<table>
<thead>
<tr>
<th>IRB Meeting</th>
<th>11/17/2017</th>
<th>2:01pm (CST)</th>
<th>WebEx Teleconference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of meeting</td>
<td>Institutional Review Board</td>
<td></td>
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<tr>
<td>Facilitator</td>
<td>Chad O’Lynn</td>
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<tr>
<td>Note taker</td>
<td>Chad O’Lynn</td>
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<tr>
<td>Attendees</td>
<td>Voting Members: Chad O’Lynn, Marty Spies, Ellen Poole, Peter Horn, Pat Fedorka, Cathy Dolan, Amy Sherer, Valda Upenieks</td>
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<tr>
<td></td>
<td>Non-Voting Members: None</td>
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<td></td>
<td>Students: None</td>
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<tr>
<td></td>
<td>Others: Kristin Kerling and Rebecca Burhenne (guests)</td>
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<tr>
<td>Non Attendees</td>
<td>Voting Members that were absent: Crystal Weikel</td>
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**11/11/17 Agenda**

| Facilitator | Chad O’Lynn |
| Discussion | No changes were requested for the agenda |
| Conclusions | N/A |
| Action Items | N/A |

**Approval of 10/20/17 Minutes**

| Facilitator | Chad O’Lynn |
| Discussion | A motion was made and seconded to approve the minutes as drafted. No changes are revisions were requested. Eight voted for approval; no nays or abstentions. |
| Conclusions | Minutes approved. |
| Action Items | N/A |

**Productivity Report**

| Facilitator | Chad O’Lynn |
| Discussion | The productivity report was reviewed. No studies were submitted for review for October 2017. Chad noted that there will possibly be studies for November or December as some are currently under review by Institutional Effectiveness. |
| Conclusions | Information item. |
| Action Items: | Chad will continue to track response time with each proposal sent for review and send reminders/ offers for assistance if necessary. | Person Responsible | Deadline |
| | Chad O’Lynn | On-going |
### Update from Single IRB Work Group

<table>
<thead>
<tr>
<th>Facilitator</th>
<th>Valda Upenieks</th>
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#### Discussion
Valda reported that she and Peter drafted a set of FAQs on reliance agreements based on one developed by Boston Children’s Hospital. Chad reported that he had reviewed it and it is quite good. Additional information may need to be added/ revised based on the review by the Adtalem legal team. Chad and Crystal are working on drafting a policy and forms. Chad met with LaKeisha Marsh, a lawyer with Adtalem to discuss a policy and process. Ms. Marsh recommended that we follow a similar process to affiliation agreements Chamberlain has with clinical agencies, in which a template is drafted and approved by the legal team. If the terms of the proposed agreement do not differ from the boiler-plate language on the template, then the template can be completed with site-specific information and be considered “approved”. Deviations will have to be reviewed by the legal time for approval. The group will have deliverables for the committee to review, hopefully, by the February IRB meeting.

#### Conclusions
The work group is making progress towards meeting its charge.

#### Action Items

<table>
<thead>
<tr>
<th>Person Responsible</th>
<th>Deadline</th>
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<tr>
<td>Valda Upenieks</td>
<td>Update at February 2017 meeting</td>
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### Informed Consent Workgroup

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<tr>
<th>Facilitator</th>
<th>Ellen Poole</th>
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#### Discussion
Ellen reported that the group has completed its work on revising the informed consent form template and the upcoming draft of the IRB Handbook and ensuring that both comply with the new Common Rule. The only other charge is to review information regarding assurances for data security and verification of electronic signatures. Chad reported that the recent PRIM&R conference sessions did not provide new information.

#### Conclusions
The work group is making progress towards its charge.

#### Action Items

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<tr>
<th>Person Responsible</th>
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<tbody>
<tr>
<td>Ellen Poole</td>
<td>Update at January 2017 meeting</td>
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Discussion: Educating Colleagues about the IRB

Facilitator: Chad O’Lynn

Discussion: Chad presented a decision tree that had been reviewed and approved by stakeholders. The decision tree (see attached) summarizes the processes for review of scholarly work at Chamberlain before the work is implemented and review of dissemination plan and products after the work has been completed. The decision tree is available on the IRB InfoGuide site and will be provided to Chamberlain faculty. IRB representatives will schedule themselves to present the decision tree and answer any questions about the IRB at faculty meetings over the next 6 months.

