

WEBVTT

NOTE duration: "00:48:35.537"

NOTE Confidence: 0.88036406

00:00:00.799 --> 00:00:02.800 Jonathan Gower from OAPD office,

NOTE Confidence: 0.88036406

00:00:02.800 --> 00:00:03.939 and, we are

NOTE Confidence: 0.9486072

00:00:04.319 --> 00:00:06.000 honored today to have, Gina

NOTE Confidence: 0.9486072

00:00:06.000 --> 00:00:07.919 Larson talking to us. I

NOTE Confidence: 0.9486072

00:00:07.919 --> 00:00:09.360 said lightheartedly toward the beginning.

NOTE Confidence: 0.9486072

00:00:09.360 --> 00:00:10.080 I went to a recent

NOTE Confidence: 0.9486072

00:00:10.080 --> 00:00:11.200 talk she gave on this,

NOTE Confidence: 0.9486072

00:00:11.759 --> 00:00:13.360 general overview information of things

NOTE Confidence: 0.9486072

00:00:13.360 --> 00:00:14.240 we should all know, and

NOTE Confidence: 0.9486072

00:00:14.240 --> 00:00:15.460 I learned so much

NOTE Confidence: 0.9801211

00:00:15.855 --> 00:00:17.695 that, I quickly invited her

NOTE Confidence: 0.9801211

00:00:17.695 --> 00:00:18.414 and asked her if she'd

NOTE Confidence: 0.9801211

00:00:18.414 --> 00:00:19.375 come talk to the next

NOTE Confidence: 0.9801211

00:00:19.375 --> 00:00:19.875 group.

NOTE Confidence: 0.95294

00:00:20.895 --> 00:00:22.575 So great to have you.
NOTE Confidence: 0.95294

00:00:22.895 --> 00:00:24.494 Thanks for joining us, and,
NOTE Confidence: 0.95294

00:00:24.735 --> 00:00:26.654 look forward to, hearing you
NOTE Confidence: 0.95294

00:00:26.654 --> 00:00:27.154 here.
NOTE Confidence: 0.99718606

00:00:27.630 --> 00:00:28.289 Thank you.
NOTE Confidence: 0.9688324

00:00:28.990 --> 00:00:29.869 Great. Thank you so much,
NOTE Confidence: 0.9688324

00:00:29.869 --> 00:00:31.789 doctor Grauer. And, likewise, I,
NOTE Confidence: 0.9688324

00:00:32.110 --> 00:00:33.790 had a wonderful time speaking
NOTE Confidence: 0.9688324

00:00:33.790 --> 00:00:35.070 with the the other group,
NOTE Confidence: 0.9688324

00:00:35.070 --> 00:00:36.430 so I'm always excited to
NOTE Confidence: 0.9688324

00:00:36.430 --> 00:00:37.629 come back and and talk
NOTE Confidence: 0.9688324

00:00:37.629 --> 00:00:39.070 about the IRB and human
NOTE Confidence: 0.9688324

00:00:39.070 --> 00:00:40.695 subjects research with our faculty
NOTE Confidence: 0.9688324

00:00:40.695 --> 00:00:41.655 as well. So thank you
NOTE Confidence: 0.9688324

00:00:41.655 --> 00:00:42.614 all for having me. I'm
NOTE Confidence: 0.9688324

00:00:42.614 --> 00:00:44.214 excited to be here. My

NOTE Confidence: 0.9688324

00:00:44.214 --> 00:00:45.495 name is Gina Larson. I'm

NOTE Confidence: 0.9688324

00:00:45.495 --> 00:00:46.854 Associate Director for the Human

NOTE Confidence: 0.9688324

00:00:46.854 --> 00:00:48.934 Research Production Program. And today

NOTE Confidence: 0.9688324

00:00:48.934 --> 00:00:49.815 I'm here to give you

NOTE Confidence: 0.9688324

00:00:49.815 --> 00:00:51.414 some general information about the

NOTE Confidence: 0.9688324

00:00:51.414 --> 00:00:53.335 Yale IRB and Human Research

NOTE Confidence: 0.9688324

00:00:53.335 --> 00:00:54.394 Production Program.

NOTE Confidence: 0.97776514

00:00:54.730 --> 00:00:56.190 We're gonna cover some just

NOTE Confidence: 0.97776514

00:00:56.489 --> 00:00:58.090 general information you should know

NOTE Confidence: 0.97776514

00:00:58.090 --> 00:00:59.370 when you're starting to engage

NOTE Confidence: 0.97776514

00:00:59.370 --> 00:01:00.809 with the IRB. We're also

NOTE Confidence: 0.97776514

00:01:00.809 --> 00:01:01.850 going to talk about what

NOTE Confidence: 0.97776514

00:01:01.850 --> 00:01:03.790 types of projects would require

NOTE Confidence: 0.97776514

00:01:03.930 --> 00:01:05.530 IRB review and approval and

NOTE Confidence: 0.97776514

00:01:05.530 --> 00:01:06.970 those that might not need

NOTE Confidence: 0.97776514

00:01:06.970 --> 00:01:08.350 IRB review and approval.
NOTE Confidence: 0.9978052

00:01:08.715 --> 00:01:09.615 And then I'll provide you
NOTE Confidence: 0.9978052

00:01:09.755 --> 00:01:10.814 with some tangible
NOTE Confidence: 0.99874747

00:01:11.515 --> 00:01:13.115 information and guidance on how
NOTE Confidence: 0.99874747

00:01:13.115 --> 00:01:14.475 to submit research studies to
NOTE Confidence: 0.99874747

00:01:14.475 --> 00:01:15.454 the Yale IRB.
NOTE Confidence: 0.99729013

00:01:15.834 --> 00:01:17.594 This includes anything from chart
NOTE Confidence: 0.99729013

00:01:17.594 --> 00:01:19.454 reviews to, interventional
NOTE Confidence: 0.98190147

00:01:19.755 --> 00:01:21.354 research, and I'll also give
NOTE Confidence: 0.98190147

00:01:21.354 --> 00:01:22.795 you some tips and tricks
NOTE Confidence: 0.98190147

00:01:22.795 --> 00:01:24.314 for things like requesting HIPAA
NOTE Confidence: 0.98190147

00:01:24.314 --> 00:01:25.410 waivers, which I know will
NOTE Confidence: 0.98190147

00:01:25.410 --> 00:01:26.850 be extremely useful for this
NOTE Confidence: 0.98190147

00:01:26.850 --> 00:01:28.290 group. I have left a
NOTE Confidence: 0.98190147

00:01:28.290 --> 00:01:29.330 good amount of time at
NOTE Confidence: 0.98190147

00:01:29.330 --> 00:01:30.610 the end for questions. So

NOTE Confidence: 0.98190147
00:01:30.610 --> 00:01:31.569 if you could hold your
NOTE Confidence: 0.98190147
00:01:31.569 --> 00:01:32.690 questions to the end, that
NOTE Confidence: 0.98190147
00:01:32.690 --> 00:01:33.510 would be fantastic.
NOTE Confidence: 0.96003085
00:01:33.970 --> 00:01:34.790 And I'll obviously,
NOTE Confidence: 0.98649704
00:01:35.170 --> 00:01:36.690 be excited and willing to
NOTE Confidence: 0.98649704
00:01:36.690 --> 00:01:37.890 answer any questions that you
NOTE Confidence: 0.98649704
00:01:37.890 --> 00:01:39.075 have at that time. Time.
NOTE Confidence: 0.98649704
00:01:39.075 --> 00:01:40.275 You also have access to
NOTE Confidence: 0.98649704
00:01:40.275 --> 00:01:41.395 these slides. There's a lot
NOTE Confidence: 0.98649704
00:01:41.395 --> 00:01:42.675 of great links that are
NOTE Confidence: 0.98649704
00:01:42.675 --> 00:01:44.355 embedded within the slide deck.
NOTE Confidence: 0.98649704
00:01:44.355 --> 00:01:45.315 So I encourage you to
NOTE Confidence: 0.98649704
00:01:45.315 --> 00:01:46.194 go back and look at
NOTE Confidence: 0.98649704
00:01:46.194 --> 00:01:46.935 these slides
NOTE Confidence: 0.99725765
00:01:47.315 --> 00:01:49.155 at your convenience after we
NOTE Confidence: 0.99725765

00:01:49.155 --> 00:01:50.215 we have this workshop.
NOTE Confidence: 0.9949737

00:01:50.595 --> 00:01:51.475 With all of that out
NOTE Confidence: 0.9949737

00:01:51.475 --> 00:01:52.275 of the way, all of
NOTE Confidence: 0.9949737

00:01:52.275 --> 00:01:52.935 that housekeeping,
NOTE Confidence: 0.9994413

00:01:53.235 --> 00:01:54.570 let's get started.
NOTE Confidence: 0.9624789

00:01:55.670 --> 00:01:56.869 So first, let's talk about
NOTE Confidence: 0.9624789

00:01:56.869 --> 00:01:58.070 what is the Yale Human
NOTE Confidence: 0.9624789

00:01:58.070 --> 00:01:59.909 Research Protection Program and what
NOTE Confidence: 0.9624789

00:01:59.909 --> 00:02:01.350 is an institutional review board,
NOTE Confidence: 0.9624789

00:02:01.350 --> 00:02:02.149 which I'm sure many of
NOTE Confidence: 0.9624789

00:02:02.149 --> 00:02:03.189 you are familiar with, but
NOTE Confidence: 0.9624789

00:02:03.189 --> 00:02:04.490 we'll go over the basics.
NOTE Confidence: 0.98112065

00:02:04.950 --> 00:02:06.345 So the Yale Human Research
NOTE Confidence: 0.98112065

00:02:06.505 --> 00:02:08.764 Protection Program supports Yale University's
NOTE Confidence: 0.98112065

00:02:08.985 --> 00:02:10.205 dedication to excellence
NOTE Confidence: 0.98958325

00:02:10.585 --> 00:02:11.705 by promoting the rights and

NOTE Confidence: 0.98958325

00:02:11.705 --> 00:02:13.325 welfare of people who participate

NOTE Confidence: 0.98958325

00:02:13.385 --> 00:02:15.465 in research that's conducted at

NOTE Confidence: 0.98958325

00:02:15.465 --> 00:02:15.965 Yale,

NOTE Confidence: 0.97776544

00:02:16.425 --> 00:02:18.585 or by Yale faculty, students,

NOTE Confidence: 0.97776544

00:02:18.585 --> 00:02:20.525 staff, or any Yale affiliates.

NOTE Confidence: 0.97771806

00:02:21.490 --> 00:02:22.870 We are an AARP accredited

NOTE Confidence: 0.97771806

00:02:23.010 --> 00:02:24.370 institution. I'm sure many of

NOTE Confidence: 0.97771806

00:02:24.370 --> 00:02:25.490 you have maybe come from

NOTE Confidence: 0.97771806

00:02:25.490 --> 00:02:27.889 other AARP accredited institutions. That's

NOTE Confidence: 0.97771806

00:02:27.889 --> 00:02:29.830 pretty much the gold standard,

NOTE Confidence: 0.9797746

00:02:30.450 --> 00:02:31.410 when it comes to human

NOTE Confidence: 0.9797746

00:02:31.410 --> 00:02:33.730 research production programs, ensuring that

NOTE Confidence: 0.9797746

00:02:33.730 --> 00:02:34.930 we go above and beyond

NOTE Confidence: 0.9797746

00:02:34.930 --> 00:02:35.990 the federal regulations

NOTE Confidence: 0.9296804

00:02:36.290 --> 00:02:37.215 to make sure that people

NOTE Confidence: 0.9296804

00:02:37.215 --> 00:02:38.675 people are protected in research,

NOTE Confidence: 0.9296804

00:02:38.894 --> 00:02:40.415 and our researchers are also

NOTE Confidence: 0.9296804

00:02:40.415 --> 00:02:41.855 going above and beyond. So

NOTE Confidence: 0.9296804

00:02:41.855 --> 00:02:42.974 we're really proud of that

NOTE Confidence: 0.9296804

00:02:42.974 --> 00:02:43.474 designation,

NOTE Confidence: 0.98519534

00:02:43.855 --> 00:02:45.155 and we do get reaccredited

NOTE Confidence: 0.8974538

00:02:45.455 --> 00:02:47.635 by aHARP every five years.

NOTE Confidence: 0.9587084

00:02:48.974 --> 00:02:50.095 So obviously, there's a lot

NOTE Confidence: 0.9587084

00:02:50.095 --> 00:02:51.215 of people that are working

NOTE Confidence: 0.9587084

00:02:51.215 --> 00:02:52.560 together to ensure that people

NOTE Confidence: 0.9587084

00:02:52.560 --> 00:02:54.000 are protected in research all

NOTE Confidence: 0.9587084

00:02:54.000 --> 00:02:55.920 across Yale, and that includes

NOTE Confidence: 0.9587084

00:02:55.920 --> 00:02:57.460 our researchers, our study

NOTE Confidence: 0.9088027

00:02:57.920 --> 00:02:59.300 coordinators, our PIs,

NOTE Confidence: 0.9390936

00:02:59.760 --> 00:03:00.500 our HRPP,

NOTE Confidence: 0.96426666

00:03:01.280 --> 00:03:02.240 and all of our other

NOTE Confidence: 0.96426666

00:03:02.240 --> 00:03:03.760 departments that we work with,

NOTE Confidence: 0.96426666

00:03:04.080 --> 00:03:05.520 within the context of of

NOTE Confidence: 0.96426666

00:03:05.520 --> 00:03:06.020 Yale.

NOTE Confidence: 0.9823852

00:03:06.415 --> 00:03:07.935 However, the biggest component of

NOTE Confidence: 0.9823852

00:03:07.935 --> 00:03:09.535 a human research production program,

NOTE Confidence: 0.9823852

00:03:09.535 --> 00:03:10.655 whether it's here at Yale

NOTE Confidence: 0.9823852

00:03:10.655 --> 00:03:12.435 or anywhere, is an institutional

NOTE Confidence: 0.9823852

00:03:12.655 --> 00:03:14.095 review board, also known as

NOTE Confidence: 0.9823852

00:03:14.095 --> 00:03:15.135 an IRB, and I'm sure

NOTE Confidence: 0.9823852

00:03:15.135 --> 00:03:16.735 that's the acronym you're probably

NOTE Confidence: 0.9823852

00:03:16.735 --> 00:03:18.335 most familiar with when it

NOTE Confidence: 0.9823852

00:03:18.335 --> 00:03:19.935 comes to human research studies

NOTE Confidence: 0.9823852

00:03:19.935 --> 00:03:21.294 and submitting those studies to

NOTE Confidence: 0.9823852

00:03:21.294 --> 00:03:22.230 an ethics board.

NOTE Confidence: 0.98396397

00:03:23.030 --> 00:03:24.870 IRBs ensure that research involving

NOTE Confidence: 0.98396397

00:03:24.870 --> 00:03:26.709 humans is conducted following the
NOTE Confidence: 0.98396397

00:03:26.709 --> 00:03:28.310 ethical principles outlined in the
NOTE Confidence: 0.98396397

00:03:28.310 --> 00:03:29.750 Belmont Report, which we'll talk
NOTE Confidence: 0.98396397

00:03:29.750 --> 00:03:31.590 about very briefly next, and
NOTE Confidence: 0.98396397

00:03:31.590 --> 00:03:33.129 all of those applicable laws,
NOTE Confidence: 0.98396397

00:03:33.190 --> 00:03:35.530 regulations, and human research standards.
NOTE Confidence: 0.9574478

00:03:35.965 --> 00:03:37.084 This includes all of our
NOTE Confidence: 0.9574478

00:03:37.084 --> 00:03:38.204 Department of Health and Human
NOTE Confidence: 0.9574478

00:03:38.204 --> 00:03:39.105 Service regulations,
NOTE Confidence: 0.99423885

00:03:39.805 --> 00:03:41.105 our FDA regulations,
NOTE Confidence: 0.96677923

00:03:41.644 --> 00:03:43.584 federal, state, and local regulations.
NOTE Confidence: 0.96761084

00:03:44.364 --> 00:03:46.045 So sometimes when you submit
NOTE Confidence: 0.96761084

00:03:46.045 --> 00:03:47.564 your applications to the IRB,
NOTE Confidence: 0.96761084

00:03:47.564 --> 00:03:48.284 you might think, you know,
NOTE Confidence: 0.96761084

00:03:48.284 --> 00:03:49.245 they're asking a lot of
NOTE Confidence: 0.96761084

00:03:49.245 --> 00:03:50.970 questions, and they're making me

NOTE Confidence: 0.96761084
00:03:50.970 --> 00:03:52.250 change this and they're asking
NOTE Confidence: 0.96761084
00:03:52.250 --> 00:03:53.530 me to clarify this point.
NOTE Confidence: 0.96761084
00:03:53.530 --> 00:03:55.050 I promise it's not because
NOTE Confidence: 0.96761084
00:03:55.050 --> 00:03:56.330 we're being mean or we're
NOTE Confidence: 0.96761084
00:03:56.330 --> 00:03:57.790 being nitpicky or anything.
NOTE Confidence: 0.99895936
00:03:58.090 --> 00:03:59.610 It truly is because we
NOTE Confidence: 0.99895936
00:03:59.610 --> 00:04:00.810 have to ensure that you
NOTE Confidence: 0.99895936
00:04:00.810 --> 00:04:02.330 are following all of these
NOTE Confidence: 0.99895936
00:04:02.330 --> 00:04:03.230 different regulations
NOTE Confidence: 0.9735746
00:04:03.835 --> 00:04:05.195 so that people are protected,
NOTE Confidence: 0.9735746
00:04:05.195 --> 00:04:06.555 but also you are protected
NOTE Confidence: 0.9735746
00:04:06.555 --> 00:04:08.175 as a researcher as well.
NOTE Confidence: 0.9732253
00:04:08.635 --> 00:04:10.635 IRBs also ensure compliance with
NOTE Confidence: 0.9732253
00:04:10.635 --> 00:04:12.795 university policies. We monitor for
NOTE Confidence: 0.9732253
00:04:12.795 --> 00:04:14.155 risk and safety concerns in
NOTE Confidence: 0.9732253

00:04:14.155 --> 00:04:15.995 human subjects research, and we
NOTE Confidence: 0.9732253

00:04:15.995 --> 00:04:17.759 consider the local context, so
NOTE Confidence: 0.9732253

00:04:17.759 --> 00:04:18.500 the interpretations,
NOTE Confidence: 0.98898333

00:04:19.039 --> 00:04:20.099 standards of practice,
NOTE Confidence: 0.9982014

00:04:20.400 --> 00:04:21.699 and community considerations
NOTE Confidence: 0.9948575

00:04:22.080 --> 00:04:23.919 of human subjects research. How
NOTE Confidence: 0.9948575

00:04:23.919 --> 00:04:25.199 is the community that you're
NOTE Confidence: 0.9948575

00:04:25.199 --> 00:04:26.240 working with going to be
NOTE Confidence: 0.9948575

00:04:26.240 --> 00:04:27.839 impacted by this research? We're
NOTE Confidence: 0.9948575

00:04:27.839 --> 00:04:28.960 considering all of that as
NOTE Confidence: 0.9948575

00:04:28.960 --> 00:04:29.460 well.
NOTE Confidence: 0.99539804

00:04:30.824 --> 00:04:31.324 Unfortunately,
NOTE Confidence: 0.9926929

00:04:31.785 --> 00:04:32.985 as you all probably know,
NOTE Confidence: 0.9926929

00:04:32.985 --> 00:04:34.345 the birth of the IRB
NOTE Confidence: 0.9926929

00:04:34.345 --> 00:04:34.845 resulted,
NOTE Confidence: 0.99956596

00:04:35.464 --> 00:04:37.164 from a history of unjustifiable

NOTE Confidence: 0.99364036

00:04:37.625 --> 00:04:40.044 crimes against humanity and unethical

NOTE Confidence: 0.99364036

00:04:40.185 --> 00:04:40.685 practices

NOTE Confidence: 0.9980226

00:04:41.224 --> 00:04:42.345 in the name of science

NOTE Confidence: 0.9980226

00:04:42.345 --> 00:04:43.085 and research.

NOTE Confidence: 0.92616206

00:04:44.089 --> 00:04:45.529 I do, this session I

NOTE Confidence: 0.92616206

00:04:45.529 --> 00:04:46.730 I go into depth about

NOTE Confidence: 0.92616206

00:04:46.730 --> 00:04:47.610 some of these things that

NOTE Confidence: 0.92616206

00:04:47.610 --> 00:04:49.050 we've seen. Obviously, you all

NOTE Confidence: 0.92616206

00:04:49.050 --> 00:04:50.650 know of the Tuskegee syphilis

NOTE Confidence: 0.92616206

00:04:50.650 --> 00:04:51.150 study,

NOTE Confidence: 0.9775522

00:04:51.450 --> 00:04:52.970 obviously, the atrocities that happened

NOTE Confidence: 0.9775522

00:04:52.970 --> 00:04:54.430 in concentration camps,

NOTE Confidence: 0.8742645

00:04:54.810 --> 00:04:56.190 during World War two,

NOTE Confidence: 0.9216337

00:04:56.505 --> 00:04:56.945 and,

NOTE Confidence: 0.9912252

00:04:57.385 --> 00:04:58.425 many other things that you

NOTE Confidence: 0.9912252

00:04:58.425 --> 00:04:59.545 see on your screen here.
NOTE Confidence: 0.9912252

00:04:59.545 --> 00:05:00.585 So because of all of
NOTE Confidence: 0.9912252

00:05:00.585 --> 00:05:01.405 these atrocities,
NOTE Confidence: 0.97072446

00:05:01.945 --> 00:05:02.825 we knew we had to
NOTE Confidence: 0.97072446

00:05:02.825 --> 00:05:04.265 put ethics boards in place,
NOTE Confidence: 0.97072446

00:05:04.265 --> 00:05:05.145 and we had to have
NOTE Confidence: 0.97072446

00:05:05.145 --> 00:05:07.405 laws and guidelines and regulations
NOTE Confidence: 0.9974911

00:05:07.865 --> 00:05:09.145 to ensure that people are
NOTE Confidence: 0.9974911

00:05:09.145 --> 00:05:09.645 protected
NOTE Confidence: 0.999184

00:05:10.025 --> 00:05:11.405 in the research endeavor.
NOTE Confidence: 0.99962306

00:05:12.589 --> 00:05:13.730 One of the biggest
NOTE Confidence: 0.98020124

00:05:14.110 --> 00:05:15.710 ethical documents that came out
NOTE Confidence: 0.98020124

00:05:15.710 --> 00:05:16.990 of these atrocities was the
NOTE Confidence: 0.98020124

00:05:16.990 --> 00:05:18.589 creation of the Belmont Report
NOTE Confidence: 0.98020124

00:05:18.589 --> 00:05:20.350 in April of nineteen seventy
NOTE Confidence: 0.98020124

00:05:20.350 --> 00:05:21.950 nine. This is still to

NOTE Confidence: 0.98020124

00:05:21.950 --> 00:05:23.010 this day the cornerstone

NOTE Confidence: 0.99101454

00:05:23.710 --> 00:05:25.470 document and statement of ethical

NOTE Confidence: 0.99101454

00:05:25.470 --> 00:05:27.230 principles that guide human subjects

NOTE Confidence: 0.99101454

00:05:27.230 --> 00:05:27.730 research.

NOTE Confidence: 0.9716804

00:05:28.085 --> 00:05:29.045 If you haven't read the

NOTE Confidence: 0.9716804

00:05:29.045 --> 00:05:31.365 Belmont Report, I definitely recommend

NOTE Confidence: 0.9716804

00:05:31.365 --> 00:05:32.325 that you do so. It's

NOTE Confidence: 0.9716804

00:05:32.325 --> 00:05:33.765 only ten pages long and

NOTE Confidence: 0.9716804

00:05:33.765 --> 00:05:35.605 the writing actually still holds

NOTE Confidence: 0.9716804

00:05:35.605 --> 00:05:37.365 up to today's language. And

NOTE Confidence: 0.9716804

00:05:37.365 --> 00:05:38.725 we actually have really close

NOTE Confidence: 0.9716804

00:05:38.725 --> 00:05:39.845 ties here at Yale to

NOTE Confidence: 0.9716804

00:05:39.845 --> 00:05:41.285 the Belmont Report because one

NOTE Confidence: 0.9716804

00:05:41.285 --> 00:05:42.950 of our faculty members was

NOTE Confidence: 0.9716804

00:05:42.950 --> 00:05:44.310 one of the authors of

NOTE Confidence: 0.9716804

00:05:44.310 --> 00:05:46.310 the Belmont Report. So definitely
NOTE Confidence: 0.9716804

00:05:46.310 --> 00:05:47.430 something that you should check
NOTE Confidence: 0.9716804

00:05:47.430 --> 00:05:48.310 out if you haven't done
NOTE Confidence: 0.9716804

00:05:48.310 --> 00:05:49.050 so already.
NOTE Confidence: 0.9907726

00:05:49.430 --> 00:05:50.710 And there's three pillars of
NOTE Confidence: 0.9907726

00:05:50.710 --> 00:05:52.710 the Belmont Report. So when
NOTE Confidence: 0.9907726

00:05:52.710 --> 00:05:54.470 IRBs are reviewing research, we
NOTE Confidence: 0.9907726

00:05:54.470 --> 00:05:55.589 have to ensure that each
NOTE Confidence: 0.9907726

00:05:55.589 --> 00:05:57.195 of these pillars is being
NOTE Confidence: 0.9907726

00:05:57.195 --> 00:05:58.154 met in order for a
NOTE Confidence: 0.9907726

00:05:58.154 --> 00:05:59.294 study to be approved.
NOTE Confidence: 0.9798825

00:05:59.915 --> 00:06:01.354 The first pillar is respect
NOTE Confidence: 0.9798825

00:06:01.354 --> 00:06:03.275 for persons, so treating people
NOTE Confidence: 0.9798825

00:06:03.275 --> 00:06:05.354 as autonomous agents, ensuring that
NOTE Confidence: 0.9798825

00:06:05.354 --> 00:06:07.035 people have a decision about
NOTE Confidence: 0.9798825

00:06:07.035 --> 00:06:08.315 if they want to participate

NOTE Confidence: 0.9798825

00:06:08.315 --> 00:06:09.514 in research or not, and

NOTE Confidence: 0.9798825

00:06:09.514 --> 00:06:11.135 they're not being forced or

NOTE Confidence: 0.9974654

00:06:11.490 --> 00:06:12.710 coerced in any way.

