Using the IRBNet system for registering biological materials

Internal IRB Submission ONLY

1. When completing the "IRB Core Protocol Data Form" in IRBNet, in the General Project Information Section I. (the 1st Section), Question #10 – "Will your research involve…." Check the box **YES** for a. Biological Materials/Gene Transfer/ Stem Cells/ Select Agents and Toxins:
    a. if biological materials (i.e., cells, tissues, organs, blood or other bodily fluids) will be collected;
    b. if human subjects will be introduced or exposed to biological materials (i.e. inclusive of animal materials, human materials, genetically modified materials, microbes or toxins), or
    c. if your protocol involves:
        i. Gene Transfer (i.e., experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules , or nucleic acids derived from recombinant or synthetic nucleic acid molecules, into human research participants);
        ii. Stem Cells; or
        iii. Select Agents and Toxins (i.e., Botulinum neurotoxins, Staphyloccoccal enterotoxins) List available at: http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html
2. If you checked **YES,** then Section XII., Biosafety/Biological Materials will appear for you to complete (towards the end of the form).
3. When completing Section XII., "Biosafety/Biological Materials", select all that apply. Depending on your selection, you will need to perform the following actions (see chart below):

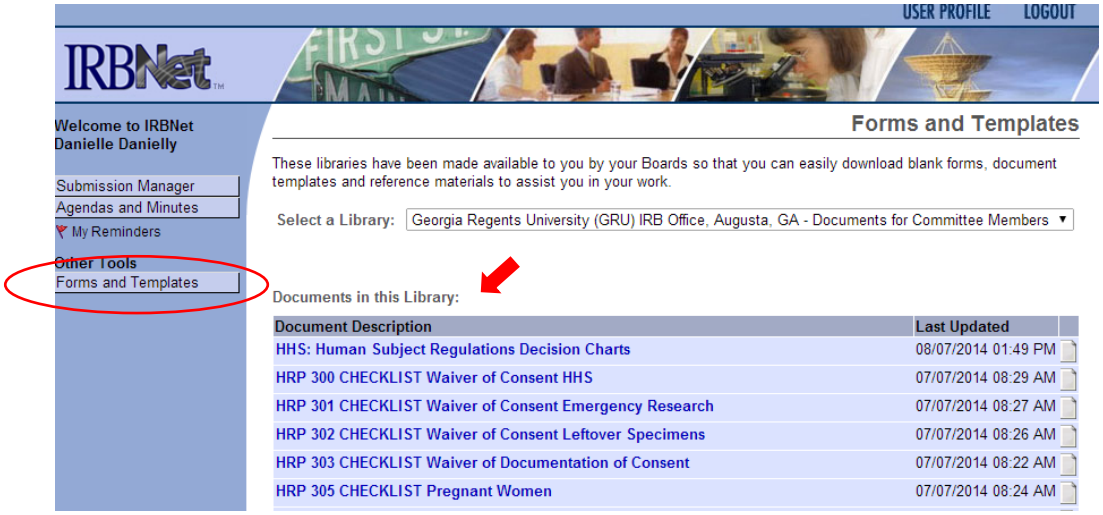
If you select:	You will need to:
✓ Biological materials will be collected	****MUST BE COMPLETED BEFORE STARTING RESEARCH**** ➢ Complete a **Clinical Biosafety Protocol Application** (in the IRBNet forms and templates library and on the Augusta University Biosafety website: http://www.augusta.edu/research/ibc/apps.php ➢ Upload it into IRBNet as part of your packet ➢ Email it to Biosafety@augusta.edu, the IRBNet ID number must be in the subject title.
✓ Introduction/Exposure of Human Subjects to Biological Materials	****MUST BE COMPLETED BEFORE STARTING RESEARCH**** ➢ Complete a **Clinical Biosafety Protocol Application** (in the IRBNet forms and templates library and on the Augusta University Biosafety website: http://www.augusta.edu/research/ibc/apps.php ➢ Upload it into IRBNet as part of your packet ➢ Email it to Biosafety@augusta.edu, the IRBNet ID number must be in the subject title.
✓ Gene Transfer	****MUST BE COMPLETED BEFORE IRB APPROVAL WILL BE RELEASED**** ****MUST BE COMPLETED BEFORE STARTING RESEARCH**** ➢ Complete the **Biosafety Protocol (BSP) "Full" Application** (only available on the Augusta University Biosafety website: http://www.augusta.edu/research/ibc/apps.php ➢ Email it to Biosafety@augusta.edu, the IRBNet ID number must be in the subject title. ➢ Upload the BSP application, Appendix M (if applicable) and the IBC approval letter into IRBNet.
✓ Stem Cells	****MUST BE COMPLETED BEFORE IRB APPROVAL WILL BE RELEASED**** ****MUST BE COMPLETED BEFORE STARTING RESEARCH**** ➢ Complete the **Biosafety Protocol (BSP) "Full" Application** (only available on the Augusta University Biosafety website: http://www.augusta.edu/research/ibc/apps.php ➢ Email it to Biosafety@augusta.edu, the IRBNet ID number must be in the subject title. ➢ Upload the BSP application and the IBC approval letter into IRBNet.
✓ Select Agents and Toxins	****MUST BE COMPLETED BEFORE IRB APPROVAL WILL BE RELEASED**** ****MUST BE COMPLETED BEFORE STARTING RESEARCH**** ➢ Complete the **Biosafety Protocol (BSP) "Full" Application** (only available on the Augusta University Biosafety website: http://www.augusta.edu/research/ibc/apps.php ➢ Email it to Biosafety@augusta.edu, the IRBNet ID number must be in the subject title. ➢ Upload the BSP application and the IBC approval letter into IRBNet.

