

WEBVTT

NOTE duration:"00:32:13"

NOTE recognizability:0.876

NOTE language:en-us

NOTE Confidence: 0.76745729875

00:00:05.220 --> 00:00:07.590 Sometimes the HP, so the human

NOTE Confidence: 0.76745729875

00:00:07.590 --> 00:00:09.649 research protection program and the

NOTE Confidence: 0.76745729875

00:00:09.649 --> 00:00:11.719 name Irbs are used interchangeably,

NOTE Confidence: 0.76745729875

00:00:11.720 --> 00:00:13.368 and I just want to make sure that

NOTE Confidence: 0.76745729875

00:00:13.368 --> 00:00:15.281 you will like at the end of my

NOTE Confidence: 0.76745729875

00:00:15.281 --> 00:00:16.835 quick presentation you will know the

NOTE Confidence: 0.76745729875

00:00:16.835 --> 00:00:18.725 difference and you will be able to

NOTE Confidence: 0.76745729875

00:00:18.725 --> 00:00:21.980 distinguish between the different roles.

NOTE Confidence: 0.76745729875

00:00:21.980 --> 00:00:24.155 Human research Protection program is

NOTE Confidence: 0.76745729875

00:00:24.155 --> 00:00:27.441 part of a larger office of Research

NOTE Confidence: 0.76745729875

00:00:27.441 --> 00:00:30.016 administration and the human Research

NOTE Confidence: 0.76745729875

00:00:30.016 --> 00:00:32.149 Protection Program is providing

NOTE Confidence: 0.76745729875

00:00:32.149 --> 00:00:35.197 administrative support to a few groups.

NOTE Confidence: 0.76745729875

00:00:35.200 --> 00:00:38.571 It's not just the Arab, although they yell.

NOTE Confidence: 0.76745729875

00:00:38.571 --> 00:00:40.556 Arab is the largest group.

NOTE Confidence: 0.76745729875

00:00:40.560 --> 00:00:42.440 We have 19 different panels.

NOTE Confidence: 0.76745729875

00:00:42.440 --> 00:00:44.120 At the end you will,

NOTE Confidence: 0.76745729875

00:00:44.120 --> 00:00:46.640 you will see a list of all of them.

NOTE Confidence: 0.76745729875

00:00:46.640 --> 00:00:49.316 We provide support to greedy active

NOTE Confidence: 0.76745729875

00:00:49.316 --> 00:00:51.100 drug research committee and.

NOTE Confidence: 0.76745729875

00:00:51.100 --> 00:00:52.723 Investigational drug committee.

NOTE Confidence: 0.76745729875

00:00:52.723 --> 00:00:57.035 So these are studies that involve or at

NOTE Confidence: 0.76745729875

00:00:57.035 --> 00:01:00.130 pet center that involve radioactive drug,

NOTE Confidence: 0.76745729875

00:01:00.130 --> 00:01:02.650 and that's actually one of the

NOTE Confidence: 0.76745729875

00:01:02.650 --> 00:01:04.910 committees that we run as well.

NOTE Confidence: 0.76745729875

00:01:04.910 --> 00:01:05.600 In addition,

NOTE Confidence: 0.76745729875

00:01:05.600 --> 00:01:07.670 we also provide support to institutional

NOTE Confidence: 0.76745729875

00:01:07.670 --> 00:01:09.430 conflict of interest Committee,

NOTE Confidence: 0.76745729875

00:01:09.430 --> 00:01:11.422 so it's one of our committees

NOTE Confidence: 0.76745729875

00:01:11.422 --> 00:01:13.098 that we schedule meetings for.

NOTE Confidence: 0.76745729875

00:01:13.098 --> 00:01:15.450 We have policies and procedures in place,

NOTE Confidence: 0.76745729875

00:01:15.450 --> 00:01:17.558 so that's part of our office, too.

NOTE Confidence: 0.76745729875

00:01:17.558 --> 00:01:19.750 In addition to that.

NOTE Confidence: 0.76745729875

00:01:19.750 --> 00:01:21.894 So these are the committees that we run.

NOTE Confidence: 0.76745729875

00:01:21.900 --> 00:01:23.448 In addition to this,

NOTE Confidence: 0.76745729875

00:01:23.448 --> 00:01:25.383 we work very closely with

NOTE Confidence: 0.76745729875

00:01:25.383 --> 00:01:27.159 different bodies within Yale,

NOTE Confidence: 0.76745729875

00:01:27.160 --> 00:01:29.330 so any ancillary committee that

NOTE Confidence: 0.76745729875

00:01:29.330 --> 00:01:31.955 is that needs to review research

NOTE Confidence: 0.76745729875

00:01:31.955 --> 00:01:34.580 and we have about 20 of them.

NOTE Confidence: 0.76745729875

00:01:34.580 --> 00:01:36.580 We have workflows in place,

NOTE Confidence: 0.76745729875

00:01:36.580 --> 00:01:39.060 so we work closely to make sure that

NOTE Confidence: 0.76745729875

00:01:39.060 --> 00:01:41.456 we know how the information travels

NOTE Confidence: 0.76745729875

00:01:41.456 --> 00:01:44.000 from that committee to the Arab.

NOTE Confidence: 0.76745729875

00:01:44.000 --> 00:01:46.562 We work very closely with Yale  
NOTE Confidence: 0.76745729875

00:01:46.562 --> 00:01:48.270 Center for Clinical Investigations  
NOTE Confidence: 0.76745729875

00:01:48.340 --> 00:01:50.590 at Yale with conflict of Interest  
NOTE Confidence: 0.76745729875

00:01:50.590 --> 00:01:52.038 Office Office of sponsored.  
NOTE Confidence: 0.76745729875

00:01:52.038 --> 00:01:54.530 Projects we work very closely to make  
NOTE Confidence: 0.76745729875

00:01:54.597 --> 00:01:56.955 sure that grants actually match and  
NOTE Confidence: 0.76745729875

00:01:56.955 --> 00:01:59.361 contracts match the protocol and the  
NOTE Confidence: 0.76745729875

00:01:59.361 --> 00:02:01.639 consent language, and vice versa.  
NOTE Confidence: 0.76745729875

00:02:01.639 --> 00:02:05.870 So that's a large umbrella of what we do.  
NOTE Confidence: 0.76745729875

00:02:05.870 --> 00:02:08.684 I will focus mostly on the Arab.  
NOTE Confidence: 0.76745729875

00:02:08.690 --> 00:02:10.530 I know you can't see it very well,  
NOTE Confidence: 0.76745729875

00:02:10.530 --> 00:02:11.870 but that's on top.  
NOTE Confidence: 0.76745729875

00:02:11.870 --> 00:02:13.545 It says the nitpicking Arab,  
NOTE Confidence: 0.76745729875

00:02:13.550 --> 00:02:14.855 that's, I understand.  
NOTE Confidence: 0.76745729875

00:02:14.855 --> 00:02:17.465 That's how often people think about  
NOTE Confidence: 0.76745729875

00:02:17.465 --> 00:02:20.005 the Arabs that they're always there to

NOTE Confidence: 0.76745729875

00:02:20.005 --> 00:02:22.618 find something that is wrong or get back to.

NOTE Confidence: 0.76745729875

00:02:22.620 --> 00:02:24.892 Go back to you on and ask for

NOTE Confidence: 0.76745729875

00:02:24.892 --> 00:02:26.520 revisions and clarifications,

NOTE Confidence: 0.76745729875

00:02:26.520 --> 00:02:28.780 but in reality the IRB.

NOTE Confidence: 0.76745729875

00:02:28.780 --> 00:02:30.635 So that's institutional review boards

NOTE Confidence: 0.76745729875

00:02:30.635 --> 00:02:33.452 is there to protect the rights and

NOTE Confidence: 0.76745729875

00:02:33.452 --> 00:02:35.240 welfare of research participants.

NOTE Confidence: 0.76745729875

00:02:35.240 --> 00:02:37.060 So when you look at the regulations,

NOTE Confidence: 0.76745729875

00:02:37.060 --> 00:02:40.300 that's what the mission of the IRB is,

NOTE Confidence: 0.76745729875

00:02:40.300 --> 00:02:44.276 and I included some text from FDA guidance,

NOTE Confidence: 0.76745729875

00:02:44.280 --> 00:02:45.008 for example,

NOTE Confidence: 0.76745729875

00:02:45.008 --> 00:02:47.192 because it's like nicely described of

NOTE Confidence: 0.76745729875

00:02:47.192 --> 00:02:49.869 what it is that IRB is supposed to do.

NOTE Confidence: 0.76745729875

00:02:49.870 --> 00:02:52.313 The RB meets that mission so protects

NOTE Confidence: 0.76745729875

00:02:52.313 --> 00:02:54.797 the rights and welfare of research

NOTE Confidence: 0.76745729875

00:02:54.797 --> 00:02:56.621 participants by reviewing the  
NOTE Confidence: 0.76745729875

00:02:56.621 --> 00:02:59.068 documents that you need to submit,  
NOTE Confidence: 0.76745729875

00:02:59.070 --> 00:03:01.515 and they look through those  
NOTE Confidence: 0.76745729875

00:03:01.515 --> 00:03:03.471 documents to make determinations  
NOTE Confidence: 0.76745729875

00:03:03.471 --> 00:03:05.588 about very specific things.  
NOTE Confidence: 0.76745729875

00:03:05.590 --> 00:03:07.285 So if you actually ever  
NOTE Confidence: 0.76745729875

00:03:07.285 --> 00:03:08.980 attend any of our meetings,  
NOTE Confidence: 0.76745729875

00:03:08.980 --> 00:03:12.076 our reviewers have checklists in place.  
NOTE Confidence: 0.76745729875

00:03:12.080 --> 00:03:14.246 There are, based on the regulations.  
NOTE Confidence: 0.76745729875

00:03:14.250 --> 00:03:15.201 So, for example,  
NOTE Confidence: 0.76745729875

00:03:15.201 --> 00:03:17.103 when they look at the consent  
NOTE Confidence: 0.76745729875

00:03:17.103 --> 00:03:18.789 or the consent process,  
NOTE Confidence: 0.76745729875

00:03:18.790 --> 00:03:20.248 they need to make sure that.  
NOTE Confidence: 0.873753629655173

00:03:20.250 --> 00:03:22.980 All of the elements that the regulations  
NOTE Confidence: 0.873753629655173

00:03:22.980 --> 00:03:25.973 describe that the consent needs to have or  
NOTE Confidence: 0.873753629655173

00:03:25.973 --> 00:03:28.583 there if they're looking at your protocol

NOTE Confidence: 0.873753629655173  
00:03:28.583 --> 00:03:31.355 and how you're going to obtain consent,  
NOTE Confidence: 0.873753629655173  
00:03:31.360 --> 00:03:34.232 they need to make sure that what you're  
NOTE Confidence: 0.873753629655173  
00:03:34.232 --> 00:03:36.478 describing actually matches the regulations.  
NOTE Confidence: 0.873753629655173  
00:03:36.480 --> 00:03:38.230 They look at the data  
NOTE Confidence: 0.873753629655173  
00:03:38.230 --> 00:03:39.280 safety monitoring plans.  
NOTE Confidence: 0.873753629655173  
00:03:39.280 --> 00:03:41.324 That's why we ask you to always  
NOTE Confidence: 0.873753629655173  
00:03:41.324 --> 00:03:43.140 include that in your protocol.  
NOTE Confidence: 0.873753629655173  
00:03:43.140 --> 00:03:45.558 There is an approval criterion that  
NOTE Confidence: 0.873753629655173  
00:03:45.558 --> 00:03:47.540 talks about confidentiality of data.  
NOTE Confidence: 0.873753629655173  
00:03:47.540 --> 00:03:50.529 That's why our protocols and our protocol.  
NOTE Confidence: 0.873753629655173  
00:03:50.530 --> 00:03:52.060 I would be submission forms.  
NOTE Confidence: 0.873753629655173  
00:03:52.060 --> 00:03:54.160 Ask specific questions about  
NOTE Confidence: 0.873753629655173  
00:03:54.160 --> 00:03:56.785 confidentiality so everything that the  
NOTE Confidence: 0.873753629655173  
00:03:56.785 --> 00:03:59.830 IRB asks for is based in regulations.  
NOTE Confidence: 0.873753629655173  
00:03:59.830 --> 00:04:03.070 It's a highly regulated business.  
NOTE Confidence: 0.873753629655173

00:04:03.070 --> 00:04:04.414 In addition to this,  
NOTE Confidence: 0.873753629655173

00:04:04.414 --> 00:04:07.317 we need to make sure as an IRB  
NOTE Confidence: 0.873753629655173

00:04:07.317 --> 00:04:09.723 that the approval criteria are met.  
NOTE Confidence: 0.873753629655173

00:04:09.730 --> 00:04:12.666 But if you doing research in other countries,  
NOTE Confidence: 0.873753629655173

00:04:12.670 --> 00:04:15.670 for example or in other states  
NOTE Confidence: 0.873753629655173

00:04:15.670 --> 00:04:17.895 that the local regulations,  
NOTE Confidence: 0.873753629655173

00:04:17.895 --> 00:04:20.770 the local policies and procedures.  
NOTE Confidence: 0.873753629655173

00:04:20.770 --> 00:04:22.534 Were followed as well.  
NOTE Confidence: 0.873753629655173

00:04:22.534 --> 00:04:25.180 But when do you actually need  
NOTE Confidence: 0.873753629655173

00:04:25.269 --> 00:04:27.729 to even worry about the Arab?  
NOTE Confidence: 0.873753629655173

00:04:27.730 --> 00:04:29.356 So in general,  
NOTE Confidence: 0.873753629655173

00:04:29.356 --> 00:04:31.524 the IRB reviews research  
NOTE Confidence: 0.873753629655173

00:04:31.524 --> 00:04:33.150 involving human subjects,  
NOTE Confidence: 0.873753629655173

00:04:33.150 --> 00:04:35.292 so if it's not research that  
NOTE Confidence: 0.873753629655173

00:04:35.292 --> 00:04:36.363 involves human subjects,  
NOTE Confidence: 0.873753629655173

00:04:36.370 --> 00:04:38.989 I will be does not have to reveal it.