NOTE Confidence: 0.97123176

00:06:13.089 --> 00:06:14.710 The second pillar is beneficence.

NOTE Confidence: 0.985946

00:06:15.010 --> 00:06:15.990 So you're maximizing

NOTE Confidence: 0.9791593

00:06:16.290 --> 00:06:17.810 benefits of research as much

NOTE Confidence: 0.9791593

00:06:17.810 --> 00:06:20.070 as possible while minimizing harms.

NOTE Confidence: 0.9791593

00:06:20.290 --> 00:06:21.490 And then the third pillar

NOTE Confidence: 0.9791593

00:06:21.490 --> 00:06:22.230 is justice.

NOTE Confidence: 0.98825765

00:06:22.690 --> 00:06:24.850 So you're selecting participants in

NOTE Confidence: 0.98825765

00:06:24.850 --> 00:06:26.875 an equitable manner. You're not

NOTE Confidence: 0.98825765

00:06:26.875 --> 00:06:28.895 maybe targeting a very vulnerable

NOTE Confidence: 0.98825765

00:06:29.194 --> 00:06:31.034 group or vulnerable population that

NOTE Confidence: 0.98825765

00:06:31.034 --> 00:06:32.154 they're going to see receive

NOTE Confidence: 0.98825765

00:06:32.154 --> 00:06:33.514 all of the negative effects

NOTE Confidence: 0.98825765

00:06:33.514 --> 00:06:34.875 of research, but at the
NOTE Confidence: 0.98825765

00:06:34.875 --> 00:06:36.395 same time, you're not only
NOTE Confidence: 0.98825765

00:06:36.395 --> 00:06:38.395 offering really great treatments and
NOTE Confidence: 0.98825765

00:06:38.395 --> 00:06:40.210 research to individuals who have
NOTE Confidence: 0.98825765

00:06:40.210 --> 00:06:41.330 the means to be able
NOTE Confidence: 0.98825765

00:06:41.330 --> 00:06:43.010 to travel and access these
NOTE Confidence: 0.98825765

00:06:43.010 --> 00:06:43.990 clinical trials.
NOTE Confidence: 0.9818599

00:06:44.370 --> 00:06:45.350 So you're you're
NOTE Confidence: 0.9976944

00:06:45.730 --> 00:06:47.669 spreading out the the burdens,
NOTE Confidence: 0.97812873

00:06:48.370 --> 00:06:49.810 and also the benefits of
NOTE Confidence: 0.97812873

00:06:49.810 --> 00:06:50.310 research,
NOTE Confidence: 0.9956059

00:06:50.690 --> 00:06:52.710 equally amongst your populations.
NOTE Confidence: 0.9830559

00:06:54.694 --> 00:06:56.294 Let's go into some federal
NOTE Confidence: 0.9830559

00:06:56.294 --> 00:06:56.794 regulations,
NOTE Confidence: 0.98060894

00:06:57.335 --> 00:06:58.694 really quickly because these are
NOTE Confidence: 0.98060894

00:06:58.694 --> 00:06:59.574 some of the things that

NOTE Confidence: 0.98060894

00:06:59.574 --> 00:07:01.254 you will likely encounter when

NOTE Confidence: 0.98060894

00:07:01.254 --> 00:07:02.854 you're submitting your research studies

NOTE Confidence: 0.98060894

00:07:02.854 --> 00:07:03.654 and some of the things

NOTE Confidence: 0.98060894

00:07:03.654 --> 00:07:04.615 that you should be aware

NOTE Confidence: 0.98060894

00:07:04.615 --> 00:07:05.895 of. You don't have to

NOTE Confidence: 0.98060894

00:07:05.895 --> 00:07:07.360 be experts in the federal

NOTE Confidence: 0.98060894

00:07:07.419 --> 00:07:09.180 regulations. That's why we're here.

NOTE Confidence: 0.98060894

00:07:09.180 --> 00:07:10.139 We will help you through

NOTE Confidence: 0.98060894

00:07:10.139 --> 00:07:11.180 them, but it's good to

NOTE Confidence: 0.98060894

00:07:11.180 --> 00:07:12.539 know where your research may

NOTE Confidence: 0.98060894

00:07:12.539 --> 00:07:13.979 or may not fall depending

NOTE Confidence: 0.98060894

00:07:13.979 --> 00:07:15.199 on your funding source

NOTE Confidence: 0.9056316

00:07:15.500 --> 00:07:16.379 so that you know if

NOTE Confidence: 0.9056316

00:07:16.379 --> 00:07:18.460 there's, certain reporting requirements or

NOTE Confidence: 0.9056316

00:07:18.460 --> 00:07:19.740 something down the road and

NOTE Confidence: 0.9056316

00:07:19.740 --> 00:07:20.720 if something happens.
NOTE Confidence: 0.94958955

00:07:21.194 --> 00:07:22.574 So first, we have the
NOTE Confidence: 0.94958955

00:07:22.634 --> 00:07:23.854 HHS regulations.
NOTE Confidence: 0.9754924

00:07:24.634 --> 00:07:26.155 This is more commonly referred
NOTE Confidence: 0.9754924

00:07:26.155 --> 00:07:27.775 to as the common rule.
NOTE Confidence: 0.9754924

00:07:28.074 --> 00:07:29.435 This was created in nineteen
NOTE Confidence: 0.9754924

00:07:29.435 --> 00:07:30.715 ninety one. We actually had
NOTE Confidence: 0.9754924

00:07:30.715 --> 00:07:31.914 a revision to the common
NOTE Confidence: 0.9754924

00:07:31.914 --> 00:07:33.514 rule in twenty seventeen that
NOTE Confidence: 0.9754924

00:07:33.514 --> 00:07:35.294 became effective in twenty eighteen.
NOTE Confidence: 0.9754924

00:07:35.514 --> 00:07:36.395 So you might have seen
NOTE Confidence: 0.9754924

00:07:36.395 --> 00:07:37.410 there were some changes to
NOTE Confidence: 0.9754924

00:07:37.410 --> 00:07:39.729 like exempt research categories and
NOTE Confidence: 0.9754924

00:07:39.729 --> 00:07:41.650 some restructuring of the consent
NOTE Confidence: 0.9754924

00:07:41.650 --> 00:07:42.770 form that needed to happen
NOTE Confidence: 0.9754924

00:07:42.770 --> 00:07:44.229 with that new key information

NOTE Confidence: 0.9754924

00:07:44.289 --> 00:07:45.650 section. These are some of

NOTE Confidence: 0.9754924

00:07:45.650 --> 00:07:46.770 the things that changed with

NOTE Confidence: 0.9754924

00:07:46.770 --> 00:07:47.970 that revision to the common

NOTE Confidence: 0.9754924

00:07:47.970 --> 00:07:49.570 rule. But these are essentially,

NOTE Confidence: 0.9754924

00:07:49.570 --> 00:07:50.370 you know, this is the

NOTE Confidence: 0.9754924

00:07:50.370 --> 00:07:51.990 basic HHS policy.

NOTE Confidence: 0.9676115

00:07:52.595 --> 00:07:53.875 This provides us with all

NOTE Confidence: 0.9676115

00:07:53.875 --> 00:07:55.155 of the information we need

NOTE Confidence: 0.9676115

00:07:55.155 --> 00:07:56.995 to understand with regards to

NOTE Confidence: 0.9676115

00:07:56.995 --> 00:07:58.435 what is required for informed

NOTE Confidence: 0.9676115

00:07:58.435 --> 00:07:58.935 consent,

NOTE Confidence: 0.96959907

00:07:59.475 --> 00:08:00.595 how are you going to

NOTE Confidence: 0.96959907

00:08:00.595 --> 00:08:03.315 handle enrolling vulnerable populations in

NOTE Confidence: 0.96959907

00:08:03.315 --> 00:08:05.074 research. So the regulations say

NOTE Confidence: 0.96959907

00:08:05.074 --> 00:08:07.650 that pregnant women, fetuses, neonates,

NOTE Confidence: 0.96959907

00:08:07.789 --> 00:08:09.889 prisoners, and children are vulnerable

NOTE Confidence: 0.96959907

00:08:09.949 --> 00:08:11.389 per the regulations. Again, we

NOTE Confidence: 0.96959907

00:08:11.389 --> 00:08:12.910 know there's much more vulnerable

NOTE Confidence: 0.96959907

00:08:12.910 --> 00:08:14.830 populations than that, but those

NOTE Confidence: 0.96959907

00:08:14.830 --> 00:08:15.870 are the ones that are

NOTE Confidence: 0.96959907

00:08:15.870 --> 00:08:17.569 carved out in the regulations.

NOTE Confidence: 0.99579656

00:08:18.485 --> 00:08:20.025 So if you have any

NOTE Confidence: 0.9964136

00:08:20.485 --> 00:08:22.185 research that's funded by NIH,

NOTE Confidence: 0.99033946

00:08:22.725 --> 00:08:23.225 NSF,

NOTE Confidence: 0.9829965

00:08:24.005 --> 00:08:24.885 any of those, I think

NOTE Confidence: 0.9829965

00:08:24.885 --> 00:08:26.245 there's over, you know, thirty

NOTE Confidence: 0.9829965

00:08:26.245 --> 00:08:27.925 to forty departments that are

NOTE Confidence: 0.9829965

00:08:27.925 --> 00:08:29.605 regulated by HHS. If you're

NOTE Confidence: 0.9829965

00:08:29.605 --> 00:08:30.985 funded by any of those,

NOTE Confidence: 0.9829965

00:08:31.129 --> 00:08:32.250 you are subject to these

NOTE Confidence: 0.9829965

00:08:32.250 --> 00:08:32.750 regulations.

NOTE Confidence: 0.9824953
00:08:33.130 --> 00:08:34.410 However, even if you are
NOTE Confidence: 0.9824953
00:08:34.410 --> 00:08:34.910 unfunded,
NOTE Confidence: 0.94969016
00:08:35.450 --> 00:08:36.330 we do, like I said
NOTE Confidence: 0.94969016
00:08:36.330 --> 00:08:37.929 before, going by those ARP
NOTE Confidence: 0.94969016
00:08:37.929 --> 00:08:39.290 standards, we go above and
NOTE Confidence: 0.94969016
00:08:39.290 --> 00:08:40.970 beyond the regulations. So we
NOTE Confidence: 0.94969016
00:08:40.970 --> 00:08:42.429 do apply these regulations
NOTE Confidence: 0.9990065
00:08:43.145 --> 00:08:44.665 even to unfunded research as
NOTE Confidence: 0.9990065
00:08:44.665 --> 00:08:45.865 well. The only thing that
NOTE Confidence: 0.9990065
00:08:45.865 --> 00:08:46.845 we don't apply
NOTE Confidence: 0.98495513
00:08:47.465 --> 00:08:49.785 equally is if there's something
NOTE Confidence: 0.98495513
00:08:49.785 --> 00:08:50.525 like a,
NOTE Confidence: 0.9617661
00:08:51.304 --> 00:08:52.285 serious noncompliance
NOTE Confidence: 0.9920812
00:08:52.585 --> 00:08:53.405 or an unanticipated
NOTE Confidence: 0.97328234
00:08:53.785 --> 00:08:55.304 problem, we don't report that
NOTE Confidence: 0.97328234

00:08:55.304 --> 00:08:56.710 to HHS if it's not
NOTE Confidence: 0.97328234

00:08:56.710 --> 00:08:58.730 funded, but everything else remains
NOTE Confidence: 0.97328234

00:08:58.790 --> 00:08:59.450 the same.
NOTE Confidence: 0.97664475

00:09:00.390 --> 00:09:01.990 In addition to HHS, we
NOTE Confidence: 0.97664475

00:09:01.990 --> 00:09:03.370 have our FDA regulations.
NOTE Confidence: 0.9908037

00:09:03.910 --> 00:09:04.710 So if you're going to
NOTE Confidence: 0.9908037

00:09:04.710 --> 00:09:05.910 be working with a drug
NOTE Confidence: 0.9908037

00:09:05.910 --> 00:09:06.730 or a device,
NOTE Confidence: 0.9716509

00:09:07.270 --> 00:09:08.790 these are the regulations that
NOTE Confidence: 0.9716509

00:09:08.790 --> 00:09:09.990 pertain to you and your
NOTE Confidence: 0.9716509

00:09:09.990 --> 00:09:10.890 research studies.
NOTE Confidence: 0.97185314

00:09:11.325 --> 00:09:12.845 Thankfully, a lot of the
NOTE Confidence: 0.97185314

00:09:12.845 --> 00:09:14.445 basic policy is the same
NOTE Confidence: 0.97185314

00:09:14.445 --> 00:09:15.565 as the Department of Health
NOTE Confidence: 0.97185314

00:09:15.565 --> 00:09:16.465 and Human Services,
NOTE Confidence: 0.94388765

00:09:16.925 --> 00:09:18.525 but there are obviously other

NOTE Confidence: 0.94388765

00:09:18.525 --> 00:09:20.365 types of subparts with FDA

NOTE Confidence: 0.94388765

00:09:20.365 --> 00:09:21.965 regulated research just because of

NOTE Confidence: 0.94388765

00:09:21.965 --> 00:09:23.405 the nature of the research.

NOTE Confidence: 0.94388765

00:09:23.405 --> 00:09:24.720 Right? So we have part

NOTE Confidence: 0.94388765

00:09:24.720 --> 00:09:26.959 eleven compliance, you've probably heard

NOTE Confidence: 0.94388765

00:09:26.959 --> 00:09:29.360 of. Those are requirements for

NOTE Confidence: 0.94388765

00:09:29.360 --> 00:09:30.500 electronic signatures.

NOTE Confidence: 0.9509298

00:09:31.120 --> 00:09:32.399 And then obviously, we have

NOTE Confidence: 0.9509298

00:09:32.399 --> 00:09:34.580 various subparts for working with

NOTE Confidence: 0.9509298

00:09:34.640 --> 00:09:35.140 INDs,

NOTE Confidence: 0.9977316

00:09:35.920 --> 00:09:36.420 biological

NOTE Confidence: 0.9967778

00:09:36.765 --> 00:09:37.265 products,

NOTE Confidence: 0.942219

00:09:37.725 --> 00:09:38.225 devices.

NOTE Confidence: 0.9766156

00:09:38.605 --> 00:09:39.605 So again, you don't have

NOTE Confidence: 0.9766156

00:09:39.605 --> 00:09:40.845 to be experts in all

NOTE Confidence: 0.9766156

00:09:40.845 --> 00:09:41.505 of these
NOTE Confidence: 0.97223455

00:09:42.285 --> 00:09:43.965 rules and and regulations, but
NOTE Confidence: 0.97223455

00:09:43.965 --> 00:09:45.645 certainly know that they may
NOTE Confidence: 0.97223455

00:09:45.645 --> 00:09:46.845 apply to your research. And
NOTE Confidence: 0.97223455

00:09:46.845 --> 00:09:48.205 it's important to be just
NOTE Confidence: 0.97223455

00:09:48.205 --> 00:09:49.920 familiar with the general structure
NOTE Confidence: 0.97223455

00:09:49.920 --> 00:09:51.520 of what we are abiding
NOTE Confidence: 0.97223455

00:09:51.520 --> 00:09:52.720 by when we're reviewing your
NOTE Confidence: 0.97223455

00:09:52.720 --> 00:09:53.620 research studies.
NOTE Confidence: 0.99537486

00:09:54.960 --> 00:09:55.920 So now that we've given
NOTE Confidence: 0.99537486

00:09:55.920 --> 00:09:56.820 you an overview
NOTE Confidence: 0.9811834

00:09:57.280 --> 00:10:00.020 of the landscape of IRBs,
NOTE Confidence: 0.9811834

00:10:00.240 --> 00:10:01.679 let's talk about what is
NOTE Confidence: 0.9811834

00:10:01.679 --> 00:10:03.120 and what is not human
NOTE Confidence: 0.9811834

00:10:03.120 --> 00:10:04.755 subjects research. Again, that that
NOTE Confidence: 0.9811834

00:10:04.755 --> 00:10:06.035 may or may not require

NOTE Confidence: 0.9811834

00:10:06.035 --> 00:10:07.575 IRB review and approval.

NOTE Confidence: 0.9914147

00:10:07.955 --> 00:10:09.155 And it's easier to start

NOTE Confidence: 0.9914147

00:10:09.155 --> 00:10:10.434 with what is not human

NOTE Confidence: 0.9914147

00:10:10.434 --> 00:10:11.635 subjects research. We get a

NOTE Confidence: 0.9914147

00:10:11.635 --> 00:10:13.075 lot of questions about various

NOTE Confidence: 0.9914147

00:10:13.075 --> 00:10:14.675 projects. What is something that

NOTE Confidence: 0.9914147

00:10:14.675 --> 00:10:15.875 you wouldn't need to submit

NOTE Confidence: 0.9914147

00:10:15.875 --> 00:10:16.775 to an IRB?

NOTE Confidence: 0.9563331

00:10:17.390 --> 00:10:19.390 One is data on deceased

NOTE Confidence: 0.9563331

00:10:19.390 --> 00:10:19.890 persons.

NOTE Confidence: 0.97567666

00:10:20.510 --> 00:10:21.390 So if you are looking

NOTE Confidence: 0.97567666

00:10:21.390 --> 00:10:23.170 at medical records or information

NOTE Confidence: 0.97567666

00:10:23.230 --> 00:10:24.670 from individuals who have passed

NOTE Confidence: 0.97567666

00:10:24.670 --> 00:10:26.510 away, you actually don't have

NOTE Confidence: 0.97567666

00:10:26.510 --> 00:10:27.550 to submit that to an

NOTE Confidence: 0.97567666

00:10:27.550 --> 00:10:28.910 IRB for review because as
NOTE Confidence: 0.97567666

00:10:28.910 --> 00:10:29.865 you'll see in the next
NOTE Confidence: 0.97567666

00:10:29.865 --> 00:10:30.904 few slides when we get
NOTE Confidence: 0.97567666

00:10:30.904 --> 00:10:32.345 into what is human subjects
NOTE Confidence: 0.97567666

00:10:32.345 --> 00:10:32.845 research,
NOTE Confidence: 0.9976676

00:10:33.145 --> 00:10:35.005 it's only about living individuals.
NOTE Confidence: 0.966187

00:10:35.705 --> 00:10:37.225 However, one caveat here that
NOTE Confidence: 0.966187

00:10:37.225 --> 00:10:38.184 I think is important to
NOTE Confidence: 0.966187

00:10:38.184 --> 00:10:40.365 note is the HIPAA Privacy
NOTE Confidence: 0.966187

00:10:40.425 --> 00:10:41.964 Rule protects the individually
NOTE Confidence: 0.99568444

00:10:42.265 --> 00:10:44.425 identifiable health information about a
NOTE Confidence: 0.99568444

00:10:44.425 --> 00:10:46.480 decedent for fifty years after
NOTE Confidence: 0.99568444

00:10:46.480 --> 00:10:47.220 they pass.
NOTE Confidence: 0.97493106

00:10:47.600 --> 00:10:48.640 So if you are looking
NOTE Confidence: 0.97493106

00:10:48.640 --> 00:10:49.140 at
NOTE Confidence: 0.9597064

00:10:50.000 --> 00:10:51.839 decedent information from somebody or

NOTE Confidence: 0.9597064

00:10:51.839 --> 00:10:52.720 a group that has passed

NOTE Confidence: 0.9597064

00:10:52.720 --> 00:10:53.839 away, you know, five years

NOTE Confidence: 0.9597064

00:10:53.839 --> 00:10:55.679 ago, ten, twenty, even though

NOTE Confidence: 0.9597064

00:10:55.679 --> 00:10:57.220 you don't need IRB approval,

NOTE Confidence: 0.9597064

00:10:57.519 --> 00:10:58.980 you will still need,

NOTE Confidence: 0.9968334

00:10:59.575 --> 00:11:01.495 approval from a HIPAA perspective.

NOTE Confidence: 0.9968334

00:11:01.495 --> 00:11:02.875 So I have linked

NOTE Confidence: 0.98833495

00:11:03.495 --> 00:11:04.795 a form here for you,

NOTE Confidence: 0.98833495

00:11:04.934 --> 00:11:06.214 which is a request for

NOTE Confidence: 0.98833495

00:11:06.214 --> 00:11:08.375 access to PHI for research

NOTE Confidence: 0.98833495

00:11:08.375 --> 00:11:09.834 purposes for decedents.

NOTE Confidence: 0.997094

00:11:10.135 --> 00:11:11.735 So that will be, useful

NOTE Confidence: 0.997094

00:11:11.735 --> 00:11:12.535 for you to have in

NOTE Confidence: 0.997094

00:11:12.535 --> 00:11:13.195 your pocket.

NOTE Confidence: 0.984225

00:11:13.839 --> 00:11:15.040 Also, what is not human

NOTE Confidence: 0.984225

00:11:15.040 --> 00:11:17.360 subjects research is obviously data
NOTE Confidence: 0.984225

00:11:17.360 --> 00:11:19.600 about health facilities, businesses, or
NOTE Confidence: 0.984225

00:11:19.600 --> 00:11:20.100 organizations.
NOTE Confidence: 0.9980972

00:11:20.800 --> 00:11:21.920 So if you're not talking
NOTE Confidence: 0.9980972

00:11:21.920 --> 00:11:23.360 to somebody, you're not collecting
NOTE Confidence: 0.9980972

00:11:23.360 --> 00:11:24.179 their information,
NOTE Confidence: 0.99755514

00:11:24.720 --> 00:11:26.320 that's not human subjects research.
NOTE Confidence: 0.99755514

00:11:26.320 --> 00:11:27.540 If you're looking at processes
NOTE Confidence: 0.99755514

00:11:27.839 --> 00:11:28.660 at an organization
NOTE Confidence: 0.9872904

00:11:29.040 --> 00:11:30.905 or, you know, bus routes
NOTE Confidence: 0.9872904

00:11:30.905 --> 00:11:32.265 and and what that means
NOTE Confidence: 0.9872904

00:11:32.265 --> 00:11:34.265 from an engineering perspective, that's
NOTE Confidence: 0.9872904

00:11:34.265 --> 00:11:35.225 not something that you would
NOTE Confidence: 0.9872904

00:11:35.225 --> 00:11:36.425 interface with a human for
NOTE Confidence: 0.9872904

00:11:36.425 --> 00:11:37.785 and ask them about themselves
NOTE Confidence: 0.9872904

00:11:37.785 --> 00:11:38.684 or their opinions.

NOTE Confidence: 0.9550742

00:11:39.145 --> 00:11:40.265 So, obviously, those types of

NOTE Confidence: 0.9550742

00:11:40.265 --> 00:11:41.640 projects are not human subjects

NOTE Confidence: 0.9550742

00:11:41.880 --> 00:11:43.640 research. And then finally, on

NOTE Confidence: 0.9550742

00:11:43.640 --> 00:11:44.300 this slide,

NOTE Confidence: 0.94302917

00:11:44.760 --> 00:11:45.500 de identified

NOTE Confidence: 0.9975758

00:11:45.880 --> 00:11:47.500 human data or specimens.