External IRB Submission (i.e. NCI, WIRB, Chesapeake)

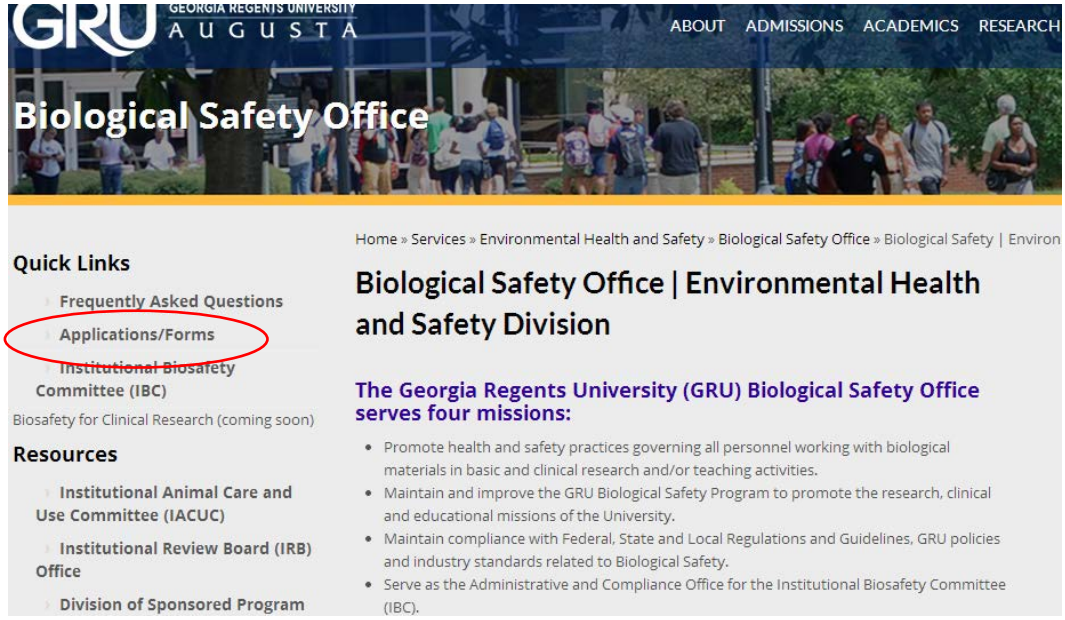
Complete the Biological Safety section of the External IRB Initial Submission Form. Complete the Clinical Biosafety Protocol or the regular Biosafety Protocol Application (based on the chart above) and submit it to the Biosafety Office, Biosafety@augusta.edu.

