

DAFTAR PUSTAKA

- Aleckovic, M. and Simon, C. (2008) 'Is teratoma formation in stem cell research a characterization tool or a window to developmental biology?', *Reproductive biomedicine online*. Netherlands, 17(2), pp. 270–280. doi: 10.1016/s1472-6483(10)60206-4.
- ANZBA (2016) *Emergency Management of Severe Burns (EMSB)*. 18th edn. Albany Creek: THE EDUCATION COMMITTEE OF AUSTRALIA AND NEW ZEALAND BURN ASSOCIATION LTD.
- Andrae, J., Gallini, R., & Betsholtz, C. (2008). Role of platelet-derived growth factors in physiology and medicine. *Genes & development*, 22(10), 1276-1312.
- Allen Jr, R. J., Soares, M. A., Haberman, I. D., Szpalski, C., Schachar, J., Lin, C. D., ... & Warren, S. M. (2014). Combination therapy accelerates diabetic wound closure. *PloS one*, 9(3), e92667.
- Atalay, S., Coruh, A., & Deniz, K. (2014). Stromal vascular fraction improves deep partial thickness burn wound healing. *Burns*, 40(7), 1375-1383
- Baglioni, S. et al. (2009) 'Characterization of human adult stem-cell populations isolated from visceral and subcutaneous adipose tissue.', *FASEB journal: official publication of the Federation of American Societies for Experimental Biology*. United States, 23(10), pp. 3494–3505. doi: 10.1096/fj.08-126946.
- Bakacak, M. et al. (2016) 'Protective Effect of Platelet Rich Plasma on Experimental Ischemia/Reperfusion Injury in Rat Ovary.', *Gynecologic and obstetric investigation*. Switzerland, 81(3), pp. 225–231. doi: 10.1159/000440617.
- Barret-Nerin, J. (2004) *Principles and Practice of Burn Surgery*. CRC Press. doi: 10.1201/b21634.
- Berlanga-Acosta, J., Gavilondo-Cowley, J., del Barco-Herrera, D. G., Martín-Machado, J., & Guillen-Nieto, G. (2011). Epidermal growth factor (EGF) and platelet-derived growth factor (PDGF) as tissue healing agents: clarifying concerns about their possible role in malignant transformation and tumor progression. *J Carcinogene Mutagene*, 2(1), 100-15.
- Borrione, P. et al. (2010) 'Platelet-rich plasma in muscle healing.', *American journal of physical medicine & rehabilitation*. United States, 89(10), pp. 854–861. doi: 10.1097/PHM.0b013e3181f1c1c7.
- Bourin, P. et al. (2013) 'Stromal cells from the adipose tissue-derived stromal vascular fraction and culture expanded adipose tissue-derived stromal/stem cells: a joint statement of the International Federation for Adipose Therapeutics and Science (IFATS) and the International So', *Cytotherapy*. England, 15(6), pp. 641–648. doi: 10.1016/j.jcyt.2013.02.006.

Cerqueira, M. T., Pirraco, R. P. and Marques, A. P. (2016) 'Stem Cells in Skin Wound Healing: Are We There Yet?', *Advances in Wound Care*, 5(4), pp. 164–175. doi: 10.1089/wound.2014.0607.

Cervelli, V. et al. (2010) 'Tissue regeneration in loss of substance on the lower limbs through use of platelet-rich plasma, stem cells from adipose tissue, and hyaluronic acid.', *Advances in skin & wound care*. United States, 23(6), pp. 262–272. doi: 10.1097/01.ASW.0000363551.82058.36.

Chieragato, K. et al. (2011) 'Epidermal growth factor, basic fibroblast growth factor and platelet-derived growth factor-bb can substitute for fetal bovine serum and compete with human platelet-rich plasma in the ex vivo expansion of mesenchymal stromal cells derived from adipose tiss', *Cytotherapy*. England, 13(8), pp. 933–943. doi: 10.3109/14653249.2011.583232.

Choi, J., Minn, K. W. and Chang, H. (2012) 'The efficacy and safety of platelet-rich plasma and adipose-derived stem cells: an update', *Archives of plastic surgery*. 2012/11/14. The Korean Society of Plastic and Reconstructive Surgeons, 39(6), pp. 585–592. doi: 10.5999/aps.2012.39.6.585.

Coalson, E., Bishop, E., Liu, W., Feng, Y., Spezia, M., Liu, B., ... & Reid, R. R. (2019). Stem cell therapy for chronic skin wounds in the era of personalized medicine: From bench to bedside. *Genes & diseases*, 6(4), 342-358.