NOTE Confidence: 0.9575992

00:11:48.120 --> 00:11:49.960 Now this is very important

NOTE Confidence: 0.9575992

00:11:49.960 --> 00:11:50.920 to note. This does not

NOTE Confidence: 0.9575992

00:11:50.920 --> 00:11:51.880 mean that you are going

NOTE Confidence: 0.9575992

00:11:51.880 --> 00:11:53.160 into the medical record and

NOTE Confidence: 0.9575992

00:11:53.160 --> 00:11:55.195 then de identifying that information

NOTE Confidence: 0.9575992

00:11:55.195 --> 00:11:56.554 yourself and then taking that

NOTE Confidence: 0.9575992

00:11:56.554 --> 00:11:58.075 data set and conducting research

NOTE Confidence: 0.9575992

00:11:58.075 --> 00:11:59.434 with that data set. It

NOTE Confidence: 0.9575992

00:11:59.434 --> 00:12:00.875 truly means that somebody is

NOTE Confidence: 0.9575992

00:12:00.875 --> 00:12:02.895 giving you a completely deidentified
NOTE Confidence: 0.9575992

00:12:03.195 --> 00:12:04.554 data set per the eighteen
NOTE Confidence: 0.9575992

00:12:04.554 --> 00:12:05.455 HIPAA identifiers.
NOTE Confidence: 0.99187213

00:12:05.995 --> 00:12:07.570 In those cases, you would
NOTE Confidence: 0.99187213

00:12:07.570 --> 00:12:08.690 need to submit that type
NOTE Confidence: 0.99187213

00:12:08.690 --> 00:12:10.370 of project to the IRB
NOTE Confidence: 0.99187213

00:12:10.370 --> 00:12:11.029 for review.
NOTE Confidence: 0.98348737

00:12:12.690 --> 00:12:13.889 Also, what is not human
NOTE Confidence: 0.98348737

00:12:13.889 --> 00:12:15.329 subjects research is a case
NOTE Confidence: 0.98348737

00:12:15.329 --> 00:12:17.269 study or a case report.
NOTE Confidence: 0.96968573

00:12:17.730 --> 00:12:19.515 As you're probably familiar with,
NOTE Confidence: 0.96968573

00:12:19.595 --> 00:12:21.195 these are presentations of a
NOTE Confidence: 0.96968573

00:12:21.195 --> 00:12:23.054 detailed critique, so the characteristics,
NOTE Confidence: 0.9831347

00:12:23.515 --> 00:12:24.895 evaluation, or treatment
NOTE Confidence: 0.98070276

00:12:25.275 --> 00:12:26.475 of one or more patients
NOTE Confidence: 0.98070276

00:12:26.475 --> 00:12:27.934 that share a common condition

NOTE Confidence: 0.98070276
00:12:28.235 --> 00:12:29.915 to provide insights into aspects
NOTE Confidence: 0.98070276
00:12:29.915 --> 00:12:31.675 of the clinical case. Let's
NOTE Confidence: 0.98070276
00:12:31.675 --> 00:12:33.054 say you have three individuals
NOTE Confidence: 0.98070276
00:12:33.275 --> 00:12:35.209 that share a very common
NOTE Confidence: 0.98070276
00:12:35.209 --> 00:12:36.829 disorder, and in the clinical
NOTE Confidence: 0.9864079
00:12:37.370 --> 00:12:38.649 sphere, you're seeing that a
NOTE Confidence: 0.9864079
00:12:38.649 --> 00:12:40.009 certain treatment is working really
NOTE Confidence: 0.9864079
00:12:40.009 --> 00:12:40.970 well for them, and you
NOTE Confidence: 0.9864079
00:12:40.970 --> 00:12:42.410 want to publish this and
NOTE Confidence: 0.9864079
00:12:42.410 --> 00:12:43.449 talk about this from a
NOTE Confidence: 0.9864079
00:12:43.449 --> 00:12:44.889 case study perspective to help
NOTE Confidence: 0.9864079
00:12:44.889 --> 00:12:46.029 others in your field
NOTE Confidence: 0.93213654
00:12:46.410 --> 00:12:47.629 understand this case.
NOTE Confidence: 0.99432415
00:12:48.084 --> 00:12:48.964 That would be okay to
NOTE Confidence: 0.99432415
00:12:48.964 --> 00:12:50.165 do without any type of
NOTE Confidence: 0.99432415

00:12:50.165 --> 00:12:51.065 IRB approval.
NOTE Confidence: 0.97842

00:12:51.845 --> 00:12:52.964 The reason is because this
NOTE Confidence: 0.97842

00:12:52.964 --> 00:12:54.325 is really analysis of a
NOTE Confidence: 0.97842

00:12:54.325 --> 00:12:55.625 unique situation,
NOTE Confidence: 0.9487771

00:12:56.084 --> 00:12:57.285 and it does not include
NOTE Confidence: 0.9487771

00:12:57.285 --> 00:12:59.705 any activities defined as research.
NOTE Confidence: 0.98690563

00:13:00.440 --> 00:13:01.980 Again, similar to the decedent
NOTE Confidence: 0.98690563

00:13:02.120 --> 00:13:03.480 information we talked about a
NOTE Confidence: 0.98690563

00:13:03.480 --> 00:13:05.240 couple of slides back, when
NOTE Confidence: 0.98690563

00:13:05.240 --> 00:13:06.700 you're publishing case studies,
NOTE Confidence: 0.99561226

00:13:07.160 --> 00:13:08.279 don't refer to it as
NOTE Confidence: 0.99561226

00:13:08.279 --> 00:13:09.480 research, but you still need
NOTE Confidence: 0.99561226

00:13:09.480 --> 00:13:11.160 to obtain permission from the
NOTE Confidence: 0.99561226

00:13:11.160 --> 00:13:11.660 individual
NOTE Confidence: 0.98273754

00:13:12.120 --> 00:13:14.304 via a non research permission
NOTE Confidence: 0.98273754

00:13:14.304 --> 00:13:15.745 form in order to use

NOTE Confidence: 0.98273754

00:13:15.745 --> 00:13:16.565 their information

NOTE Confidence: 0.9905812

00:13:17.024 --> 00:13:18.304 for that case report or

NOTE Confidence: 0.9905812

00:13:18.304 --> 00:13:19.985 case study. Again, I have

NOTE Confidence: 0.9905812

00:13:19.985 --> 00:13:21.184 linked a form for you

NOTE Confidence: 0.9905812

00:13:21.184 --> 00:13:22.404 here that you can use

NOTE Confidence: 0.9905812

00:13:22.464 --> 00:13:23.745 for those purposes. And if

NOTE Confidence: 0.9905812

00:13:23.745 --> 00:13:24.704 you do have questions on

NOTE Confidence: 0.9905812

00:13:24.704 --> 00:13:25.745 this, feel free to reach

NOTE Confidence: 0.9905812

00:13:25.745 --> 00:13:26.945 out to me directly. I'd

NOTE Confidence: 0.9905812

00:13:26.945 --> 00:13:27.745 be happy to talk with

NOTE Confidence: 0.9905812

00:13:27.745 --> 00:13:29.264 you about any case studies

NOTE Confidence: 0.9905812

00:13:29.264 --> 00:13:30.280 or case reports you might

NOTE Confidence: 0.9905812

00:13:30.280 --> 00:13:31.900 be interested in in publishing.

NOTE Confidence: 0.9933585

00:13:33.559 --> 00:13:34.760 What is also not human

NOTE Confidence: 0.9933585

00:13:34.760 --> 00:13:36.300 subjects research is activities

NOTE Confidence: 0.9708857

00:13:36.679 --> 00:13:37.820 prepped to research.
NOTE Confidence: 0.9955693

00:13:38.280 --> 00:13:39.400 So let's say you're looking
NOTE Confidence: 0.9955693

00:13:39.400 --> 00:13:41.000 at medical records or other
NOTE Confidence: 0.9955693

00:13:41.000 --> 00:13:41.500 sources
NOTE Confidence: 0.9951601

00:13:41.955 --> 00:13:43.235 to determine whether there is
NOTE Confidence: 0.9951601

00:13:43.235 --> 00:13:45.235 a sufficient population to conduct
NOTE Confidence: 0.9951601

00:13:45.235 --> 00:13:46.434 the research that you want
NOTE Confidence: 0.9951601

00:13:46.434 --> 00:13:47.895 with meaningful results.
NOTE Confidence: 0.97103524

00:13:48.275 --> 00:13:48.995 You can look at the
NOTE Confidence: 0.97103524

00:13:48.995 --> 00:13:50.595 medical records. You can look
NOTE Confidence: 0.97103524

00:13:50.595 --> 00:13:51.335 at information.
NOTE Confidence: 0.9814586

00:13:51.875 --> 00:13:54.195 However, you cannot record any
NOTE Confidence: 0.9814586

00:13:54.195 --> 00:13:55.809 identifying information. You can't go
NOTE Confidence: 0.9814586

00:13:55.809 --> 00:13:56.850 into the record and then
NOTE Confidence: 0.9814586

00:13:56.850 --> 00:13:58.290 type in some notes about,
NOTE Confidence: 0.9814586

00:13:58.290 --> 00:13:59.410 you know, there's this many

NOTE Confidence: 0.9814586
00:13:59.410 --> 00:14:00.850 patients and these are the
NOTE Confidence: 0.9814586
00:14:00.850 --> 00:14:01.970 birth dates and this is
NOTE Confidence: 0.9814586
00:14:01.970 --> 00:14:03.490 the medical information tied to
NOTE Confidence: 0.9814586
00:14:03.490 --> 00:14:04.610 it. It really is you
NOTE Confidence: 0.9814586
00:14:04.610 --> 00:14:05.889 just looking at the medical
NOTE Confidence: 0.9814586
00:14:05.889 --> 00:14:07.589 record to see if there's
NOTE Confidence: 0.96437734
00:14:08.265 --> 00:14:09.625 information that would you would
NOTE Confidence: 0.96437734
00:14:09.625 --> 00:14:10.665 be able to create a
NOTE Confidence: 0.96437734
00:14:10.665 --> 00:14:11.865 a full research study out
NOTE Confidence: 0.96437734
00:14:11.865 --> 00:14:12.825 of and and look at
NOTE Confidence: 0.96437734
00:14:12.825 --> 00:14:13.785 that data, and then you
NOTE Confidence: 0.96437734
00:14:13.785 --> 00:14:15.245 would submit to the IRB
NOTE Confidence: 0.96437734
00:14:15.385 --> 00:14:16.745 to conduct that research that
NOTE Confidence: 0.96437734
00:14:16.745 --> 00:14:17.645 you want to.
NOTE Confidence: 0.9548969
00:14:19.305 --> 00:14:20.985 Probably the biggest question that
NOTE Confidence: 0.9548969

00:14:20.985 --> 00:14:22.425 we get about is my
NOTE Confidence: 0.9548969

00:14:22.425 --> 00:14:23.760 project something that needs to
NOTE Confidence: 0.9548969

00:14:23.760 --> 00:14:25.220 be submitted to the IRB
NOTE Confidence: 0.9809846

00:14:25.760 --> 00:14:28.080 is quality improvement projects. And
NOTE Confidence: 0.9809846

00:14:28.080 --> 00:14:29.280 I know there's a lot
NOTE Confidence: 0.9809846

00:14:29.280 --> 00:14:31.060 of questions on quality improvement
NOTE Confidence: 0.967457

00:14:31.440 --> 00:14:33.200 because it's a huge gray
NOTE Confidence: 0.967457

00:14:33.200 --> 00:14:33.700 area.
NOTE Confidence: 0.9335832

00:14:34.080 --> 00:14:34.980 I will say,
NOTE Confidence: 0.9919005

00:14:35.925 --> 00:14:37.125 if you have a quality
NOTE Confidence: 0.9919005

00:14:37.125 --> 00:14:38.645 improvement project you're conducting or
NOTE Confidence: 0.9919005

00:14:38.645 --> 00:14:39.925 you're you're not quite sure,
NOTE Confidence: 0.9919005

00:14:39.925 --> 00:14:40.725 please just reach out to
NOTE Confidence: 0.9919005

00:14:40.725 --> 00:14:42.005 me directly. I'd be happy
NOTE Confidence: 0.9919005

00:14:42.005 --> 00:14:42.965 to talk about that with
NOTE Confidence: 0.9919005

00:14:42.965 --> 00:14:44.645 you. We also have a

NOTE Confidence: 0.9919005

00:14:44.645 --> 00:14:46.885 really, really nice guidance document

NOTE Confidence: 0.9919005

00:14:46.885 --> 00:14:47.785 that we've created

NOTE Confidence: 0.9420141

00:14:48.160 --> 00:14:49.600 that goes through various case

NOTE Confidence: 0.9420141

00:14:49.600 --> 00:14:51.120 studies and shows what might

NOTE Confidence: 0.9420141

00:14:51.120 --> 00:14:52.880 be a quality improvement project

NOTE Confidence: 0.9420141

00:14:52.880 --> 00:14:54.880 versus a research project, and

NOTE Confidence: 0.9420141

00:14:54.880 --> 00:14:55.680 you can kind of check

NOTE Confidence: 0.9420141

00:14:55.680 --> 00:14:57.200 off this these checks check

NOTE Confidence: 0.9420141

00:14:57.200 --> 00:14:58.260 boxes we have,

NOTE Confidence: 0.99081886

00:14:58.800 --> 00:15:00.160 in that guidance document. So

NOTE Confidence: 0.99081886

00:15:00.160 --> 00:15:01.600 I certainly recommend that you

NOTE Confidence: 0.99081886

00:15:01.600 --> 00:15:02.660 take a look at that.

NOTE Confidence: 0.99099404

00:15:03.125 --> 00:15:04.165 But what is a quality

NOTE Confidence: 0.99099404

00:15:04.165 --> 00:15:05.144 improvement project?

NOTE Confidence: 0.978562

00:15:05.685 --> 00:15:07.225 It's a data guided initiative

NOTE Confidence: 0.978562

00:15:07.445 --> 00:15:09.305 designed to improve clinical care,
NOTE Confidence: 0.978562

00:15:09.445 --> 00:15:10.584 health care operations,
NOTE Confidence: 0.9083378

00:15:11.045 --> 00:15:12.185 services and programs,
NOTE Confidence: 0.9986493

00:15:12.644 --> 00:15:14.505 or for developing new programs
NOTE Confidence: 0.9986493

00:15:14.644 --> 00:15:16.165 or services. This could be
NOTE Confidence: 0.9986493

00:15:16.165 --> 00:15:17.065 teaching evaluations,
NOTE Confidence: 0.9764798

00:15:17.780 --> 00:15:19.720 patient employee service surveys.
NOTE Confidence: 0.9843475

00:15:20.180 --> 00:15:20.980 Let me give you an
NOTE Confidence: 0.9843475

00:15:20.980 --> 00:15:22.420 example of a true quality
NOTE Confidence: 0.9843475

00:15:22.420 --> 00:15:24.260 improvement project. Let's say you
NOTE Confidence: 0.9843475

00:15:24.260 --> 00:15:25.480 are working in a clinic,
NOTE Confidence: 0.9843475

00:15:25.540 --> 00:15:26.900 and you're noticing that you're
NOTE Confidence: 0.9843475

00:15:26.900 --> 00:15:29.080 not quite happy with handwashing
NOTE Confidence: 0.9843475

00:15:29.300 --> 00:15:31.000 practices amongst the staff,
NOTE Confidence: 0.924173

00:15:31.815 --> 00:15:32.475 the clinicians,
NOTE Confidence: 0.9860442

00:15:33.175 --> 00:15:34.455 so you wanna change that

NOTE Confidence: 0.9860442
00:15:34.455 --> 00:15:34.955 behavior.
NOTE Confidence: 0.9288341
00:15:35.415 --> 00:15:36.955 Let's say you do a
NOTE Confidence: 0.9288341
00:15:37.095 --> 00:15:37.915 pre survey
NOTE Confidence: 0.8481327
00:15:38.295 --> 00:15:40.315 to assess handwashing practices.
NOTE Confidence: 0.9753642
00:15:40.855 --> 00:15:42.155 You conduct the intervention,
NOTE Confidence: 0.9897693
00:15:42.535 --> 00:15:43.335 and then you do a
NOTE Confidence: 0.9897693
00:15:43.335 --> 00:15:44.695 post survey to see if
NOTE Confidence: 0.9897693
00:15:44.695 --> 00:15:46.090 there's been a change in
NOTE Confidence: 0.9897693
00:15:46.090 --> 00:15:47.390 behavior with handwashing.
NOTE Confidence: 0.99217194
00:15:48.250 --> 00:15:49.130 Maybe at the same time,
NOTE Confidence: 0.99217194
00:15:49.130 --> 00:15:50.570 you're looking at medical records
NOTE Confidence: 0.99217194
00:15:50.570 --> 00:15:52.410 of patients and assessing rates
NOTE Confidence: 0.99217194
00:15:52.410 --> 00:15:53.770 of infection. Right? So you're
NOTE Confidence: 0.99217194
00:15:53.770 --> 00:15:54.810 trying to link if the
NOTE Confidence: 0.99217194
00:15:54.810 --> 00:15:55.950 handwashing intervention,
NOTE Confidence: 0.99736375

00:15:56.970 --> 00:15:58.250 led to a decrease in
NOTE Confidence: 0.99736375
00:15:58.250 --> 00:15:59.550 infections in the hospital.
NOTE Confidence: 0.9875878
00:16:00.095 --> 00:16:01.695 That is a true quality
NOTE Confidence: 0.9875878
00:16:01.695 --> 00:16:04.255 improvement project. Right? It's applicable
NOTE Confidence: 0.9875878
00:16:04.255 --> 00:16:06.175 to a particular setting. It's
NOTE Confidence: 0.9875878
00:16:06.175 --> 00:16:07.635 not intended to be generalizable,
NOTE Confidence: 0.99939275
00:16:08.255 --> 00:16:09.535 and it shouldn't be referred
NOTE Confidence: 0.99939275
00:16:09.535 --> 00:16:10.675 to as research.
NOTE Confidence: 0.9844251
00:16:11.135 --> 00:16:12.095 We do have people that
NOTE Confidence: 0.9844251
00:16:12.095 --> 00:16:13.775 want to publish quality improvement
NOTE Confidence: 0.9844251
00:16:13.775 --> 00:16:15.649 projects, and that's certainly okay.
NOTE Confidence: 0.98691136
00:16:16.269 --> 00:16:17.550 I would recommend in those
NOTE Confidence: 0.98691136
00:16:17.550 --> 00:16:19.889 cases that you submit a
NOTE Confidence: 0.98691136
00:16:20.029 --> 00:16:22.370 not human subjects research application
NOTE Confidence: 0.98691136
00:16:22.510 --> 00:16:23.490 to the IRB.
NOTE Confidence: 0.9618307
00:16:23.870 --> 00:16:25.230 It's essentially a form that

NOTE Confidence: 0.9618307

00:16:25.230 --> 00:16:26.829 says, hey. I'm not conducting

NOTE Confidence: 0.9618307

00:16:26.829 --> 00:16:28.525 research. I'm conducting a quality

NOTE Confidence: 0.9618307

00:16:28.525 --> 00:16:30.125 improvement project, here's a really

NOTE Confidence: 0.9618307

00:16:30.125 --> 00:16:31.245 quick snippet of what it

NOTE Confidence: 0.9618307

00:16:31.245 --> 00:16:32.445 is, you send it to

NOTE Confidence: 0.9618307

00:16:32.445 --> 00:16:33.725 the IRB and we will

NOTE Confidence: 0.9618307

00:16:33.725 --> 00:16:35.085 issue a letter that says,

NOTE Confidence: 0.9618307

00:16:35.085 --> 00:16:36.845 yep, you're correct, we reviewed

NOTE Confidence: 0.9618307

00:16:36.845 --> 00:16:37.805 it, this is a quality

NOTE Confidence: 0.9618307

00:16:37.805 --> 00:16:39.405 improvement project, it's not reach

NOTE Confidence: 0.9618307

00:16:39.565 --> 00:16:41.245 research, but the IRB has

NOTE Confidence: 0.9618307

00:16:41.245 --> 00:16:42.069 taken a look at at

NOTE Confidence: 0.9618307

00:16:42.069 --> 00:16:43.589 it because sometimes journals will

NOTE Confidence: 0.9618307

00:16:43.589 --> 00:16:44.790 ask for that type of

NOTE Confidence: 0.9618307

00:16:44.790 --> 00:16:46.709 letter from the IRB assessing

NOTE Confidence: 0.9618307

00:16:46.709 --> 00:16:48.069 that. So I would say
NOTE Confidence: 0.9618307

00:16:48.069 --> 00:16:49.350 that even though you don't
NOTE Confidence: 0.9618307

00:16:49.350 --> 00:16:50.709 need to submit these projects
NOTE Confidence: 0.9618307

00:16:50.709 --> 00:16:52.170 at all to the IRB
NOTE Confidence: 0.9618307

00:16:52.230 --> 00:16:53.449 for review and approval,
NOTE Confidence: 0.98175675

00:16:53.750 --> 00:16:54.790 if you are hoping to
NOTE Confidence: 0.98175675

00:16:54.790 --> 00:16:56.315 publish, it might be something
NOTE Confidence: 0.98175675

00:16:56.315 --> 00:16:57.435 you might want to submit
NOTE Confidence: 0.98175675

00:16:57.435 --> 00:16:58.555 to the IRB just to
NOTE Confidence: 0.98175675

00:16:58.555 --> 00:16:59.835 have that letter that says
NOTE Confidence: 0.98175675

00:16:59.835 --> 00:17:01.035 an IRB did take a
NOTE Confidence: 0.98175675

00:17:01.035 --> 00:17:01.935 look at this.
NOTE Confidence: 0.987315

00:17:03.755 --> 00:17:04.875 This is a nice, a
NOTE Confidence: 0.987315

00:17:04.875 --> 00:17:05.615 very rudimentary
NOTE Confidence: 0.99602824

00:17:05.915 --> 00:17:07.115 graph that kind of shows
NOTE Confidence: 0.99602824

00:17:07.115 --> 00:17:08.635 you various elements of your

NOTE Confidence: 0.99602824

00:17:08.635 --> 00:17:09.869 projects and when it might

NOTE Confidence: 0.99602824

00:17:09.869 --> 00:17:11.490 fall into the research bucket

NOTE Confidence: 0.99602824

00:17:11.710 --> 00:17:12.930 versus quality improvement.

NOTE Confidence: 0.9895534

00:17:13.470 --> 00:17:14.590 So what is the purpose

NOTE Confidence: 0.9895534

00:17:14.590 --> 00:17:15.790 of your study or your

NOTE Confidence: 0.9895534

00:17:15.790 --> 00:17:17.570 project? What is the design?

NOTE Confidence: 0.9895534

00:17:17.710 --> 00:17:19.230 Are there benefits? Are there

NOTE Confidence: 0.9895534

00:17:19.230 --> 00:17:20.270 risks? And what are your

NOTE Confidence: 0.9895534

00:17:20.270 --> 00:17:21.490 publication intentions?

NOTE Confidence: 0.97559506

00:17:21.904 --> 00:17:23.024 And this helps you to

NOTE Confidence: 0.97559506

00:17:23.024 --> 00:17:24.784 determine if your research might

NOTE Confidence: 0.97559506

00:17:24.784 --> 00:17:26.065 fall in if your project

NOTE Confidence: 0.97559506

00:17:26.065 --> 00:17:27.024 might fall in the research

NOTE Confidence: 0.97559506

00:17:27.024 --> 00:17:29.105 bucket versus the quality improvement

NOTE Confidence: 0.97559506

00:17:29.105 --> 00:17:30.385 bucket. But again, if you

NOTE Confidence: 0.97559506

00:17:30.385 --> 00:17:31.585 have questions on this, it's
NOTE Confidence: 0.97559506

00:17:31.585 --> 00:17:32.885 a huge gray area.
NOTE Confidence: 0.9987178

00:17:33.264 --> 00:17:34.225 I'd be happy to chat
NOTE Confidence: 0.9987178

00:17:34.225 --> 00:17:35.524 with you about your project.
NOTE Confidence: 0.98126775

00:17:36.880 --> 00:17:37.920 So now that we've talked
NOTE Confidence: 0.98126775

00:17:37.920 --> 00:17:39.760 about what is not human
NOTE Confidence: 0.98126775

00:17:39.760 --> 00:17:41.520 subjects research, let's talk about
NOTE Confidence: 0.98126775

00:17:41.520 --> 00:17:43.040 what is human subjects research
NOTE Confidence: 0.98126775

00:17:43.040 --> 00:17:44.880 that would require IRB review
NOTE Confidence: 0.98126775

00:17:44.880 --> 00:17:46.320 and approval. And before I
NOTE Confidence: 0.98126775

00:17:46.320 --> 00:17:47.040 do that, the sun is
NOTE Confidence: 0.98126775

00:17:47.040 --> 00:17:47.760 in my face, so let
NOTE Confidence: 0.98126775

00:17:47.760 --> 00:17:48.880 me just pull this shade
NOTE Confidence: 0.98126775

00:17:48.880 --> 00:17:50.420 down really quickly. I appreciate
NOTE Confidence: 0.98126775

00:17:50.480 --> 00:17:50.980 that.
NOTE Confidence: 0.99887645

00:17:52.615 --> 00:17:53.115 Okay.

NOTE Confidence: 0.9853254

00:17:53.815 --> 00:17:55.255 So we're we go by

NOTE Confidence: 0.9853254

00:17:55.255 --> 00:17:56.934 the HHS definitions here, but

NOTE Confidence: 0.9853254

00:17:56.934 --> 00:17:58.615 the FDA have very similar

NOTE Confidence: 0.9853254

00:17:58.615 --> 00:17:59.115 definitions.

NOTE Confidence: 0.97628087

00:17:59.655 --> 00:18:00.875 Let's start with the definition

NOTE Confidence: 0.97628087

00:18:01.095 --> 00:18:02.455 of research and break it

NOTE Confidence: 0.97628087

00:18:02.455 --> 00:18:03.434 down a little bit.

