11-4-2020 IRB2 meeting

Attendees:

Robin Dewalt

Bonnie Gaughan-Bailey

Gavin Grigg

Dr. Ichite

Jamie Arango

Julia Fashner

Mary Martinasek

Sandra Schoenfisch

No conflicts of interest or attestation reported when asked to the group.

Continuing Review

Protocol Title: A double blind randomized placebo controlled multicenter study to evaluate safety tolerability and efficacy on LDL-C of Evolocuamab (AMG 145) in Subjects with HIV and with Hyperlipidemia and or mixed dylipiedemia (#170015HD) (Florida Department of Health)

Submission:	**Principal Investigator:**	**Presenters:**
(Continuing Review)	Morano, Jamie MD	Ichite, Nkechi PharmD, PhD Arango, Jaime EdD

Primary Reviewer: Dr. Ichite

Continuing Review, 13 people have completed the study. The study is already completed and the enrollment is discontinued

Dr. Ichite recommends approval for the study

Secondary Reviewer: Jamie Arrango

Agrees with Dr. Ichite and said good to approve for the next year.

At this point all they are doing is continuing the analysis of the data with not contact to patients.

Dr. Ichite motion to approve

Jamie Arrango second the motion

All six attendees agree to approve

Other Business:

Received AAHRPP Reaccreditation in 2015-2016 and the accreditation is a stamp of approval that we are doing our due diligence that the research is being conducted in an appropriate manner where benefits outweigh any undue risk to any individual.

We have 196 protocols that are active and there has been a downturn due to COVID and the impact to the research being done at the Universities. Currently, 75% of the IRB studies fall in the category of Social, behavioral and social study research. Whereas, 25% are biomedical and device research with several related to HIV therapies where Health Departments offer the treatments and new therapies that are incorporated into their HIV clinics. All of our studies are all located in the state of Florida. Common Rule revisions since 2018 have allowed that we may not be the IRB of record, and this is mostly the case for a national clinical trials being conducted in the State of Florida.

The IRB's main intent is to review studies that deal with our Department of Health data with our clients in our statewide facilities and with our employees.

Recently, there have been a lot of COVID studies for determination and have been overwhelmingly identified as public health practice and for emerging therapies.

We currently review studies that involve students, children, adults unable to consent and pregnant women. We do not review studies that involve prisoners because we do not have someone on our board that has the expertise to properly represent prisoners. We are seeking someone with this specific background so we can consider these studies in the future.

Onsite on Dec 2 and 3rd will be a group discussion and everyone will have around 30 minutes of questions that will be asked of them.

This is a requirement of continued designation. IRB manager has been since implemented in order to facilitate ease of use and efficiency for review of studies. Andy has also been working on an IRB dashboard for committee members to send reminders to members with studies that are in your que and need to be completed.

Meeting invites will be sent out for calendar invites with all of the information and an overview for each member to review on the IRB.

Concluding Questions or remarks.

Sandra:

Thank everyone for their participation and their commitment is much appreciated.

Questions: None