Comella, K., Silbert, R. and Parlo, M. (2017) 'Effects of the intradiscal implantation of stromal vascular fraction plus platelet rich plasma in patients with degenerative disc disease', *Journal of translational medicine*. BioMed Central, 15(1), p. 12. doi: 10.1186/s12967-016-1109-0.

Darinskas, A. et al. (2017) 'Stromal vascular fraction cells for the treatment of critical limb ischemia: a pilot study.', *Journal of translational medicine*. England, 15(1), p. 143. doi: 10.1186/s12967-017-1243-3.

Deng, C., Wang, L., Feng, J., & Lu, F. (2018). Treatment of human chronic wounds with autologous extracellular matrix/stromal vascular fraction gel: A STROBE-compliant study. *Medicine*, 97(32).

Duran, Asli et al. (2016) Clinical and histopathological evaluation of the effects of platelet rich plasma, platelet poor plasma and topical serum physiologic treatment on wound healing caused by radiofrequency electrosurgery in rats.

Eppley, B. L., Pietrzak, W. S. and Blanton, M. (2006) 'Platelet-rich plasma: a review of biology and applications in plastic surgery.', *Plastic and reconstructive surgery*. United States, 118(6), pp. 147e-159e. doi: 10.1097/01.prs.0000239606.92676.cf.

Evrova, O., & Buschmann, J. (2017). In vitro and in vivo effects of PDGF-BB delivery strategies on tendon healing: a review. *European Cells and Materials (ECM)*, 34, 15-39.

- Farooqi, A. A. et al. (2011) 'Platelet-derived growth factor (PDGF) signaling: Detailed mechanistic insights', *International Journal of Genetics and Molecular Biology*, 3(5), pp. 72–80.
- Fathke, C., Wilson, L., Hutter, J., Kapoor, V., Smith, A., Hocking, A., & Isik, F. (2004). Contribution of bone marrow–derived cells to skin: collagen deposition and wound repair. *Stem cells*, 22(5), 812–822.
- Ferraro, G. A., Mizuno, H. and Pallua, N. (2016) 'Adipose Stem Cells: From Bench to Bedside', *Stem Cells International*. Hindawi Publishing Corporation, 2016, p. 6484038. doi: 10.1155/2016/6484038.
- FrykbergRobert, G. (2015). Challenges in the treatment of chronic wounds. *Advances in wound care*.
- Foubert, P. et al. (2016) 'Adipose-derived regenerative cell therapy for burn wound healing: A comparison of two delivery methods', *Advances in Wound Care*, 5(7), pp. 288–298. doi: 10.1089/wound.2015.0672.
- Fu, Y.-S. et al. (2006) 'Conversion of human umbilical cord mesenchymal stem cells in Wharton's jelly to dopaminergic neurons in vitro: potential therapeutic application for Parkinsonism.', *Stem cells* (Dayton, Ohio). United States, 24(1), pp. 115–124. doi: 10.1634/stemcells.2005-0053.
- Gentile, P. et al. (2017) 'Concise Review: The Use of Adipose-Derived Stromal Vascular Fraction Cells and Platelet Rich Plasma in Regenerative Plastic Surgery.', *Stem cells* (Dayton, Ohio). United States, 35(1), pp. 117–134. doi: 10.1002/stem.2498.
- Ghadially, R., Halkier-Sorensen, L. and Elias, P. M. (1992) 'Effects of petrolatum on stratum corneum structure and function', *Journal of the American Academy of Dermatology*, 26(3), pp. 387–396. doi: [https://doi.org/10.1016/0190-9622\(92\)70060-S](https://doi.org/10.1016/0190-9622(92)70060-S).
- Ghie, F. et al. (2015) 'The Use of Stem Cells in Burn Wound Healing: A Review', *BioMed Research International*. Edited by C. Kasper. Hindawi Publishing Corporation, 2015, p. 684084. doi: 10.1155/2015/684084.
- Gillenwater, J. and Garner, W. L. (2020) 'Thermal, Chemical, and Electrical Injuries', in Kevin C. Chung (ed.) *Grabb and Smith's plastic surgery*. Eighth. Philadelphia: Wolters Kluwer Health.
- Gimble, J. and Guilak, F. (2003) 'Adipose-derived adult stem cells: isolation, characterization, and differentiation potential.', *Cytotherapy*. England, 5(5), pp. 362–369. doi: 10.1080/14653240310003026.
- Gimble, J. M., Katz, A. J. and Bunnell, B. A. (2007) 'Adipose-derived stem cells for regenerative medicine.', *Circulation research*. United States, 100(9), pp. 1249–1260. doi: 10.1161/01.RES.0000265074.83288.09.
- Godwin L, Tariq MA, Crane JS. Histology, Capillary. [Updated 2021 Feb 9]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2021 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK546578/>