Conclusions: Resources developed. A plan to review the IRB with faculty is in place.

Action Items

<table>
<thead>
<tr>
<th>Plan</th>
<th>Person Responsible</th>
<th>Deadline</th>
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<tbody>
<tr>
<td>Pat will schedule time with the DNP faculty</td>
<td>Chad O’Lynn, IRB Committee members</td>
<td>June 2018</td>
</tr>
<tr>
<td>Valda will schedule time with the MPH faculty sometime for April or May</td>
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<tr>
<td>Cathy and Chad will speak to the MSN-ST faculty in December</td>
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<tr>
<td>Cathy will speak with FNP program to schedule a meeting</td>
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<tr>
<td>Amy and Chad will speak with the RNBSN faculty in December</td>
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<tr>
<td>Ellen and Marty will speak to their campus colleagues</td>
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<tr>
<td>Chad will reach out to the other campuses</td>
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Discussion: Audit Files for Study Closures and/or Continuing Review

Facilitator: Chad

Discussion: Chad reviewed the files for studies whose approvals had expired to solicit continuing reviews and/or study closures. Only two studies were missing follow up: one study has been renewed and an email notice was sent to the PI of the remaining study.

Conclusions: Audit complete

Action Items

None at this time. Chad will review the files each semester to close the loop on studies with expired approvals.

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<thead>
<tr>
<th>None at this time. Chad will review the files each semester to close the loop on studies with expired approvals.</th>
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<td></td>
<td>Chad O’Lynn</td>
<td>On-going</td>
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## Discussion: Highlights from SBER 17 IRB Conference

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<th>Facilitator</th>
<th>Chad</th>
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**Discussion:** Chad presented a handout of highlights from presentations provided at the SBER 17 conference on topics of data security, determination as to whether a study is program evaluation or research, the new Common Rule, and FERPA. (See attached.) Chad reminded the IRB that it is not their responsibility to develop data security plans for researchers, but rather, ensure that the plans provided sufficiently protect human subjects. Today’s digital environment provides many risks for harm. Chad also reviewed FERPA. Committee members received Adtalem’s FERPA policy. In general, faculty have authority to access data in students’ educational records (for data relating to a specific research study) since this constitutes a “legitimate educational interest”. However, other internal Chamberlain restrictions may apply. Committee members are encouraged to keep the FERPA materials and the conference highlights readily available as they review proposals.

### Conclusions
Information item

### Action Items
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<td>N/A</td>
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## Announcements

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<th>Facilitator</th>
<th>Chad O’Lynn</th>
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**Discussion:** At the beginning of the meeting, Chad introduced two guests. Both guests are faculty managers in our FNP program and are attending the meeting in partial completion of a course requirement. Discussion occurred at the December meeting which falls on the last day of the session prior to winter break. It was recommended to cancel the meeting.

### Conclusions
Information item

### Action Items
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<th>Deadline</th>
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<tbody>
<tr>
<td>N/A</td>
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## Meeting Adjournment

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<tr>
<th>Facilitator</th>
<th>Chad O’Lynn</th>
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**Discussion:** None

**Conclusions:** Meeting concluded at 12:58 pm Central

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Appendices located on subsequent pages.
DECISION TREE FOR REVIEWS OF SCHOLARLY WORK AT CHAMBERLAIN UNIVERSITY

(Page 1: Before implementation of project / study; Page 2: After completion of project study)

START

Develop Project / Study and Related Tools, Materials, and Protocol

Will the project/ study collect data about or from Chamberlain students, employees, programs, or facilities?

Yes

Obtain IER Review Form and submit the form and all materials, surveys, and tools to csiane2@chamberlain.edu

After Marketing approval: Does project/ study survey pertain to satisfaction, marketing, or competition research?

Yes

Submit survey and recruitment materials to Consumer Insights at Cara.Ammon@adriilem.com

After Consumer Insights approval: Is the study/ project a research** study?