NOTE Confidence: 0.873753629655173

00:04:38.990 --> 00:04:41.972 I know that different institutions may

NOTE Confidence: 0.873753629655173

00:04:41.972 --> 00:04:44.490 have additional policies in place,

NOTE Confidence: 0.873753629655173

00:04:44.490 --> 00:04:47.164 so for example they will say you,

NOTE Confidence: 0.873753629655173

00:04:47.170 --> 00:04:49.552 even if you are doing a

NOTE Confidence: 0.873753629655173

00:04:49.552 --> 00:04:50.743 quality improvement project,

NOTE Confidence: 0.873753629655173

00:04:50.750 --> 00:04:52.514 you still need to come to the

NOTE Confidence: 0.873753629655173

00:04:52.514 --> 00:04:54.180 Arab for the determination.

NOTE Confidence: 0.873753629655173

00:04:54.180 --> 00:04:56.610 The rule in the regulation is

NOTE Confidence: 0.873753629655173

00:04:56.610 --> 00:04:59.020 if it's human subjects research,

NOTE Confidence: 0.873753629655173

00:04:59.020 --> 00:05:01.200 IRB needs to review it,

NOTE Confidence: 0.873753629655173

00:05:01.200 --> 00:05:03.576 and so I underlined the terms

NOTE Confidence: 0.873753629655173

00:05:03.576 --> 00:05:06.260 that are based in regulations,

NOTE Confidence: 0.873753629655173

00:05:06.260 --> 00:05:08.972 research and human subjects.

NOTE Confidence: 0.873753629655173

00:05:08.972 --> 00:05:12.362 Anytime you create a project

NOTE Confidence: 0.873753629655173

00:05:12.370 --> 00:05:14.350 and submit it for review,

NOTE Confidence: 0.873753629655173

00:05:14.350 --> 00:05:16.142 this is how we think about it  
NOTE Confidence: 0.873753629655173

00:05:16.142 --> 00:05:18.356 and this is how we always tell  
NOTE Confidence: 0.873753629655173

00:05:18.356 --> 00:05:20.076 our investigators to think about  
NOTE Confidence: 0.873753629655173

00:05:20.076 --> 00:05:21.300 the projects too.  
NOTE Confidence: 0.873753629655173

00:05:21.300 --> 00:05:23.948 The first question and they need to be  
NOTE Confidence: 0.873753629655173

00:05:23.948 --> 00:05:26.756 asked in order is does your project  
NOTE Confidence: 0.873753629655173

00:05:26.756 --> 00:05:29.540 fit the regulatory definition of research?  
NOTE Confidence: 0.873753629655173

00:05:29.540 --> 00:05:31.340 Because it's again research  
NOTE Confidence: 0.873753629655173

00:05:31.340 --> 00:05:33.140 is a regulatory definition.  
NOTE Confidence: 0.873753629655173

00:05:33.140 --> 00:05:35.289 I I will go through that definition  
NOTE Confidence: 0.873753629655173

00:05:35.289 --> 00:05:36.210 in a second.  
NOTE Confidence: 0.873753629655173

00:05:36.210 --> 00:05:37.682 If you say no,  
NOTE Confidence: 0.873753629655173

00:05:37.682 --> 00:05:40.285 what I'm doing is actually not research.  
NOTE Confidence: 0.873753629655173

00:05:40.285 --> 00:05:42.260 It doesn't fit the regulatory  
NOTE Confidence: 0.873753629655173

00:05:42.260 --> 00:05:43.445 definition of research.  
NOTE Confidence: 0.873753629655173

00:05:43.450 --> 00:05:45.448 You do not need to come to the Arab,

NOTE Confidence: 0.873753629655173  
00:05:45.450 --> 00:05:48.770 so there is no submission that is expected.  
NOTE Confidence: 0.873753629655173  
00:05:48.770 --> 00:05:50.340 Sometimes you will get questions  
NOTE Confidence: 0.873753629655173  
00:05:50.340 --> 00:05:52.255 from a publisher or from your  
NOTE Confidence: 0.873753629655173  
00:05:52.255 --> 00:05:53.941 colleague that will to that will  
NOTE Confidence: 0.873753629655173  
00:05:53.941 --> 00:05:55.839 prompt you to submit something to  
NOTE Confidence: 0.873753629655173  
00:05:55.839 --> 00:05:57.825 their be to get their determination  
NOTE Confidence: 0.873753629655173  
00:05:57.825 --> 00:05:59.415 that what you're doing is not  
NOTE Confidence: 0.873753629655173  
00:05:59.415 --> 00:06:01.239 research and we will not reject it.  
NOTE Confidence: 0.873753629655173  
00:06:01.240 --> 00:06:02.960 We'll give you that determination,  
NOTE Confidence: 0.873753629655173  
00:06:02.960 --> 00:06:04.724 but there is no expectation at  
NOTE Confidence: 0.873753629655173  
00:06:04.724 --> 00:06:06.620 Yale that you need to have it.  
NOTE Confidence: 0.873753629655173  
00:06:06.620 --> 00:06:07.980 But if you say yes,  
NOTE Confidence: 0.873753629655173  
00:06:07.980 --> 00:06:10.374 what I'm doing is research that  
NOTE Confidence: 0.873753629655173  
00:06:10.374 --> 00:06:12.688 fits that definition that the next  
NOTE Confidence: 0.873753629655173  
00:06:12.688 --> 00:06:14.942 question that you need to ask is  
NOTE Confidence: 0.873753629655173

00:06:14.942 --> 00:06:17.158 does it involve human subjects.  
NOTE Confidence: 0.873753629655173

00:06:17.160 --> 00:06:19.280 Human subjects is a regulatory.  
NOTE Confidence: 0.873753629655173

00:06:19.280 --> 00:06:21.236 Definition I will go through it  
NOTE Confidence: 0.873753629655173

00:06:21.240 --> 00:06:23.160 in a second as well.  
NOTE Confidence: 0.873753629655173

00:06:23.160 --> 00:06:24.392 If you say no,  
NOTE Confidence: 0.873753629655173

00:06:24.392 --> 00:06:25.932 I'm doing research by doesn't  
NOTE Confidence: 0.873753629655173

00:06:25.932 --> 00:06:27.189 involve human subjects.  
NOTE Confidence: 0.873753629655173

00:06:27.190 --> 00:06:29.440 You don't have to come to the IRB either,  
NOTE Confidence: 0.873753629655173

00:06:29.440 --> 00:06:31.824 but if you say yes, I'm doing research.  
NOTE Confidence: 0.873753629655173

00:06:31.824 --> 00:06:33.456 It involves human subjects.  
NOTE Confidence: 0.916800683461538

00:06:33.460 --> 00:06:35.940 Then you know that you need to submit  
NOTE Confidence: 0.916800683461538

00:06:35.940 --> 00:06:37.988 something to our office for some  
NOTE Confidence: 0.916800683461538

00:06:37.988 --> 00:06:40.034 determination and I will talk about  
NOTE Confidence: 0.916800683461538

00:06:40.098 --> 00:06:42.576 what those determinations might be like.  
NOTE Confidence: 0.916800683461538

00:06:42.580 --> 00:06:43.792 Different levels of review.  
NOTE Confidence: 0.916800683461538

00:06:43.792 --> 00:06:45.880 But let's start with the first one.

NOTE Confidence: 0.916800683461538  
00:06:45.880 --> 00:06:47.860 Is it research?  
NOTE Confidence: 0.916800683461538  
00:06:47.860 --> 00:06:51.479 I included a citation to the regulatory  
NOTE Confidence: 0.916800683461538  
00:06:51.480 --> 00:06:53.940 to the regulation, so it's 45.  
NOTE Confidence: 0.916800683461538  
00:06:53.940 --> 00:06:55.064 Code of federal regulations.  
NOTE Confidence: 0.916800683461538  
00:06:55.064 --> 00:06:56.750 You can put it in Google,  
NOTE Confidence: 0.916800683461538  
00:06:56.750 --> 00:06:58.380 you'll you'll find that rights  
NOTE Confidence: 0.916800683461538  
00:06:58.380 --> 00:07:00.810 and I shorten it a little bit,  
NOTE Confidence: 0.916800683461538  
00:07:00.810 --> 00:07:03.270 but research is a systematic investigation  
NOTE Confidence: 0.916800683461538  
00:07:03.270 --> 00:07:06.629 that will need to generalizable knowledge.  
NOTE Confidence: 0.916800683461538  
00:07:06.630 --> 00:07:08.870 I underlined the keywords here.  
NOTE Confidence: 0.916800683461538  
00:07:08.870 --> 00:07:11.186 The systematic investigation and  
NOTE Confidence: 0.916800683461538  
00:07:11.186 --> 00:07:13.502 the generalizable knowledge because  
NOTE Confidence: 0.916800683461538  
00:07:13.502 --> 00:07:16.090 certain projects sound like research,  
NOTE Confidence: 0.916800683461538  
00:07:16.090 --> 00:07:18.282 but they are not because they do not  
NOTE Confidence: 0.916800683461538  
00:07:18.282 --> 00:07:20.699 produce or they're not intended to  
NOTE Confidence: 0.916800683461538

00:07:20.699 --> 00:07:22.507 contribute to generalizable knowledge.  
NOTE Confidence: 0.916800683461538

00:07:22.510 --> 00:07:24.135 A perfect example of something  
NOTE Confidence: 0.916800683461538

00:07:24.135 --> 00:07:25.760 that may seem like research.  
NOTE Confidence: 0.916800683461538

00:07:25.760 --> 00:07:29.140 Is not a journalistic activity,  
NOTE Confidence: 0.916800683461538

00:07:29.140 --> 00:07:31.534 so we have students who may want  
NOTE Confidence: 0.916800683461538

00:07:31.534 --> 00:07:34.159 to publish a or write an article.  
NOTE Confidence: 0.916800683461538

00:07:34.160 --> 00:07:38.143 Talk to people about their experiences for  
NOTE Confidence: 0.916800683461538

00:07:38.143 --> 00:07:41.656 for in order to for a journalistic activity.  
NOTE Confidence: 0.916800683461538

00:07:41.656 --> 00:07:42.778 That's not research,  
NOTE Confidence: 0.916800683461538

00:07:42.780 --> 00:07:44.520 even if you're talking to  
NOTE Confidence: 0.916800683461538

00:07:44.520 --> 00:07:46.260 people and collecting data about  
NOTE Confidence: 0.916800683461538

00:07:46.320 --> 00:07:47.358 them program evaluation.  
NOTE Confidence: 0.916800683461538

00:07:47.358 --> 00:07:50.550 So if you get a contract in place  
NOTE Confidence: 0.916800683461538

00:07:50.628 --> 00:07:53.895 from a program that is taking place  
NOTE Confidence: 0.916800683461538

00:07:53.895 --> 00:07:56.147 regardless of your activities.  
NOTE Confidence: 0.916800683461538

00:07:56.150 --> 00:07:58.070 And somebody asks you to evaluate

NOTE Confidence: 0.916800683461538  
00:07:58.070 --> 00:07:59.350 how successful it is,  
NOTE Confidence: 0.916800683461538  
00:07:59.350 --> 00:08:01.130 whether it works or not,  
NOTE Confidence: 0.916800683461538  
00:08:01.130 --> 00:08:02.744 just for that purpose of that  
NOTE Confidence: 0.916800683461538  
00:08:02.744 --> 00:08:04.610 of that project of that program,  
NOTE Confidence: 0.916800683461538  
00:08:04.610 --> 00:08:06.248 we would say this is not research.  
NOTE Confidence: 0.916800683461538  
00:08:06.250 --> 00:08:08.530 IRB review is not required.  
NOTE Confidence: 0.916800683461538  
00:08:08.530 --> 00:08:11.092 And the case study will say this  
NOTE Confidence: 0.916800683461538  
00:08:11.092 --> 00:08:13.547 is not research because you don't  
NOTE Confidence: 0.916800683461538  
00:08:13.547 --> 00:08:15.668 have enough data from sufficient  
NOTE Confidence: 0.916800683461538  
00:08:15.668 --> 00:08:17.758 number of individuals to lead  
NOTE Confidence: 0.916800683461538  
00:08:17.758 --> 00:08:19.012 to generalizable knowledge.  
NOTE Confidence: 0.916800683461538  
00:08:19.020 --> 00:08:23.304 You don't need to obtain IRB approval.  
NOTE Confidence: 0.916800683461538  
00:08:23.310 --> 00:08:28.382 I know that a natural question is how many?  
NOTE Confidence: 0.916800683461538  
00:08:28.382 --> 00:08:31.590 How many individuals would constitute  
NOTE Confidence: 0.916800683461538  
00:08:31.590 --> 00:08:33.190 research like a case study?  
NOTE Confidence: 0.916800683461538