- Grant, M. B. et al. (1992) 'Effects of epidermal growth factor, fibroblast growth factor, and transforming growth factor-beta on corneal cell chemotaxis.', *Investigative ophthalmology & visual science*. United States, 33(12), pp. 3292–3301.
- Hausman, G. J. and Richardson, R. L. (2004) 'Adipose tissue angiogenesis.', *Journal of animal science*. United States, 82(3), pp. 925–934. doi: 10.2527/2004.823925x.
- Hayes, M. et al. (2012) 'Clinical review: Stem cell therapies for acute lung injury/acute respiratory distress syndrome - hope or hype?', *Critical care* (London, England). England, 16(2), p. 205. doi: 10.1186/cc10570.
- Herndon, D. N. et al. (1997) 'Growth Hormone Therapy in Human Burn Injury', in Ziegler, T. R., Pierce, G. F., and Herndon, D. N. (eds) *Growth Factors and Wound Healing*. New York, NY: Springer New York, pp. 231–244.
- Hombach-Klonisch, S. et al. (2008) 'Adult stem cells and their trans-differentiation potential--perspectives and therapeutic applications', *Journal of molecular medicine* (Berlin, Germany). 2008/07/16, 86(12), pp. 1301–1314. doi: 10.1007/s00109-008-0383-6.
- Hu, Z. et al. (2009) 'Platelet-rich plasma induces mRNA expression of VEGF and PDGF in rat bone marrow stromal cell differentiation.', *Oral surgery, oral medicine, oral pathology, oral radiology, and endodontics*. United States, 107(1), pp. 43–48. doi: 10.1016/j.tripleo.2008.06.023.
- Josh, F. et al. (2012) 'Accelerated and safe proliferation of human adipose-derived stem cells in medium supplemented with human serum.', *Journal of Nippon Medical School = Nippon Ika Daigaku zasshi*. Japan, 79(6), pp. 444–452. doi: 10.1272/jnms.79.444.
- Judith, R., Nithya, M., Rose, C., & Mandal, A. B. (2010). Application of a PDGF-containing novel gel for cutaneous wound healing. *Life sciences*, 87(1-2), 1-8.
- Karagergou, E. et al. (2018) 'Adipose-derived stromal vascular fraction aids epithelialisation and angiogenesis in an animal model', *Journal of Wound Care*, 27, pp. 637–644. doi: 10.12968/jowc.2018.27.10.637.
- Kazimierczak, P., Benko, A., Nocun, M., & Przekora, A. (2019). Novel chitosan/agarose/hydroxyapatite nanocomposite scaffold for bone tissue engineering applications: Comprehensive evaluation of biocompatibility and osteoinductivity with the use of osteoblasts and mesenchymal stem cells. *International journal of nanomedicine*, 14, 6615.
- Kim, D.-Y. et al. (2014) 'Effects of platelet-rich plasma, adipose-derived stem cells, and stromal vascular fraction on the survival of human transplanted adipose tissue', *Journal of Korean medical science*. 2014/11/21. The Korean Academy of Medical Sciences, 29 Suppl 3(Suppl 3), pp. S193–S200. doi: 10.3346/jkms.2014.29.S3.S193.
- Kirschstein, R. (2001) 'Stem cells: scientific progress and future directions', *National Institutes of Health*, pp. 1–222.