Where to find the Clinical Biosafety Protocol Application and the Biosafety "Full" Protocol Application

1. The Clinical Biosafety Protocol Application can be found in IRBNet



2. The Clinical Biosafety Protocol Application AND The Biosafety Protocol "Full" Application can be found on the Biosafety Office website: http://www.augusta.edu/services/ehs/biosafe/



3. The Clinical Biosafety Protocol Application AND The Biosafety Protocol "Full" Application can be found on the Institutional Biosafety Committee website: http://www.augusta.edu/research/ibc/apps.php

Clinical Biosafety Protocol Processing by the Biosafety Office

- When the Biosafety Office receives your **Clinical Biosafety Protocol Application**, there will be two tracks for processing:

    1. Administrative approval – Expedited for minor changes, low risk agents/procedures
    2. Review by the Clinical Subcommittee of the Institutional Biosafety Committee (IBC) – 5-7 business days for higher risks agents/procedures

- If you are required to submit a **Biosafety Protocol "Full" Application** (because you selected Gene Transfer, Stem Cells or Select Agents and Toxins), there will be two tracks for processing:

    1. Review by the Clinical Subcommittee of the Institutional Biosafety Committee (IBC) – 5-7 business days for Stem Cells and use of Select Agents and Toxins
    2. Review by the Full Institutional Biosafety Committee (IBC) during a convened meeting – 4-6 working weeks for Gene Transfer or any Subcommittee Protocol that has been referred for Full Committee review.

    ****To be on the agenda for that month's meeting, protocols must be received by the 1st of the month****

- Current Umbrella Biosafety Protocol Holders – The concept of an "Umbrella Protocol" will no longer exist. Each PI or designee (i.e. coordinator) will be responsible for submitting a Clinical Biosafety Protocol for each study that is submitted in the IRBNet system. Study titles will no longer be added to an umbrella protocol by submitting an amendment to the Biosafety Office. Each study will need to have an accompanying Clinical Biosafety Protocol. The PI will be assigned a BSP Number that is unique to them. Each Clinical Biosafety Protocol submitted will be linked to that number. PIs who currently oversee Umbrella Protocols will retain their current BSP number, whereas PIs who have studies listed under an Umbrella Protocol will acquire a new number.

Biosafety Training Requirements

Training requirements for persons involved in clinical research are assigned by duty, see the chart below:

Augusta University/Augusta University Medical Center Biosafety Training Requirements		
Intended for all University and Health System personnel and/or personnel who work in University or Health System facilities on research projects, if you:	**You must satisfactorily complete the following training:**	**Training Options**
Work with biological materials in a basic/wet laboratory setting, including clinicians who have a basic/wet laboratory.	**Initial Biosafety and Bloodborne Pathogen Training** *An initial online training session is required prior to initiation of work.* *Annual Biosafety Refresher required thereafter.* *To be assigned contact the Biological Safety Office*	**Initial training** offered online (Workforce Learn Online), the initial training module may be accessed at: train.augusta.edu **Annual biosafety refresher training** offered online (Workforce Learn Online), the refresher training module may be accessed at: train.augusta.edu
Work with biological materials in a clinical laboratory setting. *Involves taking human blood, tissues or fluid specimens from patients who are not considered infectious with any agent ≥RG3, preparation of serum or plasma samples, aliquotting of specimens.	**Initial Biosafety and Bloodborne Pathogen Training** *An initial online training session is required prior to initiation of work.* *Annual Biosafety Refresher required thereafter.* *To be assigned contact the Biological Safety Office*	**Initial training** offered online (Workforce Learn Online), the initial training module may be accessed at: train.augusta.edu **Annual biosafety refresher training** offered online (Workforce Learn Online), the refresher training module may be accessed at: train.augusta.edu
Involved in research that is subject to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids Molecules. *Introduction of genetically modified materials into human research subjects (i.e. DNA vaccines, personalized therapies)	**NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules** *An initial online training session is required prior to initiation of work.* *To be assigned contact the Biological Safety Office*	**Initial training** offered online (Workforce Learn Online), the initial training module may be accessed at: train.augusta.edu
Responsible for marking, labeling, packaging, shipping, transporting, or receiving Biohazards (infectious agents, biological toxins, human clinical specimens, animal diagnostic specimens, dry ice, liquid nitrogen, genetically modified organisms)	**Shipping Biological Substances and Support Materials** *Required biennially (i.e. once every 2 years)* *To be assigned contact the Biological Safety Office*	**Shipping Biological Substances and Support Materials offered** online (Workforce Learn Online), the refresher training module may be accessed at: train.augusta.edu