00:08:33.190 --> 00:08:34.546 Is it just one or two?  
NOTE Confidence: 0.916800683461538

00:08:34.550 --> 00:08:36.214 Or if I have five people that I  
NOTE Confidence: 0.916800683461538

00:08:36.214 --> 00:08:37.907 want to write about or publish,  
NOTE Confidence: 0.916800683461538

00:08:37.910 --> 00:08:39.215 is that research?  
NOTE Confidence: 0.916800683461538

00:08:39.215 --> 00:08:42.260 We always go back to the investigator  
NOTE Confidence: 0.916800683461538

00:08:42.345 --> 00:08:45.117 and ask that questions like how many  
NOTE Confidence: 0.916800683461538

00:08:45.117 --> 00:08:48.759 people do you need to yield meaningful data.  
NOTE Confidence: 0.916800683461538

00:08:48.760 --> 00:08:50.338 One person generally will say you  
NOTE Confidence: 0.916800683461538

00:08:50.338 --> 00:08:52.234 can publish you as you need to  
NOTE Confidence: 0.916800683461538

00:08:52.234 --> 00:08:53.020 ask for permission.  
NOTE Confidence: 0.916800683461538

00:08:53.020 --> 00:08:55.540 Whether you can use that person's data,  
NOTE Confidence: 0.916800683461538

00:08:55.540 --> 00:08:58.000 but that's not a research.  
NOTE Confidence: 0.916800683461538

00:08:58.000 --> 00:08:59.508 There are certain activities  
NOTE Confidence: 0.916800683461538

00:08:59.508 --> 00:09:00.639 preparatory to research,  
NOTE Confidence: 0.916800683461538

00:09:00.640 --> 00:09:02.572 so if you're going to look  
NOTE Confidence: 0.916800683461538

00:09:02.572 --> 00:09:03.538 at medical records,

NOTE Confidence: 0.916800683461538  
00:09:03.540 --> 00:09:06.018 for example to see whether you  
NOTE Confidence: 0.916800683461538  
00:09:06.018 --> 00:09:07.670 even have sufficient population  
NOTE Confidence: 0.916800683461538  
00:09:07.740 --> 00:09:09.296 to pull from that activity.  
NOTE Confidence: 0.916800683461538  
00:09:09.296 --> 00:09:11.186 Self is not considered research.  
NOTE Confidence: 0.916800683461538  
00:09:11.190 --> 00:09:13.556 You just cannot write any identifiers down.  
NOTE Confidence: 0.916800683461538  
00:09:13.560 --> 00:09:16.116 So you cannot remove any Phi  
NOTE Confidence: 0.916800683461538  
00:09:16.116 --> 00:09:17.546 from a HIPAA covered entity,  
NOTE Confidence: 0.916800683461538  
00:09:17.550 --> 00:09:21.456 but that activity itself is not research.  
NOTE Confidence: 0.916800683461538  
00:09:21.460 --> 00:09:22.206 Another example,  
NOTE Confidence: 0.916800683461538  
00:09:22.206 --> 00:09:24.817 and that's where the Gray area happens  
NOTE Confidence: 0.916800683461538  
00:09:24.817 --> 00:09:27.187 is a quality improvement project.  
NOTE Confidence: 0.916800683461538  
00:09:27.190 --> 00:09:29.980 We say that called the improvement  
NOTE Confidence: 0.916800683461538  
00:09:29.980 --> 00:09:32.077 project is evaluation of how  
NOTE Confidence: 0.916800683461538  
00:09:32.077 --> 00:09:34.800 something works or you you put an  
NOTE Confidence: 0.916800683461538  
00:09:34.877 --> 00:09:37.301 intervention in place and then you  
NOTE Confidence: 0.916800683461538

00:09:37.301 --> 00:09:40.520 check how it works in a very specific  
NOTE Confidence: 0.916800683461538

00:09:40.520 --> 00:09:43.191 setting so your the the purpose of  
NOTE Confidence: 0.916800683461538

00:09:43.191 --> 00:09:46.239 that activity is not to take it and  
NOTE Confidence: 0.916800683461538

00:09:46.239 --> 00:09:48.168 generalizable to other other hospitals.  
NOTE Confidence: 0.916800683461538

00:09:48.168 --> 00:09:49.046 For example,  
NOTE Confidence: 0.916800683461538

00:09:49.046 --> 00:09:50.363 other healthcare operations  
NOTE Confidence: 0.916800683461538

00:09:50.363 --> 00:09:51.680 you can publish  
NOTE Confidence: 0.867015755833333

00:09:51.748 --> 00:09:53.585 about it. You can say this is  
NOTE Confidence: 0.867015755833333

00:09:53.585 --> 00:09:55.570 what we did in our hospital,  
NOTE Confidence: 0.867015755833333

00:09:55.570 --> 00:09:57.810 but you just have to call it call  
NOTE Confidence: 0.867015755833333

00:09:57.810 --> 00:09:59.162 improvement project. And not research.  
NOTE Confidence: 0.867015755833333

00:09:59.162 --> 00:10:01.010 And then you do not need IRB  
NOTE Confidence: 0.867015755833333

00:10:01.076 --> 00:10:02.856 approval or review or approval.  
NOTE Confidence: 0.867015755833333

00:10:02.860 --> 00:10:04.786 We have certain checklists in place  
NOTE Confidence: 0.867015755833333

00:10:04.786 --> 00:10:07.521 that you can use to see whether or  
NOTE Confidence: 0.867015755833333

00:10:07.521 --> 00:10:09.597 not your project fits that definition,

NOTE Confidence: 0.867015755833333

00:10:09.600 --> 00:10:11.470 but if it turns out that it is and it's

NOTE Confidence: 0.867015755833333

00:10:11.526 --> 00:10:13.500 very clear that it's quality improvement,

NOTE Confidence: 0.867015755833333

00:10:13.500 --> 00:10:16.160 you do not have to submit anything to the RB.

NOTE Confidence: 0.867015755833333

00:10:16.160 --> 00:10:17.600 You can. If you want to,

NOTE Confidence: 0.867015755833333

00:10:17.600 --> 00:10:19.496 but but you don't have to.

NOTE Confidence: 0.867015755833333

00:10:19.500 --> 00:10:21.198 So that was the first question,

NOTE Confidence: 0.867015755833333

00:10:21.200 --> 00:10:22.373 is it research?

NOTE Confidence: 0.867015755833333

00:10:22.373 --> 00:10:24.719 Is it a systematic investigation that

NOTE Confidence: 0.867015755833333

00:10:24.719 --> 00:10:27.337 will lead to generalizable knowledge?

NOTE Confidence: 0.867015755833333

00:10:27.340 --> 00:10:28.664 If you say no?

NOTE Confidence: 0.867015755833333

00:10:28.664 --> 00:10:31.600 As I said, no IRB review is required,

NOTE Confidence: 0.867015755833333

00:10:31.600 --> 00:10:33.060 but if you say yes,

NOTE Confidence: 0.867015755833333

00:10:33.060 --> 00:10:35.610 the next question is does

NOTE Confidence: 0.867015755833333

00:10:35.610 --> 00:10:37.650 it involve human subjects?

NOTE Confidence: 0.867015755833333

00:10:37.650 --> 00:10:39.286 That's a regulatory definition.

NOTE Confidence: 0.867015755833333

00:10:39.286 --> 00:10:42.251 A human subject is a living individual  
NOTE Confidence: 0.867015755833333

00:10:42.251 --> 00:10:45.289 about whom you're going to obtain data,  
NOTE Confidence: 0.867015755833333

00:10:45.290 --> 00:10:47.385 either through interaction with that  
NOTE Confidence: 0.867015755833333

00:10:47.385 --> 00:10:50.030 person or interaction with their private,  
NOTE Confidence: 0.867015755833333

00:10:50.030 --> 00:10:51.494 identifiable information.  
NOTE Confidence: 0.867015755833333

00:10:51.494 --> 00:10:55.886 I underlined the key elements here.  
NOTE Confidence: 0.867015755833333

00:10:55.890 --> 00:10:57.588 Sometimes we go back and forth  
NOTE Confidence: 0.867015755833333

00:10:57.588 --> 00:10:59.175 with some of our investigators  
NOTE Confidence: 0.867015755833333

00:10:59.175 --> 00:11:01.130 because they submit proposals and  
NOTE Confidence: 0.867015755833333

00:11:01.130 --> 00:11:03.810 then it turns out that the data  
NOTE Confidence: 0.867015755833333

00:11:03.810 --> 00:11:05.904 they're obtaining or the tissue that  
NOTE Confidence: 0.867015755833333

00:11:05.904 --> 00:11:07.616 they're working with is actually.  
NOTE Confidence: 0.867015755833333

00:11:07.616 --> 00:11:08.972 From diseased individuals and  
NOTE Confidence: 0.867015755833333

00:11:08.972 --> 00:11:10.518 then it turns out well,  
NOTE Confidence: 0.867015755833333

00:11:10.520 --> 00:11:11.880 this is this is research,  
NOTE Confidence: 0.867015755833333

00:11:11.880 --> 00:11:13.940 but it doesn't involve human

NOTE Confidence: 0.867015755833333

00:11:13.940 --> 00:11:16.000 subject because the person needs

NOTE Confidence: 0.867015755833333

00:11:16.071 --> 00:11:18.066 to be living needs to be alive

NOTE Confidence: 0.867015755833333

00:11:18.066 --> 00:11:21.868 for IRB regulations to to apply.

NOTE Confidence: 0.867015755833333

00:11:21.870 --> 00:11:24.866 So what type of studies would not

NOTE Confidence: 0.867015755833333

00:11:24.866 --> 00:11:26.880 constitute human subjects research?

NOTE Confidence: 0.867015755833333

00:11:26.880 --> 00:11:29.880 If you're talking to people and

NOTE Confidence: 0.867015755833333

00:11:29.880 --> 00:11:31.880 you're asking questions about

NOTE Confidence: 0.867015755833333

00:11:31.971 --> 00:11:34.676 policies and procedures in place,

NOTE Confidence: 0.867015755833333

00:11:34.680 --> 00:11:37.240 you asking about a makeup of a hospital,

NOTE Confidence: 0.867015755833333

00:11:37.240 --> 00:11:37.946 for example,

NOTE Confidence: 0.867015755833333

00:11:37.946 --> 00:11:40.417 like how many people are working here,

NOTE Confidence: 0.867015755833333

00:11:40.420 --> 00:11:42.424 what is your policy on how

NOTE Confidence: 0.867015755833333

00:11:42.424 --> 00:11:44.580 you deal with this situation?

NOTE Confidence: 0.867015755833333

00:11:44.580 --> 00:11:46.300 Even though you're doing research

NOTE Confidence: 0.867015755833333

00:11:46.300 --> 00:11:48.020 and you're talking to people,

NOTE Confidence: 0.867015755833333

00:11:48.020 --> 00:11:50.060 you're not obtaining information  
NOTE Confidence: 0.867015755833333

00:11:50.060 --> 00:11:52.232 about people, but rather things.  
NOTE Confidence: 0.867015755833333

00:11:52.232 --> 00:11:54.152 We would say it's research  
NOTE Confidence: 0.867015755833333

00:11:54.152 --> 00:11:55.929 doesn't involve human subjects.  
NOTE Confidence: 0.867015755833333

00:11:55.930 --> 00:11:58.274 You don't have to come to the Arab.  
NOTE Confidence: 0.867015755833333

00:11:58.280 --> 00:11:59.900 The example that I just gave.  
NOTE Confidence: 0.867015755833333

00:11:59.900 --> 00:12:02.068 If you obtaining information  
NOTE Confidence: 0.867015755833333

00:12:02.068 --> 00:12:03.694 about deceased individuals,  
NOTE Confidence: 0.867015755833333

00:12:03.700 --> 00:12:05.436 HIPAA regulations may apply,  
NOTE Confidence: 0.867015755833333

00:12:05.436 --> 00:12:08.040 but it's not human subjects research,  
NOTE Confidence: 0.867015755833333

00:12:08.040 --> 00:12:10.128 so you do not require higher  
NOTE Confidence: 0.867015755833333

00:12:10.128 --> 00:12:11.520 be review or approval.  
NOTE Confidence: 0.867015755833333

00:12:11.520 --> 00:12:14.928 Or if you are getting a large data  
NOTE Confidence: 0.867015755833333

00:12:14.928 --> 00:12:17.596 set with deidentified data that you  
NOTE Confidence: 0.867015755833333

00:12:17.596 --> 00:12:20.600 cannot readily ascertain who the person is,  
NOTE Confidence: 0.867015755833333

00:12:20.600 --> 00:12:22.490 who that data belongs to.

