37.012 --> 00:47:39.309 We can open it up to questions now

NOTE Confidence: 0.884187522

00:47:39.320 --> 00:47:40.970 if anyone has has one.

NOTE Confidence: 0.896355342727273

00:47:45.500 --> 00:47:46.928 And I'd suggest if you do

NOTE Confidence: 0.896355342727273

00:47:46.928 --> 00:47:48.100 you can just speak up.

NOTE Confidence: 0.896355342727273

00:47:48.100 --> 00:47:50.650 It's hard to monitor the. Umm.

NOTE Confidence: 0.790956466666667

00:47:52.170 --> 00:47:53.305 Gallery of Faces or you

NOTE Confidence: 0.790956466666667

00:47:53.305 --> 00:47:54.999 can put it in the chat and.