- Kuwada, S. K. and Li, X. (2000) 'Integrin $\alpha 5/\beta 1$ mediates fibronectin-dependent epithelial cell proliferation through epidermal growth factor receptor activation', *Molecular biology of the cell*. The American Society for Cell Biology, 11(7), pp. 2485–2496. doi: 10.1091/mbc.11.7.2485.
- Larouche, J., Sheoran, S., Maruyama, K., & Martino, M. M. (2018). Immune regulation of skin wound healing: mechanisms and novel therapeutic targets. *Advances in wound care*, 7(7), 209-231.
- Lawrence, W. T. (1998) 'Physiology of the acute wound.', *Clinics in plastic surgery*. United States, 25(3), pp. 321–340.
- Liu, L. et al. (2009) 'Evaluation of Interleukin-8 in Expressed Prostatic Secretion as a Reliable Biomarker of Inflammation in Benign Prostatic Hyperplasia', *Urology*. Elsevier Inc., 74(2), pp. 340–344. doi: 10.1016/j.urology.2009.02.064.
- Lo, B. and Parham, L. (2009) 'Ethical issues in stem cell research', *Endocrine reviews*. 2009/04/14. The Endocrine Society, 30(3), pp. 204–213. doi: 10.1210/er.2008-0031.
- MacLeod, A. S. and Mansbridge, J. N. (2016) 'The Innate Immune System in Acute and Chronic Wounds', *Advances in wound care*. Mary Ann Liebert, Inc., 5(2), pp. 65–78. doi: 10.1089/wound.2014.0608.
- Markiewicz-Gospodarek, A., Kozioł, M., Tobiasz, M., Baj, J., Radzikowska-Büchner, E., & Przekora, A. (2022). Burn Wound Healing: Clinical Complications, Medical Care, Treatment, and Dressing Types: The Current State of Knowledge for Clinical Practice. *International journal of environmental research and public health*, 19(3), 1338. <https://doi.org/10.3390/ijerph19031338>
- McGee, G. S. et al. (1988) 'Recombinant basic fibroblast growth factor accelerates wound healing.', *The Journal of surgical research*. United States, 45(1), pp. 145–153. doi: 10.1016/0022-4804(88)90034-0.
- Moenadjat, Y. et al. (2013) 'The application of human umbilical cord blood mononuclear cells in the management of deep partial thickness burn', *Medical Journal of Indonesia*, 22(2 SE-Clinical Research). doi: 10.13181/mji.v22i2.534.
- Moss, L. S. (2010) 'Treatment of the burn patient in primary care.', *Advances in skin & wound care*. United States, 23(11), pp. 516–517. doi: 10.1097/01.ASW.0000390374.34201.c8.
- Nauta, A. et al. (2013) 'Adipose-derived stromal cells overexpressing vascular endothelial growth factor accelerate mouse excisional wound healing.', *Molecular therapy : the journal of the American Society of Gene Therapy*. United States, 21(2), pp. 445–455. doi: 10.1038/mt.2012.234.
- Nazzari, M. et al. (2019) 'Wound Healing', in F. Charles Brunnicardi et al. (eds) *Schwartz's Principles of Surgery*. Eleventh. New York: McGraw-Hill, pp. 271–304.

- Nikolidakis, D. and Jansen, J. A. (2008) 'The biology of platelet-rich plasma and its application in oral surgery: literature review.', *Tissue engineering. Part B, Reviews*. United States, 14(3), pp. 249–258. doi: 10.1089/ten.teb.2008.0062.
- Park, J. W., Hwang, S. R. and Yoon, I.-S. (2017) 'Advanced Growth Factor Delivery Systems in Wound Management and Skin Regeneration', *Molecules* (Basel, Switzerland). MDPI, 22(8), p. 1259. doi: 10.3390/molecules22081259.
- Petry, T. et al. (2017) 'Review of data on the dermal penetration of mineral oils and waxes used in cosmetic applications', *Toxicology Letters*, 280, pp. 70–78. doi: <https://doi.org/10.1016/j.toxlet.2017.07.899>.
- Przekora, A. (2020). A concise review on tissue engineered artificial skin grafts for chronic wound treatment: can we reconstruct functional skin tissue in vitro?. *Cells*, 9(7), 1622.
- Rah, D. K. et al. (2017) 'Effect of Platelet-Rich Plasma on Ischemia-Reperfusion Injury in a Skin Flap Mouse Model', *International journal of medical sciences*. Ivyspring International Publisher, 14(9), pp. 829–839. doi: 10.7150/ijms.19573.
- Raposo, E. et al. (2016) 'Adipose-derived Stem Cells Added to Platelet-rich Plasma for Chronic Skin Ulcer Therapy.', *Wounds: a compendium of clinical research and practice*. United States, 28(4), pp. 126–131.
- Rigotti, G., Marchi, A. and Sbarbati, A. (2009) 'Adipose-derived mesenchymal stem cells: past, present, and future.', *Aesthetic plastic surgery*. United States, pp. 271–273. doi: 10.1007/s00266-009-9339-7.
- Rohovsky, S. and D'Amore, P. A. (1997) 'Growth Factors and Angiogenesis in Wound Healing', in Thomas R. Ziegler, Pierce, G. F., and Herndon, D. N. (eds) *Growth Factors and Wound Healing*. New York, NY: Springer New York, pp. 8–26. doi: 10.1007/978-1-4612-1876-0_2.
- Rosenstrauch, D. et al. (2005) 'Stem celltherapy for ischemic heart failure', *Texas Heart Institute journal*, 32(3), pp. 339–347.
- Rumalla, V. K. and Borah, G. L. (2001) 'Cytokines, growth factors, and plastic surgery.', *Plastic and reconstructive surgery*. United States, 108(3), pp. 719–733. doi: 10.1097/00006534-200109010-00019.
- Ruusala, A. et al. (1998) 'Platelet-derived growth factor (PDGF)-induced actin rearrangement is deregulated in cells expressing a mutant Y778F PDGF β -receptor', *Journal of Cell Science*, 111(1), pp. 111–120. doi: 10.1242/jcs.111.1.111.
- Schaffer, C. J. and Nanney, L. B. (1996) 'Cell biology of wound healing.', *International review of cytology*. United States, 169, pp. 151–181. doi: 10.1016/s0074-7696(08)61986-5.
- Schöler, H. R. (2016) 'The Potential of Stem Cells: An Inventory', in Schipanski, D., Knoepfle, N., and S L Sorgner (eds) *Humanbiotechnology as Social Challenge An Interdisciplinary Introduction to Bioethics*. First. London: Taylor & Francis, pp. 1–28.