NOTE Confidence: 0.867015755833333

00:12:22.490 --> 00:12:24.295 We would say it's researching

NOTE Confidence: 0.867015755833333

00:12:24.295 --> 00:12:25.739 doesn't involve human subjects.

NOTE Confidence: 0.867015755833333

00:12:25.740 --> 00:12:27.402 You don't have to submit anything

NOTE Confidence: 0.867015755833333

00:12:27.402 --> 00:12:28.233 to the Arab.

NOTE Confidence: 0.853831596

00:12:31.080 --> 00:12:33.180 So that's it is that research

NOTE Confidence: 0.853831596

00:12:33.180 --> 00:12:34.580 doesn't involve human subjects.

NOTE Confidence: 0.853831596

00:12:34.580 --> 00:12:36.120 If you said yes, yes,

NOTE Confidence: 0.853831596

00:12:36.120 --> 00:12:37.740 that means that she have to

NOTE Confidence: 0.853831596

00:12:37.740 --> 00:12:39.140 submit something to the Arab.

NOTE Confidence: 0.853831596

00:12:39.140 --> 00:12:41.140 Now the submission is required,

NOTE Confidence: 0.853831596

00:12:41.140 --> 00:12:43.296 and when it comes through to us,

NOTE Confidence: 0.853831596

00:12:43.300 --> 00:12:45.230 we need to make determination

NOTE Confidence: 0.853831596

00:12:45.230 --> 00:12:47.160 about the level of review.

NOTE Confidence: 0.853831596

00:12:47.160 --> 00:12:49.400 So this shows how a

NOTE Confidence: 0.853831596

00:12:49.400 --> 00:12:51.640 stringent level of review is.

NOTE Confidence: 0.853831596

00:12:51.640 --> 00:12:53.868 We have exemption determinations  
NOTE Confidence: 0.853831596

00:12:53.868 --> 00:12:56.096 then if that doesn't.  
NOTE Confidence: 0.853831596

00:12:56.100 --> 00:12:58.398 If your submission doesn't fit the  
NOTE Confidence: 0.853831596

00:12:58.398 --> 00:13:00.640 exemption determination or any categories,  
NOTE Confidence: 0.853831596

00:13:00.640 --> 00:13:02.530 I will explain that in a second.  
NOTE Confidence: 0.853831596

00:13:02.530 --> 00:13:04.371 Then you will go to expedited review  
NOTE Confidence: 0.853831596

00:13:04.371 --> 00:13:06.575 and if it doesn't fit the expedited  
NOTE Confidence: 0.853831596

00:13:06.575 --> 00:13:08.603 review categories then we send it  
NOTE Confidence: 0.853831596

00:13:08.661 --> 00:13:10.740 to full board and that's where all  
NOTE Confidence: 0.853831596

00:13:10.740 --> 00:13:13.295 those panels that you will see at the  
NOTE Confidence: 0.853831596

00:13:13.295 --> 00:13:15.514 end come into a place because that's  
NOTE Confidence: 0.853831596

00:13:15.514 --> 00:13:18.170 the panel that will review the submission.  
NOTE Confidence: 0.853831596

00:13:18.170 --> 00:13:20.606 So let's start with the exemption.  
NOTE Confidence: 0.853831596

00:13:20.610 --> 00:13:23.376 If you start reading the regulations  
NOTE Confidence: 0.853831596

00:13:23.376 --> 00:13:25.220 about human subjects research,  
NOTE Confidence: 0.853831596

00:13:25.220 --> 00:13:28.150 that's the 45 CFR 46.

NOTE Confidence: 0.853831596  
00:13:28.150 --> 00:13:31.534 The way they start is by saying these  
NOTE Confidence: 0.853831596  
00:13:31.534 --> 00:13:34.150 regulations apply to all human subjects.  
NOTE Confidence: 0.853831596  
00:13:34.150 --> 00:13:34.617 Research,  
NOTE Confidence: 0.853831596  
00:13:34.617 --> 00:13:36.018 except these categories,  
NOTE Confidence: 0.853831596  
00:13:36.018 --> 00:13:38.353 and there are eight categories,  
NOTE Confidence: 0.853831596  
00:13:38.360 --> 00:13:39.530 so exemption,  
NOTE Confidence: 0.853831596  
00:13:39.530 --> 00:13:42.455 determination or exempt research means  
NOTE Confidence: 0.853831596  
00:13:42.455 --> 00:13:45.944 that the regulations don't apply to  
NOTE Confidence: 0.853831596  
00:13:45.944 --> 00:13:48.699 those research involving human subjects.  
NOTE Confidence: 0.853831596  
00:13:48.700 --> 00:13:50.312 There are eight determination.  
NOTE Confidence: 0.853831596  
00:13:50.312 --> 00:13:52.327 There are eight different categories.  
NOTE Confidence: 0.853831596  
00:13:52.330 --> 00:13:53.326 Most institutions,  
NOTE Confidence: 0.853831596  
00:13:53.326 --> 00:13:54.322 including Yale,  
NOTE Confidence: 0.853831596  
00:13:54.322 --> 00:13:57.310 is only using six of them,  
NOTE Confidence: 0.853831596  
00:13:57.310 --> 00:13:59.630 and the reason for it is that the  
NOTE Confidence: 0.853831596

00:13:59.630 --> 00:14:01.960 two the exemption determinations that  
NOTE Confidence: 0.853831596

00:14:01.960 --> 00:14:04.750 are described in the regulations.  
NOTE Confidence: 0.853831596

00:14:04.750 --> 00:14:07.360 Don't have any guidance that the  
NOTE Confidence: 0.853831596

00:14:07.360 --> 00:14:09.100 the agencies federal agencies  
NOTE Confidence: 0.853831596

00:14:09.175 --> 00:14:10.860 didn't give us much guidance  
NOTE Confidence: 0.853831596

00:14:10.860 --> 00:14:13.529 about how to put it in operation,  
NOTE Confidence: 0.853831596

00:14:13.530 --> 00:14:16.614 so it has to do with repositories  
NOTE Confidence: 0.853831596

00:14:16.614 --> 00:14:19.034 and using data from repositories  
NOTE Confidence: 0.853831596

00:14:19.034 --> 00:14:21.780 for people who provided the broad  
NOTE Confidence: 0.853831596

00:14:21.780 --> 00:14:24.342 consent to use their data for future,  
NOTE Confidence: 0.853831596

00:14:24.350 --> 00:14:27.166 it's very difficult to put it in practice,  
NOTE Confidence: 0.853831596

00:14:27.170 --> 00:14:29.053 so we decided that at Yale and  
NOTE Confidence: 0.853831596

00:14:29.053 --> 00:14:31.090 again as many other institutions,  
NOTE Confidence: 0.853831596

00:14:31.090 --> 00:14:33.743 we only going to use 6 categories  
NOTE Confidence: 0.853831596

00:14:33.743 --> 00:14:34.880 of exempt research.  
NOTE Confidence: 0.853831596

00:14:34.880 --> 00:14:37.796 So it has to be a minimal risk study

NOTE Confidence: 0.853831596

00:14:37.796 --> 00:14:41.057 that fits in one of those six categories.

NOTE Confidence: 0.853831596

00:14:41.060 --> 00:14:45.020 There is a concept of limited IRB review.

NOTE Confidence: 0.853831596

00:14:45.020 --> 00:14:49.124 Two of those categories my my

NOTE Confidence: 0.853831596

00:14:49.124 --> 00:14:51.176 involve sensitive information.

NOTE Confidence: 0.853831596

00:14:51.180 --> 00:14:53.427 So for example you are talking to

NOTE Confidence: 0.853831596

00:14:53.427 --> 00:14:55.333 people and asking them questions

NOTE Confidence: 0.853831596

00:14:55.333 --> 00:14:57.093 and writing down identifiable

NOTE Confidence: 0.853831596

00:14:57.093 --> 00:14:59.269 information so their name but

NOTE Confidence: 0.853831596

00:14:59.269 --> 00:15:00.999 the topic is quite sensitive.

NOTE Confidence: 0.853831596

00:15:01.000 --> 00:15:03.532 So if somebody if somebody learned

NOTE Confidence: 0.853831596

00:15:03.532 --> 00:15:05.220 that information that actually

NOTE Confidence: 0.853831596

00:15:05.286 --> 00:15:07.038 may put people at risk for,

NOTE Confidence: 0.853831596

00:15:07.040 --> 00:15:08.776 there might be some legal or precautions.

NOTE Confidence: 0.853831596

00:15:08.780 --> 00:15:11.404 Or maybe there is risk to their harm.

NOTE Confidence: 0.853831596

00:15:11.410 --> 00:15:14.301 Reputation in those cases IRB needs to

NOTE Confidence: 0.853831596

00:15:14.301 --> 00:15:17.123 review it for one approval criterion  
NOTE Confidence: 0.853831596

00:15:17.123 --> 00:15:20.623 and that has to do with confidentiality.  
NOTE Confidence: 0.853831596

00:15:20.630 --> 00:15:24.928 Examples of research that could be exempt.  
NOTE Confidence: 0.853831596

00:15:24.930 --> 00:15:26.827 I listed just a few of them,  
NOTE Confidence: 0.853831596

00:15:26.830 --> 00:15:29.115 but it's usually talking about  
NOTE Confidence: 0.853831596

00:15:29.115 --> 00:15:31.816 surveys or interviews, focus groups,  
NOTE Confidence: 0.853831596

00:15:31.816 --> 00:15:34.468 observations of public behavior.  
NOTE Confidence: 0.853831596

00:15:34.470 --> 00:15:37.692 I actually underline the public because  
NOTE Confidence: 0.853831596

00:15:37.692 --> 00:15:40.434 you cannot propose going into church,  
NOTE Confidence: 0.853831596

00:15:40.434 --> 00:15:44.870 for example, to observe people's behavior.  
NOTE Confidence: 0.853831596

00:15:44.870 --> 00:15:46.662 There we would say that it's there  
NOTE Confidence: 0.853831596

00:15:46.662 --> 00:15:48.029 is an expectation of privacy,  
NOTE Confidence: 0.853831596

00:15:48.030 --> 00:15:49.950 so we would not issue.  
NOTE Confidence: 0.853831596

00:15:49.950 --> 00:15:51.394 Exemption determination would actually  
NOTE Confidence: 0.853831596

00:15:51.394 --> 00:15:54.189 send it to the next level of review.  
NOTE Confidence: 0.853831596

00:15:54.190 --> 00:15:56.050 If you're doing research

NOTE Confidence: 0.853831596  
00:15:56.050 --> 00:15:57.445 on educational techniques,  
NOTE Confidence: 0.904253437058824  
00:15:57.450 --> 00:15:59.514 you want to introduce two different  
NOTE Confidence: 0.904253437058824  
00:15:59.514 --> 00:16:01.347 ways of teaching and material  
NOTE Confidence: 0.904253437058824  
00:16:01.347 --> 00:16:03.282 to to different classrooms and  
NOTE Confidence: 0.904253437058824  
00:16:03.282 --> 00:16:05.414 then then compare the results.  
NOTE Confidence: 0.904253437058824  
00:16:05.414 --> 00:16:08.030 That could be an exempt determination.  
NOTE Confidence: 0.904253437058824  
00:16:08.030 --> 00:16:10.780 Research we have a benign  
NOTE Confidence: 0.904253437058824  
00:16:10.780 --> 00:16:12.430 intervention behavioral intervention,  
NOTE Confidence: 0.904253437058824  
00:16:12.430 --> 00:16:14.620 so you're asking people to.  
NOTE Confidence: 0.904253437058824  
00:16:14.620 --> 00:16:16.900 Play a video game and then you ask  
NOTE Confidence: 0.904253437058824  
00:16:16.900 --> 00:16:18.817 them questions about that video game.  
NOTE Confidence: 0.904253437058824  
00:16:18.820 --> 00:16:20.980 Those types of research studies  
NOTE Confidence: 0.904253437058824  
00:16:20.980 --> 00:16:23.140 would go through would received  
NOTE Confidence: 0.904253437058824  
00:16:23.209 --> 00:16:25.060 an exemption determination,  
NOTE Confidence: 0.904253437058824  
00:16:25.060 --> 00:16:27.676 so even though it's called exempt from the  
NOTE Confidence: 0.904253437058824

00:16:27.676 --> 00:16:30.057 IRB reviewer exempt from the regulations,  
NOTE Confidence: 0.904253437058824

00:16:30.060 --> 00:16:32.643 you still have to come to the  
NOTE Confidence: 0.904253437058824

00:16:32.643 --> 00:16:35.650 AB to get that determination.  
NOTE Confidence: 0.904253437058824

00:16:35.650 --> 00:16:37.630 So that's so that's exempt that  
NOTE Confidence: 0.904253437058824