Yes

Implement project

After IRB approval: will project/ study use branded* survey/ materials?

No

Implement project/ study

After IRB approval: implement study

No

Implement project

No

Will project/ study use student facing surveys?

Yes

Submit survey and recruitment materials to Marketing for review to Projects@chamberlain.edu

No

Is the study/ project a research** study?

Yes

Implement project

After IRB approval: implement study

No

Implement project


IRB: Institutional Review Board: Information and forms available at: https://library.chamberlain.edu/IRB + CFE Center for Faculty Excellence [https://library.chamberlain.edu/CFE/]

*projects sponsored by Chamberlain and materials carry the Chamberlain logo  
**for definition of “research” go to https://library.chamberlain.edu/IRB

***Visit the following website for more information on requirements for submitted materials: http://www.nursinglibrarians.org/vhi/policies/author_policies.html
Chamberlain University IRB Meeting Minutes

DECISION TREE FOR REVIEWS OF SCHOLARLY WORK AT CHAMBERLAIN UNIVERSITY
(Page 1: Before implementation of project / study; Page 2: After completion of project / study)

START

Do you wish to submit an abstract to present your findings at a conference?

Yes

Obtain Faculty Abstract Approval Request form/template from the CFE portal and submit to facultypresentation@chamberlain.edu at least 3 weeks prior to abstract submission deadline.

No

Do you wish to disseminate your findings to external audiences?

Yes

Do you wish to submit a manuscript?

Yes

If accepted, obtain Faculty Poster, Presentation, & Publication form/template from the CFE portal and submit form/template and materials to facultypresentation@chamberlain.edu at least 5 weeks prior to conference materials submission deadline.

No

Obtain Faculty Poster, Presentation, & Publication form/template from the CFE portal and submit form and manuscript to facultypresentation@chamberlain.edu.

No

Once approved, submit manuscript to Journal.

Present findings to appropriate internal audiences.

No

Thank you.

Yes

Are you interested in submitting your materials to the Virginia Henderson*** Global Nursing e-Repository?

Submit materials to HendersonRepositorySubmissions@chamberlain.edu.

No

Once approved, Marketing will work with you in developing materials and granting final approvals.

** Visit the following website for more information on requirements for submitted materials: http://www.nursinglibrary.org/vh/pages/author_policies.html
Research Data Security

- Development of an adequate plan for security of research data is the responsibility of the researcher
- Appropriate security needed to a) comply with rules and regulations; b) protect confidentiality; c) guard against inappropriate access to data; d) protect data integrity (unauthorized alteration of data) and integrity of researcher and institution; and is accessible (e.g. back-up copies/access)
- Studies may have requirements to adhere to multiple regulations: Common Rule, HIPAA, FERPA, Patient Safety Rule, etc. Must always follow the most stringent
- Risks of inadequate data security
  - Risk to human subject—breach of confidentiality, identity theft, fraud, etc.
  - Risk to study—loss of data or data integrity
  - Risk to institution—loss of public trust, litigation
  - Risk to investigator—loss to time and money, loss of data, disciplinary action, litigation
- Strategies
  - Anonymize (or do not collect) HIPAA personal identifiers
  - Keep identifiers/codes separate from data files and de-identified data
  - If using mobile devices to collect, view, or store data:
    - Do not use your personal mobile device
    - Require a PIN/log in to open device and an additional PIN/log in to access data files
    - Avoid storing data/downloading files onto mobile device. Instead, keep data and files stored on a secure cloud and simply access files from the device
    - Encrypt sensitive data
    - Have capability (app) to locate device if lost/stolen
    - Have capability to lock and/or erase all files remotely if device lost/stolen
    - Change passwords immediately if device is lost/stolen
    - Never download apps onto device from an unknown, unproven, or non-trustworthy source
    - Use only a secure browser
    - Always update systems and apps
    - Always turn off Wi-fi, Bluetooth, or other virtual private networks when not actively using them
    - Backup your data in a secure source
    - If subjects are using devices to enter data, have them log in to a secure site to enter data; do not have them enter data into the device files or have them send data via text or email
    - If you expect subjects to download an app onto their own personal devices, be transparent on the risks and conditions of the specific app
  - If using a cloud
Chamberlain University IRB Meeting Minutes