- Sethi, A. et al. (2016) 'Moisturizers: The Slippery Road', Indian journal of dermatology. Medknow Publications & Media Pvt Ltd, 61(3), pp. 279–287. doi: 10.4103/0019-5154.182427.
- Shpichka, A. et al. (2019) 'Skin tissue regeneration for burn injury', Stem Cell Research and Therapy. Stem Cell Research & Therapy, 10(1), pp. 1–16. doi: 10.1186/s13287-019-1203-3.
- Singh, V. K. et al. (2016) 'Describing the Stem Cell Potency: The Various Methods of Functional Assessment and In silico Diagnostics.', Frontiers in cell and developmental biology. Switzerland, 4, p. 134. doi: 10.3389/fcell.2016.00134.
- Stessuk, T. et al. (2016) 'Platelet-rich plasma (PRP) and adipose-derived mesenchymal stem cells: stimulatory effects on proliferation and migration of fibroblasts and keratinocytes in vitro.', Archives of dermatological research. Germany, 308(7), pp. 511–520. doi: 10.1007/s00403-016-1676-1.
- Sun, M., He, Y., Zhou, T., Zhang, P., Gao, J., & Lu, F. (2017). Adipose extracellular matrix/stromal vascular fraction gel secretes angiogenic factors and enhances skin wound healing in a murine model. BioMed Research International, 2017.
- Tantuway, V. et al. (2016) 'Autologous grafting of non manipulated freshly isolated - adipose tissue derived stromal vascular fraction in single surgical sitting for treatment of knee osteoarthritis', International Journal of Research in Orthopaedics, 3, p. 107. doi: 10.18203/issn.2455-4510.IntJResOrthop20164834.
- Tohidnezhad, M. et al. (2011) 'Platelet-released growth factors can accelerate tenocyte proliferation and activate the anti-oxidant response element', Histochemistry and Cell Biology, 135(5), pp. 453–460. doi: 10.1007/s00418-011-0808-0.
- Toussaint, J. and Singer, A. J. (2014) 'The evaluation and management of thermal injuries: 2014 update', Clinical and experimental emergency medicine. The Korean Society of Emergency Medicine, 1(1), pp. 8–18. doi: 10.15441/ceem.14.029.
- Tsien, L. (2006) 'Stem Cell Basics', Postgraduate Obstetrics & Gynecology, 26(24), pp. 1–6. doi: 10.1097/00256406-200612310-00001.
- Van Pham, P. et al. (2013) 'Activated platelet-rich plasma improves adipose-derived stem cell transplantation efficiency in injured articular cartilage.', Stem cell research & therapy. England, 4(4), p. 91. doi: 10.1186/scrt277.
- Westermarck, B. and Heldin, C. H. (1993) 'Platelet-derived growth factor structure, function and implications in normal and malignant cell growth', Acta Oncologica, 32(2), pp. 101–105. doi: 10.3109/02841869309083897.
- Watterson, K. R., Lanning, D. A., Diegelmann, R. F., & Spiegel, S. (2007). Regulation of fibroblast functions by lysophospholipid mediators: potential roles in wound healing. Wound Repair and Regeneration, 15(5), 607-616.
- Widowati, W. and Widyanto, R. M. (2013) 'Sel Punca sebagai Transformasi Alternatif Terapi', Zenit, 2(1), pp. 1–5.