NOTE Confidence: 0.97334415

00:18:03.734 --> 00:18:05.515 Research is a systematic investigation,

NOTE Confidence: 0.96102685

00:18:06.210 --> 00:18:08.450 including research development, testing, and

NOTE Confidence: 0.96102685

00:18:08.450 --> 00:18:08.950 evaluation

NOTE Confidence: 0.93996936

00:18:09.650 --> 00:18:11.270 designed to develop or contribute

NOTE Confidence: 0.93996936

00:18:11.490 --> 00:18:12.230 to generalizable

NOTE Confidence: 0.97677046

00:18:12.609 --> 00:18:13.890 knowledge. So you want to

NOTE Confidence: 0.97677046

00:18:13.890 --> 00:18:14.929 add to literature in your

NOTE Confidence: 0.97677046

00:18:14.929 --> 00:18:15.429 field,

NOTE Confidence: 0.9749921

00:18:15.970 --> 00:18:17.250 you want to contribute to
NOTE Confidence: 0.9749921

00:18:17.250 --> 00:18:17.909 that literature,
NOTE Confidence: 0.92962307

00:18:18.289 --> 00:18:20.150 and you have a hypothesis,
NOTE Confidence: 0.92962307

00:18:20.289 --> 00:18:21.590 you have research questions,
NOTE Confidence: 0.9850828

00:18:22.045 --> 00:18:23.425 that is the true definition
NOTE Confidence: 0.9850828

00:18:23.484 --> 00:18:25.585 of research, the systematic investigation.
NOTE Confidence: 0.95813745

00:18:26.365 --> 00:18:27.885 And a human subject is
NOTE Confidence: 0.95813745

00:18:27.885 --> 00:18:29.645 a living individual. Remember, we
NOTE Confidence: 0.95813745

00:18:29.645 --> 00:18:31.645 talked about decedents before? It's
NOTE Confidence: 0.95813745

00:18:31.645 --> 00:18:33.645 a living individual about whom
NOTE Confidence: 0.95813745

00:18:33.645 --> 00:18:36.119 an investigator conducting research either
NOTE Confidence: 0.95813745

00:18:36.119 --> 00:18:38.300 obtains information or biospecimens
NOTE Confidence: 0.9768644

00:18:38.920 --> 00:18:40.920 through intervening or interacting with
NOTE Confidence: 0.9768644

00:18:40.920 --> 00:18:41.420 somebody,
NOTE Confidence: 0.9909899

00:18:41.880 --> 00:18:44.060 or they obtain, use, study,
NOTE Confidence: 0.9909899

00:18:44.200 --> 00:18:46.220 analyze, or generate identifiable

NOTE Confidence: 0.9804461

00:18:46.680 --> 00:18:48.619 private information or biospecimens.

NOTE Confidence: 0.99839807

00:18:49.445 --> 00:18:50.405 So in order for you

NOTE Confidence: 0.99839807

00:18:50.405 --> 00:18:51.684 to have a project that

NOTE Confidence: 0.99839807

00:18:51.684 --> 00:18:53.785 requires IRB review and approval,

NOTE Confidence: 0.9480098

00:18:54.165 --> 00:18:55.304 it has to involve,

NOTE Confidence: 0.9776585

00:18:55.765 --> 00:18:57.545 human subject per this definition,

NOTE Confidence: 0.9776585

00:18:57.845 --> 00:18:58.645 and you have to be

NOTE Confidence: 0.9776585

00:18:58.645 --> 00:19:00.665 conducting research per this definition.

NOTE Confidence: 0.9776585

00:19:00.725 --> 00:19:01.925 And then that's something that

NOTE Confidence: 0.9776585

00:19:01.925 --> 00:19:03.365 the IRB would need to

NOTE Confidence: 0.9776585

00:19:03.365 --> 00:19:03.865 see.

NOTE Confidence: 0.97376186

00:19:05.039 --> 00:19:06.320 This is again another very

NOTE Confidence: 0.97376186

00:19:06.320 --> 00:19:08.259 simple decision tree for you,

NOTE Confidence: 0.99362856

00:19:08.559 --> 00:19:09.840 to help walk you through

NOTE Confidence: 0.99362856

00:19:09.840 --> 00:19:10.960 if you are conducting a

NOTE Confidence: 0.99362856

00:19:10.960 --> 00:19:12.899 research project, and it's essentially

NOTE Confidence: 0.99362856

00:19:13.119 --> 00:19:14.480 the definitions that we just

NOTE Confidence: 0.99362856

00:19:14.480 --> 00:19:15.679 went over in the previous

NOTE Confidence: 0.99362856

00:19:15.679 --> 00:19:16.179 slide.

NOTE Confidence: 0.99520236

00:19:17.945 --> 00:19:19.305 So we review a lot

NOTE Confidence: 0.99520236

00:19:19.305 --> 00:19:20.585 of different types of research.

NOTE Confidence: 0.99520236

00:19:20.585 --> 00:19:21.305 I know this is a

NOTE Confidence: 0.99520236

00:19:21.305 --> 00:19:22.505 very busy slide, but I

NOTE Confidence: 0.99520236

00:19:22.505 --> 00:19:23.465 will break it down for

NOTE Confidence: 0.99520236

00:19:23.465 --> 00:19:24.685 you step by step.

NOTE Confidence: 0.9984747

00:19:25.305 --> 00:19:26.205 We see

NOTE Confidence: 0.999381

00:19:26.744 --> 00:19:27.965 research that involves

NOTE Confidence: 0.9878289

00:19:28.585 --> 00:19:29.085 interventional,

NOTE Confidence: 0.9537329

00:19:29.945 --> 00:19:31.885 drugs. We see devices.

NOTE Confidence: 0.98671407

00:19:32.840 --> 00:19:34.200 We see greater than minimal

NOTE Confidence: 0.98671407

00:19:34.200 --> 00:19:35.100 risk studies,

NOTE Confidence: 0.9870095
00:19:35.560 --> 00:19:37.640 we see studies that involve
NOTE Confidence: 0.9870095
00:19:37.640 --> 00:19:38.140 controversial
NOTE Confidence: 0.8796155
00:19:38.520 --> 00:19:39.740 issues, prisoners,
NOTE Confidence: 0.9960397
00:19:40.600 --> 00:19:41.900 most of that is reviewed
NOTE Confidence: 0.9960397
00:19:41.960 --> 00:19:43.420 at the full board level.
NOTE Confidence: 0.98836094
00:19:43.800 --> 00:19:45.160 That means that we have
NOTE Confidence: 0.98836094
00:19:45.160 --> 00:19:46.284 IRB chairpersons,
NOTE Confidence: 0.9644395
00:19:46.744 --> 00:19:48.365 experts in the field, community
NOTE Confidence: 0.9644395
00:19:48.424 --> 00:19:50.424 members that meet, and they
NOTE Confidence: 0.9644395
00:19:50.424 --> 00:19:52.265 actually review the study together.
NOTE Confidence: 0.9644395
00:19:52.265 --> 00:19:53.644 They go over the
NOTE Confidence: 0.91847485
00:19:54.265 --> 00:19:55.484 risks, the benefits,
NOTE Confidence: 0.99186915
00:19:55.945 --> 00:19:57.164 are all of the criteria
NOTE Confidence: 0.9363624
00:19:57.705 --> 00:19:59.385 per the federal regulations being
NOTE Confidence: 0.9363624
00:19:59.385 --> 00:20:00.845 met, is it ethical?
NOTE Confidence: 0.9649183

00:20:01.170 --> 00:20:02.290 So they're meeting to really
NOTE Confidence: 0.9649183

00:20:02.290 --> 00:20:03.250 talk about this, and you'll
NOTE Confidence: 0.9649183

00:20:03.250 --> 00:20:04.690 get your approval from the
NOTE Confidence: 0.9649183

00:20:04.690 --> 00:20:07.010 fully convened board. Again, these
NOTE Confidence: 0.9649183

00:20:07.010 --> 00:20:08.310 are those greater than minimal
NOTE Confidence: 0.9649183

00:20:08.369 --> 00:20:10.310 studies, drug device studies.
NOTE Confidence: 0.98424625

00:20:11.090 --> 00:20:12.210 The really cool thing about
NOTE Confidence: 0.98424625

00:20:12.210 --> 00:20:13.490 Yale, which may be different
NOTE Confidence: 0.98424625

00:20:13.490 --> 00:20:15.010 than some institutions that you've
NOTE Confidence: 0.98424625

00:20:15.010 --> 00:20:16.369 been at, is we actually
NOTE Confidence: 0.98424625

00:20:16.369 --> 00:20:17.115 have nineteen
NOTE Confidence: 0.8951585

00:20:17.595 --> 00:20:18.095 IRBs,
NOTE Confidence: 0.98461217

00:20:18.635 --> 00:20:19.835 which is a huge number.
NOTE Confidence: 0.98461217

00:20:19.835 --> 00:20:21.434 Some institutions only have, you
NOTE Confidence: 0.98461217

00:20:21.434 --> 00:20:22.635 know, one or two or
NOTE Confidence: 0.98461217

00:20:22.635 --> 00:20:24.155 three. Because we have so

NOTE Confidence: 0.98461217

00:20:24.155 --> 00:20:25.994 many IRBs, we meet several

NOTE Confidence: 0.98461217

00:20:25.994 --> 00:20:27.115 times a week. So once

NOTE Confidence: 0.98461217

00:20:27.115 --> 00:20:28.635 you submit your study, it

NOTE Confidence: 0.98461217

00:20:28.635 --> 00:20:29.915 will get assigned to a

NOTE Confidence: 0.98461217

00:20:29.915 --> 00:20:30.415 meeting,

NOTE Confidence: 0.9806338

00:20:30.799 --> 00:20:32.159 you know, very, very shortly.

NOTE Confidence: 0.9806338

00:20:32.159 --> 00:20:33.119 And as long as you

NOTE Confidence: 0.9806338

00:20:33.119 --> 00:20:34.960 are, working with us and

NOTE Confidence: 0.9806338

00:20:34.960 --> 00:20:36.400 when we're asking questions, you're

NOTE Confidence: 0.9806338

00:20:36.400 --> 00:20:37.440 getting back to us really

NOTE Confidence: 0.9806338

00:20:37.440 --> 00:20:39.200 quickly. Thankfully, we're able to

NOTE Confidence: 0.9806338

00:20:39.200 --> 00:20:40.260 approve those studies

NOTE Confidence: 0.8478368

00:20:40.799 --> 00:20:41.619 at a relatively,

NOTE Confidence: 0.96641237

00:20:43.295 --> 00:20:44.734 good good level, and then

NOTE Confidence: 0.96641237

00:20:44.734 --> 00:20:45.934 it doesn't take too long

NOTE Confidence: 0.96641237

00:20:45.934 --> 00:20:47.315 to approve those studies.
NOTE Confidence: 0.9808284

00:20:48.095 --> 00:20:49.855 We also have expedited studies
NOTE Confidence: 0.9808284

00:20:49.855 --> 00:20:51.455 that we see. So these
NOTE Confidence: 0.9808284

00:20:51.455 --> 00:20:52.494 are studies that are always
NOTE Confidence: 0.9808284

00:20:52.494 --> 00:20:53.955 going to be minimal risk,
NOTE Confidence: 0.9808284

00:20:54.095 --> 00:20:55.295 and they fit into one
NOTE Confidence: 0.9808284

00:20:55.295 --> 00:20:57.250 of the expedited categories that
NOTE Confidence: 0.9808284

00:20:57.250 --> 00:20:59.030 we have per the regulations.
NOTE Confidence: 0.9501932

00:20:59.970 --> 00:21:01.590 These are studies that maybe
NOTE Confidence: 0.9501932

00:21:01.650 --> 00:21:03.330 involve a it's it's not
NOTE Confidence: 0.9501932

00:21:03.330 --> 00:21:04.530 greater than minimal risk, but
NOTE Confidence: 0.9501932

00:21:04.530 --> 00:21:05.810 maybe there's, like, a blood
NOTE Confidence: 0.9501932

00:21:05.810 --> 00:21:07.250 draw involved, or there's some
NOTE Confidence: 0.9501932

00:21:07.250 --> 00:21:08.869 type of, like, physical intervention,
NOTE Confidence: 0.9501932

00:21:09.010 --> 00:21:10.185 or maybe it's a very
NOTE Confidence: 0.9501932

00:21:10.345 --> 00:21:11.645 sensitive research project,

NOTE Confidence: 0.9792333
00:21:12.105 --> 00:21:13.225 you're working with a very
NOTE Confidence: 0.9792333
00:21:13.225 --> 00:21:14.205 vulnerable population,
NOTE Confidence: 0.9774668
00:21:14.825 --> 00:21:16.185 that might be something that
NOTE Confidence: 0.9774668
00:21:16.185 --> 00:21:17.385 would push it into an
NOTE Confidence: 0.9774668
00:21:17.385 --> 00:21:18.445 expedited level,
NOTE Confidence: 0.93553424
00:21:18.825 --> 00:21:19.885 and again, it's
NOTE Confidence: 0.9493865
00:21:20.265 --> 00:21:21.385 not reviewed at this full
NOTE Confidence: 0.9493865
00:21:21.385 --> 00:21:22.665 board level so it's a
NOTE Confidence: 0.9493865
00:21:22.665 --> 00:21:23.705 little bit quicker of a
NOTE Confidence: 0.9493865
00:21:23.705 --> 00:21:24.205 process
NOTE Confidence: 0.9787468
00:21:24.660 --> 00:21:26.660 similar to exempt research. So
NOTE Confidence: 0.9787468
00:21:26.660 --> 00:21:28.420 exempt research is probably the
NOTE Confidence: 0.9787468
00:21:28.420 --> 00:21:30.040 most research that we see,
NOTE Confidence: 0.9944934
00:21:30.340 --> 00:21:31.780 and it's the lowest risk
NOTE Confidence: 0.9944934
00:21:31.780 --> 00:21:32.980 research, but there's a lot
NOTE Confidence: 0.9944934

00:21:32.980 --> 00:21:34.180 of different types of research
NOTE Confidence: 0.9944934

00:21:34.180 --> 00:21:35.380 that can be done under
NOTE Confidence: 0.9944934

00:21:35.380 --> 00:21:37.000 the exempt research categories.
NOTE Confidence: 0.9810243

00:21:37.925 --> 00:21:38.965 I will say here at
NOTE Confidence: 0.9810243

00:21:38.965 --> 00:21:40.505 Yale, we do require
NOTE Confidence: 0.9890342

00:21:40.885 --> 00:21:43.225 that investigators submit exempt research
NOTE Confidence: 0.9890342

00:21:43.285 --> 00:21:44.484 to the IRB. I know
NOTE Confidence: 0.9890342

00:21:44.484 --> 00:21:46.345 some institutions allow investigators
NOTE Confidence: 0.98145074

00:21:46.804 --> 00:21:48.165 to make their own exempt
NOTE Confidence: 0.98145074

00:21:48.165 --> 00:21:48.665 determinations.
NOTE Confidence: 0.98298985

00:21:49.205 --> 00:21:50.244 We do not allow that
NOTE Confidence: 0.98298985

00:21:50.244 --> 00:21:51.205 at Yale. So you will
NOTE Confidence: 0.98298985

00:21:51.205 --> 00:21:52.325 need to submit those chart
NOTE Confidence: 0.98298985

00:21:52.325 --> 00:21:53.500 reviews to us. You will
NOTE Confidence: 0.98298985

00:21:53.500 --> 00:21:54.779 need to submit those interview
NOTE Confidence: 0.98298985

00:21:54.779 --> 00:21:56.320 and survey studies to us,

NOTE Confidence: 0.98298985

00:21:56.380 --> 00:21:57.260 and we'll get you that

NOTE Confidence: 0.98298985

00:21:57.260 --> 00:21:58.380 approval. Again, it's a pretty

NOTE Confidence: 0.98298985

00:21:58.380 --> 00:21:59.340 quick it's a it's a

NOTE Confidence: 0.98298985

00:21:59.340 --> 00:22:00.700 pretty quick turnaround for our

NOTE Confidence: 0.98298985

00:22:00.700 --> 00:22:02.720 exempt research. So it's

NOTE Confidence: 0.98584765

00:22:03.179 --> 00:22:04.299 within a few days to

NOTE Confidence: 0.98584765

00:22:04.299 --> 00:22:05.419 a week as long as

NOTE Confidence: 0.98584765

00:22:05.419 --> 00:22:06.460 you're getting back to us

NOTE Confidence: 0.98584765

00:22:06.460 --> 00:22:07.500 if we have questions to

NOTE Confidence: 0.98584765

00:22:07.500 --> 00:22:08.859 you. So that's that's really

NOTE Confidence: 0.98584765

00:22:08.859 --> 00:22:09.765 great. And I'll walk you

NOTE Confidence: 0.98584765

00:22:09.765 --> 00:22:11.045 through that process in just

NOTE Confidence: 0.98584765

00:22:11.045 --> 00:22:11.945 a few slides.

NOTE Confidence: 0.964351

00:22:12.805 --> 00:22:13.925 So, again, these are all

NOTE Confidence: 0.964351

00:22:13.925 --> 00:22:15.385 of our minimal risk surveys,

NOTE Confidence: 0.964351

00:22:15.445 --> 00:22:17.685 interviews, focus groups, observation of

NOTE Confidence: 0.964351

00:22:17.685 --> 00:22:20.025 public behavior, research on educational

NOTE Confidence: 0.964351

00:22:20.165 --> 00:22:20.665 techniques,

NOTE Confidence: 0.9669722

00:22:21.285 --> 00:22:22.565 review of data that is

NOTE Confidence: 0.9669722

00:22:22.565 --> 00:22:24.380 either publicly available or no

NOTE Confidence: 0.9669722

00:22:24.380 --> 00:22:25.760 identifiers are being recorded.

NOTE Confidence: 0.9793825

00:22:26.140 --> 00:22:27.179 And the biggest one that

NOTE Confidence: 0.9793825

00:22:27.179 --> 00:22:28.940 we see is the HIPAA

NOTE Confidence: 0.9793825

00:22:28.940 --> 00:22:30.380 category, essentially, is what we

NOTE Confidence: 0.9793825

00:22:30.380 --> 00:22:31.600 call it. So that's secondary

NOTE Confidence: 0.9793825

00:22:31.820 --> 00:22:34.140 research use of identifiable private

NOTE Confidence: 0.9793825

00:22:34.140 --> 00:22:34.640 information

NOTE Confidence: 0.9907723

00:22:35.295 --> 00:22:36.755 or identifiable biospecimens

NOTE Confidence: 0.98897564

00:22:37.215 --> 00:22:39.295 regulated under HIPAA. So many

NOTE Confidence: 0.98897564

00:22:39.295 --> 00:22:40.735 of our medical record reviews

NOTE Confidence: 0.98897564

00:22:40.735 --> 00:22:42.255 that we see. It also

NOTE Confidence: 0.98897564

00:22:42.255 --> 00:22:44.035 includes this new interesting category

NOTE Confidence: 0.98897564

00:22:44.095 --> 00:22:45.215 that was added in the

NOTE Confidence: 0.98897564

00:22:45.215 --> 00:22:46.435 twenty eighteen regulations

NOTE Confidence: 0.98341334

00:22:47.149 --> 00:22:48.769 called benign behavioral interventions.

NOTE Confidence: 0.9936255

00:22:49.070 --> 00:22:49.570 So,

NOTE Confidence: 0.9957973

00:22:49.950 --> 00:22:50.909 that was a new one

NOTE Confidence: 0.9957973

00:22:50.909 --> 00:22:52.389 that was interesting for us

NOTE Confidence: 0.9957973

00:22:52.389 --> 00:22:54.509 to, navigate as as that

NOTE Confidence: 0.9957973

00:22:54.509 --> 00:22:55.730 was added in the regulations.

NOTE Confidence: 0.9898979

00:22:57.389 --> 00:22:58.350 Okay. So let's talk a

NOTE Confidence: 0.9898979

00:22:58.350 --> 00:22:59.549 little bit about chart reviews

NOTE Confidence: 0.9898979

00:22:59.549 --> 00:23:00.429 because I know many of

NOTE Confidence: 0.9898979

00:23:00.429 --> 00:23:01.149 you are going to be

NOTE Confidence: 0.9898979

00:23:01.149 --> 00:23:02.609 submitting these to the IRB.

NOTE Confidence: 0.94313765

00:23:03.185 --> 00:23:04.225 So these are found at

NOTE Confidence: 0.94313765

00:23:04.225 --> 00:23:06.085 exempt category four.
NOTE Confidence: 0.98372215

00:23:06.945 --> 00:23:08.385 You will have when you're
NOTE Confidence: 0.98372215

00:23:08.385 --> 00:23:09.665 submitting these to the IRB,
NOTE Confidence: 0.98372215

00:23:09.665 --> 00:23:10.545 there's going to be an
NOTE Confidence: 0.98372215

00:23:10.545 --> 00:23:12.465 exemption request form that's going
NOTE Confidence: 0.98372215

00:23:12.465 --> 00:23:13.505 to ask you about the
NOTE Confidence: 0.98372215

00:23:13.505 --> 00:23:15.265 category you believe your research
NOTE Confidence: 0.98372215

00:23:15.265 --> 00:23:16.470 is. You don't have to
NOTE Confidence: 0.98372215

00:23:16.470 --> 00:23:17.750 be right. The IRB will
NOTE Confidence: 0.98372215

00:23:17.750 --> 00:23:18.630 help you out here, but
NOTE Confidence: 0.98372215

00:23:18.630 --> 00:23:19.510 it's good to know if
NOTE Confidence: 0.98372215

00:23:19.510 --> 00:23:20.869 you are conducting a medical
NOTE Confidence: 0.98372215

00:23:20.869 --> 00:23:22.470 record review, it will be
NOTE Confidence: 0.98372215

00:23:22.470 --> 00:23:24.010 that exempt category four.
NOTE Confidence: 0.9787972

00:23:24.470 --> 00:23:26.010 Specifically, this little,
NOTE Confidence: 0.9063214

00:23:26.550 --> 00:23:28.230 little little I, three little

NOTE Confidence: 0.9063214

00:23:28.230 --> 00:23:29.770 i's or or number three.

NOTE Confidence: 0.98759097

00:23:30.095 --> 00:23:31.695 So this is secondary research

NOTE Confidence: 0.98759097

00:23:31.695 --> 00:23:32.895 for which consent is not

NOTE Confidence: 0.98759097

00:23:32.895 --> 00:23:33.395 required.

NOTE Confidence: 0.9801117

00:23:33.935 --> 00:23:36.035 Secondary research uses of identifiable

NOTE Confidence: 0.9801117

00:23:36.335 --> 00:23:38.915 private information or identifiable biospecimens

NOTE Confidence: 0.9801117

00:23:39.215 --> 00:23:40.335 if at least one of

NOTE Confidence: 0.9801117

00:23:40.335 --> 00:23:42.275 the following criteria is met.

NOTE Confidence: 0.9801117

00:23:42.409 --> 00:23:43.690 So for those chart reviews,

NOTE Confidence: 0.9801117

00:23:43.690 --> 00:23:45.549 it's this third point here.

NOTE Confidence: 0.98606914

00:23:45.850 --> 00:23:47.869 The research involves only information

NOTE Confidence: 0.98606914

00:23:48.010 --> 00:23:50.090 collection and analysis involving the

NOTE Confidence: 0.98606914

00:23:50.090 --> 00:23:51.789 investigator's use of identifiable

NOTE Confidence: 0.99972904

00:23:52.090 --> 00:23:52.830 health information

NOTE Confidence: 0.99215657

00:23:53.690 --> 00:23:55.450 that is regulated under these

NOTE Confidence: 0.99215657

00:23:55.450 --> 00:23:55.950 regulations
NOTE Confidence: 0.978274

00:23:56.415 --> 00:23:57.695 and for the purposes of
NOTE Confidence: 0.978274

00:23:57.695 --> 00:23:58.675 health care operations
NOTE Confidence: 0.9864854

00:23:59.055 --> 00:24:00.415 or research. So, again, this
NOTE Confidence: 0.9864854

00:24:00.415 --> 00:24:02.095 is that HIPAA category to
NOTE Confidence: 0.9864854

00:24:02.095 --> 00:24:03.075 be aware of.
NOTE Confidence: 0.99882495

00:24:04.015 --> 00:24:05.455 So how can protected health
NOTE Confidence: 0.99882495

00:24:05.455 --> 00:24:07.295 information be used in research?
NOTE Confidence: 0.99882495

00:24:07.295 --> 00:24:08.494 There's a few different ways
NOTE Confidence: 0.99882495

00:24:08.494 --> 00:24:09.795 that you can use PHI
NOTE Confidence: 0.99882495

00:24:09.855 --> 00:24:10.895 in the conduct of your
NOTE Confidence: 0.99882495

00:24:10.895 --> 00:24:11.395 research.
NOTE Confidence: 0.9880004

00:24:12.049 --> 00:24:14.290 One is just obtaining a
NOTE Confidence: 0.9880004

00:24:14.290 --> 00:24:16.369 participant's authorization. So in order
NOTE Confidence: 0.9880004

00:24:16.369 --> 00:24:18.049 to use or disclose PHI
NOTE Confidence: 0.9880004

00:24:18.049 --> 00:24:19.750 for research, you can obtain

NOTE Confidence: 0.84070766

00:24:20.130 --> 00:24:20.630 authorization

NOTE Confidence: 0.99695444

00:24:21.570 --> 00:24:22.630 from the individual.