00:16:37.630 --> 00:16:38.950 that's that's exempt research.  
NOTE Confidence: 0.904253437058824

00:16:38.950 --> 00:16:39.408 I think.  
NOTE Confidence: 0.904253437058824

00:16:39.408 --> 00:16:41.550 I wanted to add something else to to this,  
NOTE Confidence: 0.904253437058824

00:16:41.550 --> 00:16:43.420 but it just escaped me.  
NOTE Confidence: 0.904253437058824

00:16:43.420 --> 00:16:46.080 It's in your best interest to know  
NOTE Confidence: 0.904253437058824

00:16:46.080 --> 00:16:48.948 whether your study could be exempt or not,  
NOTE Confidence: 0.904253437058824

00:16:48.950 --> 00:16:50.700 because the submission to the  
NOTE Confidence: 0.904253437058824

00:16:50.700 --> 00:16:52.450 Arab to receive an exemption  
NOTE Confidence: 0.904253437058824

00:16:52.510 --> 00:16:54.258 determination is very simple.  
NOTE Confidence: 0.904253437058824

00:16:54.260 --> 00:16:56.312 It's just one form that you  
NOTE Confidence: 0.904253437058824

00:16:56.312 --> 00:16:57.680 complete submitted and the  
NOTE Confidence: 0.904253437058824

00:16:57.745 --> 00:16:59.707 turn around time is very quick,

NOTE Confidence: 0.904253437058824  
00:16:59.710 --> 00:17:01.902 so why you do not need to know  
NOTE Confidence: 0.904253437058824  
00:17:01.902 --> 00:17:03.266 the difference between the  
NOTE Confidence: 0.904253437058824  
00:17:03.266 --> 00:17:04.770 expedited and full board,  
NOTE Confidence: 0.904253437058824  
00:17:04.770 --> 00:17:06.954 it's in your best interest to know whether  
NOTE Confidence: 0.904253437058824  
00:17:06.954 --> 00:17:08.789 you're study would qualify for exempt.  
NOTE Confidence: 0.904253437058824  
00:17:08.790 --> 00:17:09.834 Office or not,  
NOTE Confidence: 0.904253437058824  
00:17:09.834 --> 00:17:11.574 because there is just fewer  
NOTE Confidence: 0.904253437058824  
00:17:11.574 --> 00:17:13.616 documents that you need to fill out.  
NOTE Confidence: 0.904253437058824  
00:17:13.620 --> 00:17:16.868 OK, we said the first level is exempt.  
NOTE Confidence: 0.904253437058824  
00:17:16.870 --> 00:17:18.460 Research has to be minimal risk.  
NOTE Confidence: 0.904253437058824  
00:17:18.460 --> 00:17:21.220 Study fit into certain definition.  
NOTE Confidence: 0.904253437058824  
00:17:21.220 --> 00:17:21.878 Certain category.  
NOTE Confidence: 0.904253437058824  
00:17:21.878 --> 00:17:23.852 If you study does not fit  
NOTE Confidence: 0.904253437058824  
00:17:23.852 --> 00:17:25.899 in any of those categories,  
NOTE Confidence: 0.904253437058824  
00:17:25.900 --> 00:17:28.260 the next level is expedited.  
NOTE Confidence: 0.904253437058824

00:17:28.260 --> 00:17:30.175 Expedited review is a misleading  
NOTE Confidence: 0.904253437058824

00:17:30.175 --> 00:17:32.435 name because it has nothing to  
NOTE Confidence: 0.904253437058824

00:17:32.435 --> 00:17:34.079 do with how fast it's done.  
NOTE Confidence: 0.904253437058824

00:17:34.080 --> 00:17:37.620 It has to do with who can actually review it.  
NOTE Confidence: 0.904253437058824

00:17:37.620 --> 00:17:39.352 The regulation states either  
NOTE Confidence: 0.904253437058824

00:17:39.352 --> 00:17:41.517 the chair or a designee,  
NOTE Confidence: 0.904253437058824

00:17:41.520 --> 00:17:43.940 which means that our regulatory  
NOTE Confidence: 0.904253437058824

00:17:43.940 --> 00:17:46.728 analyst in the office majority of  
NOTE Confidence: 0.904253437058824

00:17:46.728 --> 00:17:49.272 them are very experienced and they  
NOTE Confidence: 0.904253437058824

00:17:49.272 --> 00:17:52.273 got this designation from the Chair  
NOTE Confidence: 0.904253437058824

00:17:52.273 --> 00:17:54.858 to review research studies via  
NOTE Confidence: 0.904253437058824

00:17:54.858 --> 00:17:57.400 expedited review and so it has to  
NOTE Confidence: 0.904253437058824

00:17:57.400 --> 00:17:59.549 the study needs to be of minimal  
NOTE Confidence: 0.904253437058824

00:17:59.549 --> 00:18:01.530 risk and fit one of the categories.  
NOTE Confidence: 0.904253437058824

00:18:01.530 --> 00:18:03.578 I included a list here so you can  
NOTE Confidence: 0.904253437058824

00:18:03.578 --> 00:18:06.207 click on it and we'll take you to the

NOTE Confidence: 0.904253437058824

00:18:06.207 --> 00:18:08.310 page that describes all the categories.

NOTE Confidence: 0.904253437058824

00:18:08.310 --> 00:18:11.342 Or if it's already an approved study and

NOTE Confidence: 0.904253437058824

00:18:11.342 --> 00:18:13.967 you're proposing a minor modification to it,

NOTE Confidence: 0.904253437058824

00:18:13.970 --> 00:18:16.749 an expedited review procedural kick in too,

NOTE Confidence: 0.904253437058824

00:18:16.750 --> 00:18:19.235 so it's only one person can review

NOTE Confidence: 0.904253437058824

00:18:19.235 --> 00:18:22.247 it if that person will say, well,

NOTE Confidence: 0.904253437058824

00:18:22.247 --> 00:18:24.432 the study doesn't actually fit

NOTE Confidence: 0.904253437058824

00:18:24.432 --> 00:18:25.306 approval criteria,

NOTE Confidence: 0.904253437058824

00:18:25.310 --> 00:18:27.866 it will have to go to a full board,

NOTE Confidence: 0.904253437058824

00:18:27.870 --> 00:18:29.310 or the reviewer will ask

NOTE Confidence: 0.904253437058824

00:18:29.310 --> 00:18:30.750 you to make some revisions.

NOTE Confidence: 0.904253437058824

00:18:30.750 --> 00:18:31.550 And if you say no,

NOTE Confidence: 0.904253437058824

00:18:31.550 --> 00:18:32.926 I really want to keep it that way.

NOTE Confidence: 0.904253437058824

00:18:32.930 --> 00:18:35.750 They cannot disapprove the study,

NOTE Confidence: 0.904253437058824

00:18:35.750 --> 00:18:39.334 so only a full board can disapprove research.

NOTE Confidence: 0.904253437058824

00:18:39.340 --> 00:18:41.518 So if the research your proposal  
NOTE Confidence: 0.904253437058824

00:18:41.518 --> 00:18:43.660 does not fit exempts criteria,  
NOTE Confidence: 0.904253437058824

00:18:43.660 --> 00:18:47.060 it does not feel expedited  
NOTE Confidence: 0.904253437058824

00:18:47.060 --> 00:18:49.100 fit expedited criteria,  
NOTE Confidence: 0.904253437058824

00:18:49.100 --> 00:18:52.380 or if the reviewer.  
NOTE Confidence: 0.904253437058824

00:18:52.380 --> 00:18:54.487 It says that it doesn't fit approval  
NOTE Confidence: 0.904253437058824

00:18:54.487 --> 00:18:56.548 criteria and wants to send it to board.  
NOTE Confidence: 0.904253437058824

00:18:56.550 --> 00:18:58.130 That's when your study will  
NOTE Confidence: 0.904253437058824

00:18:58.130 --> 00:19:00.230 be sent to full board review.  
NOTE Confidence: 0.904253437058824

00:19:00.230 --> 00:19:03.450 Both actually take similar time to review,  
NOTE Confidence: 0.904253437058824

00:19:03.450 --> 00:19:05.106 so there is no much difference.  
NOTE Confidence: 0.943128943636363

00:19:05.110 --> 00:19:07.035 When I look at the metrics of  
NOTE Confidence: 0.943128943636363

00:19:07.035 --> 00:19:09.056 how fast it takes. And again you  
NOTE Confidence: 0.943128943636363

00:19:09.056 --> 00:19:10.508 don't need to know the difference.  
NOTE Confidence: 0.943128943636363

00:19:10.510 --> 00:19:12.515 You're not requesting expedited versus  
NOTE Confidence: 0.943128943636363

00:19:12.515 --> 00:19:15.080 fulbert review when you submission comes in,

NOTE Confidence: 0.943128943636363

00:19:15.080 --> 00:19:16.884 that's where it's triaged

NOTE Confidence: 0.943128943636363

00:19:16.884 --> 00:19:18.688 to that appropriate level.

NOTE Confidence: 0.943128943636363

00:19:18.690 --> 00:19:21.360 So let me walk you through

NOTE Confidence: 0.943128943636363

00:19:21.360 --> 00:19:23.140 quickly the submission process

NOTE Confidence: 0.943128943636363

00:19:23.223 --> 00:19:25.485 when study comes to Yale IRB,

NOTE Confidence: 0.943128943636363

00:19:25.490 --> 00:19:27.170 I am not going to talk

NOTE Confidence: 0.943128943636363

00:19:27.170 --> 00:19:28.830 about our system in detail.

NOTE Confidence: 0.943128943636363

00:19:28.830 --> 00:19:30.477 If you want me to come back and to

NOTE Confidence: 0.943128943636363

00:19:30.477 --> 00:19:31.976 give you training on the system,

NOTE Confidence: 0.943128943636363

00:19:31.980 --> 00:19:33.270 I'm happy to do so.

NOTE Confidence: 0.943128943636363

00:19:33.270 --> 00:19:34.986 We have monthly trainings as well

NOTE Confidence: 0.943128943636363

00:19:34.986 --> 00:19:37.257 so you can come to one of those

NOTE Confidence: 0.943128943636363

00:19:37.257 --> 00:19:39.344 trainings and and we will train you

NOTE Confidence: 0.943128943636363

00:19:39.344 --> 00:19:41.606 on how to use electronic system.

NOTE Confidence: 0.943128943636363

00:19:41.610 --> 00:19:44.666 What I will say is that when studies

NOTE Confidence: 0.943128943636363

00:19:44.666 --> 00:19:47.310 created in electronic IRB system,  
NOTE Confidence: 0.943128943636363

00:19:47.310 --> 00:19:49.938 we refer to as. Iris IRB.  
NOTE Confidence: 0.943128943636363

00:19:49.940 --> 00:19:52.200 It goes through different States  
NOTE Confidence: 0.943128943636363

00:19:52.200 --> 00:19:55.200 and the first state is preview.  
NOTE Confidence: 0.943128943636363

00:19:55.200 --> 00:19:59.960 Preview is the moment where HRPP analysts,  
NOTE Confidence: 0.943128943636363

00:19:59.960 --> 00:20:01.124 so they're not from.  
NOTE Confidence: 0.943128943636363

00:20:01.124 --> 00:20:02.288 They're not representing IRB,  
NOTE Confidence: 0.943128943636363

00:20:02.290 --> 00:20:04.258 they're representing the HRPP  
NOTE Confidence: 0.943128943636363

00:20:04.258 --> 00:20:06.718 or looking at your submission,  
NOTE Confidence: 0.943128943636363

00:20:06.720 --> 00:20:08.538 and there are reviewing it to  
NOTE Confidence: 0.943128943636363

00:20:08.538 --> 00:20:10.486 make sure that you compliant  
NOTE Confidence: 0.943128943636363

00:20:10.486 --> 00:20:12.478 with institutional requirements.  
NOTE Confidence: 0.943128943636363

00:20:12.480 --> 00:20:14.587 So if they ask you for clarifications,  
NOTE Confidence: 0.943128943636363

00:20:14.590 --> 00:20:16.183 they're usually about.  
NOTE Confidence: 0.943128943636363

00:20:16.183 --> 00:20:17.776 Maybe you didn't.  
NOTE Confidence: 0.943128943636363

00:20:17.780 --> 00:20:19.244 Usually about institutional requirements,

NOTE Confidence: 0.943128943636363

00:20:19.244 --> 00:20:21.074 so they're looking at your

NOTE Confidence: 0.943128943636363

00:20:21.074 --> 00:20:22.398 training they're looking at.

NOTE Confidence: 0.943128943636363

00:20:22.400 --> 00:20:24.686 At the conflict of interest disclosures,

NOTE Confidence: 0.943128943636363

00:20:24.690 --> 00:20:26.692 they're going to look at whether or

NOTE Confidence: 0.943128943636363

00:20:26.692 --> 00:20:29.172 not you have all the other ancillary

NOTE Confidence: 0.943128943636363

00:20:29.172 --> 00:20:31.122 approvals that might be applicable,

NOTE Confidence: 0.943128943636363

00:20:31.130 --> 00:20:33.048 or if you didn't submit it correctly,

NOTE Confidence: 0.943128943636363

00:20:33.050 --> 00:20:35.026 they were going to ask for it too.

