

Framingham State Food Study
Documentation of CORI/SORI discussion for community based participation

3/18/15 Meeting to discuss community participation: in attendance Drs. Vaden Goad, Hamel, Ludwig, Ebbeling, Luoto, Rita Colucci, Gloria Klein, Ralph Eddy, Eric Gustafson

Group met to discuss considerations of community based participation. Rita presented Brad's campus and security concerns and the University's liability and risk. Group decided to request CORI/SORI for campus based participants contingent upon BCH IRB approval.

4/8/15 Pat emailed Erin asking for a copy of the University's CORI/SORI form. Erin's response follows:

Here is FSU's CORI/SORI authorization form. I am not sure why participants in this project need CORI/SORI checks completed because they are not employees; but maybe you have a reason this needs to be done. I've attached the CORI Policy as well as the the Minors on Campus Policy and the Operational Guide.

If you decide to move forward with the CORI/SORIs, we'll need to discuss which office should process them, as the HR only processes them for full-time employees and the VPs handle their respective areas. Or, its possible you may want to hire a service to do this, as there is a cost if you have to do an out of state background check.

Maybe the three of us should meet to discuss?

Thanks, Erin
Erin Nechipurenko

4/8/15 Reply from Pat to Erin—this provides the background of why we were requesting CORI/SORI for community participants.

Hi Erin, thanks for the documents. Let me give you some background on the CORI/SORI--

Our recruitment efforts need to cast a wider net in order to get the number of participants needed for cohort II (and III which will take place in AY 16-17). In meeting with administration (Rita, Linda, Dale) and the PIs from Boston Children's Hospital, the decision was made to reach out to the FSU neighbors, alums, and also the community (likely within a 5-10 mile radius of the campus) for additional subjects. Community participants will need to come to campus Monday-Friday and eat at least one meal on campus and pick-up the other meals; this could be either breakfast, lunch, or dinner.

This led to a discussion about participants from the community being on campus and security concerns which were expressed by Brad (would subjects have FSU ID cards, how to limit the campus accessibility of a participant, limit the use of the Athletic Center for example, all versus the fact that it is a public campus). The decision was to include the request for a CORI/SORI for any community participant.

BCH's IRB has just approved the reach-out to community subjects. I would think Academic Affairs would handle the CORI/SORI since the grant project is sponsored by that office.

End of April, 2015--conference call with Rita, Erin and Pat: After further investigation, Erin expressed a concern as to whether FSU has the authorization to run CORIs for volunteer study participants since they are not employees of the University. "When I looked at our authorization to run checks, it appears that we can only run them on employees, volunteers, licensees, and housing applicants. "

End of April, 2015 Conference with Rita, Brad and Pat—discussed alternatives to CORI/SORI checks for volunteers based on Erin's concerns (above).

4/23/16—email from Pat to Rita and Erin—questions asked by BCH as to why community participants were not considered volunteers and therefore could the University would be authorized to conduct the CORI/SORI.

Rita, I met today with Gloria Klein, Project Director, and reviewed our discussion about the CORI/SORI.

Erin--to bring you up to date. Rita and I met last week with Brad. Based on this discussion two options were presented to BCH today: 1)conduct Open Access CORIS/SORIS at a cost of \$50/participant or 2) on the FS2 application/letter of consent use the same verbage--Have you been convicted of a felony?--and have community participants sign off (meaning an individual could be dishonest as no one will check).

BCH expressed concerns. They like the idea of having everyone CORI/SORI (especially) checked. The House staffing is sometimes scheduled so that a young research assistant could be in the House alone (not often but it does happen). So BCH believes the checks will help maintain safety and security (as does Brad).

Secondly, BCH has submitted the community participant addendum through their IRB (based upon our earlier meeting with Administration). It was approved with the CORI/SORI language. The rationale BCH used for the IRB was that participants are community **volunteers** coming to campus to participate in a clinical research trial.

The key word here--now being questioned from BCH--is volunteer. According to Erin's earlier email--

"When I looked at our authorization to run checks, it appears that we can only run them on employees, **volunteers**, licensees, and housing applicants. "

So why would volunteers--from the community participants--not fall into the University's purview to request CORI/SORI? The bottom line is now that BCH would like to have potential community participants complete the CORI/SORI; like Brad they believe it will help maintain safety and security. If at all possible we would not like to have the grant pay \$50/person if we can use the above noted **volunteer** category.

4/29/15: Conference call with Rita, Erin and Pat to discuss University's perspective on the word volunteer and why FSU does not want to CORI/SORI the community participants. This call was based on BCH's questions noted in above email.

4/29/2015—Email from Pat to Gloria after a conference call with Rita, Erin and Pat . Provides reasons as to why the University does not want to CORI/SORI community participants and why the word "volunteer" does not apply.

Gloria, I have just gotten off a conference call with Rita and Erin, Assistant VP of Human Resources, regarding the CORI/SORI process for community participants. Let me try to summarize--Rita, please add to this conversation if I have been remiss.

Per our last discussion on this issue, you questioned why the University could not CORI/SORI **volunteers** - according to the University's authorization to run checks on employees, volunteers, licensees, and housing applicants.

While we are calling the future potential community participant "volunteers" for the Food Study, in fact they are not volunteers in the true sense of the word. i.e. they will not be coming to campus to perform a "job" or assist in a program/activity which is what the HR term "volunteer" refers to. In fact the University does not encourage volunteers on campus due to reasons noted below.

From the Human Resources perspective--to call a participant a "volunteer" will open up a can of worms that we likely do not want to engage. Volunteers will have to take a state ethics test, sign off on an equal opportunity policy, etc.--i.e. they will have to be onboarded somewhat like a regular employee. This means someone will need to be responsible for the onboarding process and for review of the background checks.

Secondly, HR has pointed out that only employees hired after September of '13 have had CORI checks or who work in specific departments (like the child development center, etc.). This means that our own fac/staff and students would not necessarily have been CORI-d. HR points this out only to note that if we do CORI/SORI we will be treating one group differently than another (which may not be an issue of concern).

So: FSU cannot authorize CORI/SORI for the study community participants. FS2 can decide to keep this condition but we would need to run open access CORIs which will cost the grant \$50/person. More so, we will need to consider who will review the CORI and make decisions about the results--what will bar a participant from the study? The reviewer will likely be someone within FS2/FSU--either Denise or me (which also means a cost to the grant). Currently in HR an employee is not automatically barred from employment if there is a black mark/criminal activity on the CORI--it depends on what the mark is (for example, drunk driving).

RE: SORI--this can be done at no charge through one of the state offices. However, it takes a long time to get the results...so this means someone could have already started the study (recruited in July, starts in mid-August with no CORI results until a couple of months later). Rita suggests we could say something like--dependent on successful CORI passing.

5/1/2015 Email from Pat to Gloria and Rita—this summarizes the final steps:

Gloria and I met earlier today. The plan:

1. Add language to a campus participant form asking if they have been convicted of a felony. Rita, could you provide the specific language (per Brad) that students, faculty and staff sign on an application.
2. A second question will be added: Will you consent to a CORI/SORI?
3. A CORI will possibly be completed (open access) if the person answers they have been convicted. If the person refuses to consent to a CORI/SORI, the individual will not be considered for the study.