- Wijaya Jefri, Josh F, Soekamto TH, Adriani JR, Jonatan B, Mizuno H, Faruk M. The Combination of Stromal Vascular Fraction Cells and Platelet-Rich Plasma on Endotelial Growht Factor in Full Thickness Burn Injury. *J of Mediteranian*. 2021;14:3049-3061
- Williams, C. (2011) ‘Assessment and management of paediatric burn injuries.’, *Nursing standard* (Royal College of Nursing (Great Britain) : 1987). England, 25(25), pp. 60-64,66,68. doi: 10.7748/ns2011.02.25.25.60.c8349.
- Witte, M. B. and Barbul, A. (1997) ‘General principles of wound healing.’, *The Surgical clinics of North America*. United States, 77(3), pp. 509–528. doi: 10.1016/s0039-6109(05)70566-1.
- Wobus, A. M. and Boheler, K. R. (2005) ‘Embryonic Stem Cells: Prospects for Developmental Biology and Cell Therapy’, *Physiological Reviews*. American Physiological Society, 85(2), pp. 635–678. doi: 10.1152/physrev.00054.2003.
- Zakrzewski, W. et al. (2019) ‘Stem cells: past, present, and future’, *Stem Cell Research & Therapy*, 10(1), p. 68. doi: 10.1186/s13287-019-1165-5.
- Zuk, P. A. et al. (2002) ‘Human adipose tissue is a source of multipotent stem cells’, *Molecular biology of the cell*. The American Society for Cell Biology, 13(12), pp. 4279–4295. doi: 10.1091/mbc.e02-02-0105.



REKOMENDASI PERSETUJUAN ETIK

Nomor : 853/UN4.6.4.5.31/ PP36/ 2021

Tanggal: 31 Desember 2021

Dengan ini Menyatakan bahwa Protokol dan Dokumen yang Berhubungan Dengan Protokol berikut ini telah mendapatkan Persetujuan Etik :

No Protokol	UH21120781	No Sponsor Protokol	
Peneliti Utama	dr. Arham jaya	Sponsor	
Judul Peneliti	EFEK STROMAL VASCULAR FRACTION (SVF) dan PLATELET RICH PLASMA (PRP) TERHADAP KADAR serum Platelet-derived GROWTH FACTOR - bb (pdgf-bb) dalam penyembuhan luka bakar full thickness pada model tikus Wistar		
No Versi Protokol	1	Tanggal Versi	21 Desember 2021
No Versi PSP		Tanggal Versi	
Tempat Penelitian	Laboratorium Hasanuddin University Medical - Research Center (HUM-RC) dan Laboratorium Hewan FKUH Makassar		
Jenis Review	☐ Exempted ☒ Expedited ☐ Fullboard Tanggal	Masa Berlaku 31 Desember 2021 sampai 31 Desember 2022	Frekuensi review lanjutan
Ketua KEPK FKUH RSUH dan RSWs	Nama Prof.Dr.dr. Suryani As'ad, M.Sc.,Sp.GK (K)	Tanda tangan	
Sekretaris KEPK FKUH RSUH dan RSWs	Nama dr. Agussalim Bukhari, M.Med.,Ph.D.,Sp.GK (K)	Tanda tangan	

Kewajiban Peneliti Utama:

- Menyerahkan Amandemen Protokol untuk persetujuan sebelum di implementasikan
- Menyerahkan Laporan SAE ke Komisi Etik dalam 24 Jam dan dilengkapi dalam 7 hari dan Laporan SUSAR dalam 72 Jam setelah Peneliti Utama menerima laporan
- Menyerahkan Laporan Kemajuan (progress report) setiap 6 bulan untuk penelitian resiko tinggi dan setiap setahun untuk penelitian resiko rendah
- Menyerahkan laporan akhir setelah Penelitian berakhir
- Melaporkan penyimpangan dari protokol yang disetujui (protocol deviation / violation)
- Mematuhi semua peraturan yang ditentukan