NOTE Confidence: 0.943128943636363

00:20:35.030 --> 00:20:38.030 But once the preview is completed,

NOTE Confidence: 0.943128943636363

00:20:38.030 --> 00:20:40.046 so the institutional review is completed,

NOTE Confidence: 0.943128943636363

00:20:40.050 --> 00:20:41.680 that's when the study moves

NOTE Confidence: 0.943128943636363

00:20:41.680 --> 00:20:42.984 to the Arab review.

NOTE Confidence: 0.943128943636363

00:20:42.990 --> 00:20:45.489 And if you get questions from the

NOTE Confidence: 0.943128943636363

00:20:45.489 --> 00:20:47.949 RB that's about approval criteria.

NOTE Confidence: 0.943128943636363

00:20:47.950 --> 00:20:50.050 So IRB review is very focused.

NOTE Confidence: 0.943128943636363

00:20:50.050 --> 00:20:52.658 They're all looking at does your study fit?

NOTE Confidence: 0.943128943636363

00:20:52.660 --> 00:20:55.365 The approval criteria are as

NOTE Confidence: 0.943128943636363

00:20:55.365 --> 00:20:57.529 described in the regulations.

NOTE Confidence: 0.943128943636363

00:20:57.530 --> 00:20:59.570 What are the institutional requirements?

NOTE Confidence: 0.943128943636363

00:20:59.570 --> 00:21:01.908 I only included a few of them

NOTE Confidence: 0.943128943636363

00:21:01.908 --> 00:21:02.910 and that's people.

NOTE Confidence: 0.943128943636363

00:21:02.910 --> 00:21:04.446 How how people would start with.

NOTE Confidence: 0.943128943636363

00:21:04.450 --> 00:21:06.396 So the first thing that we always

NOTE Confidence: 0.943128943636363

00:21:06.396 --> 00:21:08.000 look at this institutional review

NOTE Confidence: 0.943128943636363

00:21:08.000 --> 00:21:10.457 stage is whether or not you can

NOTE Confidence: 0.943128943636363

00:21:10.457 --> 00:21:12.688 serve as the principal investigator.

NOTE Confidence: 0.943128943636363

00:21:12.690 --> 00:21:14.885 Faculty Handbook has very specific

NOTE Confidence: 0.943128943636363

00:21:14.885 --> 00:21:17.619 criteria of who can and cannot

NOTE Confidence: 0.943128943636363

00:21:17.619 --> 00:21:19.894 serve as the principal investigator

NOTE Confidence: 0.943128943636363

00:21:19.894 --> 00:21:22.719 Pi on the sponsor project and

NOTE Confidence: 0.943128943636363

00:21:22.719 --> 00:21:25.044 our office adopted those rules.

NOTE Confidence: 0.943128943636363

00:21:25.050 --> 00:21:27.276 So if your appointment at Yale.

NOTE Confidence: 0.943128943636363

00:21:27.280 --> 00:21:28.676 Doesn't fit that criteria.

NOTE Confidence: 0.943128943636363

00:21:28.676 --> 00:21:30.770 We will either look for special

NOTE Confidence: 0.943128943636363

00:21:30.834 --> 00:21:32.928 permission to serve as the investigate

NOTE Confidence: 0.943128943636363

00:21:32.928 --> 00:21:35.170 Pi as the principal investigator.

NOTE Confidence: 0.943128943636363

00:21:35.170 --> 00:21:37.116 There are different ways of getting it,

NOTE Confidence: 0.943128943636363

00:21:37.120 --> 00:21:39.466 or if you consider a trainee,

NOTE Confidence: 0.943128943636363

00:21:39.470 --> 00:21:42.256 we're going to ask you to identify

NOTE Confidence: 0.943128943636363

00:21:42.256 --> 00:21:43.450 a faculty advisor.

NOTE Confidence: 0.943128943636363

00:21:43.450 --> 00:21:45.115 Have the faculty advisor to

NOTE Confidence: 0.943128943636363

00:21:45.115 --> 00:21:47.271 complete that station that they take

NOTE Confidence: 0.943128943636363

00:21:47.271 --> 00:21:48.987 responsibility for your research,

NOTE Confidence: 0.943128943636363

00:21:48.990 --> 00:21:51.666 and upload it in our system.

NOTE Confidence: 0.943128943636363

00:21:51.670 --> 00:21:53.728 Another thing that we look for,

NOTE Confidence: 0.943128943636363

00:21:53.730 --> 00:21:55.458 and actually this is number one

NOTE Confidence: 0.943128943636363

00:21:55.458 --> 00:21:57.370 reason why we send submissions.

NOTE Confidence: 0.943128943636363

00:21:57.370 --> 00:22:00.040 Back right at the first stop

NOTE Confidence: 0.943128943636363

00:22:00.040 --> 00:22:01.820 is the training requirements.

NOTE Confidence: 0.943128943636363

00:22:01.820 --> 00:22:03.770 If you're from a HIPAA covered

NOTE Confidence: 0.943128943636363

00:22:03.770 --> 00:22:05.639 entity entity and and you are,

NOTE Confidence: 0.943128943636363

00:22:05.640 --> 00:22:07.677 you need to have a HIPAA training.

NOTE Confidence: 0.943128943636363

00:22:07.680 --> 00:22:09.858 You need to have human subjects

NOTE Confidence: 0.943128943636363

00:22:09.858 --> 00:22:11.310 protection training taken within

NOTE Confidence: 0.886337537142857

00:22:11.368 --> 00:22:14.246 the last three years, and in addition,

NOTE Confidence: 0.886337537142857

00:22:14.246 --> 00:22:19.214 if your study fits the NIH criteria for

NOTE Confidence: 0.886337537142857

00:22:19.214 --> 00:22:23.199 clinical research for clinical trial,

NOTE Confidence: 0.886337537142857

00:22:23.200 --> 00:22:25.240 you also need to have good

NOTE Confidence: 0.886337537142857

00:22:25.240 --> 00:22:26.260 clinical practice training.

NOTE Confidence: 0.886337537142857

00:22:26.260 --> 00:22:27.590 So it's not just you.

NOTE Confidence: 0.886337537142857

00:22:27.590 --> 00:22:28.954 As a principal investigator,

NOTE Confidence: 0.886337537142857

00:22:28.954 --> 00:22:30.659 it's every single person that

NOTE Confidence: 0.886337537142857  
00:22:30.659 --> 00:22:32.239 is listed on your study.  
NOTE Confidence: 0.886337537142857  
00:22:32.240 --> 00:22:34.095 So if somebody doesn't have the training,  
NOTE Confidence: 0.886337537142857  
00:22:34.100 --> 00:22:36.524 we'll send it back to you so that  
NOTE Confidence: 0.886337537142857  
00:22:36.524 --> 00:22:38.663 you can either take the person  
NOTE Confidence: 0.886337537142857  
00:22:38.663 --> 00:22:41.404 off the study or we submit with  
NOTE Confidence: 0.886337537142857  
00:22:41.404 --> 00:22:43.360 the full training completed.  
NOTE Confidence: 0.886337537142857  
00:22:43.360 --> 00:22:45.978 We going to look for conflict of  
NOTE Confidence: 0.886337537142857  
00:22:45.978 --> 00:22:47.905 interest disclosures for for anybody  
NOTE Confidence: 0.886337537142857  
00:22:47.905 --> 00:22:50.119 who is listed as an investigator.  
NOTE Confidence: 0.886337537142857  
00:22:50.120 --> 00:22:51.938 So if your or investigator,  
NOTE Confidence: 0.886337537142857  
00:22:51.940 --> 00:22:54.299 we're going to make sure that you  
NOTE Confidence: 0.886337537142857  
00:22:54.299 --> 00:22:56.594 have disclosures on file with the COI  
NOTE Confidence: 0.886337537142857  
00:22:56.594 --> 00:22:58.180 office we're going to review that.  
NOTE Confidence: 0.886337537142857  
00:22:58.180 --> 00:23:00.766 Disclosure to see whether there is  
NOTE Confidence: 0.886337537142857  
00:23:00.766 --> 00:23:02.490 any significant financial interest  
NOTE Confidence: 0.886337537142857

00:23:02.557 --> 00:23:04.369 that is related to the study,  
NOTE Confidence: 0.886337537142857

00:23:04.370 --> 00:23:05.494 and if there is,  
NOTE Confidence: 0.886337537142857

00:23:05.494 --> 00:23:07.450 will inform the IRB to say oh,  
NOTE Confidence: 0.886337537142857

00:23:07.450 --> 00:23:09.952 you need to review this disclosure  
NOTE Confidence: 0.886337537142857

00:23:09.952 --> 00:23:13.230 because there might be conflict of interest.  
NOTE Confidence: 0.886337537142857

00:23:13.230 --> 00:23:15.394 Some studies require ancillary  
NOTE Confidence: 0.886337537142857

00:23:15.394 --> 00:23:17.558 committee review and approval.  
NOTE Confidence: 0.886337537142857

00:23:17.560 --> 00:23:18.884 As I said earlier,  
NOTE Confidence: 0.886337537142857

00:23:18.884 --> 00:23:20.870 there were about 20 of them.  
NOTE Confidence: 0.886337537142857

00:23:20.870 --> 00:23:21.534 For example,  
NOTE Confidence: 0.886337537142857

00:23:21.534 --> 00:23:23.526 if you're doing research with minors,  
NOTE Confidence: 0.886337537142857

00:23:23.530 --> 00:23:25.560 there is pediatric Protocol Review  
NOTE Confidence: 0.886337537142857

00:23:25.560 --> 00:23:28.320 committee that will need to review it.  
NOTE Confidence: 0.886337537142857

00:23:28.320 --> 00:23:31.590 If you doing research with.  
NOTE Confidence: 0.886337537142857

00:23:31.590 --> 00:23:33.720 What is it that research with  
NOTE Confidence: 0.886337537142857

00:23:33.720 --> 00:23:35.559 oncology patients there is a

NOTE Confidence: 0.886337537142857  
00:23:35.559 --> 00:23:36.979 committee that reviews it.  
NOTE Confidence: 0.886337537142857  
00:23:36.980 --> 00:23:39.316 So if there is something that it was  
NOTE Confidence: 0.886337537142857  
00:23:39.316 --> 00:23:41.160 a applicable ancillary committee,  
NOTE Confidence: 0.886337537142857  
00:23:41.160 --> 00:23:43.496 we're going to look at this to make  
NOTE Confidence: 0.886337537142857  
00:23:43.496 --> 00:23:45.507 sure that you already have the.  
NOTE Confidence: 0.886337537142857  
00:23:45.510 --> 00:23:47.110 Approval in place or sometimes  
NOTE Confidence: 0.886337537142857  
00:23:47.110 --> 00:23:49.301 we use our system to communicate  
NOTE Confidence: 0.886337537142857  
00:23:49.301 --> 00:23:51.409 with that ancillary committee.  
NOTE Confidence: 0.886337537142857  
00:23:51.410 --> 00:23:53.826 So we're going to initiate that as well.  
NOTE Confidence: 0.886337537142857  
00:23:53.830 --> 00:23:55.816 We're also going to look at  
NOTE Confidence: 0.886337537142857  
00:23:55.816 --> 00:23:56.809 the necessary documents.  
NOTE Confidence: 0.886337537142857  
00:23:56.810 --> 00:23:59.138 I include that links to the  
NOTE Confidence: 0.886337537142857  
00:23:59.138 --> 00:24:00.690 training and COI disclosures.  
NOTE Confidence: 0.886337537142857  
00:24:00.690 --> 00:24:02.810 So if you get the slides and if you need it,  
NOTE Confidence: 0.886337537142857  
00:24:02.810 --> 00:24:04.388 you can just click on them  
NOTE Confidence: 0.886337537142857

00:24:04.388 --> 00:24:05.850 and we'll take you there.  
NOTE Confidence: 0.886337537142857  
00:24:05.850 --> 00:24:07.800 So what are the necessary documents?  
NOTE Confidence: 0.886337537142857  
00:24:07.800 --> 00:24:09.550 There are quite a few of them.  
NOTE Confidence: 0.886337537142857  
00:24:09.550 --> 00:24:11.254 You always need to have a  
NOTE Confidence: 0.886337537142857  
00:24:11.254 --> 00:24:12.390 protocol unless you have.  
NOTE Confidence: 0.886337537142857  
00:24:12.390 --> 00:24:14.830 Unless it's an exempt request,  
NOTE Confidence: 0.886337537142857  
00:24:14.830 --> 00:24:16.274 then instead of protocol.  
NOTE Confidence: 0.886337537142857  
00:24:16.274 --> 00:24:18.079 Going to use exemption request  
NOTE Confidence: 0.886337537142857  
00:24:18.079 --> 00:24:20.249 and again it's much much shorter.  
NOTE Confidence: 0.886337537142857  
00:24:20.250 --> 00:24:22.440 Yale doesn't have a very  
NOTE Confidence: 0.886337537142857  
00:24:22.440 --> 00:24:24.630 specific form for a protocol.  
NOTE Confidence: 0.886337537142857  
00:24:24.630 --> 00:24:26.406 I will go through it in a second.  
NOTE Confidence: 0.886337537142857  
00:24:26.410 --> 00:24:28.650 You always need to have an IRB submission  
NOTE Confidence: 0.886337537142857  
00:24:28.650 --> 00:24:30.424 form because there are certain things  
NOTE Confidence: 0.886337537142857  
00:24:30.424 --> 00:24:32.164 that wouldn't be in a protocol.  
NOTE Confidence: 0.886337537142857  
00:24:32.170 --> 00:24:34.594 There will be an IRB submission form that's