- Never store sensitive data on a commercial cloud; use your own cloud or a cloud provided by your institution that is secure/ requires a PIN and login
- Data collection using Chamberlain platforms must use an approved application (e.g. Qualtrics). The Chamberlain Surveying Standard Operating Procedures provides more information

Program Evaluation versus Regulated Research
("Regulated" research is research subject to IRB review)

- Generally speaking, “research” is considered a systematic investigation with the purpose of generating new and generalizable knowledge
- Generally speaking, “program evaluation” is a systematic and internal investigation using standardized procedures.
- A specific project can be BOTH regulated research and program evaluation
- Projects that include components/aspects of regulated research must have those components/aspects reviewed by the IRB
- Although there is not a clear line between research and program evaluation, one should consider the following:
  - Intent
    - Research relates to the generation/discovery of new knowledge
    - Program evaluation relates to the application of known knowledge
    - Questions
      - What is the purpose/aim of the project?
      - Who is the intended audience of the project findings?
  - Process
    - Questions
      - Does the project plan to introduce a new or untested process?
      - Does the project plan to analyze a process already implemented or routine in the organization?
      - Research often incorporates elements randomization and experimentation
  - Participation
    - Question
      - Is participation in the project mandatory?
      - Regulated research involves voluntary participation
      - Participation in program evaluation may be voluntary or may be mandatory
Updates from New Common Rule

- Most information presented already familiar
- May want to consider “limited review” option for the four exemption categories where this type of review is allowed
  o Exempt studies using educational tests, surveys, interviews, or observations of public behavior in which information is recorded in a manner such that the identity of subjects can readily be ascertained directly or through identifiers
  o Exempt studies involving benign behavioral interventions of adults for which they prospectively agreed to in which information is recorded in a manner such that the identity of subjects can readily be ascertained directly or through identifiers
  o Storage of private information or biospecimens for secondary research
  o Secondary research that requires broad consent (new type of consent that is optional for IRB to allow)

FERPA (Family Educational Rights and Privacy Act)

(Please refer to official Adtalem/Chamberlain policies. The following information was presented at the conference. Additional questions may be submitted with “FERPA QUESTION” in the subject line to: responsiblecommunication@adtalem.com.)

- Designed to afford rights to students and to the parents of students who are minors
  o Right to inspect their education records
  o Right to request correction of errors in their education records
  o Right to privacy of disclosure of their education records
  o Right to file a complaint with the US Dept. of Education
- Generally, schools must have written permission from students (or parents of minor student) to grant access to educational records

Education records include
  o School ID #
  o SSN#
  o DOB
  o Gender, Race/ethnicity, country of citizenship
  o Graded papers, exams
  o Transcripts/information contained in transcripts (e.g. grades, GPA)
  o Class rosters
  o Financial aid information
  o Notes of conversations with the student
  o Emails containing information about a student
  o Student writing samples
  o Immunization records
  o Student athlete records

- Education records DO NOT include
  o Peer graded papers
  o Online discussions/posts
  o Law enforcement records
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- Employment records (except work-study)
- Medical records (except student athlete records)---but covered by HIPAA
- Alumni records
- Self-reported information
- Directory information

- Information published in the school directory (unless the student has requested restriction of directory information) and information voluntarily provided by a student does NOT fall under FERPA protections

- Who can access information in education records WITHOUT signed permission?
  - Organizations / school conducting QA/QI projects designed to improve the institution
  - Schools receiving student as a transfer student
  - Financial aid providers
  - Accrediting organizations
  - Persons/ agencies with a judicial order or subpoena
    - School officials with a legitimate educational interest as part of their regular job duties
      - What constitutes “legitimate educational interest” is defined by the school

- IRB CANNOT waive FERPA requirements
- The official record keeper (e.g. the school) is responsible for FERPA compliance, not the IRB
- Researchers who have been granted an exception by the school to access records without permission provide the exception notice with their IRB submission
- Students who turn 18 during the study must be consented as adults