NOTE Confidence: 0.9596298

00:24:23.250 --> 00:24:24.130 Let's say you're doing a

NOTE Confidence: 0.9596298

00:24:24.130 --> 00:24:25.410 drug study or a device

NOTE Confidence: 0.9596298

00:24:25.410 --> 00:24:26.929 study or even a a

NOTE Confidence: 0.9596298

00:24:26.929 --> 00:24:28.095 focus group and you're talking

NOTE Confidence: 0.9596298

00:24:28.095 --> 00:24:29.715 with somebody or you're intervening,

NOTE Confidence: 0.96788883

00:24:30.734 --> 00:24:32.975 obviously it's important for you

NOTE Confidence: 0.96788883

00:24:32.975 --> 00:24:34.734 to get that consent from

NOTE Confidence: 0.96788883

00:24:34.734 --> 00:24:35.935 that individual and if you're

NOTE Confidence: 0.96788883

00:24:35.935 --> 00:24:37.555 dealing with protected health information

NOTE Confidence: 0.96788883

00:24:37.775 --> 00:24:38.994 in addition to consent

NOTE Confidence: 0.932317

00:24:39.295 --> 00:24:40.415 you will need that HIPAA

NOTE Confidence: 0.932317

00:24:40.415 --> 00:24:40.915 authorization.

NOTE Confidence: 0.97723603

00:24:41.960 --> 00:24:43.660 At Yale, our consent templates

NOTE Confidence: 0.97723603

00:24:43.720 --> 00:24:45.080 templates actually have a built
NOTE Confidence: 0.97723603

00:24:45.080 --> 00:24:46.840 in HIPAA authorization form as
NOTE Confidence: 0.97723603

00:24:46.840 --> 00:24:48.520 well, so they only essentially
NOTE Confidence: 0.97723603

00:24:48.520 --> 00:24:49.580 sign one document
NOTE Confidence: 0.9559789

00:24:49.960 --> 00:24:51.740 that contains an embedded
NOTE Confidence: 0.9555079

00:24:52.040 --> 00:24:53.720 research authorization form, but you
NOTE Confidence: 0.9555079

00:24:53.720 --> 00:24:54.859 can also have a standalone
NOTE Confidence: 0.9555079

00:24:54.920 --> 00:24:56.200 form as well if that's
NOTE Confidence: 0.9555079

00:24:56.200 --> 00:24:57.825 something that you're interested in.
NOTE Confidence: 0.99951434

00:24:58.385 --> 00:24:59.345 What do I mean by
NOTE Confidence: 0.99951434

00:24:59.345 --> 00:25:01.424 using or disclosing PHI for
NOTE Confidence: 0.99951434

00:25:01.424 --> 00:25:01.924 research?
NOTE Confidence: 0.9550137

00:25:02.465 --> 00:25:03.664 Use is the use of
NOTE Confidence: 0.9550137

00:25:03.664 --> 00:25:04.164 PHI.
NOTE Confidence: 0.93061775

00:25:05.424 --> 00:25:08.085 Use means communicating, utilizing, examining,
NOTE Confidence: 0.93061775

00:25:08.144 --> 00:25:08.885 or analyzing

NOTE Confidence: 0.9662073

00:25:09.345 --> 00:25:11.205 PHI within the covered entity,

NOTE Confidence: 0.97989744

00:25:11.619 --> 00:25:13.480 And disclosure means the release,

NOTE Confidence: 0.97989744

00:25:13.539 --> 00:25:15.539 transfer, provision of access to,

NOTE Confidence: 0.97989744

00:25:15.539 --> 00:25:17.140 or divulging in any manner

NOTE Confidence: 0.97989744

00:25:17.140 --> 00:25:19.240 of information outside the entity

NOTE Confidence: 0.97989744

00:25:19.299 --> 00:25:20.359 holding the information.

NOTE Confidence: 0.9136454

00:25:20.740 --> 00:25:22.100 It's a very technical terms,

NOTE Confidence: 0.9136454

00:25:22.100 --> 00:25:22.760 but essentially,

NOTE Confidence: 0.9975764

00:25:23.940 --> 00:25:25.559 are you taking somebody's

NOTE Confidence: 0.96870285

00:25:25.955 --> 00:25:28.035 PHI? Are you identifying? Are

NOTE Confidence: 0.96870285

00:25:28.035 --> 00:25:29.315 you, is it leaving the

NOTE Confidence: 0.96870285

00:25:29.315 --> 00:25:30.755 covered entity? Is it leaving

NOTE Confidence: 0.96870285

00:25:30.755 --> 00:25:31.875 Yale? Is it going to

NOTE Confidence: 0.96870285

00:25:31.875 --> 00:25:33.975 other researchers at other institutions?

NOTE Confidence: 0.9849937

00:25:35.075 --> 00:25:35.955 So, again, if you have

NOTE Confidence: 0.9849937

00:25:35.955 --> 00:25:37.075 questions on that, let me
NOTE Confidence: 0.9849937

00:25:37.075 --> 00:25:38.275 know, but just wanted to
NOTE Confidence: 0.9849937

00:25:38.275 --> 00:25:40.035 provide the definitions for you
NOTE Confidence: 0.9849937

00:25:40.035 --> 00:25:40.535 here.
NOTE Confidence: 0.9996466

00:25:41.530 --> 00:25:42.510 In order to
NOTE Confidence: 0.9777185

00:25:42.890 --> 00:25:44.490 use or disclose PHI, you
NOTE Confidence: 0.9777185

00:25:44.490 --> 00:25:46.430 could also request a waiver
NOTE Confidence: 0.9777185

00:25:46.490 --> 00:25:47.550 of HIPAA authorization.
NOTE Confidence: 0.9981472

00:25:48.010 --> 00:25:48.970 This is what you're going
NOTE Confidence: 0.9981472

00:25:48.970 --> 00:25:50.170 to need to request when
NOTE Confidence: 0.9981472

00:25:50.170 --> 00:25:51.369 you're looking at those medical
NOTE Confidence: 0.9981472

00:25:51.369 --> 00:25:53.150 record reviews, those chart reviews.
NOTE Confidence: 0.9861473

00:25:53.770 --> 00:25:56.265 Obviously, it's not always possible
NOTE Confidence: 0.9861473

00:25:56.405 --> 00:25:58.405 to obtain informed consent or
NOTE Confidence: 0.9861473

00:25:58.405 --> 00:25:59.705 obtain HIPAA authorization
NOTE Confidence: 0.9623114

00:26:00.005 --> 00:26:00.825 from individuals.

NOTE Confidence: 0.94758874

00:26:01.205 --> 00:26:02.405 Let's say you're looking at

NOTE Confidence: 0.94758874

00:26:02.405 --> 00:26:04.005 a thousand records, right, or

NOTE Confidence: 0.94758874

00:26:04.005 --> 00:26:05.045 you're looking at ten thousand

NOTE Confidence: 0.94758874

00:26:05.045 --> 00:26:06.744 records or five hundred records.

NOTE Confidence: 0.9940393

00:26:07.180 --> 00:26:08.000 It would be impractical

NOTE Confidence: 0.98804694

00:26:08.540 --> 00:26:09.580 for you to go and

NOTE Confidence: 0.98804694

00:26:09.580 --> 00:26:11.680 get consent and research authorization

NOTE Confidence: 0.93555427

00:26:12.380 --> 00:26:13.920 for those, from those individuals

NOTE Confidence: 0.93555427

00:26:13.980 --> 00:26:15.580 to access their data for

NOTE Confidence: 0.93555427

00:26:15.580 --> 00:26:16.480 research purposes.

NOTE Confidence: 0.95287186

00:26:16.780 --> 00:26:17.980 So you can request a

NOTE Confidence: 0.95287186

00:26:17.980 --> 00:26:19.660 waiver of HIPAA authorization from

NOTE Confidence: 0.95287186

00:26:19.660 --> 00:26:21.345 the privacy board, which here

NOTE Confidence: 0.95287186

00:26:21.345 --> 00:26:22.865 at Yale, the Yale IRB

NOTE Confidence: 0.95287186

00:26:22.865 --> 00:26:24.225 serves as the privacy board.

NOTE Confidence: 0.95287186

00:26:24.225 --> 00:26:25.505 So you can request that
NOTE Confidence: 0.95287186

00:26:25.505 --> 00:26:27.045 authorize waiver of authorization
NOTE Confidence: 0.9827914

00:26:27.744 --> 00:26:29.105 in your IRB application, and
NOTE Confidence: 0.9827914

00:26:29.105 --> 00:26:29.905 I'll show you how to
NOTE Confidence: 0.9827914

00:26:29.905 --> 00:26:31.425 do that. And then finally,
NOTE Confidence: 0.9827914

00:26:31.425 --> 00:26:32.545 you can certainly use and
NOTE Confidence: 0.9827914

00:26:32.545 --> 00:26:34.304 disclose PHI for research when
NOTE Confidence: 0.9827914

00:26:34.304 --> 00:26:35.744 you're working with decedents, which
NOTE Confidence: 0.9827914

00:26:35.744 --> 00:26:37.480 we already talked about, and
NOTE Confidence: 0.9827914

00:26:37.480 --> 00:26:39.340 activities prep to research.
NOTE Confidence: 0.99809396

00:26:40.919 --> 00:26:42.059 So what are the criteria
NOTE Confidence: 0.99809396

00:26:42.279 --> 00:26:43.980 for a waiver or alteration
NOTE Confidence: 0.99809396

00:26:44.119 --> 00:26:45.179 of HIPAA authorization?
NOTE Confidence: 0.9992509

00:26:46.119 --> 00:26:47.640 In order to use or
NOTE Confidence: 0.9992509

00:26:47.640 --> 00:26:49.559 disclose PHI, we have to
NOTE Confidence: 0.9992509

00:26:49.559 --> 00:26:50.460 ensure that

NOTE Confidence: 0.999254
00:26:50.804 --> 00:26:52.404 that disclosure is going to
NOTE Confidence: 0.999254
00:26:52.404 --> 00:26:53.524 involve no more than a
NOTE Confidence: 0.999254
00:26:53.524 --> 00:26:55.225 minimal risk to the privacy
NOTE Confidence: 0.999254
00:26:55.284 --> 00:26:55.865 of individuals
NOTE Confidence: 0.9877103
00:26:56.565 --> 00:26:58.004 based on the presence of
NOTE Confidence: 0.9877103
00:26:58.004 --> 00:27:00.004 the following elements. One, is
NOTE Confidence: 0.9877103
00:27:00.004 --> 00:27:01.284 there an adequate plan to
NOTE Confidence: 0.9877103
00:27:01.284 --> 00:27:02.424 protect the identifiers
NOTE Confidence: 0.99137175
00:27:02.770 --> 00:27:04.549 from improper use of disclosure?
NOTE Confidence: 0.9988715
00:27:04.929 --> 00:27:06.290 Is there an adequate plan
NOTE Confidence: 0.9988715
00:27:06.290 --> 00:27:07.830 to destroy the identifiers
NOTE Confidence: 0.9988651
00:27:08.130 --> 00:27:09.590 at the earliest convenience?
NOTE Confidence: 0.98573196
00:27:10.210 --> 00:27:11.490 Is there an adequate written
NOTE Confidence: 0.98573196
00:27:11.490 --> 00:27:13.090 assurance that the PHI will
NOTE Confidence: 0.98573196
00:27:13.090 --> 00:27:15.105 not be reused or disclosed
NOTE Confidence: 0.98573196

00:27:15.105 --> 00:27:16.465 to any other person or
NOTE Confidence: 0.98573196
00:27:16.465 --> 00:27:16.965 entity?
NOTE Confidence: 0.9875232
00:27:17.505 --> 00:27:18.865 And can the research not
NOTE Confidence: 0.9875232
00:27:18.865 --> 00:27:20.945 be practically carried out without
NOTE Confidence: 0.9875232
00:27:20.945 --> 00:27:22.484 the waiver or alteration
NOTE Confidence: 0.9732978
00:27:23.265 --> 00:27:25.345 and, cannot be conducted without
NOTE Confidence: 0.9732978
00:27:25.345 --> 00:27:26.545 access to and the use
NOTE Confidence: 0.9732978
00:27:26.545 --> 00:27:28.325 of that PHI? So, again,
NOTE Confidence: 0.9732978
00:27:28.549 --> 00:27:29.830 for the most part, many
NOTE Confidence: 0.9732978
00:27:29.830 --> 00:27:31.030 chart reviews are going to
NOTE Confidence: 0.9732978
00:27:31.030 --> 00:27:33.190 meet this this criteria, and
NOTE Confidence: 0.9732978
00:27:33.190 --> 00:27:34.070 you're going to be able
NOTE Confidence: 0.9732978
00:27:34.070 --> 00:27:36.150 to request that waiver of
NOTE Confidence: 0.9732978
00:27:36.150 --> 00:27:36.970 HIPAA authorization.
NOTE Confidence: 0.9835578
00:27:38.390 --> 00:27:39.350 So I'll show you this
NOTE Confidence: 0.9835578
00:27:39.350 --> 00:27:41.030 in just a few, slides

NOTE Confidence: 0.9835578

00:27:41.030 --> 00:27:42.390 here, but when you're going

NOTE Confidence: 0.9835578

00:27:42.390 --> 00:27:43.845 to be submitting your research

NOTE Confidence: 0.9835578

00:27:43.845 --> 00:27:45.205 studies to the IRB, if

NOTE Confidence: 0.9835578

00:27:45.205 --> 00:27:46.885 it is exempt research, maybe

NOTE Confidence: 0.9835578

00:27:46.885 --> 00:27:48.725 it's that exempt category four,

NOTE Confidence: 0.9835578

00:27:48.725 --> 00:27:50.424 you're looking at medical records,

NOTE Confidence: 0.9847652

00:27:50.725 --> 00:27:52.244 there's a question on the

NOTE Confidence: 0.9847652

00:27:52.244 --> 00:27:54.325 exemption request form, it's question

NOTE Confidence: 0.9847652

00:27:54.325 --> 00:27:55.605 number seven. It's going to

NOTE Confidence: 0.9847652

00:27:55.605 --> 00:27:57.010 ask you to list all

NOTE Confidence: 0.9847652

00:27:57.010 --> 00:27:58.530 health information that will be

NOTE Confidence: 0.9847652

00:27:58.530 --> 00:27:59.830 recorded for the research.

NOTE Confidence: 0.9902947

00:28:00.450 --> 00:28:01.809 Only the items that are

NOTE Confidence: 0.9902947

00:28:01.809 --> 00:28:03.809 listed on this exemption request

NOTE Confidence: 0.9902947

00:28:03.809 --> 00:28:05.809 form may be recorded. Okay?

NOTE Confidence: 0.9902947

00:28:05.809 --> 00:28:06.609 So you have to make
NOTE Confidence: 0.9902947

00:28:06.609 --> 00:28:08.450 sure that every identifier you're
NOTE Confidence: 0.9902947

00:28:08.450 --> 00:28:09.410 going to be looking at
NOTE Confidence: 0.9902947

00:28:09.410 --> 00:28:11.085 in the medical record is
NOTE Confidence: 0.9902947

00:28:11.085 --> 00:28:12.924 included in your exemption request
NOTE Confidence: 0.9902947

00:28:12.924 --> 00:28:13.424 form.
NOTE Confidence: 0.98720187

00:28:13.725 --> 00:28:15.165 If you're using an Excel
NOTE Confidence: 0.98720187

00:28:15.165 --> 00:28:16.385 spreadsheet to provide,
NOTE Confidence: 0.88655525

00:28:16.765 --> 00:28:18.445 JDAT with your request, you
NOTE Confidence: 0.88655525

00:28:18.445 --> 00:28:20.044 can upload the document in
NOTE Confidence: 0.88655525

00:28:20.044 --> 00:28:20.865 IRS IRB
NOTE Confidence: 0.97658974

00:28:21.165 --> 00:28:22.365 and include a reference to
NOTE Confidence: 0.97658974

00:28:22.365 --> 00:28:24.044 the spreadsheet in this section
NOTE Confidence: 0.97658974

00:28:24.044 --> 00:28:25.804 of the exemption request form.
NOTE Confidence: 0.97658974

00:28:25.804 --> 00:28:26.700 So I'm sure many of
NOTE Confidence: 0.97658974

00:28:26.700 --> 00:28:27.580 you have done this. If

NOTE Confidence: 0.97658974
00:28:27.580 --> 00:28:29.020 you have not, whenever you
NOTE Confidence: 0.97658974
00:28:29.020 --> 00:28:30.380 want to look at medical
NOTE Confidence: 0.97658974
00:28:30.380 --> 00:28:31.980 records for research purposes that
NOTE Confidence: 0.97658974
00:28:31.980 --> 00:28:33.179 are not your own records,
NOTE Confidence: 0.97658974
00:28:33.179 --> 00:28:34.380 they're, you know, in epic
NOTE Confidence: 0.97658974
00:28:34.380 --> 00:28:35.740 or something and you're interested
NOTE Confidence: 0.97658974
00:28:35.740 --> 00:28:36.799 in a certain population,
NOTE Confidence: 0.97445506
00:28:37.500 --> 00:28:38.620 you first need to get
NOTE Confidence: 0.97445506
00:28:38.620 --> 00:28:40.095 IRB approval to do so.
NOTE Confidence: 0.97445506
00:28:40.095 --> 00:28:41.294 You have the list of
NOTE Confidence: 0.97445506
00:28:41.294 --> 00:28:42.815 identifiers that you're going to
NOTE Confidence: 0.97445506
00:28:42.815 --> 00:28:44.575 want access to, and you'll
NOTE Confidence: 0.97445506
00:28:44.575 --> 00:28:45.934 work with the joint data
NOTE Confidence: 0.97445506
00:28:45.934 --> 00:28:47.375 analytics team who is going
NOTE Confidence: 0.97445506
00:28:47.375 --> 00:28:48.575 to ask for your IRB
NOTE Confidence: 0.97445506

00:28:48.575 --> 00:28:50.095 approval, and they're the ones
NOTE Confidence: 0.97445506

00:28:50.095 --> 00:28:51.615 that actually provide you the
NOTE Confidence: 0.97445506

00:28:51.615 --> 00:28:52.115 information
NOTE Confidence: 0.9859205

00:28:52.575 --> 00:28:54.174 that you're requesting. So just
NOTE Confidence: 0.9859205

00:28:54.174 --> 00:28:55.315 keep that in mind.
NOTE Confidence: 0.99466145

00:28:55.860 --> 00:28:57.940 Some common identifiers that are
NOTE Confidence: 0.99466145

00:28:57.940 --> 00:28:59.140 quite obvious that you might
NOTE Confidence: 0.99466145

00:28:59.140 --> 00:29:00.120 be looking for
NOTE Confidence: 0.9652579

00:29:00.420 --> 00:29:02.040 are things like name, address,
NOTE Confidence: 0.9652579

00:29:02.260 --> 00:29:04.740 social security number, medical record
NOTE Confidence: 0.9652579

00:29:04.740 --> 00:29:06.660 number, phone number, email, a
NOTE Confidence: 0.9652579

00:29:06.660 --> 00:29:07.800 full face photo.
NOTE Confidence: 0.970172

00:29:08.105 --> 00:29:09.645 But there's also less obvious
NOTE Confidence: 0.970172

00:29:09.705 --> 00:29:11.225 identifiers. So if you want
NOTE Confidence: 0.970172

00:29:11.225 --> 00:29:12.685 to collect these or,
NOTE Confidence: 0.97885674

00:29:13.625 --> 00:29:14.985 you don't realize that these

NOTE Confidence: 0.97885674

00:29:14.985 --> 00:29:16.505 also might be identifiers that

NOTE Confidence: 0.97885674

00:29:16.505 --> 00:29:17.865 you shouldn't be sharing or

NOTE Confidence: 0.97885674

00:29:17.865 --> 00:29:18.365 accessing,

NOTE Confidence: 0.9726048

00:29:19.145 --> 00:29:20.585 those include things like just

NOTE Confidence: 0.9726048

00:29:20.585 --> 00:29:22.105 general dates. This could be

NOTE Confidence: 0.9726048

00:29:22.105 --> 00:29:22.830 dates of

NOTE Confidence: 0.9988565

00:29:23.309 --> 00:29:24.929 visit, dates of surgery,

NOTE Confidence: 0.9694787

00:29:25.390 --> 00:29:27.549 health plan number, account number,

NOTE Confidence: 0.9694787

00:29:27.549 --> 00:29:29.809 license number, license plate,

NOTE Confidence: 0.9662857

00:29:30.269 --> 00:29:32.830 device number, IP addresses is

NOTE Confidence: 0.9662857

00:29:32.830 --> 00:29:34.110 something we don't think about

NOTE Confidence: 0.9662857

00:29:34.110 --> 00:29:34.769 a lot,

NOTE Confidence: 0.9469391

00:29:35.390 --> 00:29:36.830 finger and voice prints, or

NOTE Confidence: 0.9469391

00:29:36.830 --> 00:29:38.289 other unique identifying

NOTE Confidence: 0.9783809

00:29:39.125 --> 00:29:40.265 numbers, characteristics,

NOTE Confidence: 0.99134326

00:29:40.565 --> 00:29:41.465 or codes.
NOTE Confidence: 0.89014316

00:29:43.045 --> 00:29:43.925 So these, I
NOTE Confidence: 0.996346

00:29:44.725 --> 00:29:45.845 if there's anything that you
NOTE Confidence: 0.996346

00:29:45.845 --> 00:29:47.045 remember from this presentation, I
NOTE Confidence: 0.996346

00:29:47.045 --> 00:29:48.085 hope it's a lot, but
NOTE Confidence: 0.996346

00:29:48.085 --> 00:29:48.965 I would say the next
NOTE Confidence: 0.996346

00:29:48.965 --> 00:29:50.405 two slides will be very
NOTE Confidence: 0.996346

00:29:50.405 --> 00:29:51.880 useful for you to have
NOTE Confidence: 0.996346

00:29:51.880 --> 00:29:53.000 in your pocket when you're
NOTE Confidence: 0.996346

00:29:53.000 --> 00:29:54.360 submitting your studies to the
NOTE Confidence: 0.996346

00:29:54.360 --> 00:29:54.860 IRB.
NOTE Confidence: 0.998114

00:29:55.640 --> 00:29:57.640 This first slide is sample
NOTE Confidence: 0.998114

00:29:57.640 --> 00:29:58.860 text that you can use
NOTE Confidence: 0.9790512

00:29:59.320 --> 00:30:00.760 when you're trying to describe
NOTE Confidence: 0.9790512

00:30:00.760 --> 00:30:01.960 how data is going to
NOTE Confidence: 0.9790512

00:30:01.960 --> 00:30:03.559 be recorded so that subjects

NOTE Confidence: 0.9790512

00:30:03.559 --> 00:30:04.700 will not be identified.

NOTE Confidence: 0.9958019

00:30:05.345 --> 00:30:06.305 So you will need to

NOTE Confidence: 0.9958019

00:30:06.305 --> 00:30:07.825 tailor this as appropriate for

NOTE Confidence: 0.9958019

00:30:07.825 --> 00:30:09.265 your study, but you'll essentially

NOTE Confidence: 0.9958019

00:30:09.265 --> 00:30:10.385 be able to copy this

NOTE Confidence: 0.9958019

00:30:10.385 --> 00:30:10.885 information,

NOTE Confidence: 0.99382824

00:30:11.665 --> 00:30:12.705 and then paste it when

NOTE Confidence: 0.99382824

00:30:12.705 --> 00:30:13.745 it's asked of you in

NOTE Confidence: 0.99382824

00:30:13.745 --> 00:30:15.345 the IRB application or the

NOTE Confidence: 0.99382824

00:30:15.345 --> 00:30:16.805 exemption request form.

NOTE Confidence: 0.98633826

00:30:17.370 --> 00:30:18.810 So, you can see on

NOTE Confidence: 0.98633826

00:30:18.810 --> 00:30:20.330 your screen here, it's just

NOTE Confidence: 0.98633826

00:30:20.330 --> 00:30:21.770 indicating that, you know, patient

NOTE Confidence: 0.98633826

00:30:21.770 --> 00:30:23.450 medical record numbers obtained from

NOTE Confidence: 0.98633826

00:30:23.450 --> 00:30:24.810 a JDate request will be

NOTE Confidence: 0.98633826

00:30:24.810 --> 00:30:26.670 recorded onto a master list.

NOTE Confidence: 0.98633826

00:30:26.890 --> 00:30:27.850 There's going to be a

NOTE Confidence: 0.98633826

00:30:27.850 --> 00:30:28.890 code. This is how it's

NOTE Confidence: 0.98633826

00:30:28.890 --> 00:30:29.870 going to be assigned.

NOTE Confidence: 0.9824846

00:30:30.330 --> 00:30:31.770 The master list is going

NOTE Confidence: 0.9824846

00:30:31.770 --> 00:30:32.810 to be stored in an

NOTE Confidence: 0.9824846

00:30:32.810 --> 00:30:34.625 Excel spreadsheet on SharePoint. It's

NOTE Confidence: 0.9824846

00:30:34.625 --> 00:30:36.005 only going to be available

NOTE Confidence: 0.9824846

00:30:36.145 --> 00:30:37.845 to x y z individuals,

NOTE Confidence: 0.997135

00:30:38.705 --> 00:30:39.905 and then it talks about

NOTE Confidence: 0.997135

00:30:39.905 --> 00:30:41.424 password protection. So this should

NOTE Confidence: 0.997135

00:30:41.424 --> 00:30:43.025 be really useful for you

NOTE Confidence: 0.997135

00:30:43.025 --> 00:30:44.385 when you're submitting your projects

NOTE Confidence: 0.997135

00:30:44.385 --> 00:30:45.285 to the IRB.