NOTE Confidence: 0.886337537142857  
00:24:34.594 --> 00:24:36.948 a document available in Iris IRB library.  
NOTE Confidence: 0.886337537142857  
00:24:36.950 --> 00:24:38.318 So in our system,  
NOTE Confidence: 0.886337537142857  
00:24:38.318 --> 00:24:40.028 because we are doing research  
NOTE Confidence: 0.886337537142857  
00:24:40.028 --> 00:24:41.010 during pandemic,  
NOTE Confidence: 0.886337537142857  
00:24:41.010 --> 00:24:43.278 we still have a form called safety  
NOTE Confidence: 0.886337537142857  
00:24:43.278 --> 00:24:44.250 protocol during pandemic.  
NOTE Confidence: 0.886337537142857  
00:24:44.250 --> 00:24:45.513 That's just one.  
NOTE Confidence: 0.886337537142857  
00:24:45.513 --> 00:24:47.618 Page document that just describes  
NOTE Confidence: 0.886337537142857  
00:24:47.618 --> 00:24:50.999 how we're going to protect your participants,  
NOTE Confidence: 0.886337537142857  
00:24:51.000 --> 00:24:52.860 but also stuff that works with  
NOTE Confidence: 0.886337537142857  
00:24:52.860 --> 00:24:54.580 you or or third party.  
NOTE Confidence: 0.886337537142857  
00:24:54.580 --> 00:24:56.566 Anybody who can come into contact  
NOTE Confidence: 0.886337537142857  
00:24:56.566 --> 00:24:58.631 with you during this research to  
NOTE Confidence: 0.886337537142857  
00:24:58.631 --> 00:25:00.653 make sure that we're not exposing  
NOTE Confidence: 0.886337537142857  
00:25:00.653 --> 00:25:02.440 people to unnecessary risk.  
NOTE Confidence: 0.886337537142857

00:25:02.440 --> 00:25:04.224 If you're obtaining consents,  
NOTE Confidence: 0.886337537142857

00:25:04.224 --> 00:25:07.799 you're not asking for a waiver of consent,  
NOTE Confidence: 0.886337537142857

00:25:07.800 --> 00:25:09.594 we're going to look at the  
NOTE Confidence: 0.886337537142857

00:25:09.594 --> 00:25:11.420 consent script or the document.  
NOTE Confidence: 0.923911136666667

00:25:11.420 --> 00:25:13.733 Or if you asking for a waiver of consent,  
NOTE Confidence: 0.923911136666667

00:25:13.740 --> 00:25:16.106 that something that you would ask in  
NOTE Confidence: 0.923911136666667

00:25:16.106 --> 00:25:18.175 either be submission form any measures  
NOTE Confidence: 0.923911136666667

00:25:18.175 --> 00:25:20.499 created for the purposes of the study,  
NOTE Confidence: 0.923911136666667

00:25:20.500 --> 00:25:22.060 we need to be uploaded.  
NOTE Confidence: 0.923911136666667

00:25:22.060 --> 00:25:24.040 If you're doing international research,  
NOTE Confidence: 0.923911136666667

00:25:24.040 --> 00:25:25.960 we're going to look for their  
NOTE Confidence: 0.923911136666667

00:25:25.960 --> 00:25:27.760 specific checklist that we require.  
NOTE Confidence: 0.923911136666667

00:25:27.760 --> 00:25:29.951 There is letters of support from local  
NOTE Confidence: 0.923911136666667

00:25:29.951 --> 00:25:32.378 like NGOs that will help you with that.  
NOTE Confidence: 0.923911136666667

00:25:32.380 --> 00:25:34.830 Research and if you need to have  
NOTE Confidence: 0.923911136666667

00:25:34.830 --> 00:25:36.709 special permission, we're going to

NOTE Confidence: 0.923911136666667  
00:25:36.709 --> 00:25:39.067 look for those documents as well.  
NOTE Confidence: 0.923911136666667  
00:25:39.070 --> 00:25:40.618 As I said earlier,  
NOTE Confidence: 0.923911136666667  
00:25:40.618 --> 00:25:42.940 Yale does not require a specific  
NOTE Confidence: 0.923911136666667  
00:25:43.022 --> 00:25:44.390 protocol template.  
NOTE Confidence: 0.923911136666667  
00:25:44.390 --> 00:25:45.467 If you come.  
NOTE Confidence: 0.923911136666667  
00:25:45.467 --> 00:25:47.621 If you come from a different  
NOTE Confidence: 0.923911136666667  
00:25:47.621 --> 00:25:49.707 institution and you had a temple like  
NOTE Confidence: 0.923911136666667  
00:25:49.707 --> 00:25:51.489 to using at a different institution,  
NOTE Confidence: 0.923911136666667  
00:25:51.490 --> 00:25:52.606 you can use that as well,  
NOTE Confidence: 0.923911136666667  
00:25:52.610 --> 00:25:55.370 as long as has all of  
NOTE Confidence: 0.923911136666667  
00:25:55.370 --> 00:25:56.750 those required elements,  
NOTE Confidence: 0.923911136666667  
00:25:56.750 --> 00:25:59.249 we have a subscription to protocol builder,  
NOTE Confidence: 0.923911136666667  
00:25:59.250 --> 00:26:00.342 which is a software.  
NOTE Confidence: 0.923911136666667  
00:26:00.342 --> 00:26:02.369 There was a link on our website  
NOTE Confidence: 0.923911136666667  
00:26:02.369 --> 00:26:04.307 I included here too that will  
NOTE Confidence: 0.923911136666667

00:26:04.307 --> 00:26:06.210 help you build the protocol  
NOTE Confidence: 0.923911136666667

00:26:06.210 --> 00:26:07.950 by asking specific questions.  
NOTE Confidence: 0.923911136666667

00:26:07.950 --> 00:26:09.186 We have some word.  
NOTE Confidence: 0.923911136666667

00:26:09.186 --> 00:26:10.731 Portions of the templates from  
NOTE Confidence: 0.923911136666667

00:26:10.731 --> 00:26:12.094 protocol builder in our library  
NOTE Confidence: 0.923911136666667

00:26:12.094 --> 00:26:13.939 you can use that as well and  
NOTE Confidence: 0.923911136666667

00:26:13.939 --> 00:26:15.661 there are some other tools that  
NOTE Confidence: 0.923911136666667

00:26:15.661 --> 00:26:17.592 included here that you can you.  
NOTE Confidence: 0.923911136666667

00:26:17.592 --> 00:26:19.716 You may actually like some of  
NOTE Confidence: 0.923911136666667

00:26:19.716 --> 00:26:21.839 those protocol templates too.  
NOTE Confidence: 0.923911136666667

00:26:21.840 --> 00:26:23.536 In terms of consent,  
NOTE Confidence: 0.923911136666667

00:26:23.536 --> 00:26:26.080 if you're very familiar with regulations,  
NOTE Confidence: 0.923911136666667

00:26:26.080 --> 00:26:27.768 you can definitely just  
NOTE Confidence: 0.923911136666667

00:26:27.768 --> 00:26:29.456 draft your own consent.  
NOTE Confidence: 0.923911136666667

00:26:29.460 --> 00:26:31.236 Just make sure that all of  
NOTE Confidence: 0.923911136666667

00:26:31.236 --> 00:26:32.420 the elements are included.

NOTE Confidence: 0.923911136666667  
00:26:32.420 --> 00:26:34.580 We created templates for  
NOTE Confidence: 0.923911136666667  
00:26:34.580 --> 00:26:36.740 your for our investigators,  
NOTE Confidence: 0.923911136666667  
00:26:36.740 --> 00:26:39.660 so if this is not externally sponsored study,  
NOTE Confidence: 0.923911136666667  
00:26:39.660 --> 00:26:41.440 you have to draft consent.  
NOTE Confidence: 0.923911136666667  
00:26:41.440 --> 00:26:43.736 You can go to the consent form  
NOTE Confidence: 0.923911136666667  
00:26:43.736 --> 00:26:46.399 section in our library in the system,  
NOTE Confidence: 0.923911136666667  
00:26:46.400 --> 00:26:48.430 and there are some templates available for  
NOTE Confidence: 0.923911136666667  
00:26:48.430 --> 00:26:50.657 you already has all the required elements.  
NOTE Confidence: 0.923911136666667  
00:26:50.660 --> 00:26:52.106 Just asked you to fill in.  
NOTE Confidence: 0.923911136666667  
00:26:52.110 --> 00:26:53.682 Certain pieces of information.  
NOTE Confidence: 0.923911136666667  
00:26:53.682 --> 00:26:55.647 If you working with colleagues  
NOTE Confidence: 0.923911136666667  
00:26:55.647 --> 00:26:57.645 from a different institution and  
NOTE Confidence: 0.923911136666667  
00:26:57.645 --> 00:26:59.565 they are sponsoring the study.  
NOTE Confidence: 0.923911136666667  
00:26:59.570 --> 00:27:00.770 So they wrote the protocol,  
NOTE Confidence: 0.923911136666667  
00:27:00.770 --> 00:27:02.528 they wrote the templates or if  
NOTE Confidence: 0.923911136666667

00:27:02.528 --> 00:27:04.240 you working with a sponsor.  
NOTE Confidence: 0.923911136666667

00:27:04.240 --> 00:27:06.207 So somebody already gave you a template,  
NOTE Confidence: 0.923911136666667

00:27:06.210 --> 00:27:06.884 use those.  
NOTE Confidence: 0.923911136666667

00:27:06.884 --> 00:27:08.906 Don't don't try to copy everything  
NOTE Confidence: 0.923911136666667

00:27:08.906 --> 00:27:11.389 and move it into like a yell version.  
NOTE Confidence: 0.923911136666667

00:27:11.390 --> 00:27:13.686 Use the templates that you were given.  
NOTE Confidence: 0.923911136666667

00:27:13.690 --> 00:27:16.383 There is a document called consent  
NOTE Confidence: 0.923911136666667

00:27:16.383 --> 00:27:18.848 Glossary in the consent section  
NOTE Confidence: 0.923911136666667

00:27:18.848 --> 00:27:21.970 that includes all of the required.  
NOTE Confidence: 0.923911136666667

00:27:21.970 --> 00:27:24.094 Language that we want to see  
NOTE Confidence: 0.923911136666667

00:27:24.094 --> 00:27:25.156 in consent forms.  
NOTE Confidence: 0.923911136666667

00:27:25.160 --> 00:27:27.272 Like if your study is taking  
NOTE Confidence: 0.923911136666667

00:27:27.272 --> 00:27:28.680 place at PET Center,  
NOTE Confidence: 0.923911136666667

00:27:28.680 --> 00:27:31.137 Pet Center has language that needs to go in.  
NOTE Confidence: 0.923911136666667

00:27:31.140 --> 00:27:33.450 We also included certain paragraphs  
NOTE Confidence: 0.923911136666667

00:27:33.450 --> 00:27:36.918 that we know our IRB likes to see,

NOTE Confidence: 0.923911136666667  
00:27:36.920 --> 00:27:38.825 so that's a preferred language  
NOTE Confidence: 0.923911136666667  
00:27:38.825 --> 00:27:40.730 that was previously approved for  
NOTE Confidence: 0.923911136666667  
00:27:40.800 --> 00:27:42.800 like risks of certain procedures.  
NOTE Confidence: 0.923911136666667  
00:27:42.800 --> 00:27:45.040 So just make sure that it matches.  
NOTE Confidence: 0.923911136666667  
00:27:45.040 --> 00:27:47.002 Go through that document and see  
NOTE Confidence: 0.923911136666667  
00:27:47.002 --> 00:27:49.497 if you need to use any of this,  
NOTE Confidence: 0.923911136666667  
00:27:49.500 --> 00:27:52.724 but don't try to copy and paste it.  
NOTE Confidence: 0.923911136666667  
00:27:52.730 --> 00:27:55.530 Let me talk very quickly about external Irbs,  
NOTE Confidence: 0.923911136666667  
00:27:55.530 --> 00:27:57.978 because almost 50% of our studies  
NOTE Confidence: 0.923911136666667  
00:27:57.978 --> 00:27:59.680 that are externally sponsored  
NOTE Confidence: 0.923911136666667  
00:27:59.680 --> 00:28:02.030 actually go to external Irbs.  
NOTE Confidence: 0.923911136666667  
00:28:02.030 --> 00:28:06.550 So Yale IRB is the IRB of record for Yale,  
NOTE Confidence: 0.923911136666667  
00:28:06.550 --> 00:28:09.316 but we have agreements with other  
NOTE Confidence: 0.923911136666667  
00:28:09.320 --> 00:28:11.525 IRB's from other institutions we  
NOTE Confidence: 0.923911136666667  
00:28:11.525 --> 00:28:13.730 have agreements with a commercial  
NOTE Confidence: 0.829106065833333

00:28:13.805 --> 00:28:15.377 certain commercial IRB's.  
NOTE Confidence: 0.8291060658333333

00:28:15.377 --> 00:28:17.946 There are some some studies or networks  
NOTE Confidence: 0.8291060658333333

00:28:17.946 --> 00:28:20.501 of studies that it's actually requirement  
NOTE Confidence: 0.8291060658333333

00:28:20.501 --> 00:28:22.686 that if you're doing research.  
NOTE Confidence: 0.8291060658333333

00:28:22.690 --> 00:28:24.400 Is part of stroke net.  
NOTE Confidence: 0.8291060658333333

00:28:24.400 --> 00:28:27.080 We have to go through a very specific  
NOTE Confidence: 0.8291060658333333

00:28:27.080 --> 00:28:29.618 IRB so we have those agreements as well.  
NOTE Confidence: 0.8291060658333333

00:28:29.620 --> 00:28:32.970 Or sometimes maybe you have a a colleague  
NOTE Confidence: 0.8291060658333333

00:28:32.970 --> 00:28:35.343 that you want to work with and now the  
NOTE Confidence: 0.8291060658333333

00:28:35.343 --> 00:28:37.449 regulations actually require a single IRB.  
NOTE Confidence: 0.8291060658333333

00:28:37.450 --> 00:28:39.502 If it's multi site research and  
NOTE Confidence: 0.8291060658333333

00:28:39.502 --> 00:28:41.317 that colleague is going through  
NOTE Confidence: 0.8291060658333333

00:28:41.317 --> 00:28:42.857 his or her institution,  
NOTE Confidence: 0.8291060658333333

00:28:42.860 --> 00:28:45.132 we will be able to enter into agreement  
NOTE Confidence: 0.8291060658333333

00:28:45.132 --> 00:28:46.924 with that institutions that we can  
NOTE Confidence: 0.8291060658333333

00:28:46.924 --> 00:28:49.189 see the review to the IRB as well.

NOTE Confidence: 0.829106065833333  
00:28:49.190 --> 00:28:51.640 So if you ever asked from someone,  
NOTE Confidence: 0.829106065833333  
00:28:51.640 --> 00:28:52.458 does Yale.  
NOTE Confidence: 0.829106065833333  
00:28:52.458 --> 00:28:54.912 Need to review or enter into  
NOTE Confidence: 0.829106065833333  
00:28:54.912 --> 00:28:56.929 reliance agreement with other Irbs.  
NOTE Confidence: 0.829106065833333  
00:28:56.930 --> 00:28:58.322 The answer is yes.  
NOTE Confidence: 0.829106065833333  
00:28:58.322 --> 00:29:01.230 We we work with Irbs all the time.  
NOTE Confidence: 0.829106065833333  
00:29:01.230 --> 00:29:04.587 But even if you go to a different IRB,  
NOTE Confidence: 0.829106065833333  
00:29:04.590 --> 00:29:07.008 that institutional review that I just  
NOTE Confidence: 0.829106065833333  
00:29:07.008 --> 00:29:09.240 described earlier about the training,  
NOTE Confidence: 0.829106065833333  
00:29:09.240 --> 00:29:12.200 the making sure that you have the COI  
NOTE Confidence: 0.829106065833333  
00:29:12.200 --> 00:29:14.374 disclosures still needs to happen  
NOTE Confidence: 0.829106065833333  
00:29:14.374 --> 00:29:16.644 because it's the institutional review.  
NOTE Confidence: 0.829106065833333  
00:29:16.650 --> 00:29:19.790 So even if you want to go to an external IRB,  
NOTE Confidence: 0.829106065833333  
00:29:19.790 --> 00:29:21.854 you still have to submit something  
NOTE Confidence: 0.829106065833333  
00:29:21.854 --> 00:29:25.120 in our system will do that review of  
NOTE Confidence: 0.829106065833333

00:29:25.120 --> 00:29:27.006 institutional compliance or compliance  
NOTE Confidence: 0.829106065833333

00:29:27.006 --> 00:29:28.470 with institutional requirements.  
NOTE Confidence: 0.829106065833333

00:29:28.470 --> 00:29:30.330 We'll check whether we have a  
NOTE Confidence: 0.829106065833333

00:29:30.330 --> 00:29:31.570 reliance agreement in place.  
NOTE Confidence: 0.829106065833333

00:29:31.570 --> 00:29:32.236 If not,  
NOTE Confidence: 0.829106065833333

00:29:32.236 --> 00:29:34.234 we'll establish one and then we'll  
NOTE Confidence: 0.829106065833333

00:29:34.234 --> 00:29:36.325 write a letter saying that you're  
NOTE Confidence: 0.829106065833333

00:29:36.325 --> 00:29:39.114 OK to go to that external IRB and  
NOTE Confidence: 0.829106065833333

00:29:39.114 --> 00:29:41.494 submit your proposal to the other IRB.  
NOTE Confidence: 0.829106065833333

00:29:41.500 --> 00:29:44.308 We just need to keep track of those  
NOTE Confidence: 0.829106065833333

00:29:44.308 --> 00:29:46.540 studies in our system after you  
NOTE Confidence: 0.829106065833333

00:29:46.540 --> 00:29:48.580 get approval from the external IRB,  
NOTE Confidence: 0.829106065833333

00:29:48.580 --> 00:29:50.435 you still need to make sure that  
NOTE Confidence: 0.829106065833333

00:29:50.435 --> 00:29:52.493 our system is updated with all the  
NOTE Confidence: 0.829106065833333

00:29:52.493 --> 00:29:54.993 approval letters and up to date so you  
NOTE Confidence: 0.829106065833333

00:29:54.993 --> 00:29:57.233 don't have to submit all the modifications,

NOTE Confidence: 0.829106065833333

00:29:57.240 --> 00:30:00.144 but you need to keep the most recent

NOTE Confidence: 0.829106065833333

00:30:00.144 --> 00:30:02.899 approval letter for the study in our system.

NOTE Confidence: 0.829106065833333

00:30:02.900 --> 00:30:04.675 But all the modifications continuing

NOTE Confidence: 0.829106065833333

00:30:04.675 --> 00:30:07.239 reviews go directly to the external IRB.

NOTE Confidence: 0.829106065833333

00:30:07.240 --> 00:30:08.506 It's just that young needs to

NOTE Confidence: 0.829106065833333

00:30:08.506 --> 00:30:09.931 keep track of all those studies

NOTE Confidence: 0.829106065833333

00:30:09.931 --> 00:30:11.515 because we are as an institution,

NOTE Confidence: 0.829106065833333

00:30:11.520 --> 00:30:15.170 we are responsible for them.

NOTE Confidence: 0.829106065833333

00:30:15.170 --> 00:30:18.274 I included a list of some of our

NOTE Confidence: 0.829106065833333

00:30:18.274 --> 00:30:20.620 individuals in our office so that

NOTE Confidence: 0.829106065833333

00:30:20.620 --> 00:30:23.154 you may work with most of our office

NOTE Confidence: 0.829106065833333

00:30:23.154 --> 00:30:25.190 is of course at this point remote,

NOTE Confidence: 0.829106065833333

00:30:25.190 --> 00:30:28.206 but we have our offices are 25 science park,

NOTE Confidence: 0.829106065833333

00:30:28.206 --> 00:30:29.900 so if you wanted to meet with

NOTE Confidence: 0.829106065833333

00:30:29.960 --> 00:30:30.908 someone in person,

NOTE Confidence: 0.829106065833333

00:30:30.910 --> 00:30:32.340 you can schedule a meeting.  
NOTE Confidence: 0.8291060658333333

00:30:32.340 --> 00:30:34.155 We'll meet you there included  
NOTE Confidence: 0.8291060658333333

00:30:34.155 --> 00:30:36.566 the names of all the assistant  
NOTE Confidence: 0.8291060658333333

00:30:36.566 --> 00:30:39.166 directors and advisors within the  
NOTE Confidence: 0.8291060658333333

00:30:39.170 --> 00:30:41.708 office and names of the managers.  
NOTE Confidence: 0.8291060658333333

00:30:41.710 --> 00:30:43.831 Because I expect I suspect that you  
NOTE Confidence: 0.8291060658333333

00:30:43.831 --> 00:30:46.089 will probably go directly to a manager.  
NOTE Confidence: 0.8291060658333333

00:30:46.090 --> 00:30:48.256 If you have questions about yeah.  
NOTE Confidence: 0.8291060658333333

00:30:48.260 --> 00:30:49.596 Irby or your protocol,  
NOTE Confidence: 0.8291060658333333

00:30:49.596 --> 00:30:52.369 these are the people that you will be  
NOTE Confidence: 0.8291060658333333

00:30:52.369 --> 00:30:54.819 working with and sometimes if they don't,  
NOTE Confidence: 0.8291060658333333

00:30:54.820 --> 00:30:56.080 they cannot answer your question.  
NOTE Confidence: 0.8291060658333333

00:30:56.080 --> 00:30:57.320 They're going to triage or  
NOTE Confidence: 0.8291060658333333

00:30:57.320 --> 00:30:58.560 to somebody on their teams,  
NOTE Confidence: 0.8291060658333333

00:30:58.560 --> 00:31:00.618 like a regulatory analyst that can.  
NOTE Confidence: 0.8291060658333333

00:31:00.620 --> 00:31:03.244 That can answer the question if you ever

NOTE Confidence: 0.829106065833333

00:31:03.244 --> 00:31:05.960 need to have like a general question,

NOTE Confidence: 0.829106065833333

00:31:05.960 --> 00:31:08.885 you can send it to HR Pate l.edu.

NOTE Confidence: 0.829106065833333

00:31:08.885 --> 00:31:11.370 We check those emails daily and their

NOTE Confidence: 0.842112831578948

00:31:11.446 --> 00:31:14.317 triage to someone who is on call that day.

NOTE Confidence: 0.842112831578948

00:31:14.320 --> 00:31:16.504 So every day there is a different person.

NOTE Confidence: 0.842112831578948

00:31:16.510 --> 00:31:17.626 And we'll get back to you.

NOTE Confidence: 0.842112831578948

00:31:17.630 --> 00:31:18.746 Or you can leave a message,

NOTE Confidence: 0.842112831578948

00:31:18.750 --> 00:31:21.142 but I think email is nice because then

NOTE Confidence: 0.842112831578948

00:31:21.142 --> 00:31:23.888 you can see that information in writing.

NOTE Confidence: 0.842112831578948

00:31:23.890 --> 00:31:26.123 This is a list that included the

NOTE Confidence: 0.842112831578948

00:31:26.123 --> 00:31:28.469 link to our panel information,

NOTE Confidence: 0.842112831578948

00:31:28.470 --> 00:31:31.008 but this is the list of all of our

NOTE Confidence: 0.842112831578948

00:31:31.008 --> 00:31:33.586 panels and when they meet and who serves

NOTE Confidence: 0.842112831578948

00:31:33.586 --> 00:31:36.355 as the chair and the vice chair so you

NOTE Confidence: 0.842112831578948

00:31:36.355 --> 00:31:38.598 can see what what's panels, we have.

NOTE Confidence: 0.842112831578948

00:31:38.598 --> 00:31:40.650 Some of them are very specialized.  
NOTE Confidence: 0.842112831578948

00:31:40.650 --> 00:31:43.485 You don't request a review by specific  
NOTE Confidence: 0.842112831578948

00:31:43.485 --> 00:31:46.820 IRB we sent when your study comes in.  
NOTE Confidence: 0.842112831578948

00:31:46.820 --> 00:31:49.249 They were we we have like very  
NOTE Confidence: 0.842112831578948

00:31:49.249 --> 00:31:51.378 specific schedule so we send your  
NOTE Confidence: 0.842112831578948

00:31:51.378 --> 00:31:53.418 study to the next available IRB.  
NOTE Confidence: 0.842112831578948

00:31:53.420 --> 00:31:55.009 If it's Pi initiated we send it  
NOTE Confidence: 0.842112831578948

00:31:55.009 --> 00:31:57.105 to the we give ourselves two weeks  
NOTE Confidence: 0.842112831578948

00:31:57.105 --> 00:31:58.800 to work through your protocol,  
NOTE Confidence: 0.842112831578948

00:31:58.800 --> 00:32:00.840 but everything else goes to the  
NOTE Confidence: 0.842112831578948

00:32:00.840 --> 00:32:02.774 next available so that it's just  
NOTE Confidence: 0.842112831578948

00:32:02.774 --> 00:32:04.108 a week waiting time.  
NOTE Confidence: 0.842112831578948

00:32:04.108 --> 00:32:07.006 OK, so this is what I had.