NOTE Confidence: 0.9927132

00:30:46.020 --> 00:30:47.380 And then the second one

NOTE Confidence: 0.9927132

00:30:47.380 --> 00:30:49.220 is the request for a

NOTE Confidence: 0.9927132
00:30:49.220 --> 00:30:50.980 waiver of HIPAA authorization for
NOTE Confidence: 0.9927132
00:30:50.980 --> 00:30:52.260 those chart reviews. So, again,
NOTE Confidence: 0.9927132
00:30:52.260 --> 00:30:53.380 you'll need to tailor this
NOTE Confidence: 0.9927132
00:30:53.380 --> 00:30:55.000 as appropriate to your study,
NOTE Confidence: 0.9969056
00:30:55.300 --> 00:30:56.580 but this is essentially the
NOTE Confidence: 0.9969056
00:30:56.580 --> 00:30:58.360 language that can be used
NOTE Confidence: 0.9969056
00:30:58.625 --> 00:31:00.225 to request that full waiver
NOTE Confidence: 0.9969056
00:31:00.225 --> 00:31:00.885 of authorization.
NOTE Confidence: 0.99735266
00:31:01.185 --> 00:31:02.305 Again, this is something that
NOTE Confidence: 0.99735266
00:31:02.305 --> 00:31:03.745 you can find in the
NOTE Confidence: 0.99735266
00:31:03.745 --> 00:31:05.365 exemption request form,
NOTE Confidence: 0.986062
00:31:05.985 --> 00:31:07.505 or the IRB submission form,
NOTE Confidence: 0.986062
00:31:07.505 --> 00:31:08.625 which is the document that
NOTE Confidence: 0.986062
00:31:08.625 --> 00:31:10.145 would you would instead use
NOTE Confidence: 0.986062
00:31:10.145 --> 00:31:11.345 if you are conducting a
NOTE Confidence: 0.986062

00:31:11.345 --> 00:31:12.885 drug or a device trial.
NOTE Confidence: 0.9981607

00:31:14.520 --> 00:31:15.480 So now that we've talked
NOTE Confidence: 0.9981607

00:31:15.480 --> 00:31:16.840 about all of the basics,
NOTE Confidence: 0.9981607

00:31:16.840 --> 00:31:18.200 how do you actually submit
NOTE Confidence: 0.9981607

00:31:18.200 --> 00:31:19.880 your research application to the
NOTE Confidence: 0.9981607

00:31:19.880 --> 00:31:20.780 Yale IRB?
NOTE Confidence: 0.98931855

00:31:21.480 --> 00:31:23.320 Before you submit, ask yourself,
NOTE Confidence: 0.98931855

00:31:23.320 --> 00:31:24.360 can you serve as the
NOTE Confidence: 0.98931855

00:31:24.360 --> 00:31:25.420 principal investigator?
NOTE Confidence: 0.95213056

00:31:25.815 --> 00:31:26.774 So we go by the
NOTE Confidence: 0.95213056

00:31:26.774 --> 00:31:29.014 Yale faculty handbook regarding who
NOTE Confidence: 0.95213056

00:31:29.014 --> 00:31:30.215 can serve as a principal
NOTE Confidence: 0.95213056

00:31:30.215 --> 00:31:30.715 investigator.
NOTE Confidence: 0.95854765

00:31:31.575 --> 00:31:32.774 I would say that most
NOTE Confidence: 0.95854765

00:31:32.774 --> 00:31:34.215 faculty are able to serve
NOTE Confidence: 0.95854765

00:31:34.215 --> 00:31:36.075 as PI's. The only individuals

NOTE Confidence: 0.95854765

00:31:36.215 --> 00:31:37.335 that we don't allow to

NOTE Confidence: 0.95854765

00:31:37.335 --> 00:31:38.855 serve as PI's, from a

NOTE Confidence: 0.95854765

00:31:38.855 --> 00:31:41.115 faculty perspective is adjunct faculty.

NOTE Confidence: 0.97282577

00:31:41.550 --> 00:31:43.150 So in those cases, adjunct

NOTE Confidence: 0.97282577

00:31:43.150 --> 00:31:44.590 faculty will need to give

NOTE Confidence: 0.97282577

00:31:44.590 --> 00:31:46.190 special permission to serve as

NOTE Confidence: 0.97282577

00:31:46.190 --> 00:31:48.030 the PI from the dean

NOTE Confidence: 0.97282577

00:31:48.030 --> 00:31:49.630 of their department. So we

NOTE Confidence: 0.97282577

00:31:49.630 --> 00:31:50.510 do have a form that

NOTE Confidence: 0.97282577

00:31:50.510 --> 00:31:51.790 can be completed in those

NOTE Confidence: 0.97282577

00:31:51.790 --> 00:31:52.290 circumstances.

NOTE Confidence: 0.8932143

00:31:53.644 --> 00:31:54.544 Also, ask yourself,

NOTE Confidence: 0.92608356

00:31:54.924 --> 00:31:56.705 what training does your team

NOTE Confidence: 0.92608356

00:31:56.764 --> 00:31:57.644 and and do you need

NOTE Confidence: 0.92608356

00:31:57.644 --> 00:31:58.304 to complete?

NOTE Confidence: 0.9945227

00:31:58.605 --> 00:32:00.384 We do require human subject
NOTE Confidence: 0.9945227
00:32:00.445 --> 00:32:01.424 protection training.
NOTE Confidence: 0.99385256
00:32:01.804 --> 00:32:03.004 This is done via the
NOTE Confidence: 0.99385256
00:32:03.004 --> 00:32:03.504 CITI
NOTE Confidence: 0.9885647
00:32:03.884 --> 00:32:05.085 program, which I'm sure many
NOTE Confidence: 0.9885647
00:32:05.085 --> 00:32:06.205 of you have worked with
NOTE Confidence: 0.9885647
00:32:06.205 --> 00:32:06.705 before.
NOTE Confidence: 0.91533786
00:32:07.210 --> 00:32:09.290 We also require HIPAA training
NOTE Confidence: 0.91533786
00:32:09.290 --> 00:32:10.890 that's done within here within
NOTE Confidence: 0.91533786
00:32:10.890 --> 00:32:12.250 Yale that for anyone that's
NOTE Confidence: 0.91533786
00:32:12.250 --> 00:32:13.210 going to be working with
NOTE Confidence: 0.91533786
00:32:13.210 --> 00:32:14.430 protective health information.
NOTE Confidence: 0.98240125
00:32:14.810 --> 00:32:15.610 And then if you're going
NOTE Confidence: 0.98240125
00:32:15.610 --> 00:32:17.150 to be conducting a clinical
NOTE Confidence: 0.98240125
00:32:17.210 --> 00:32:17.710 trial,
NOTE Confidence: 0.9887627
00:32:18.170 --> 00:32:19.210 you will need to take

NOTE Confidence: 0.9887627

00:32:19.210 --> 00:32:19.710 GCP

NOTE Confidence: 0.9856185

00:32:20.205 --> 00:32:21.404 training as well, and that

NOTE Confidence: 0.9856185

00:32:21.404 --> 00:32:22.525 can be done via the

NOTE Confidence: 0.9856185

00:32:22.525 --> 00:32:23.965 CITI program. So I have

NOTE Confidence: 0.9856185

00:32:23.965 --> 00:32:25.664 included links for you here.

NOTE Confidence: 0.99525476

00:32:26.445 --> 00:32:28.684 Also, are any ancillary groups

NOTE Confidence: 0.99525476

00:32:28.684 --> 00:32:30.044 going to need to review

NOTE Confidence: 0.99525476

00:32:30.044 --> 00:32:31.725 your research as well? Just

NOTE Confidence: 0.99525476

00:32:31.725 --> 00:32:32.605 to give you an idea,

NOTE Confidence: 0.99525476

00:32:32.605 --> 00:32:33.804 if you're working with, you

NOTE Confidence: 0.99525476

00:32:33.804 --> 00:32:35.245 know, radiation, we have a

NOTE Confidence: 0.99525476

00:32:35.245 --> 00:32:36.800 radiation safety committee that will

NOTE Confidence: 0.99525476

00:32:36.800 --> 00:32:38.160 need to review your research.

NOTE Confidence: 0.99525476

00:32:38.160 --> 00:32:39.440 If you're working with children,

NOTE Confidence: 0.99525476

00:32:39.440 --> 00:32:41.060 we have a pediatric protocol

NOTE Confidence: 0.99525476

00:32:41.120 --> 00:32:42.880 review committee that reviews all
NOTE Confidence: 0.99525476

00:32:42.880 --> 00:32:44.880 research involving children. So once
NOTE Confidence: 0.99525476

00:32:44.880 --> 00:32:46.320 you submit your application to
NOTE Confidence: 0.99525476

00:32:46.320 --> 00:32:46.980 the IRB,
NOTE Confidence: 0.99887615

00:32:47.280 --> 00:32:48.320 we might tell you that
NOTE Confidence: 0.99887615

00:32:48.320 --> 00:32:49.360 you need to contact these
NOTE Confidence: 0.99887615

00:32:49.360 --> 00:32:50.500 ancillary groups
NOTE Confidence: 0.9846861

00:32:50.815 --> 00:32:52.095 in order to get their,
NOTE Confidence: 0.99925953

00:32:52.495 --> 00:32:53.735 approval for your study as
NOTE Confidence: 0.99925953

00:32:53.735 --> 00:32:54.355 well. Thankfully,
NOTE Confidence: 0.98784745

00:32:55.535 --> 00:32:57.375 that can be accommodated for
NOTE Confidence: 0.98784745

00:32:57.375 --> 00:32:58.335 the most part in the
NOTE Confidence: 0.98784745

00:32:58.335 --> 00:33:00.255 IRIS IRB system, which is
NOTE Confidence: 0.98784745

00:33:00.255 --> 00:33:01.535 the system that you'll use
NOTE Confidence: 0.98784745

00:33:01.535 --> 00:33:03.315 to submit your IRB applications.
NOTE Confidence: 0.99379593

00:33:05.030 --> 00:33:06.070 So, again, these are some

NOTE Confidence: 0.99379593

00:33:06.070 --> 00:33:07.270 documents that you might need

NOTE Confidence: 0.99379593

00:33:07.270 --> 00:33:09.030 for review. I will say

NOTE Confidence: 0.99379593

00:33:09.030 --> 00:33:10.390 one great thing about our

NOTE Confidence: 0.99379593

00:33:10.390 --> 00:33:11.669 system is it's a very

NOTE Confidence: 0.99379593

00:33:11.669 --> 00:33:14.150 heavy document upload system. So

NOTE Confidence: 0.99379593

00:33:14.150 --> 00:33:15.909 instead of having, like, fifty

NOTE Confidence: 0.99379593

00:33:15.909 --> 00:33:17.110 pages that you have to

NOTE Confidence: 0.99379593

00:33:17.110 --> 00:33:18.575 complete, there's only a few

NOTE Confidence: 0.99379593

00:33:18.575 --> 00:33:20.435 pages in the IRB application,

NOTE Confidence: 0.99379593

00:33:20.575 --> 00:33:21.955 that electronic system,

NOTE Confidence: 0.9690864

00:33:22.335 --> 00:33:23.215 but we ask you to

NOTE Confidence: 0.9690864

00:33:23.215 --> 00:33:24.415 upload a lot of those

NOTE Confidence: 0.9690864

00:33:24.415 --> 00:33:26.415 documents. So your protocol, consent

NOTE Confidence: 0.9690864

00:33:26.415 --> 00:33:28.035 forms, recruitment materials,

NOTE Confidence: 0.93892944

00:33:28.815 --> 00:33:29.935 anything else that you're going

NOTE Confidence: 0.93892944

00:33:29.935 --> 00:33:30.895 to need to conduct your
NOTE Confidence: 0.93892944

00:33:30.895 --> 00:33:32.255 study, that those are going
NOTE Confidence: 0.93892944

00:33:32.255 --> 00:33:33.790 to be uploaded as documents
NOTE Confidence: 0.93892944

00:33:33.790 --> 00:33:34.530 in the application,
NOTE Confidence: 0.9977264

00:33:34.910 --> 00:33:36.270 but it's pretty straightforward about
NOTE Confidence: 0.9977264

00:33:36.270 --> 00:33:37.310 where you actually need to
NOTE Confidence: 0.9977264

00:33:37.310 --> 00:33:38.370 put those documents.
NOTE Confidence: 0.9646189

00:33:39.150 --> 00:33:40.190 So I'll start out with
NOTE Confidence: 0.9646189

00:33:40.190 --> 00:33:41.870 when you're conducting exempt research.
NOTE Confidence: 0.9646189

00:33:41.870 --> 00:33:42.990 Let's say you're do those
NOTE Confidence: 0.9646189

00:33:43.070 --> 00:33:44.530 you're doing those chart reviews,
NOTE Confidence: 0.9646189

00:33:44.590 --> 00:33:46.450 those interviews, focus groups,
NOTE Confidence: 0.9987157

00:33:46.855 --> 00:33:48.634 you will complete this exemption
NOTE Confidence: 0.9987157

00:33:48.774 --> 00:33:50.054 request form that I've linked
NOTE Confidence: 0.9987157

00:33:50.054 --> 00:33:50.875 for you there.
NOTE Confidence: 0.9310814

00:33:52.134 --> 00:33:53.735 This can be uploaded as

NOTE Confidence: 0.9310814

00:33:53.735 --> 00:33:56.054 your protocol, essentially, in IRS

NOTE Confidence: 0.9310814

00:33:56.054 --> 00:33:56.554 IRB.

NOTE Confidence: 0.9944904

00:33:56.934 --> 00:33:58.215 And, obviously, in addition to

NOTE Confidence: 0.9944904

00:33:58.215 --> 00:33:59.894 that, you'll upload any consent

NOTE Confidence: 0.9944904

00:33:59.894 --> 00:34:00.934 documents you may or may

NOTE Confidence: 0.9944904

00:34:00.934 --> 00:34:02.315 not be using, surveys,

NOTE Confidence: 0.726792

00:34:02.830 --> 00:34:03.330 questions,

NOTE Confidence: 0.9635972

00:34:03.710 --> 00:34:06.050 recruitment materials, letters of support,

NOTE Confidence: 0.9635972

00:34:06.110 --> 00:34:07.730 etcetera. So that's a pretty,

NOTE Confidence: 0.9959532

00:34:08.590 --> 00:34:09.489 easy application

NOTE Confidence: 0.9804171

00:34:09.870 --> 00:34:11.310 to complete this form and

NOTE Confidence: 0.9804171

00:34:11.310 --> 00:34:13.170 then upload into IRS IRB.

NOTE Confidence: 0.99267256

00:34:13.870 --> 00:34:15.010 If you are conducting

NOTE Confidence: 0.99039763

00:34:15.325 --> 00:34:17.085 expedited or full board research,

NOTE Confidence: 0.99039763

00:34:17.085 --> 00:34:18.045 so let's say you're working

NOTE Confidence: 0.99039763

00:34:18.045 --> 00:34:19.425 with drugs or devices,
NOTE Confidence: 0.9993871

00:34:20.364 --> 00:34:21.725 you will need to complete
NOTE Confidence: 0.9993871

00:34:21.725 --> 00:34:22.465 a protocol
NOTE Confidence: 0.9939056

00:34:22.844 --> 00:34:24.844 and the IRB submission form
NOTE Confidence: 0.9939056

00:34:24.844 --> 00:34:26.525 and upload those in IRIS
NOTE Confidence: 0.9939056

00:34:26.525 --> 00:34:27.025 IRB.
NOTE Confidence: 0.99700326

00:34:27.450 --> 00:34:29.050 We do have templates available
NOTE Confidence: 0.99700326

00:34:29.050 --> 00:34:30.170 for you in the IRIS
NOTE Confidence: 0.99700326

00:34:30.170 --> 00:34:31.849 IRB library that you can
NOTE Confidence: 0.99700326

00:34:31.849 --> 00:34:33.290 use for your protocol. We've
NOTE Confidence: 0.99700326

00:34:33.290 --> 00:34:35.690 got various biomedical templates, social
NOTE Confidence: 0.99700326

00:34:35.690 --> 00:34:36.830 behavioral templates,
NOTE Confidence: 0.9801079

00:34:37.690 --> 00:34:39.070 and we are actually revising
NOTE Confidence: 0.9801079

00:34:39.130 --> 00:34:40.810 those then. They're looking really
NOTE Confidence: 0.9801079

00:34:40.810 --> 00:34:42.089 good. Those should be available
NOTE Confidence: 0.9801079

00:34:42.089 --> 00:34:43.185 in the spring, so we're

NOTE Confidence: 0.9801079

00:34:43.185 --> 00:34:44.065 happy about that, but we

NOTE Confidence: 0.9801079

00:34:44.065 --> 00:34:45.185 do have some nice templates

NOTE Confidence: 0.9801079

00:34:45.185 --> 00:34:46.325 for you there currently.

NOTE Confidence: 0.99936783

00:34:47.105 --> 00:34:48.065 You will also need to

NOTE Confidence: 0.99936783

00:34:48.065 --> 00:34:50.245 upload this IRB submission form.

NOTE Confidence: 0.9766825

00:34:50.625 --> 00:34:52.805 This is essentially a complimentary

NOTE Confidence: 0.99894214

00:34:53.185 --> 00:34:54.864 document to the protocol that

NOTE Confidence: 0.99894214

00:34:54.864 --> 00:34:56.145 asks a little bit more

NOTE Confidence: 0.99894214

00:34:56.145 --> 00:34:57.905 information about your study with

NOTE Confidence: 0.99894214

00:34:57.905 --> 00:34:58.290 regards

NOTE Confidence: 0.9749529

00:34:58.770 --> 00:34:59.989 to local context.

NOTE Confidence: 0.9690483

00:35:00.450 --> 00:35:01.890 So what waivers are you

NOTE Confidence: 0.9690483

00:35:01.890 --> 00:35:03.330 requesting? Let's say you're doing

NOTE Confidence: 0.9690483

00:35:03.330 --> 00:35:04.770 that drug device trial, you

NOTE Confidence: 0.9690483

00:35:04.770 --> 00:35:05.969 need to request some type

NOTE Confidence: 0.9690483

00:35:05.969 --> 00:35:07.890 of HIPAA waiver, that's actually
NOTE Confidence: 0.9690483

00:35:07.890 --> 00:35:09.330 done in the IRB submission
NOTE Confidence: 0.9690483

00:35:09.330 --> 00:35:10.710 form instead of the exemption
NOTE Confidence: 0.9690483

00:35:10.770 --> 00:35:11.989 request form obviously,
NOTE Confidence: 0.97924435

00:35:13.105 --> 00:35:15.125 and more information about recruitment
NOTE Confidence: 0.97924435

00:35:15.344 --> 00:35:16.385 is is asked in the
NOTE Confidence: 0.97924435

00:35:16.385 --> 00:35:18.065 IRB submission form. So keep
NOTE Confidence: 0.97924435

00:35:18.065 --> 00:35:19.285 in mind if you're conducting
NOTE Confidence: 0.97924435

00:35:19.344 --> 00:35:21.045 that full board or expedited
NOTE Confidence: 0.97924435

00:35:21.105 --> 00:35:22.864 research, both of these documents
NOTE Confidence: 0.97924435

00:35:22.864 --> 00:35:23.925 will need to be uploaded.
NOTE Confidence: 0.9754261

00:35:24.719 --> 00:35:26.160 Regardless of if your research
NOTE Confidence: 0.9754261

00:35:26.160 --> 00:35:28.320 is exempt, expedited, full board,
NOTE Confidence: 0.9754261

00:35:28.320 --> 00:35:29.680 everything else also needs to
NOTE Confidence: 0.9754261

00:35:29.680 --> 00:35:31.200 be uploaded. So, again, those
NOTE Confidence: 0.9754261

00:35:31.200 --> 00:35:33.680 consent documents, assent documents, we

NOTE Confidence: 0.9754261
00:35:33.680 --> 00:35:35.280 do have templates available for
NOTE Confidence: 0.9754261
00:35:35.280 --> 00:35:36.420 you in the library.
NOTE Confidence: 0.9569663
00:35:36.975 --> 00:35:38.495 Something that's great to to
NOTE Confidence: 0.9569663
00:35:38.495 --> 00:35:39.375 announce is that we did
NOTE Confidence: 0.9569663
00:35:39.375 --> 00:35:41.375 just update our ascent forms.
NOTE Confidence: 0.9569663
00:35:41.375 --> 00:35:43.295 So for adolescents and children,
NOTE Confidence: 0.9569663
00:35:43.295 --> 00:35:44.655 we did just update those
NOTE Confidence: 0.9569663
00:35:44.655 --> 00:35:46.335 forms to be more user
NOTE Confidence: 0.9569663
00:35:46.335 --> 00:35:48.015 friendly for children. So those
NOTE Confidence: 0.9569663
00:35:48.015 --> 00:35:49.215 are available in the Iris
NOTE Confidence: 0.9569663
00:35:49.215 --> 00:35:50.195 Iribe library.
NOTE Confidence: 0.9880585
00:35:50.640 --> 00:35:52.319 And, again, upload any other
NOTE Confidence: 0.9880585
00:35:52.319 --> 00:35:53.440 documents that are going to
NOTE Confidence: 0.9880585
00:35:53.440 --> 00:35:55.299 be part of your research.
NOTE Confidence: 0.9981898
00:35:56.000 --> 00:35:57.619 If you are conducting international
NOTE Confidence: 0.9981898

00:35:57.760 --> 00:35:59.119 research, we also will ask
NOTE Confidence: 0.9981898

00:35:59.119 --> 00:36:00.739 that you complete this international
NOTE Confidence: 0.9981898

00:36:00.960 --> 00:36:01.460 checklist
NOTE Confidence: 0.97950613

00:36:01.839 --> 00:36:03.200 and upload it in IRIS
NOTE Confidence: 0.97950613

00:36:03.200 --> 00:36:04.500 IRB as well.
NOTE Confidence: 0.97849095

00:36:05.995 --> 00:36:07.355 This is the iris IRB
NOTE Confidence: 0.97849095

00:36:07.355 --> 00:36:09.375 library. What's nice about iris
NOTE Confidence: 0.97849095

00:36:09.435 --> 00:36:11.195 IRB is it's you log
NOTE Confidence: 0.97849095

00:36:11.195 --> 00:36:12.495 in with your Yale NetID.
NOTE Confidence: 0.97849095

00:36:12.635 --> 00:36:13.675 So if you just Google
NOTE Confidence: 0.97849095

00:36:13.675 --> 00:36:15.355 iris IRB, or I've provided
NOTE Confidence: 0.97849095

00:36:15.355 --> 00:36:16.315 a link for you later
NOTE Confidence: 0.97849095

00:36:16.315 --> 00:36:17.930 on, you will log in
NOTE Confidence: 0.97849095

00:36:17.930 --> 00:36:19.450 with your Yale NetID and
NOTE Confidence: 0.97849095

00:36:19.450 --> 00:36:20.489 password. You don't have to
NOTE Confidence: 0.97849095

00:36:20.489 --> 00:36:21.450 sign up for a separate

NOTE Confidence: 0.97849095

00:36:21.450 --> 00:36:23.289 account, so it's pretty easy

NOTE Confidence: 0.97849095

00:36:23.289 --> 00:36:25.049 to navigate and and get

NOTE Confidence: 0.97849095

00:36:25.049 --> 00:36:26.029 into the system.

NOTE Confidence: 0.98140544

00:36:26.410 --> 00:36:27.210 If you go to the

NOTE Confidence: 0.98140544

00:36:27.210 --> 00:36:28.890 library, which is this banner

NOTE Confidence: 0.98140544

00:36:28.890 --> 00:36:30.885 up top, you can access

NOTE Confidence: 0.98140544

00:36:30.945 --> 00:36:32.785 our protocol templates. Again, that's

NOTE Confidence: 0.98140544

00:36:32.785 --> 00:36:33.585 where you're going to find

NOTE Confidence: 0.98140544

00:36:33.585 --> 00:36:35.265 the exemption request form, all

NOTE Confidence: 0.98140544

00:36:35.265 --> 00:36:36.625 of our biomedical and social

NOTE Confidence: 0.98140544

00:36:36.625 --> 00:36:37.605 behavioral templates.

NOTE Confidence: 0.9930183

00:36:37.985 --> 00:36:38.785 If you click on the

NOTE Confidence: 0.9930183

00:36:38.785 --> 00:36:40.225 breadcrumbs here, this is where

NOTE Confidence: 0.9930183

00:36:40.225 --> 00:36:41.745 you can also access consent

NOTE Confidence: 0.9930183

00:36:41.745 --> 00:36:42.565 form templates,

NOTE Confidence: 0.9385231

00:36:43.380 --> 00:36:45.299 our handbooks and manuals, so
NOTE Confidence: 0.9385231

00:36:45.299 --> 00:36:47.400 our SOP manual, our investigator
NOTE Confidence: 0.9385231

00:36:47.539 --> 00:36:48.039 manual.
NOTE Confidence: 0.99569947

00:36:48.339 --> 00:36:49.380 And then if you click
NOTE Confidence: 0.99569947

00:36:49.380 --> 00:36:51.219 on the IRB tab that's
NOTE Confidence: 0.99569947

00:36:51.219 --> 00:36:51.799 up here,
NOTE Confidence: 0.9962564

00:36:52.180 --> 00:36:53.299 you will also have access
NOTE Confidence: 0.9962564

00:36:53.299 --> 00:36:54.500 to our help center, which
NOTE Confidence: 0.9962564

00:36:54.500 --> 00:36:56.114 has some really nice guides
NOTE Confidence: 0.9962564

00:36:56.114 --> 00:36:56.614 about
NOTE Confidence: 0.990539

00:36:56.915 --> 00:36:57.415 submitting,
NOTE Confidence: 0.9948412

00:36:58.195 --> 00:36:58.695 clarifications
NOTE Confidence: 0.99944717

00:36:58.995 --> 00:37:00.055 back to the IRB
NOTE Confidence: 0.9821269

00:37:00.435 --> 00:37:02.135 and other types of training
NOTE Confidence: 0.9821269

00:37:02.275 --> 00:37:02.775 videos.
NOTE Confidence: 0.97829735

00:37:04.915 --> 00:37:06.035 So the last thing I'll

NOTE Confidence: 0.97829735

00:37:06.035 --> 00:37:07.555 talk about is what happens

NOTE Confidence: 0.97829735

00:37:07.555 --> 00:37:09.570 once you submit that project

NOTE Confidence: 0.97829735

00:37:09.570 --> 00:37:11.170 to the IRB. What does

NOTE Confidence: 0.97829735

00:37:11.170 --> 00:37:12.530 the review process and the

NOTE Confidence: 0.97829735

00:37:12.530 --> 00:37:13.510 flow look like?

NOTE Confidence: 0.94517636

00:37:13.890 --> 00:37:14.390 Investigators,

NOTE Confidence: 0.94605625

00:37:14.690 --> 00:37:15.969 when they submit all those

NOTE Confidence: 0.94605625

00:37:15.969 --> 00:37:17.670 documents in IRS IRB,

NOTE Confidence: 0.99747753

00:37:18.290 --> 00:37:19.730 that application is going to

NOTE Confidence: 0.99747753

00:37:19.730 --> 00:37:21.090 be assigned to a Yale

NOTE Confidence: 0.99747753

00:37:21.090 --> 00:37:22.150 IRB regulatory

NOTE Confidence: 0.97163564

00:37:22.450 --> 00:37:23.925 analyst. They're going to conduct

NOTE Confidence: 0.97163564

00:37:23.925 --> 00:37:24.965 a pre review of your

NOTE Confidence: 0.97163564

00:37:24.965 --> 00:37:26.165 application. They're going to make

NOTE Confidence: 0.97163564

00:37:26.165 --> 00:37:27.045 sure that all of your

NOTE Confidence: 0.97163564

00:37:27.045 --> 00:37:28.265 training is complete,
NOTE Confidence: 0.97237676

00:37:28.725 --> 00:37:31.125 that you have uploaded everything
NOTE Confidence: 0.97237676

00:37:31.125 --> 00:37:31.625 correctly,
NOTE Confidence: 0.9841345

00:37:32.165 --> 00:37:33.785 and then they'll either triage
NOTE Confidence: 0.9841345

00:37:33.925 --> 00:37:35.685 that application to the fully
NOTE Confidence: 0.9841345

00:37:35.685 --> 00:37:37.445 convened IRB for, again, those
NOTE Confidence: 0.9841345

00:37:37.445 --> 00:37:38.940 greater than minimal risk or
NOTE Confidence: 0.9841345

00:37:38.940 --> 00:37:39.839 drug device
NOTE Confidence: 0.98055726

00:37:40.219 --> 00:37:41.739 studies, or they will, send
NOTE Confidence: 0.98055726

00:37:41.739 --> 00:37:43.020 it to an IRB chair
NOTE Confidence: 0.98055726

00:37:43.020 --> 00:37:44.700 or a designated reviewer for
NOTE Confidence: 0.98055726

00:37:44.700 --> 00:37:46.319 exempt or expedited research.
NOTE Confidence: 0.9807235

00:37:46.859 --> 00:37:48.219 They're going to look at
NOTE Confidence: 0.9807235

00:37:48.219 --> 00:37:49.420 your study. They may have
NOTE Confidence: 0.9807235

00:37:49.420 --> 00:37:51.099 questions for you, so please
NOTE Confidence: 0.9807235

00:37:51.099 --> 00:37:52.219 note that once you submit

NOTE Confidence: 0.9807235

00:37:52.219 --> 00:37:54.045 your study, you might get

NOTE Confidence: 0.9807235

00:37:54.045 --> 00:37:55.805 emails from the IRIS IRB

NOTE Confidence: 0.9807235

00:37:55.805 --> 00:37:57.484 system saying there's action needed

NOTE Confidence: 0.9807235

00:37:57.484 --> 00:37:58.145 from you.

NOTE Confidence: 0.97073007

00:37:58.445 --> 00:38:00.705 Please, please complete those

NOTE Confidence: 0.9821482

00:38:01.165 --> 00:38:01.665 clarifications

NOTE Confidence: 0.9740448

00:38:02.045 --> 00:38:03.825 as quickly as possible because

NOTE Confidence: 0.9740448

00:38:04.045 --> 00:38:05.244 the sooner you get back

NOTE Confidence: 0.9740448

00:38:05.244 --> 00:38:06.364 to us, the sooner we're

NOTE Confidence: 0.9740448

00:38:06.364 --> 00:38:07.585 gonna approve your study.

NOTE Confidence: 0.9819514

00:38:07.940 --> 00:38:08.980 So we might just have

NOTE Confidence: 0.9819514

00:38:08.980 --> 00:38:09.940 one or two things you

NOTE Confidence: 0.9819514

00:38:09.940 --> 00:38:11.220 need to change, just get

NOTE Confidence: 0.9819514

00:38:11.220 --> 00:38:12.280 that done quickly

NOTE Confidence: 0.95869964

00:38:12.580 --> 00:38:13.780 so that you can start

NOTE Confidence: 0.95869964

00:38:13.780 --> 00:38:14.500 your research,
NOTE Confidence: 0.91557705

00:38:14.820 --> 00:38:16.680 quickly and and everyone's happy.
NOTE Confidence: 0.9942494

00:38:17.380 --> 00:38:18.500 So once we are done
NOTE Confidence: 0.9942494

00:38:18.500 --> 00:38:20.180 cleaning up your application, all
NOTE Confidence: 0.9942494

00:38:20.180 --> 00:38:20.680 clarifications
NOTE Confidence: 0.96920806

00:38:20.980 --> 00:38:22.180 from the IRB have been
NOTE Confidence: 0.96920806

00:38:22.180 --> 00:38:22.680 addressed.
NOTE Confidence: 0.9851744

00:38:23.205 --> 00:38:24.905 You will receive an email
NOTE Confidence: 0.9851744

00:38:25.125 --> 00:38:26.725 that has a link to
NOTE Confidence: 0.9851744

00:38:26.725 --> 00:38:28.325 your approval letter. So then
NOTE Confidence: 0.9851744

00:38:28.325 --> 00:38:29.525 you are ready to begin
NOTE Confidence: 0.9851744

00:38:29.525 --> 00:38:30.885 your research once you do
NOTE Confidence: 0.9851744

00:38:30.885 --> 00:38:32.405 receive that approval letter from
NOTE Confidence: 0.9851744

00:38:32.405 --> 00:38:33.145 the IRB.
NOTE Confidence: 0.9458682

00:38:33.445 --> 00:38:34.825 It'll be a a PDF
NOTE Confidence: 0.9458682

00:38:34.885 --> 00:38:35.385 document

NOTE Confidence: 0.98261166
00:38:35.710 --> 00:38:37.550 in your IRIS IRB application
NOTE Confidence: 0.98261166
00:38:37.550 --> 00:38:39.090 that you can certainly download.
NOTE Confidence: 0.9415204
00:38:39.630 --> 00:38:40.670 Be sure to read that
NOTE Confidence: 0.9415204
00:38:40.670 --> 00:38:42.270 letter also before you start
NOTE Confidence: 0.9415204
00:38:42.270 --> 00:38:43.630 your research because there might
NOTE Confidence: 0.9415204
00:38:43.630 --> 00:38:45.230 be information the IRB needs
NOTE Confidence: 0.9415204
00:38:45.230 --> 00:38:46.750 to convey with you convey
NOTE Confidence: 0.9415204
00:38:46.750 --> 00:38:47.790 to you in that in
NOTE Confidence: 0.9415204
00:38:47.790 --> 00:38:49.710 that letter. So certainly read
NOTE Confidence: 0.9415204
00:38:49.710 --> 00:38:50.690 the the approval,
NOTE Confidence: 0.99757844
00:38:51.165 --> 00:38:52.605 before you you begin your
NOTE Confidence: 0.99757844
00:38:52.605 --> 00:38:53.105 research.
NOTE Confidence: 0.9875076
00:38:54.445 --> 00:38:55.805 So these are our additional
NOTE Confidence: 0.9875076
00:38:55.805 --> 00:38:57.165 resources I wanted to share
NOTE Confidence: 0.9875076
00:38:57.165 --> 00:38:57.825 with you.
NOTE Confidence: 0.9856658

00:38:58.125 --> 00:38:59.405 We have our website. We
NOTE Confidence: 0.9856658

00:38:59.405 --> 00:39:00.945 have our policies and procedures,
NOTE Confidence: 0.9856658

00:39:01.165 --> 00:39:03.085 our our standard operating procedure
NOTE Confidence: 0.9856658

00:39:03.085 --> 00:39:04.945 manual, our investigator manual,
NOTE Confidence: 0.9769564

00:39:05.370 --> 00:39:06.730 and a link to IRIS
NOTE Confidence: 0.9769564

00:39:06.730 --> 00:39:07.230 IRB.
NOTE Confidence: 0.9804471

00:39:07.850 --> 00:39:08.890 I will also say if
NOTE Confidence: 0.9804471

00:39:08.890 --> 00:39:10.010 you're new to Yale or
NOTE Confidence: 0.9804471

00:39:10.010 --> 00:39:11.130 even if you're not new
NOTE Confidence: 0.9804471

00:39:11.130 --> 00:39:12.810 to Yale, a really useful
NOTE Confidence: 0.9804471

00:39:12.810 --> 00:39:14.670 guidance document is our guidance
NOTE Confidence: 0.9804471

00:39:14.730 --> 00:39:16.090 four ten. This is all
NOTE Confidence: 0.9804471

00:39:16.090 --> 00:39:18.090 about research recruitment at Yale
NOTE Confidence: 0.9804471

00:39:18.090 --> 00:39:19.630 and Yale New Haven Hospital.
NOTE Confidence: 0.985766

00:39:20.055 --> 00:39:21.015 How do you work with
NOTE Confidence: 0.985766

00:39:21.015 --> 00:39:21.515 MyChart

NOTE Confidence: 0.99144983

00:39:21.815 --> 00:39:23.434 to send out MyChart messages?

NOTE Confidence: 0.9811074

00:39:24.055 --> 00:39:26.055 What is acceptable with regards

NOTE Confidence: 0.9811074

00:39:26.055 --> 00:39:27.494 to approaching somebody in health

NOTE Confidence: 0.9811074

00:39:27.494 --> 00:39:29.015 care facilities and asking them

NOTE Confidence: 0.9811074

00:39:29.015 --> 00:39:30.934 to participate in research? So

NOTE Confidence: 0.9811074

00:39:30.934 --> 00:39:32.614 we just updated this a

NOTE Confidence: 0.9811074

00:39:32.614 --> 00:39:34.075 little over a year ago,

NOTE Confidence: 0.9819937

00:39:34.469 --> 00:39:35.590 and we worked with our

NOTE Confidence: 0.9819937

00:39:35.590 --> 00:39:36.790 colleagues at the health system

NOTE Confidence: 0.9819937

00:39:36.790 --> 00:39:37.989 as well. So this is

NOTE Confidence: 0.9819937

00:39:37.989 --> 00:39:39.430 a really nice document to

NOTE Confidence: 0.9819937

00:39:39.430 --> 00:39:40.090 get you,

NOTE Confidence: 0.9781987

00:39:40.950 --> 00:39:42.790 fully educated on what we

NOTE Confidence: 0.9781987

00:39:42.790 --> 00:39:43.989 allow or don't allow when

NOTE Confidence: 0.9781987

00:39:43.989 --> 00:39:45.430 it comes to research recruitment.

NOTE Confidence: 0.9781987

00:39:45.430 --> 00:39:46.310 So take a look at
NOTE Confidence: 0.9781987

00:39:46.310 --> 00:39:47.735 that. And the last thing
NOTE Confidence: 0.9781987

00:39:47.735 --> 00:39:49.015 I'll say before I take
NOTE Confidence: 0.9781987

00:39:49.015 --> 00:39:50.215 any questions from the group
NOTE Confidence: 0.9781987

00:39:50.215 --> 00:39:52.135 is we truly are committed
NOTE Confidence: 0.9781987

00:39:52.135 --> 00:39:53.094 in our office to a
NOTE Confidence: 0.9781987

00:39:53.094 --> 00:39:54.875 partnership with our research community.
NOTE Confidence: 0.9781987

00:39:54.935 --> 00:39:56.935 We're always available to answer
NOTE Confidence: 0.9781987

00:39:56.935 --> 00:39:57.435 questions,
NOTE Confidence: 0.9919782

00:39:58.215 --> 00:39:59.255 to talk with you about
NOTE Confidence: 0.9919782

00:39:59.255 --> 00:39:59.995 your project,
NOTE Confidence: 0.9857739

00:40:00.309 --> 00:40:01.270 and we're always going to
NOTE Confidence: 0.9857739

00:40:01.270 --> 00:40:02.789 ensure that you are supported
NOTE Confidence: 0.9857739

00:40:02.789 --> 00:40:03.829 so that you can conduct
NOTE Confidence: 0.9857739

00:40:03.829 --> 00:40:04.869 all of the great research
NOTE Confidence: 0.9857739

00:40:04.869 --> 00:40:06.390 that you do and ensure

NOTE Confidence: 0.9857739
00:40:06.390 --> 00:40:07.589 that the research that you
NOTE Confidence: 0.9857739
00:40:07.589 --> 00:40:08.869 do conduct is safe and
NOTE Confidence: 0.9857739
00:40:08.869 --> 00:40:10.309 ethical. I promise we're a
NOTE Confidence: 0.9857739
00:40:10.309 --> 00:40:11.989 very friendly bunch, and, again,
NOTE Confidence: 0.9857739
00:40:11.989 --> 00:40:13.589 we're always happy to to
NOTE Confidence: 0.9857739
00:40:13.589 --> 00:40:14.890 collaborate with you.
NOTE Confidence: 0.99904805
00:40:15.344 --> 00:40:16.805 So with that being said,
NOTE Confidence: 0.9788265
00:40:17.265 --> 00:40:18.465 I did wanna leave a
NOTE Confidence: 0.9788265
00:40:18.465 --> 00:40:19.425 good amount of time for
NOTE Confidence: 0.9788265
00:40:19.425 --> 00:40:20.625 questions, and I'm happy to
NOTE Confidence: 0.9788265
00:40:20.625 --> 00:40:21.984 take any questions at this
NOTE Confidence: 0.9788265
00:40:21.984 --> 00:40:22.484 time.
NOTE Confidence: 0.99983615
00:40:27.025 --> 00:40:28.165 Thank you so much.
NOTE Confidence: 0.94727427
00:40:30.300 --> 00:40:31.900 Maybe as people if people
NOTE Confidence: 0.94727427
00:40:31.900 --> 00:40:33.440 have plenty of questions, but
NOTE Confidence: 0.94727427

00:40:33.660 --> 00:40:35.040 one that I'm always surprised

NOTE Confidence: 0.94727427

00:40:35.100 --> 00:40:36.540 on is how quick the

NOTE Confidence: 0.94727427

00:40:36.540 --> 00:40:37.980 process is. You know, with

NOTE Confidence: 0.94727427

00:40:37.980 --> 00:40:39.680 exemptions being the most common

NOTE Confidence: 0.94727427

00:40:39.739 --> 00:40:40.719 other than when

NOTE Confidence: 0.97539026

00:40:41.100 --> 00:40:42.239 the people submitting

NOTE Confidence: 0.9836305

00:40:42.825 --> 00:40:44.344 kinda don't follow through on

NOTE Confidence: 0.9836305

00:40:44.344 --> 00:40:45.785 the queries to them. How

NOTE Confidence: 0.9836305

00:40:45.785 --> 00:40:46.665 long would you tell people

NOTE Confidence: 0.9836305

00:40:46.665 --> 00:40:47.864 it should take on average?

NOTE Confidence: 0.9836305

00:40:47.864 --> 00:40:48.905 Like, do you see coming

NOTE Confidence: 0.9836305

00:40:48.905 --> 00:40:50.125 out of the office? Like,

NOTE Confidence: 0.98402977

00:40:50.505 --> 00:40:51.645 what do you tell people?

NOTE Confidence: 0.9958976

00:40:51.945 --> 00:40:53.484 Yeah. That's a great question.

NOTE Confidence: 0.9958976

00:40:53.545 --> 00:40:54.505 So I would say that

NOTE Confidence: 0.9958976

00:40:54.505 --> 00:40:56.364 for exempt or expedited research,

NOTE Confidence: 0.9958976

00:40:56.610 --> 00:40:57.890 as long as you are

NOTE Confidence: 0.9958976

00:40:57.890 --> 00:40:59.270 responding to the IRB,

NOTE Confidence: 0.9699583

00:41:00.050 --> 00:41:01.490 a week to two weeks

NOTE Confidence: 0.9699583

00:41:01.490 --> 00:41:02.610 from when you submit is

NOTE Confidence: 0.9699583

00:41:02.610 --> 00:41:03.730 when you should receive your

NOTE Confidence: 0.9699583

00:41:03.730 --> 00:41:05.330 approval, which is we're really

NOTE Confidence: 0.9699583

00:41:05.330 --> 00:41:07.250 proud of that. So, obviously,

NOTE Confidence: 0.9699583

00:41:07.250 --> 00:41:08.450 there's outliers, as you say,

NOTE Confidence: 0.9699583

00:41:08.450 --> 00:41:09.855 doctor Grauer. So if you

NOTE Confidence: 0.9699583

00:41:09.855 --> 00:41:11.055 submit your study and the

NOTE Confidence: 0.9699583

00:41:11.055 --> 00:41:12.575 IRB the next day ask

NOTE Confidence: 0.9699583

00:41:12.575 --> 00:41:13.855 for clarifications and you don't

NOTE Confidence: 0.9699583

00:41:13.855 --> 00:41:15.295 respond for a month, that's

NOTE Confidence: 0.9699583

00:41:15.295 --> 00:41:16.094 another thing. But for the

NOTE Confidence: 0.9699583

00:41:16.094 --> 00:41:17.295 most part, I'd say one

NOTE Confidence: 0.9699583

00:41:17.295 --> 00:41:18.975 to two weeks max probably
NOTE Confidence: 0.9699583

00:41:18.975 --> 00:41:19.635 for those.
NOTE Confidence: 0.9731171

00:41:20.094 --> 00:41:21.549 For full board, it's a
NOTE Confidence: 0.9731171

00:41:21.789 --> 00:41:22.989 it just depends on full
NOTE Confidence: 0.9731171

00:41:22.989 --> 00:41:24.269 board. I would say that
NOTE Confidence: 0.9731171

00:41:24.269 --> 00:41:25.710 it can be as little
NOTE Confidence: 0.9731171

00:41:25.710 --> 00:41:26.210 as
NOTE Confidence: 0.9452704

00:41:27.549 --> 00:41:28.369 three weeks,
NOTE Confidence: 0.99873656

00:41:29.230 --> 00:41:30.589 but it just depends on
NOTE Confidence: 0.99873656

00:41:30.589 --> 00:41:31.089 the
NOTE Confidence: 0.9891934

00:41:31.710 --> 00:41:33.795 study, how elaborate the study
NOTE Confidence: 0.9891934

00:41:33.795 --> 00:41:35.635 is, the interventions involved, if
NOTE Confidence: 0.9891934

00:41:35.635 --> 00:41:37.155 there's a vulnerable population. So
NOTE Confidence: 0.9891934

00:41:37.155 --> 00:41:38.114 that's a little bit harder
NOTE Confidence: 0.9891934

00:41:38.114 --> 00:41:39.094 to parse out.
NOTE Confidence: 0.92389333

00:41:39.795 --> 00:41:40.295 Yeah.

NOTE Confidence: 0.92589796

00:41:40.675 --> 00:41:41.795 Good question. I would tell

NOTE Confidence: 0.92589796

00:41:41.795 --> 00:41:43.415 you my experience with expedited

NOTE Confidence: 0.9682508

00:41:43.795 --> 00:41:45.234 or exempt is is even

NOTE Confidence: 0.9682508

00:41:45.234 --> 00:41:46.114 faster than that. You are

NOTE Confidence: 0.9682508

00:41:46.114 --> 00:41:47.415 certainly, if anything, overestimating.

NOTE Confidence: 0.9987882

00:41:47.890 --> 00:41:48.390 Okay.

NOTE Confidence: 0.9597873

00:41:49.090 --> 00:41:49.969 Well, good. I'm glad to

NOTE Confidence: 0.9597873

00:41:49.969 --> 00:41:51.730 hear that. You yes. It

NOTE Confidence: 0.9597873

00:41:51.730 --> 00:41:52.930 can be a a day

NOTE Confidence: 0.9597873

00:41:52.930 --> 00:41:54.369 sometimes for exempt research, but

NOTE Confidence: 0.9597873

00:41:54.369 --> 00:41:55.190 I like to,

NOTE Confidence: 0.9228305

00:41:55.489 --> 00:41:56.770 just in case, give ourselves

NOTE Confidence: 0.9228305

00:41:56.770 --> 00:41:57.810 a little bit of of

NOTE Confidence: 0.9228305

00:41:57.810 --> 00:41:59.010 leisure. Great that you do,

NOTE Confidence: 0.9228305

00:41:59.010 --> 00:42:00.530 but just everyone knows, it's

NOTE Confidence: 0.9228305

00:42:00.530 --> 00:42:01.650 it's pretty fast. So it
NOTE Confidence: 0.9228305

00:42:01.650 --> 00:42:03.055 surprises me. Glad you've had
NOTE Confidence: 0.9228305

00:42:03.055 --> 00:42:04.435 a good experience with that.
NOTE Confidence: 0.9972751

00:42:04.735 --> 00:42:05.235 Yeah.
NOTE Confidence: 0.90214944

00:42:06.175 --> 00:42:07.015 Am I one other kind
NOTE Confidence: 0.90214944

00:42:07.015 --> 00:42:08.335 of before we kinda push
NOTE Confidence: 0.90214944

00:42:08.335 --> 00:42:09.535 for anybody else? But one
NOTE Confidence: 0.90214944

00:42:09.535 --> 00:42:10.335 of the things I find
NOTE Confidence: 0.90214944

00:42:10.335 --> 00:42:11.555 is it's a little anonymous
NOTE Confidence: 0.90214944

00:42:11.695 --> 00:42:13.135 feeling when you kinda send
NOTE Confidence: 0.90214944

00:42:13.135 --> 00:42:15.235 to these, like, general mailboxes,
NOTE Confidence: 0.9987184

00:42:16.094 --> 00:42:17.670 but I've been very impressed
NOTE Confidence: 0.9987184

00:42:17.670 --> 00:42:18.890 how quickly it becomes
NOTE Confidence: 0.9616704

00:42:19.750 --> 00:42:20.790 a email dialogue with a
NOTE Confidence: 0.9616704

00:42:20.790 --> 00:42:22.230 person, as opposed to a
NOTE Confidence: 0.9616704

00:42:22.230 --> 00:42:23.349 general mailbox. Because I I

NOTE Confidence: 0.9616704

00:42:23.349 --> 00:42:24.469 don't know. Y'all kinda feel

NOTE Confidence: 0.9616704

00:42:24.469 --> 00:42:25.369 like some of these

NOTE Confidence: 0.94571483

00:42:25.830 --> 00:42:28.489 office, like, centralized things, it

NOTE Confidence: 0.94571483

00:42:28.710 --> 00:42:29.589 you kinda feel like, is

NOTE Confidence: 0.94571483

00:42:29.589 --> 00:42:30.950 somebody really reading that? And

NOTE Confidence: 0.94571483

00:42:30.950 --> 00:42:32.250 my experience has been

NOTE Confidence: 0.70270985

00:42:37.325 --> 00:42:38.225 if asked for.

NOTE Confidence: 0.96656984

00:42:39.005 --> 00:42:40.125 That's thank you for saying

NOTE Confidence: 0.96656984

00:42:40.205 --> 00:42:41.165 I'm I'm I'm so glad

NOTE Confidence: 0.96656984

00:42:41.165 --> 00:42:42.205 that that's been your experience,

NOTE Confidence: 0.96656984

00:42:42.205 --> 00:42:43.405 but you're you're totally right.

NOTE Confidence: 0.96656984

00:42:43.405 --> 00:42:44.445 As soon as you submit

NOTE Confidence: 0.96656984

00:42:44.445 --> 00:42:46.125 your application, there is somebody

NOTE Confidence: 0.96656984

00:42:46.125 --> 00:42:47.370 that is assigned to your

NOTE Confidence: 0.96656984

00:42:47.690 --> 00:42:48.890 So you're gonna start getting

NOTE Confidence: 0.96656984

00:42:48.890 --> 00:42:50.330 emails from that person. That

NOTE Confidence: 0.96656984

00:42:50.330 --> 00:42:51.690 person is dedicated to your

NOTE Confidence: 0.96656984

00:42:51.690 --> 00:42:53.370 research study. I will say

NOTE Confidence: 0.96656984

00:42:53.370 --> 00:42:54.410 even if you send like,

NOTE Confidence: 0.96656984

00:42:54.410 --> 00:42:55.210 you have you see our

NOTE Confidence: 0.96656984

00:42:55.210 --> 00:42:55.710 our

NOTE Confidence: 0.9013175

00:42:56.090 --> 00:42:57.210 email there, it's h r

NOTE Confidence: 0.9013175

00:42:57.210 --> 00:42:58.090 p p at yale dot

NOTE Confidence: 0.9013175

00:42:58.090 --> 00:42:58.970 e d u. That's our

NOTE Confidence: 0.9013175

00:42:58.970 --> 00:42:59.870 general email.

NOTE Confidence: 0.9976899

00:43:00.265 --> 00:43:01.565 We have staff members,

NOTE Confidence: 0.99978334

00:43:02.265 --> 00:43:03.484 looking at those emails

NOTE Confidence: 0.976598

00:43:03.785 --> 00:43:04.525 every single

NOTE Confidence: 0.96982366

00:43:04.825 --> 00:43:06.505 basically, twenty four seven because

NOTE Confidence: 0.96982366

00:43:06.505 --> 00:43:07.465 the world that we live

NOTE Confidence: 0.96982366

00:43:07.465 --> 00:43:08.265 in, we have to be

NOTE Confidence: 0.96982366

00:43:08.265 --> 00:43:09.465 on call to ensure that

NOTE Confidence: 0.96982366

00:43:09.465 --> 00:43:11.165 there's not emergencies happening.

NOTE Confidence: 0.9904399

00:43:11.465 --> 00:43:12.744 So when you submit that,

NOTE Confidence: 0.9904399

00:43:12.744 --> 00:43:13.625 we are going to have

NOTE Confidence: 0.9904399

00:43:13.625 --> 00:43:15.030 a response to you, I'd

NOTE Confidence: 0.9904399

00:43:15.030 --> 00:43:16.310 say, within a couple of

NOTE Confidence: 0.9904399

00:43:16.310 --> 00:43:17.830 hours. We say twenty four

NOTE Confidence: 0.9904399

00:43:17.830 --> 00:43:19.270 hours, but we've never I've

NOTE Confidence: 0.9904399

00:43:19.270 --> 00:43:20.710 never had anyone not be

NOTE Confidence: 0.9904399

00:43:20.710 --> 00:43:21.850 responded to in,

NOTE Confidence: 0.97616714

00:43:22.310 --> 00:43:23.670 twenty four hours. So we're

NOTE Confidence: 0.97616714

00:43:23.670 --> 00:43:24.710 proud of that as well.

NOTE Confidence: 0.97616714

00:43:24.710 --> 00:43:25.510 But, again, if you do

NOTE Confidence: 0.97616714

00:43:25.510 --> 00:43:26.870 have individual questions as well,

NOTE Confidence: 0.97616714

00:43:26.870 --> 00:43:28.070 you can always contact me,

NOTE Confidence: 0.97616714

00:43:28.070 --> 00:43:29.265 and I'm always happy to
NOTE Confidence: 0.97616714

00:43:29.344 --> 00:43:30.625 either field the question or
NOTE Confidence: 0.97616714

00:43:30.625 --> 00:43:31.664 or talk with you directly
NOTE Confidence: 0.97616714

00:43:31.664 --> 00:43:32.404 about that.
NOTE Confidence: 0.94340456

00:43:34.625 --> 00:43:35.265 Gary, do you have any
NOTE Confidence: 0.94340456

00:43:35.344 --> 00:43:36.065 it looks like you might
NOTE Confidence: 0.94340456

00:43:36.065 --> 00:43:37.025 have a question. I had
NOTE Confidence: 0.94340456

00:43:37.025 --> 00:43:37.984 a question. I actually had
NOTE Confidence: 0.94340456

00:43:37.984 --> 00:43:39.184 a couple of questions. The
NOTE Confidence: 0.94340456

00:43:39.184 --> 00:43:40.065 first, can you give me
NOTE Confidence: 0.94340456

00:43:40.065 --> 00:43:42.020 their email address to contact
NOTE Confidence: 0.94340456

00:43:42.080 --> 00:43:43.440 IRB? I've been looking for
NOTE Confidence: 0.94340456

00:43:43.440 --> 00:43:44.480 a address if I had
NOTE Confidence: 0.94340456

00:43:44.480 --> 00:43:44.980 questions.
NOTE Confidence: 0.9974023

00:43:45.360 --> 00:43:46.320 So what what is the
NOTE Confidence: 0.9974023

00:43:46.320 --> 00:43:47.520 email address if I have

NOTE Confidence: 0.9974023
00:43:47.520 --> 00:43:48.739 questions to ask?
NOTE Confidence: 0.97113
00:43:49.520 --> 00:43:50.560 Sure. So the general one
NOTE Confidence: 0.97113
00:43:50.560 --> 00:43:51.600 is this h r p
NOTE Confidence: 0.97113
00:43:51.600 --> 00:43:52.800 p at yale dot e
NOTE Confidence: 0.97113
00:43:52.800 --> 00:43:53.460 d u.
NOTE Confidence: 0.90235424
00:43:53.920 --> 00:43:55.140 H r p
NOTE Confidence: 0.98903096
00:43:55.645 --> 00:43:57.565 p? Yes. H as in
NOTE Confidence: 0.98903096
00:43:57.565 --> 00:43:59.425 human, r as in Ralph,
NOTE Confidence: 0.9077228
00:43:59.885 --> 00:44:01.325 and p and p as
NOTE Confidence: 0.9077228
00:44:01.325 --> 00:44:02.785 in pen and pen.
NOTE Confidence: 0.8478135
00:44:04.045 --> 00:44:04.445 At,
NOTE Confidence: 0.9858538
00:44:05.005 --> 00:44:06.125 h r p p at
NOTE Confidence: 0.9858538
00:44:06.125 --> 00:44:07.185 human research?
NOTE Confidence: 0.93199515
00:44:07.645 --> 00:44:08.925 At yale dot e d
NOTE Confidence: 0.93199515
00:44:08.925 --> 00:44:10.469 u. At Yale. Just like
NOTE Confidence: 0.93199515

00:44:10.469 --> 00:44:12.390 our normal Sorry. Email. Yeah.
NOTE Confidence: 0.93199515

00:44:12.390 --> 00:44:13.989 Yeah. That's good. Sorry. Time
NOTE Confidence: 0.93199515

00:44:13.989 --> 00:44:15.030 for my coffee in the
NOTE Confidence: 0.93199515

00:44:15.030 --> 00:44:16.870 evening, I guess. My other
NOTE Confidence: 0.93199515

00:44:16.870 --> 00:44:17.670 question was,
NOTE Confidence: 0.9576933

00:44:18.150 --> 00:44:19.210 so I'm a pathologist,
NOTE Confidence: 0.9592497

00:44:19.590 --> 00:44:20.870 and if I had like
NOTE Confidence: 0.9592497

00:44:20.870 --> 00:44:22.275 you mentioned that if if
NOTE Confidence: 0.9592497

00:44:22.275 --> 00:44:23.734 it is a study that
NOTE Confidence: 0.9592497

00:44:23.795 --> 00:44:24.295 involves,
NOTE Confidence: 0.92894024

00:44:24.755 --> 00:44:25.734 using specimens,
NOTE Confidence: 0.94615614

00:44:26.355 --> 00:44:27.655 like, I'm looking at biopsies
NOTE Confidence: 0.94615614

00:44:27.795 --> 00:44:29.734 or exigent specimens from patients,
NOTE Confidence: 0.94615614

00:44:29.954 --> 00:44:30.934 that is exempt.
NOTE Confidence: 0.9135192

00:44:32.515 --> 00:44:34.214 My question was if
NOTE Confidence: 0.99764246

00:44:34.539 --> 00:44:35.579 if if I want to

NOTE Confidence: 0.99764246
00:44:35.579 --> 00:44:36.880 do any kind of molecular
NOTE Confidence: 0.99764246
00:44:37.019 --> 00:44:37.519 analysis
NOTE Confidence: 0.9920881
00:44:38.140 --> 00:44:38.859 on those,
NOTE Confidence: 0.9898899
00:44:40.299 --> 00:44:40.799 specimens,
NOTE Confidence: 0.97942436
00:44:41.259 --> 00:44:43.099 is that still considered exempt?
NOTE Confidence: 0.97942436
00:44:43.099 --> 00:44:44.700 I always submit an IRB
NOTE Confidence: 0.97942436
00:44:44.700 --> 00:44:46.619 for whatever I'm doing because
NOTE Confidence: 0.97942436
00:44:46.619 --> 00:44:48.239 there is chart review involved,
NOTE Confidence: 0.9344293
00:44:48.684 --> 00:44:50.525 And I always submitted IRB
NOTE Confidence: 0.9344293
00:44:50.525 --> 00:44:51.585 for chart review.
NOTE Confidence: 0.94766986
00:44:52.204 --> 00:44:53.404 Mhmm. But if there are
NOTE Confidence: 0.94766986
00:44:53.404 --> 00:44:55.244 additional studies that are that
NOTE Confidence: 0.94766986
00:44:55.244 --> 00:44:56.204 are that I am going
NOTE Confidence: 0.94766986
00:44:56.204 --> 00:44:57.025 to be performing
NOTE Confidence: 0.9756962
00:44:57.885 --> 00:44:59.424 on the patient's specimens,
NOTE Confidence: 0.9790141

00:45:01.325 --> 00:45:02.765 under what category should I
NOTE Confidence: 0.9790141

00:45:02.765 --> 00:45:03.585 submit it?
NOTE Confidence: 0.97768664

00:45:04.660 --> 00:45:05.460 Yeah. That's a good question.
NOTE Confidence: 0.97768664

00:45:05.460 --> 00:45:06.260 So I guess my first
NOTE Confidence: 0.97768664

00:45:06.260 --> 00:45:07.860 question is the the research
NOTE Confidence: 0.97768664

00:45:07.860 --> 00:45:08.820 that you're talking about, the
NOTE Confidence: 0.97768664

00:45:08.820 --> 00:45:09.620 first part of it, are
NOTE Confidence: 0.97768664

00:45:09.620 --> 00:45:10.120 those
NOTE Confidence: 0.8376553

00:45:10.660 --> 00:45:12.520 discarded samples or those
NOTE Confidence: 0.9955286

00:45:12.820 --> 00:45:14.100 samples you're collecting as part
NOTE Confidence: 0.9955286

00:45:14.100 --> 00:45:14.840 of the research?
NOTE Confidence: 0.971634

00:45:15.860 --> 00:45:17.380 No. No. They are, they
NOTE Confidence: 0.971634

00:45:17.380 --> 00:45:19.060 are I'm not collecting anything
NOTE Confidence: 0.971634

00:45:19.060 --> 00:45:19.364 new,
NOTE Confidence: 0.9378406

00:45:19.925 --> 00:45:21.364 as part of the research.
NOTE Confidence: 0.9378406

00:45:21.364 --> 00:45:22.325 It is I see. It

NOTE Confidence: 0.9378406

00:45:22.325 --> 00:45:23.844 is, it is the specimens

NOTE Confidence: 0.9378406

00:45:23.844 --> 00:45:25.364 that are already present in

NOTE Confidence: 0.9378406

00:45:25.525 --> 00:45:26.565 I see. In the lab.

NOTE Confidence: 0.9378406

00:45:26.565 --> 00:45:27.925 Yeah. Like a registry or

NOTE Confidence: 0.9378406

00:45:27.925 --> 00:45:30.005 something. Is that Yes. Yeah.

NOTE Confidence: 0.9378406

00:45:30.005 --> 00:45:31.445 Okay. Okay. Yeah. I would

NOTE Confidence: 0.9378406

00:45:31.445 --> 00:45:31.925 say that,

NOTE Confidence: 0.99934006

00:45:32.750 --> 00:45:33.809 that's a good question.

NOTE Confidence: 0.9985229

00:45:34.430 --> 00:45:35.630 Always submit those types of

NOTE Confidence: 0.9985229

00:45:35.630 --> 00:45:37.010 projects to the IRB.

NOTE Confidence: 0.9715531

00:45:37.469 --> 00:45:38.270 We do have a

NOTE Confidence: 0.97323024

00:45:39.150 --> 00:45:40.349 this wouldn't work in this

NOTE Confidence: 0.97323024

00:45:40.349 --> 00:45:41.489 case. We have a repository

NOTE Confidence: 0.97323024

00:45:41.710 --> 00:45:42.829 template that we just created.

NOTE Confidence: 0.97323024

00:45:42.829 --> 00:45:43.549 I would say in these

NOTE Confidence: 0.97323024

00:45:43.549 --> 00:45:44.049 cases,
NOTE Confidence: 0.98284405

00:45:44.670 --> 00:45:45.469 if you don't know the
NOTE Confidence: 0.98284405

00:45:45.469 --> 00:45:46.515 exact category, I would have
NOTE Confidence: 0.98284405

00:45:46.515 --> 00:45:47.355 to look at the research
NOTE Confidence: 0.98284405

00:45:47.355 --> 00:45:48.795 you're submitting before giving you
NOTE Confidence: 0.98284405

00:45:48.795 --> 00:45:50.075 a category. But that's okay
NOTE Confidence: 0.98284405

00:45:50.075 --> 00:45:50.875 to just, like, leave it
NOTE Confidence: 0.98284405

00:45:50.875 --> 00:45:51.755 blank on the form, and
NOTE Confidence: 0.98284405

00:45:51.755 --> 00:45:52.795 the IRB will help you
NOTE Confidence: 0.98284405

00:45:52.795 --> 00:45:54.155 decide, like, which category it
NOTE Confidence: 0.98284405

00:45:54.155 --> 00:45:54.955 falls in based on the
NOTE Confidence: 0.98284405

00:45:54.955 --> 00:45:56.255 parameters of your research.
NOTE Confidence: 0.9906142

00:45:57.035 --> 00:45:58.235 Okay. Yeah. And I might
NOTE Confidence: 0.9906142

00:45:58.235 --> 00:46:00.155 email somebody at this address
NOTE Confidence: 0.9906142

00:46:00.155 --> 00:46:01.440 to see if they can
NOTE Confidence: 0.9906142

00:46:01.440 --> 00:46:02.960 help me with what category

NOTE Confidence: 0.9906142
00:46:02.960 --> 00:46:04.640 it is, giving specific details
NOTE Confidence: 0.9906142
00:46:04.640 --> 00:46:05.460 about my,
NOTE Confidence: 0.95396423
00:46:06.239 --> 00:46:08.000 case. Or or I or
NOTE Confidence: 0.95396423
00:46:08.000 --> 00:46:09.200 you recommend that I just
NOTE Confidence: 0.95396423
00:46:09.200 --> 00:46:10.239 submit it and leave it
NOTE Confidence: 0.95396423
00:46:10.239 --> 00:46:11.359 blank, and they'll get back
NOTE Confidence: 0.95396423
00:46:11.359 --> 00:46:12.020 to me?
NOTE Confidence: 0.9847005
00:46:12.320 --> 00:46:13.440 I think it's, it's good
NOTE Confidence: 0.9847005
00:46:13.440 --> 00:46:15.645 to maybe email this, inbox
NOTE Confidence: 0.9847005
00:46:15.645 --> 00:46:16.765 first because they'll be able
NOTE Confidence: 0.9847005
00:46:16.765 --> 00:46:17.805 to put you in contact
NOTE Confidence: 0.9847005
00:46:17.805 --> 00:46:19.325 with the exact person that
NOTE Confidence: 0.9847005
00:46:19.325 --> 00:46:20.765 you'll will need to answer
NOTE Confidence: 0.9847005
00:46:20.765 --> 00:46:21.885 that question, and they'll be
NOTE Confidence: 0.9847005
00:46:21.885 --> 00:46:22.925 super helpful. And then in
NOTE Confidence: 0.9847005

00:46:22.925 --> 00:46:24.125 the meantime, you can start

NOTE Confidence: 0.9847005

00:46:24.125 --> 00:46:25.565 working on your application and

NOTE Confidence: 0.9847005

00:46:25.565 --> 00:46:26.364 get it ready to go.

NOTE Confidence: 0.9847005

00:46:26.364 --> 00:46:27.565 So once they respond, you

NOTE Confidence: 0.9847005

00:46:27.565 --> 00:46:29.070 know what category it is.

NOTE Confidence: 0.9945948

00:46:29.630 --> 00:46:30.450 Sounds great.

NOTE Confidence: 0.99399304

00:46:30.750 --> 00:46:31.950 I have one more question.

NOTE Confidence: 0.99399304

00:46:31.950 --> 00:46:33.390 So if I'm doing some

NOTE Confidence: 0.99399304

00:46:33.390 --> 00:46:35.230 research where I'm collaborating with

NOTE Confidence: 0.99399304

00:46:35.230 --> 00:46:36.370 an outside institution,

NOTE Confidence: 0.9811471

00:46:36.750 --> 00:46:37.390 I know I have to

NOTE Confidence: 0.9811471

00:46:37.390 --> 00:46:39.330 do a material transfer agreement.

NOTE Confidence: 0.9811471

00:46:39.550 --> 00:46:41.150 Is that separate from the

NOTE Confidence: 0.9811471

00:46:41.150 --> 00:46:42.670 IRB, or do I have

NOTE Confidence: 0.9811471

00:46:42.670 --> 00:46:43.870 to include that in the

NOTE Confidence: 0.9811471

00:46:43.870 --> 00:46:45.444 IRB as well? That's a

NOTE Confidence: 0.9811471

00:46:45.444 --> 00:46:46.885 great question. That is separate

NOTE Confidence: 0.9811471

00:46:46.885 --> 00:46:48.645 from the IRB process. Yep.

NOTE Confidence: 0.9811471

00:46:48.645 --> 00:46:49.924 Okay. But you're totally on

NOTE Confidence: 0.9811471

00:46:49.924 --> 00:46:51.204 board with that that needing

NOTE Confidence: 0.9811471

00:46:51.204 --> 00:46:52.805 to happen. Yep. Yeah. And

NOTE Confidence: 0.9811471

00:46:52.805 --> 00:46:54.565 my last question is, if

NOTE Confidence: 0.9811471

00:46:54.565 --> 00:46:56.424 I'm collaborating with an outside

NOTE Confidence: 0.9811471

00:46:56.484 --> 00:46:58.265 company, like, I'm getting funds

NOTE Confidence: 0.970687

00:46:58.830 --> 00:47:00.030 from a company to do

NOTE Confidence: 0.970687

00:47:00.030 --> 00:47:00.910 this. I know a lot

NOTE Confidence: 0.970687

00:47:00.910 --> 00:47:01.570 of research

NOTE Confidence: 0.97215325

00:47:01.870 --> 00:47:04.530 is funded by federal agencies.

NOTE Confidence: 0.97215325

00:47:04.590 --> 00:47:05.550 But if if it is

NOTE Confidence: 0.97215325

00:47:05.550 --> 00:47:06.770 a research that is,

NOTE Confidence: 0.9857033

00:47:07.390 --> 00:47:07.890 getting,

NOTE Confidence: 0.99959284

00:47:08.430 --> 00:47:09.969 getting funded by
NOTE Confidence: 0.8439586

00:47:10.430 --> 00:47:11.250 by a company,
NOTE Confidence: 0.96489483

00:47:11.594 --> 00:47:12.955 Is there anything different that
NOTE Confidence: 0.96489483

00:47:12.955 --> 00:47:13.994 I do for the IRB?
NOTE Confidence: 0.96489483

00:47:13.994 --> 00:47:15.295 I'm, of course, a PI.
NOTE Confidence: 0.97319293

00:47:15.755 --> 00:47:16.255 No,
NOTE Confidence: 0.96157163

00:47:16.875 --> 00:47:18.475 PHI or no information is
NOTE Confidence: 0.96157163

00:47:18.475 --> 00:47:19.594 going to go to the
NOTE Confidence: 0.96157163

00:47:19.594 --> 00:47:20.094 company,
NOTE Confidence: 0.89768434

00:47:20.795 --> 00:47:22.335 about this except some,
NOTE Confidence: 0.99899477

00:47:23.195 --> 00:47:24.234 some of the data that
NOTE Confidence: 0.99899477

00:47:24.234 --> 00:47:25.535 they will use for sequencing
NOTE Confidence: 0.99899477

00:47:25.594 --> 00:47:27.030 or some studies. So do
NOTE Confidence: 0.99899477

00:47:27.030 --> 00:47:28.390 I have to make some
NOTE Confidence: 0.99899477

00:47:28.390 --> 00:47:29.670 kind of a modification to
NOTE Confidence: 0.99899477

00:47:29.670 --> 00:47:30.330 the IRB?

NOTE Confidence: 0.9744538

00:47:30.630 --> 00:47:31.670 Is there a place in

NOTE Confidence: 0.9744538

00:47:31.670 --> 00:47:33.850 the IRB to include this?

NOTE Confidence: 0.9915055

00:47:34.310 --> 00:47:35.110 Sure. So is this a

NOTE Confidence: 0.9915055

00:47:35.110 --> 00:47:36.730 study that is already approved?

NOTE Confidence: 0.9684377

00:47:37.270 --> 00:47:38.550 No. No. It's something that

NOTE Confidence: 0.9684377

00:47:38.550 --> 00:47:39.690 I will do in future.

NOTE Confidence: 0.9684377

00:47:39.905 --> 00:47:41.105 Got you. Yes. So, no,

NOTE Confidence: 0.9684377

00:47:41.105 --> 00:47:42.305 there's nothing different you would

NOTE Confidence: 0.9684377

00:47:42.305 --> 00:47:43.265 need to do except for

NOTE Confidence: 0.9684377

00:47:43.265 --> 00:47:44.224 you would need to list

NOTE Confidence: 0.9684377

00:47:44.224 --> 00:47:45.425 them as a funding source

NOTE Confidence: 0.9684377

00:47:45.425 --> 00:47:47.045 in the IRIS IRB application.

NOTE Confidence: 0.9691765

00:47:47.505 --> 00:47:48.464 And I'm sure you'll work

NOTE Confidence: 0.9691765

00:47:48.464 --> 00:47:49.825 with the Office of Sponsored

NOTE Confidence: 0.9691765

00:47:49.825 --> 00:47:51.505 Projects, OSP, who will set

NOTE Confidence: 0.9691765

00:47:51.505 --> 00:47:52.464 up the award, and it
NOTE Confidence: 0.9691765

00:47:52.464 --> 00:47:53.505 will actually you'll be able
NOTE Confidence: 0.9691765

00:47:53.505 --> 00:47:54.489 to link it in the
NOTE Confidence: 0.9691765

00:47:54.489 --> 00:47:56.350 IRIS IRB system. You'll kinda
NOTE Confidence: 0.9691765

00:47:56.410 --> 00:47:57.290 be able to pull up
NOTE Confidence: 0.9691765

00:47:57.290 --> 00:47:59.290 that, funding source in that,
NOTE Confidence: 0.9691765

00:47:59.530 --> 00:48:00.570 where it says, like, local
NOTE Confidence: 0.9691765

00:48:00.570 --> 00:48:01.850 funding sources or something. So
NOTE Confidence: 0.9691765

00:48:01.850 --> 00:48:02.810 that's the only thing that
NOTE Confidence: 0.9691765

00:48:02.810 --> 00:48:03.610 would be different in this
NOTE Confidence: 0.9691765

00:48:03.610 --> 00:48:04.430 case. Okay.
NOTE Confidence: 0.9548674

00:48:04.810 --> 00:48:06.410 Sounds good. Great question. So
NOTE Confidence: 0.9548674

00:48:06.410 --> 00:48:07.610 much. Yeah. This is very
NOTE Confidence: 0.9548674

00:48:07.610 --> 00:48:09.515 helpful. I really appreciate it.
NOTE Confidence: 0.9548674

00:48:09.515 --> 00:48:10.395 Good. Yeah. Let us know
NOTE Confidence: 0.9548674

00:48:10.395 --> 00:48:11.295 if you have questions.

NOTE Confidence: 0.99472314

00:48:11.675 --> 00:48:13.135 Okay. Sounds great. Thanks.

NOTE Confidence: 0.99961734

00:48:13.435 --> 00:48:14.335 Yeah. Thank you.

NOTE Confidence: 0.99524814

00:48:15.275 --> 00:48:16.475 Those were great. Any other

NOTE Confidence: 0.99524814

00:48:16.475 --> 00:48:16.975 questions?

NOTE Confidence: 0.9981906

00:48:23.580 --> 00:48:24.080 Okay.

NOTE Confidence: 0.8991235

00:48:24.620 --> 00:48:25.180 Well, thank you for your

NOTE Confidence: 0.8991235

00:48:25.180 --> 00:48:27.260 time. For joining and giving

NOTE Confidence: 0.8991235

00:48:27.260 --> 00:48:28.240 us all this information.